

AMERICAN OPTICAL CORPORATION
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42 CFR PART 84, PUBLIC HEARING
JANUARY 27, 1988
WASHINGTON, DC

Good morning,

MY NAME IS JOSEPH ZDROK, AND I AM THE REGULATORY AFFAIRS MANAGER AT AMERICAN OPTICAL CORPORATION, SOUTHBRIDGE, MASSACHUSETTS. AMERICAN OPTICAL IS A MANUFACTURER OF RESPIRATORY PRODUCTS AND WE OBJECT TO THE NIOSH REQUIREMENT OF WORKPLACE AND SIMULATED WORKPLACE TESTING FOR RESPIRATOR CERTIFICATION.

THE PROPOSED REGULATION HAS BEEN REVISED TO ALLOW TESTING AND CERTIFYING RESPIRATORS FOR USE IN MINES AND MINING ONLY. WHILE THE MINE SAFETY AND HEALTH ACT OF 1977 REQUIRES NIOSH TO APPROVE AND CERTIFY RESPIRATORS FOR MINES AND MINING, THE ACT DOES NOT PREVENT NIOSH FROM APPROVING AND CERTIFYING RESPIRATORS FOR NON-MINING USE. IN FACT, NIOSH HAS IN THE PAST ADDRESSED THE NEEDS OF NON-MINING GENERAL INDUSTRY FOR CERTIFIED RESPIRATORS. MORE THAN 90% OF THE NIOSH APPROVED RESPIRATORS IN USE TODAY ARE USED IN NON-MINING APPLICATIONS. OTHER REGULATORY AGENCIES SUCH AS EPA, OSHA AND NRC REQUIRE NIOSH CERTIFIED RESPIRATORS FOR NON-MINING USE. IN MANY INSTANCES THE RESPIRATOR NEEDS OF THE GENERAL INDUSTRY USER CONFLICT WITH THE RESPIRATOR NEEDS OF THE MINER. (FOR EXAMPLE, AN SCBA WITH A HARNESS DESIGNED TO MEET THE NEEDS OF A FIRE FIGHTER IN

MINES MAY NOT MEET THE NEEDS OF THE NUCLEAR INDUSTRY WHERE DECONTAMINATION IS A MAJOR FACTOR, SINCE THE FIREPROOF DESIGN WOULD MOST LIKELY ENTAIL USING A SOMEWHAT POROUS MATERIAL THAT WOULD TRAP RADIOACTIVE MATERIAL.) THE SCOPE OF THE PROPOSED RESPIRATOR CERTIFICATION PROGRAM SHOULD BE EXPANDED TO INCLUDE THE VAST MAJORITY OF RESPIRATOR USERS IN GENERAL INDUSTRY.

THE PROPOSED REGULATION WILL ALSO REQUIRE ALL WORKPLACE TESTING TO BE DONE IN MINES OR MINING OPERATIONS. THERE ARE NOT ENOUGH OPERATIONAL MINES THAT EXIST IN THE U.S. TO ACCOMMODATE ALL THE MANUFACTURERS OF RESPIRATORS FOR THE NUMBER OF TESTS REQUIRED. IF ALL THE RESPIRATOR MANUFACTURERS ATTEMPTED TO TEST SEVERAL RESPIRATORS PER YEAR AND CONSIDERING A TYPICAL TEST WILL TAKE AT LEAST THIRTY (30) DAYS TO COMPLETE, THE EXISTING MINES WOULD HAVE A TEST IN PROGRESS 100% OF THE TIME. IT IS OBVIOUS THAT SUCH DISRUPTIVE PRACTICES WOULD NOT BE TOLERATED BY THE MINES AND THEY WILL MORE THAN LIKELY REFUSE TO COOPERATE. ALSO, MOST TYPES OF RESPIRATORS MAY AT SOME TIME BE USED IN MINES, HOWEVER, SUBJECTS WEARING ORGANIC VAPOR OR PAINT SPRAY RESPIRATORS, FOR EXAMPLE, WOULD BE HARD TO LOCATE.

WORKPLACE TEST RESULTS ARE UNRELIABLE IN PREDICTING RESPIRATORY PERFORMANCE. THE INHERENT VARIABILITY OF THE DATA MAKES IT UNUSABLE FOR CERTIFICATION AND DOES NOT ASSURE RELIABILITY OF THE RESPIRATOR TO THE USER. FURTHERMORE, ANALYTICAL METHODS WITH VERY HIGH SENSITIVITY MUST BE USED IN ORDER TO MAKE MEANINGFUL MEASUREMENTS. FOR THE FEW METHODS THAT DO EXIST, NECESSARY HANDLING OF

THE SAMPLES IN THE WORKPLACE GREATLY INCREASES THE POSSIBILITY OF CONTAMINATION OF THE SAMPLES.

TECHNOLOGY DOES NOT EXIST TODAY TO PERFORM WORKPLACE TESTING OF RESPIRATORS AGAINST MOST HAZARDOUS SUBSTANCES FOUND IN THE WORKPLACE. ANALYTICAL METHODS DO NOT HAVE SENSITIVITY SUFFICIENT TO MAKE MEANINGFUL MEASUREMENTS OF PERFORMANCE, ESPECIALLY WITH THOSE RESPIRATORS HAVING HIGH ASSIGNED PROTECTION FACTORS (APF). ADDITIONALLY, NO TEST METHODS EXIST FOR FIELD TESTING GAS AND VAPOR RESPIRATORS.

RESPIRATORS SUCH AS PRESSURE DEMAND SCBA OR AIRLINES WITH ANTICIPATED PROTECTION FACTORS IN THE 1000 - 10,000 RANGE, IT IS NECESSARY TO HAVE CONTAMINANT CONCENTRATIONS THAT ARE MUCH HIGHER THAN THE PRACTICAL LIMIT OF ANALYTICAL DETECTION - ANALYTICAL CHEMISTS HAVE A RULE OF THUMB THAT SAYS AT LEAST 10,000 - 100,000 TIMES HIGHER. FINDING WORKPLACES WITH SUCH CONSISTENTLY HIGH CONTAMINANT CONCENTRATIONS, AND SUFFICIENT NUMBERS OF WORKERS IN THESE HIGH CONCENTRATIONS WHOSE EXPOSURES ARE OF A DURATION SUFFICIENT TO COLLECT VALID SAMPLES OVER A REASONABLE PERIOD OF TIME, WOULD BE IMPOSSIBLE. IT IS HIGHLY UNLIKELY THAT SUCH WORKPLACES EXIST ANYWHERE, LET ALONE IN MINES.

FINALLY, WORKPLACE STUDIES ARE EXTREMELY COSTLY. NIOSH RELEASED A DRAFT OF A WORKPLACE FIELD TEST PROTOCOL FOR PEER REVIEW IN AUGUST OF 1987. THE PURPOSE OF THE RESEARCH PROTOCOL WAS TO VERIFY THE ASSIGNED PROTECTION FACTORS FOR HALF AND FULL FACEPIECE NEGATIVE PRESSURE RESPIRATORS. IN ORDER TO MAKE ANY MEANINGFUL COST ESTIMATES, HOWEVER, A TEST PROTOCOL IS NEEDED. BECAUSE NO PROVEN RELIABLE PROTOCOL EXISTS, THE RESPIRATOR MANUFACTURERS WERE FORCED TO USE THE DRAFT RESEARCH PROTOCOL DEVELOPED BY NIOSH AS A BASIS FOR THE COST ESTIMATE.

THE PROTOCOL STATES THAT 126 DATA POINTS WILL BE REQUIRED FOR EACH SUBSTANCE TESTED IN EACH OF THE INDUSTRIES STUDIED. NIOSH STATES THAT 3-6 SUBSTANCES FOR EACH TYPE OF RESPIRATOR WILL BE REQUIRED. FOR THE COST ESTIMATE, THE INDUSTRY SELECTED A CONSERVATIVE NUMBER OF THREE SUBSTANCES. FOR EXAMPLE, FOR A DUST RESPIRATOR, 3 DIFFERENT TYPE DUSTS WILL BE TESTED; FOR AN ORGANIC VAPOR RESPIRATOR, 3 DIFFERENT ORGANIC VAPORS; FOR AN AIR LINE RESPIRATOR, 3 DIFFERENT SUBSTANCES, ETC. THE PROTOCOL ALSO STATED THAT DIFFERENT FACILITIES IN NUMEROUS INDUSTRIES WOULD BE STUDIED. FOR THIS COST ESTIMATE, THE INDUSTRY CONSERVATIVELY CHOSE TO NOT FACTOR IN THE NEED TO EVALUATE DIFFERENT FACILITIES OR INDUSTRIES.

EXPERIENCE IN THE INDUSTRY HAS SHOWS THAT TO OBTAIN 126 DATA POINTS IT HAS BEEN NECESSARY TO COLLECT SAMPLES FROM 200 TESTS IN THE WORKPLACE. APPROXIMATELY 75 OF THE DATA POINTS WILL BE DISCARDED AFTER OR DURING ANALYSIS BECAUSE THE WORKPLACE CONCENTRATIONS OF THE CONTAMINANT WERE TOO HIGH OR TOO LOW FOR VALID ANALYSIS. IN

IN ADDITION, SOME TESTS WILL BE INVALIDATED IN THE FIELD DUE TO PUMP FAILURE, SAMPLE OR SAMPLE LINE DISCONNECTIONS.

THE OVERALL COST ESTIMATE TO DO AN IN-FIELD EVALUATION OF RESPIRATOR PERFORMANCE AGAINST ONE SUBSTANCE IS \$53,000 AND 0.9 PERSON YEARS OF EFFORT.

THE TREMENDOUS EXPENSE OF FIELD TESTING WILL PLACE A SEVERE BURDEN ON THE USER COMMUNITY, SINCE THE COSTS WILL ULTIMATELY BE BORNE BY THE USER.

EVEN WITH THESE VERY CONSERVATIVE ASSUMPTIONS, IT IS ESTIMATED THAT A MANUFACTURER WITH A COMPREHENSIVE PRODUCT LINE WOULD ENCOUNTER A NEED TO CONDUCT OVER 1000 SUCH FIELD EVALUATIONS, A TREMENDOUSLY LARGE TESTING BURDEN. THIS ADDS UP TO DIRECT COSTS OF OVER 53 MILLION DOLLARS AND OVER 1000 PERSON YEARS OF EFFORT FOR THAT MANUFACTURER. THIS COST WILL, OF COURSE, ULTIMATELY BE PASSED ALONG TO THE CONSUMER AND WILL RESULT IN FEWER MODELS OF RESPIRATORS AVAILABLE TO THE USER.

BECAUSE OF THESE CONCERNS AND THE IMPACT THAT THIS PROPOSED REGULATION COULD HAVE ON RESPIRATOR USERS AND MANUFACTURERS, WE SUGGEST THAT IN THE BEST INTEREST OF EVERYONE AFFECTED, THAT THIS PROPOSAL SHOULD BE WITHDRAWN. *This document should also be revised taking into account the comments offered at this meeting and re-published with a test protocol, NIOSH should also consider entering into negotiated rulemaking prior to republishing in order to take advantage of the best available respirator⁵-technology.*