DAYTON T. BROWN INC.

STATEMENT CONCERNING NIOSH ROLE IN TESTING AND CERTIFYING PERSONAL PROTECTIVE EQUIPMENT

PRESENTED BY

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DAYTON T. BROWN INC.

ON BEHALF OF MY COMPANY, DAYTON T. BROWN, INC., I WOULD LIKE TO THANK YOU FOR THE OPPORTUNITY YOU HAVE GIVEN US TO OFFER OUR COMMENTS ON THE ROLE OF NIOSH IN TESTING AND CERTIFICATION OF PERSONAL PROTECTIVE EQUIPMENT.

DAYTON T. BROWN, INC. IS AN ENGINEERING AND TESTING FIRM WHICH HAS CONDUCTED RESEARCH, DEVELOPMENT, AND TESTING PROGRAMS ON MILITARY AND CIVILIAN PERSONAL PROTECTIVE EQUIPMENT FOR SOME THIRTY YEARS. AS AN INDEPENDENT LABORATORY AND A NIOSH RESEARCH CONTRACTOR, WE ARE PARTICULARLY CONCERNED ABOUT THE SUBJECT OF PRIVATE LABORATORY CERTIFICATION FOR THE ACTUAL TESTING AND CERTIFICATION OF RESPIRATORS AND OTHER PROTECTIVE EQUIPMENT.

IN LIEU OF COMMENTING ONLY ON SPECIFIC ELEMENTS OF THE FEDERAL REGISTER NOTICE, WE WILL OFFER BOTH GENERAL COMMENTS ON THE NIOSH PROGRAM AND ALSO PRESENT OUR OPINION REGARDING CERTAIN TOPICS IN THE NOTICE AND CONSULTANTS REPORT.

OVER THE PAST EIGHT YEARS, WE HAVE MAINTAINED CLOSE TECHNICAL CONTACT WITH MEMBERS OF THE NIOSH TESTING AND CERTIFICATION BRANCH. ALTHOUGH WE ARE NOT EQUIPMENT MANUFACTURERS AND HAVE NOT BEEN PARTICIPANTS IN THE PRESENT CERTIFICATION PROCESS, IT IS OUR OPINION THAT THE TCB STAFF HAS BEEN DEDICATED, PROFESSIONAL, AND TECHNICALLY ASTUTE IN EXECUTING THEIR RESPONSIBILITIES.

WE FEEL THAT IN NIOSH ASSUMING FULL RESPONSIBILITY FOR STANDARDS DEVELOPMENT, CERTIFICATION, QUALITY ASSURANCE, AND ENFORCEMENT, PROBLEMS HAVE BEEN CREATED. IT IS OUR OPINION THAT NIOSH HAS ASSUMED TOO MUCH RESPONSIBILITY AND THAT SOME SHOULD BE TRANSFERRED TO THE MANUFACTURING COMMUNITY.

IN ORDER TO EFFECT A TRANSFER OF RESPONSIBILITY, AT WHATEVER LEVEL, WE RECOMMEND THAT NIOSH DEVELOP AND PUBLISH DETAILED, STANDARDIZED LABORATORY TEST PROCEDURES. SUCH PROCEDURES SHOULD CONTAIN STEP BY STEP TEST INSTRUCTIONS AND DATA SHEETS WHICH WILL PRODUCE RELIABLE DATA, PROVEN REPEATABLE THROUGH INTER-LABORATORY CORRELATION TESTS.

NIOSH HAS EXPENDED CONSIDERABLE EFFORT IN EVOLVING PERFORMANCE STANDARDS FOR RESPIRATORS. AS NIOSH IS THE SOLE TESTING AND CERTIFYING AGENCY, PUBLISHING OF DETAILED PROCEDURES HAS NOT BEEN NECESSARY. UNFORTUNATELY, WITHOUT SUCH PROCEDURES, IT MAY BE IMPOSSIBLE FOR NIOSH TO RELINQUISH SOME OF ITS RESPONSIBILITIES.

IT IS OUR OPINION, FOR INSTANCE, THAT MANUFACTURERS HAVE HAD TO RELY ON NIOSH TO EVALUATE PROTOTYPE RESPIRATORS BECAUSE THIS IS THE ONLY WAY THEY MAY BE ASSURED THAT THEIR FINAL PRODUCT WOULD PASS CERTIFICATION. UNDER THE PRESENT SYSTEM, MANUFACTURERS CANNOT BE CONFIDENT THAT THEIR IN-HOUSE, PRE-SUBMISSION TESTING AND EVALUATION WILL PRODUCE THE SAME RESULT AS THE NIOSH EVALUATION. WE FEEL THIS HAS ALSO AFFECTED TWO OTHER AREAS MENTIONED IN THE NOTICE. FIRST, THE NUMBER OF REQUESTS NIOSH HAS FOR MANUFACTURERS TO WITNESS TESTS IS MORE THAN LIKELY INFLUENCED BY THE MANUFACTURERS BEING LESS THAN CONFIDENT THAT THEIR LABORATORY RESULTS WILL BE REPLICATED. SECOND, THE SITUATION WHERE SPECIAL UNPUBLISHED TEST REQUIREMENTS ARE USED BY NIOSH COULD NOT OCCUR IF PUBLISHED DETAILED PROCEDURES WERE REQUIRED.

THE LACK OF DETAILED PROCEDURES ALSO AFFECTS NIOSH'S ABILITY TO CONTRACT FOR TESTING SERVICES IN ORDER TO LIGHTEN THE BURDEN ON THEIR OWN STAFF.

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THIS BRINGS US TO THE SUBJECT OF PRIVATE LABORATORY TESTING. WE ASSUME HERE THAT THE PRIMARY EMPHASIS IN CONSIDERING THIS OPTION IS FOR NIOSH TO REDUCE INTERNAL OPERATING COSTS AND TO DECREASE THE TIME REQUIRED FOR APPROVAL.

WE FEEL THAT NIOSH SHOULD MAINTAIN RESPONSIBILITY FOR FIELD AUDIT ENFORCEMENT TESTING REGARDLESS OF WHO PERFORMS THE INITIAL CERTIFICATION TESTS, THE MANUFACTURERS THEMSELVES, PRIVATE LABORATORIES, OR NIOSH.

WE SEE TWO MAJOR PROBLEMS IN HAVING PRIVATE LABORATORIES CERTIFY EQUIPMENT: FIRST IN DEFINING WHAT A PRIVATE LABORATORY IS, AND SECOND, MINIMIZING THE LIABILITIES OF THE LABORATORY.

BASED ON OUR PAST EXPERIENCE, WE FEEL IT WOULD BE VERY DIFFICULT FOR NIOSH TO REQUIRE THAT A MANUFACTURER'S OWN LABORATORY OR AN AFFILIATE COULD NOT BE ACCREDITED TO CERTIFY THE EQUIPMENT. NIOSH MAY THUS BE FACED WITH A SITUATION WHERE THEY WIND UP WITH A MANUFACTURER SELF-CERTIFICATION PROGRAM, WHEN THIS IS NOT THE DESIRED OUTCOME OF A PRIVATE LABORATORY ACCREDITATION PROGRAM.

IN TERMS OF LABORATORY LIABILITY, WE CONCUR WITH THE FINDINGS OF THE CONSULTANTS REPORT. THE COST OF LIABILITY PROTECTION AND LITIGATION MAY VERY WELL OUTWEIGH ANY BENEFITS DERIVED BY AN INDEPENDENT LABORATORY CERTIFYING EQUIPMENT.

WE FEEL THAT DUE TO THE NATURE OF THE EQUIPMENT BEING CERTIFIED AND THE AFOREMENTIONED PROBLEM AREAS, NIOSH SHOULD REMAIN THE SOLE CERTIFYING AGENCY.

IF NIOSH WISHES TO REDUCE THE LOADING OF ITS STAFF, IT SHOULD DO SO THROUGH REQUIRING MANUFACTURERS TO SUPPLY ADDITIONAL TEST DATA, IN ACCORDANCE WITH NIOSH DEVELOPED TEST PROCEDURES, WITH THEIR PRODUCT SUBMISSION, OR BY CONTRACTING THE SERVICES OF INDEPENDENT LABORATORIES.