

DOCKET OFFICE COPY

TECHNICAL CONCERNS ASSOCIATED WITH WORKPLACE PROTECTION FACTOR TESTING.

Comments prepared by A.R. Johnston on behalf of the Industrial Safety Equipment Association (ISEA) for presentation on January 10, 1991 at the NIOSH Technical Conference on Assessment of Performance Levels for Industrial Respirators.

SUMMARY

Performance capabilities of respirators have traditionally been evaluated by testing filter efficiency, fit, total inward leakage, or other measures of performance under well defined and well controlled laboratory conditions. In the recent years, increasing emphasis has been placed on development of test methods for evaluating respirator performance in the workplace. The goal has been to define the level of protection achieved by persons wearing respiratory protection in the work environment.

Workplace protection factor (WPF) testing shows excellent promise as a tool for increasing knowledge about capabilities of respiratory protection, but a number of technical issues need to be resolved before optimal test protocols and data analysis methods can be defined. At this point, there are still too many uncontrollable variables and too many unknowns associated with such testing to allow standardized, reproducible test methods to be defined. As a result, although continued workplace protection factor

testing research should be encouraged, such testing is not currently suitable for incorporation into certification standards.

BACKGROUND INFORMATION

In situations where respirators are relied on for worker protection, it is important that respirator programs include a means for assuring the quality and effectiveness of respirators in use. A common starting point for this process is selection of approved respirators. Certification criteria include well defined laboratory methods for testing filter efficiency, cartridge service life, breathing resistance, and other properties of respirators. These laboratory methods are well controlled to assure that important variables such as temperature, humidity, test agent concentration, and airflow are maintained in a manner that assures predictable, reproducible, and equitable results regardless of respirator type or manufacturer.

Researchers evaluating respirators frequently use results from these or similar laboratory tests as performance benchmarks; however, the ability of laboratory data to predict performance of respirators in specific workplaces is not always clear. Conditions in the workplace have variable temperatures, humidities, air contaminant concentrations, particle size distributions, etc. This has resulted in

interest in evaluating performance of respirators under actual workplace conditions.

Interest in and discussion about workplace testing of respirators increased significantly following NIOSH's proposal to incorporate workplace protection factor (WPF) testing or simulated WPF testing into the respirator certification process. Much of the discussion has centered around the question: What WPF test procedures, if any, would be suitable for incorporation into certification standards?

The basic answer to this question is that incorporation of WPF test requirements into certification standards would only make sense if it was possible to define standardized test methods which have the ability to ensure collection or generation of meaningful and reproducible protection factor results for all types of respirators.

It would be nice to have enough knowledge about and control over WPF testing to define test methods which would meet this objective. Unfortunately, it is not yet technically feasible to do so. Workplace protection factor testing is still best classified as research activity. Despite significant progress made in understanding variables associated with workplace testing, a number of important technical issues remain unresolved.

We have personally conducted many workplace protection factor studies. We have also thoroughly reviewed test methodologies and data analysis techniques used in workplace studies conducted by others. Through this work, a number of issues related to the technical feasibility of conducting workplace protection factor studies have been identified. These issues can be classified into several general categories, including study objectives, site selection, subject selection and preparation, sampling procedures, analytical methods, and data analysis procedures. Within each of these categories there are several potential sources of variability which are not yet (and may not be) controllable to the extent necessary for ensuring a fair and equitable certification test.

TEST OBJECTIVES

The objective of testing respirators in the workplace must be clearly defined before a suitable test protocol can be developed. The term protection factor has several different meanings, depending on the context in which it is used. The American Industrial Hygiene Association (AIHA) Respiratory Protection Committee, with input from NIOSH and other organizations, has suggested definitions of protection factor terms, including Workplace Protection Factor.

Unfortunately, official recognition or acceptance of these definitions has been slow.

Lack of universally accepted protection factor definitions has led to inconsistent use of protection factor terminology, which in turn has resulted in significantly different approaches to respirator testing in the workplace. According to current definitions, the goal of a Workplace Protection Factor (WPF) study should to determine the protection capabilities of a respirator (i.e., the protection factor provided by a respirator which has been properly selected, properly fit tested, included in a properly defined and operating respirator program, tested while being properly worn and used, etc.).

The actual AIHA definition is as follows:

Workplace Protection Factor (WPF) (Co/Ci): A measure of the protection provided in the workplace, under the conditions of that workplace, by a properly selected, fit tested and functioning respirator when correctly worn and used. It is defined as the workplace contaminant concentration which the user would inhale if he were not wearing the respirator (Co) divided by the workplace contaminant concentration inside the respirator facepiece (Ci). Both Co and Ci are determined from samples taken

simultaneously, only while the respirator is properly worn and used during normal work activities.

Although a large number of "protection factor" studies have been conducted in various workplaces, most have not provided data that would meet this definition of a workplace protection factor. Many have resulted in estimates of Effective Protection Factors. Still more have provided estimates of Program Protection Factors.

Effective Protection Factor (EPF) studies have evaluated performance of respirators which were properly selected, fitted, fit tested, and used, but sampling was conducted during periods of respirator use, as well as during periods of non-wear time. Program Protection Factor (PPF) studies have evaluated respirators which may or may not have been properly fit tested, worn, stored, or otherwise used in accordance with manufacturer's selection and use guidelines.

Results from EPF and PPF studies have the ability to provide estimates of how well a respirator program is set up or functioning. They do not have the ability to measure respirator performance capability. They also do not provide information about the added difficulties encountered when attempting to conduct true WPF tests.

As a result, actual experience with workplace protection factor testing is much more limited than might be assumed from a review of literature references. Agreement on and improved use of protection factor terminology is a necessary first step toward development of acceptable workplace protection factor test protocols and expansion of experience with actual workplace protection factor testing.

SITE SELECTION

Techniques for sampling inside of respirator facepieces might reasonably be used in virtually any workplace if the goal is to estimate air contaminant exposures of workers wearing respirators. The same is not true if the intention of such sampling is to generate workplace protection factor information. Valid workplace protection factors depend on the researcher's ability to control, and/or identify and understand the impact of multiple variables.

Important site selection considerations include:

- * Type of operation
- * Number of workers wearing respirators
- * Physical layout and accessibility to work areas
- * Logistics of having several observers in work areas
- * Distance between work areas and mobility needed
- * Availability of "clean" areas for sample set up and removal

- * Variability of work processes/work cycles
- * Type of ventilation and variability
- * Duration and frequency of respirator use
- * Work rates and movements
- * Amount of interruption of work tasks that can be tolerated
- * Impact of necessary interference with workers
- * Safety rules in effect
- * Type(s) of respirators routinely used
- * Other protective equipment in use
- * Types of air contaminants present
- * Availability of air sampling data
- * Completeness of respirator program
- * Compliance with fit testing and training elements
- * Management interest and commitment to a study

Available sites for conducting meaningful workplace protection factor tests quickly become limited when a thorough screening process involving elements such as those above is applied. A good study will require at least 25 suitable workers, high concentrations of air contaminants for which analytical methods of suitable specificity and sensitivity are available, virtually continuous use of respirators (e.g., 1-2 hours without breaks, several times per day), work sites that are easily accessible and safe for observers, management willingness to commit to worker time away from the job for sample set up and training as

necessary, appropriate in-house education, training, and respirator use programs, etc. Each of these factors can vary significantly within and between various work locations. This makes it extremely difficult to envision any means of defining achievable workplace test conditions which would approach the level of standardization and control necessary for a reasonable quality assurance or respirator certification test.

SUBJECT SELECTION AND PREPARATION

If the goal of testing respirators in the workplace is to generate exposure data as part of an industrial hygiene evaluation, virtually any worker could be a suitable test subject. The situation is considerably different when the purpose of the testing is to generate workplace protection factor information.

Critical needs for subject selection in a workplace protection factor study include:

- * Willingness to participate in the study
- * Level of education, training, and experience with the respirator to be tested
- * Fit capability and fit test experience
- * Physical characteristics, such as rate of beard growth
- * Level of exposure to the contaminant of interest

- * Job tasks and duration
- * Mobility.

Workplace protection factors cannot be generated unless test subjects are:

- * Familiar with the respirator
- * Performing a job for which it is appropriate
- * Trained in proper fitting and use
- * Capable of getting a good fit; and
- * Willing to follow established respirator use policies and volunteer for participation in the testing.

The worker's level of experience should be identified, since it may have a significant impact on test results. Other criteria, such as age, work rate, facial size, facial hair, eye glass requirements, medical or job restrictions, and work location must be controlled or recorded as necessary to allow meaningful interpretation of study results.

In some cases, it is necessary to conduct education and training programs or perform fit tests prior to initiating workplace protection factor tests. Fit tests must be suitable for the type of respirator involved. Several attempts at workplace protection factor testing, including at least one study published by NIOSH, have not met this

requirement. Where qualitative fit tests are used, those with validated protocols should be used. Where quantitative fit tests are used, manufacturers' recommendations, recent work on test variability and test design, and recent OSHA and ANSI guidelines should be referenced. For example, if the TSI Portacount or older equipment utilizing small particle oil mists are used for quantitative fit testing, respirators being fit tested must be equipped with high efficiency filters. Testing of respirators with non-HEPA filters is a misuse of this equipment and will misrepresent the fit capabilities of the respirator in question.

If control or documentation of the many subject related variables is assured, it may be possible to generate meaningful workplace protection factors for the test site in question. Unfortunately, because of the extreme amount of variability possible with test subjects and their jobs, it may be difficult or impossible to extrapolate results to other operations or different conditions at the same location. Extrapolation of results to other workers or other locations introduces even more uncertainty.

It is difficult to conceive of any possible certification protocol for workplace testing which could incorporate different respirators, different test subjects, different test locations, and different operating conditions, yet still come up with results that assure fair and equitable

treatment of all respirators. Certification tests must be reproducible and must assure equitable treatment of all respirators. "State of the art" workplace protection factor test methods do not meet these criteria and are therefore not currently suitable for certification testing.

SAMPLING PROCEDURES

Current in-facepiece sampling procedures do not yet appear to assure reproducible results in the laboratory, let alone in the workplace. Respirators must be fitted with a probe for this type of testing. Various probe locations have been evaluated with different face seal leak sites and different breathing patterns. A sampling bias related to probe location, probe depth into the facepiece, and sampling method (continuous flow versus pulsed flow) has been identified. A problem with unaccountable variability (sometimes called random error) has also been noted.

Laboratory research on sampling bias has concentrated on vaporous test agents. More work is needed to:

- * Evaluate sampling bias with particulate test agents
- * Better define sources of random error
- * Determine how the laboratory research relates to workplace testing; and
- * Identify and validate improved sampling methods that can be incorporated into workplace studies.

It is clear that optimal sampling methods have not yet been defined. Even fairly simple decisions such as where to probe a respirator have not been fully resolved. It is known that probe location is critical, but a consensus on where and how to probe respirators has not been reached. The most utilized practice at present appears to be location of the probe in the test subject's breathing zone, approximately midway between the nose and the mouth, inset from the inner surface of the respirator (as opposed to mounted flush against it). This may or may not ultimately be found to be the best location, but will likely continue to be used until more conclusive information on optimal probe location is available.

Other concerns and possible variables include probe design, integrity and tightness of the probe's seal with the respirator, (must not leak), and integrity of the connection between the probe and the sampling train.

Commonly available personal sampling pumps appear to be appropriate for in-facepiece sampling. Airflow rates of 1-2 Lpm have been used in most workplace sampling to avoid significant pressure changes inside respirator facepieces.

Commonly available sample collection devices may also be appropriate, but several concerns exist in this area. For

example, moisture build-up from exhaled breath can cause substantially increased pressure drop across filters and result in collapse of backup pads. This invalidates samples being collected. Stiffer, plastic backup pads have been found to reduce, but not eliminate collapse. Heated coils wrapped around filter cassettes have been suggested as another option. This reportedly works well with some types of respirators, but it may be only partially effective with others.

Moisture from exhaled breath is also a concern with gas and vapor sampling. 100% relative humidity has the potential to significantly change analyte recovery from sorbent materials. High humidity also affects sorbent tube life. Other concerns with gases and vapors include the metabolic fate of the analyte, possible effects of concurrent skin exposure to a liquid form of the chemical, lung absorption and retention from prior exposures, and odor thresholds.

Workplace studies conducted to date have concentrated on particulate contaminants, so very little is known about these and other gas and vapor sampling concerns. Much more research is needed for gas and vapor respirators to define key variables of concern and begin to assess their potential impact on workplace protection factor results. Gas and vapor respirators represent a large percentage of those in use in the workplace. Thus, lack of information in this

area is another major limitation on our ability to develop test methods with suitable reproducibility and accuracy for inclusion into respirator certification standards.

Sampling strategies must also be considered. In-facepiece sampling procedures recommended in Europe (i.e, for determining total inward leakage into respirators) involve sampling during the inhalation portion of the breathing cycle only. This has been suggested as a way to more accurately measure contaminant concentrations leaking into respirators. The theory is that the dilution effect from exhaled breath will be minimized; however, this may not hold true in practice. Air contaminants do not appear to mix well within respirator cavities during inhalation. Thus, it is possible that inhalation only sampling could significantly increase sampling bias.

Exhalation only sampling has shown better results in the laboratory, but these studies have involved vapors only, have not been done on people, and have not been confirmed in the workplace. Workplace protection factor tests reported to date have involved sampling during inhalation and exhalation. This is likely continue until this issue is further resolved, but resolution is necessary before any standardized sampling methodology can be accepted. This does not appear to be a short term research project.

Another important requirement is collection of a sufficient number of samples to allow meaningful statistical analysis. If plans are to complete all sampling prior to initiating laboratory analyses, extra samples (perhaps two to three times the minimum felt necessary for statistical purposes) need to be collected in case some samples must later be invalidated. This can be necessary due to failure to meet analytical acceptance criteria or failure to comply with the sampling protocol.

Validity of samples collected on test subjects will depend on whether or not an appropriate level of observation of test subjects was provided. In our experience, it is not possible to generate workplace protection factors without one observer for each subject being tested. Even then, the attention and care paid to the test protocol by the observer is critical to generation of meaningful results. This may have been a problem in many studies which have reported results as workplace protection factors (relates to terminology issue discussed earlier).

ANALYTICAL METHODS

The selection of an analytical method for a workplace protection factor study is complicated by a need for extremely good sensitivity for samples collected inside respirators, while at the same time being able to handle

sample loadings orders of magnitude higher outside the respirators. Other potential complicating factors include high moisture content of exhaled breath which passes through inside samples (mentioned above), limited sampling times due to duration of job tasks, and presence of gases or vapors (from previous exposures) or particles such as cigarette smoke in exhaled breath.

The benefits and limitations of analytical methods need to be carefully considered. A number of methods have been evaluated for particulate contaminants. The best analytical methods are very specific and very sensitive. Methods such as gravimetric analysis are easy to perform, but have poor sensitivity and cannot distinguish workplace contaminants which leaked into a respirator from other contaminants not related to the workplace (e.g., cigarette smoke, spit, sputum, or sweat).

Microscopy methods sometimes have good sensitivity and specificity, sometimes have neither, and always present a filter overloading concern. Proton induced x-ray emission (PIXE) analysis, inductively coupled plasma (ICP) analysis, graphite furnace atomic absorption, and radioimmunoassay have good to excellent sensitivity and specificity, but also have their own inherent limitations. In short, there is no single best method for evaluating particulate respirator performance. Different respirators with different

applications will require different analytical methods, which in turn will have different variables and different levels of reproducibility.

Potential sampling and analytical methods for in-facepiece sampling of gases and vapors in the workplace are not as well defined. Charcoal, silica gel, and other sorbent materials most commonly used in gas and vapor sampling devices have major limitations under 100% relative humidity atmospheres. Thermal desorption tubes show good promise for overcoming humidity concerns, but much more work is needed in this area.

More work is also needed to address potential sampling/analytical problems. For example, deposition of particles on the walls of filter cassettes has been raised as a concern. This is not a significant concern with lapel samples, since filter loadings are orders of magnitude higher than any contaminant collected on cassette walls. The same may not be true with samples collected from inside respirators; however, there is not necessarily a consistent, predictable pattern to cassette wall deposition. More research is needed.

Some general rules for the sensitivity of an analytical method for workplace protection factor studies have been suggested. The goal of these studies is normally to

determine if a respirator has the capability to achieve the Assigned Protection Factor for a specific class (e.g., an APF of 10 for a half mask respirator). In order to make this determination, the analytical detection limit must be low enough to ensure that outside (lapel) samples collect sufficient material, in a reasonable sampling time, to be able to show if a WPF is equal to or greater than the APF. In other words, at an absolute minimum, the following criteria must be met:

Outside Sample

Analyte Weight = APF X Mean Field Blank Analyte Weight
(e.g., ng)

Since analytical confidence is generally poor at or near the detection limit, it would be better to apply more stringent acceptance criteria, especially for respirators with lower assigned protection factors. For example:

Outside Sample

Analyte Weight = 10 X APF X Mean Field Blank Analyte Weight
(e.g., ng)

or,

Outside Sample

Analyte Weight = 100 X APF X Mean Field Blank Analyte Weight
(e.g., ng)

Following these rules, for a workplace protection factor study on a half mask respirator (APF of 10), sample sets with outside sample weights less than 10 times the mean field blank level could not be used to generate workplace protection factors (they must be invalidated). For a half mask respirator study to be considered well designed, target outside sample loadings and sample acceptance criteria would be better set at least 100 times the expected mean field blank weight, with 1000 times the mean field blank weight preferred by some researchers.

If the detection limit of the analytical method selected is found to be incapable of meeting these criteria, sampling times must be increased (if possible), an alternate analytical method selected, an alternate test site selected, or the study terminated. It is important to note that this is a **sample loading** phenomena, not a concentration phenomena. Increased sample loading can obviously be more quickly achieved when air contaminant concentrations are higher, but higher concentrations themselves will not necessarily provide any better data than lower concentrations.

Analytical precision is another concern. Results of personal samples collected for industrial hygiene evaluations are generally considered acceptable if precision is +/- 25% or better. Since samples collected inside of respirators are frequently at or near detection limits, this may not be a reasonable limitation for in-facepiece sampling. Levels of +/- 35% or +/- 50% may be the best achievable. This means that analytical variability alone might be expected to easily exceed +/- 50% for any single WPF value calculated. Acceptable confidence levels have not been defined for workplace protection factors. More work is needed to define sample acceptance criteria appropriate for the sampling and analytical limitations that currently exist.

DATA ANALYSIS PROCEDURES

With all the variability inherent in sampling strategies, sampling methods, analytical methods, and overall study designs, it is not surprising to see a variety of opinions on analyzing and interpreting data from workplace tests. A considerable amount of research has been done to identify and control sources of variability associated with in-facepiece sampling, but there are still a number of unknown or incompletely defined variables. This does not mean that results from workplace protection factor testing have no

value; however, it does mean they must be interpreted carefully.

Individual data points from in-facepiece sampling continue to be highly subject to what has been classed random error. This means that very little confidence can be placed in any single workplace protection factor values obtained. The impact of random error can be minimized and more meaningful information generated when data are analyzed as a part of a population or when data are combined to generate time-weighted average workplace protection factors. Rules for data handling need to be established up front to help with study design and facilitate evaluation of resulting data.

The following basic rules may be a good starting point for workplace protection factor studies, but more research and discussion is needed on these issues before any standardized protocols can be adopted.

1. Prior to sample analyses, invalidate sample sets affected by sampling problems, such as leaky probes, loose sampling devices, loose hoses, malfunctioning pumps, removal of the respirator while pumps were running, or other observations which indicate the protocol was not met.
2. After sample analyses, reject sample sets with

insufficient inside or outside sample loading or unacceptable analytical precision. Outside sample loadings should be at least 100-1000 times the mean field blank value. Inside sample loadings should be greater than the field blank value.

3. Use the mean value of field blanks to correct inside and outside sample loadings.
4. Use corrected sample loadings for concentration and protection factor calculations.
5. Consider whether or not corrections are desirable for 100% relative humidity sampling, lung retention, or other factors referenced earlier.
6. Calculate appropriate measures of distribution, such as geometric means, geometric standard deviations, and fifth percentiles.
7. Identify potential outliers. Investigate reasons. Retain or reject data points in question as appropriate.
8. Examine data to determine if protection factors generated are independent of outside sample loading. If not, reevaluate amount of mass collected.

9. Test for differences among respirators, test subjects, observers, operations, days, etc. as appropriate for the study design.

10. Define any problems encountered with data analysis that may make the results unsuitable for defining protection factors. Be sure to clearly describe conditions for which the study may be relevant. Avoid overinterpretation of results.

Some of these points are open for debate. For example, some researchers feel that inside sample loadings should be at least two standard deviations higher than the mean field blank value. This would make it virtually impossible to generate workplace protection factor data, especially for respirators with higher performance capabilities. Other researchers favor retaining inside samples with loadings less than mean blank values and modifying blank correction procedures.

Examination of data with respect to outside sample loading relates to analytical confidence (referenced above), as well as to concerns raised about the relationship between outside sample loading and resulting workplace protection factors. It is assumed that a respirator being worn by an individual has a protection capability which should be measurable in the terms of a single number (i.e., a workplace protection

factor). It is often further assumed that, if the fit or function of the respirator is not altered and aspects such as particle size distribution are unchanged, the protection factor afforded by the respirator will remain relatively constant over a range of air contaminant conditions. This appears to be the basis for development of assigned protection factors.

A significant correlation is known to exist between sample loading (analyte mass) and analytical precision. The closer the sample loading is to the analytical detection limit, the less confidence there is in the number reported.

Conversely, at least within a certain range, analytical confidence increases with sample loading. Eventually a point is reached where this relationship changes and the level of confidence reaches a point where it remains virtually constant for all sample loadings (again, within a certain range of values).

Carrying this a step further, in order to increase confidence levels in workplace protection factors, it would be beneficial to optimize sample loadings. This is difficult (often impossible) to do with samples collected inside respirators; however, a certain amount of control over outside sample loadings may be possible.

A "rule of thumb" to use for outside sample loadings was referenced above. A number of workplace protection factor studies have been analyzed to determine what happens if this rule is not followed. This review was reported at the 1989 American Industrial Hygiene Conference in St. Louis. Six different studies, including one conducted by NIOSH, were examined. In all six cases, a correlation was found between outside sample loading and workplace protection factors.

The correlation observed was not between individual sample loadings and individual workplace protection factors. For reasons already discussed, it is believed that the variability of individual results (due to multiple factors) is simply too high for meaningful correlations of attributes such as these to be identified. The correlation seen was between sample loadings and workplace protection factors for various populations or sub-sets of data.

For example, two separate supplied air respirator studies were set up for the purpose of quantifying protection provided against silica and other dusts. Using the silica dust results as an example, one of the studies resulted in collection of a total of 37 sample sets. The other study resulted in collection of 32 sample sets. The assigned protection factor for the respirators tested was 1000.

Using the above rules, the absolute minimum acceptable outside sample loading for these studies would be 1000 times the mean value of the field blank. Only 17 of the 37 samples from the first study met this criteria. None of the 32 samples from the second study met this criteria. Results of the studies are summarized below, categorized based on number of samples within each study that exceeded various multiples of the mean field blank values.

No. Samples	Field Blank Multiple*	Geom. Mean WPF	Geom. Std. Dev.	5th.. %tile
Study 1:				
37	10X	2143	3.6	259
32	200X	2340	3.5	324
28	400X	3135	2.5	673
22	600X	4150	2.2	1167
17	1000X	4076	2.3	1038
15	1200X	4023	2.2	1096
Study 2:				
32	10X	220	5.3	14
24	25X	360	4.6	29
18	50X	482	3.1	75
14	100X	904	2.6	186
10	200X	1142	3.0	187
8	300X	1417	3.0	224

Just looking at the data, there is an apparent trend toward higher protection factors for data sub-sets with higher outside sample loadings. If outside sample acceptance

criteria were set such that any outside sample loadings greater than 10 times the mean field blank value were accepted, the geometric mean WPF would be 2143 for the first study and 220 for the second. At an acceptance criteria of 200 times the blank, the calculated geometric mean WPF would be 2340 for the first study and 1142 for the second. At an acceptance criteria of 1000 times the blank, the geometric mean WPF for the first study becomes 4076. A number cannot be calculated for the second study, since there are no data sets left to use.

A log-log plot of geometric mean WPF versus mean outside filter weight for the various data sub-sets showed a strong correlation between outside filter loading and WPF. In the first study, the plot showed a slope of approximately 1 ($\text{Log WPF} = 1.22 + 0.932 \text{ Log Si Filter Wt}$) and a correlation coefficient of 0.972. In the second study, the data plot also showed a slope of about 1 ($\text{Log WPF} = 0.91 + 1.11 \text{ Log Si Filter Weight}$), with a correlation coefficient of 0.997.

Since the studies used the same basic respirator, the same sampling methods, and the same analytical techniques, the data were plotted on the same graph for comparison purposes. The data do not overlap, but the results obtained from one study could have been used to predict the results from the second study.

Outside sample loadings were not at optimal levels in either study. In both cases, collection of more material on outside filters would have been expected to result in higher workplace protection factor results. This is a critical concern. The amount of material collected on an outside samples should have little or nothing to do with workplace protection factors actually being provided by respirators. Thus, if test results are showing a strong correlation between these factors, test methodologies need to be modified to minimize that correlation. It appears to be possible to accomplish this goal by establishing minimum loadings for sample acceptance; however, this may mean that many (and perhaps most or all) samples analyzed need to be invalidated because they do not meet sample acceptance criteria.

Beyond statistical considerations and debates about sample loading or similar factors, a more simple observation needs to be better addressed. WPF studies conducted to date have shown significant ranges of outside concentrations and workplace protection factors. There are many examples of high concentrations (well above TLVs) and low WPFs in the same study, but they have occurred only in different sample sets. There has not been a single case where workers have been overexposed to the air contaminant present. Where higher protection factors have been needed, they have been achieved. Where lower protection factors were observed,

lower protection factors were all that was needed. This is clearly not a random occurrence. It adds further credence to the need for a thorough assessment of sample acceptance criteria.

CONCLUSION

Workplace protection factor testing can be useful for evaluating performance of respirators in the workplace, but the accuracy and reproducibility needed for a valid certification test are not currently achievable with this type of testing. It is not yet possible to standardize test protocols, sample collection, sample analysis, data analyses, and data interpretation in a manner that would adequately address unresolved technical concerns.

Additional research will likely address many of the key issues that exist today. Nevertheless, it appears equally likely that the additional research will identify other concerns, and that the immense number of variables associated with workplace protection factor testing will simply not be controllable to the extent necessary to allow it to be used equitably as a certification tool.

Technical Concerns Associated With WPF Testing

- Promising Tool
- Variables Not Fully Defined
- Results Not Yet Reproducible

Background Information

- Performance Measurement Tools Important
- Certification Tests Often Relied Upon
- Questions About Extrapolation to Workplace
- WPF Tests Measure Workplace Performance
- WPF Testing Cannot Yet Be Standardized
- Certification Tests Must be Controllable and Reproducible

Technical Concerns

- Study Objectives/Terminology
- Test Site Selection
- Subject Selection/Preparation
- Sampling Procedures
- Analytical Methods
- Data Analysis Procedures

Test Objectives

Terminology Critical

Has Not Been Consistently Used

AIHA Has Published Definitions

Most Prior Studies Not WPF Tests

Experience with Actual WPF Tests
Very Limited

Site Selection Considerations

Type of Operation

Number of Workers in Respirators

- Physical Layout of Facility
- Logistics for Multiple Observers
- Mobility Needed Between Areas
- Clean Area Availability
- Work Process/Cycle Variability

Site Selection Considerations (Continued)

Type of Ventilation/Variability

Duration/Frequency of Respirator Use

Work Rates and Movements

Work Interruption Tolerable

Impact of Interference With Workers

Safety Rules in Effect

Site Selection Considerations (Continued)

- Type of Respirators Used
- Other Protective Equipment Used
- Types of Air Contaminants
- Air Sampling Data Available
- Completeness of Respirator Program
- Compliance with Program Elements
- Management Interest in WPF Study

Test Subject Considerations

Willingness to Participate in Study

Level of Education, Training, and
Experience with Respirator

Fit Capability and Fit Test Experience

Physical Characteristics (Beards, etc.)

Level of Air Contaminant Exposure

Type of Job(s) and Duration

Mobility/Ease of Observation

Test Subject Requirements

- Familiar With Respirator
- Performing Job for Which It is Appropriate
- Trained in Proper Fitting and Use
- Capable of Getting Good Fit
- Willing to Continuously Wear Respirator
- Voluntary Participant in Study

Fit Test Issues

- Fit Testing Must Be Done
- Validated Methods Must Be Used
- Methods Used Must Be Appropriate for the Respirator(s) Tested

Test Subject Variables

- Difficult or Impossible to Control
- Different for Different Work Sites
- Not Reproducible
- Not Consistent with Needs of Valid, Equitable Certification Tests

Sampling Concerns

- Probe Location
- Leak Sites
- Sampling Bias
- Random Error

Research Needs

- Evaluation of Sampling Bias with Particulate Test Agents
- Better Definition of Sources of Random Error
- How Laboratory Research Relates to Workplace Testing
- Improved and Validated Sampling Methods

Sampling Methods

- Optimal Methods Not Yet Definable
- More Research Needed on Sample Collection Devices
- More Research Needed on Effects of Humidity
- More Research Needed on G&V Respirators
- More Research Needed on Sampling Strategies
- Observation Needs More Attention

Analytical Method Concerns

- Extreme Difference Between Inside and Outside Sample Loadings
- High Moisture Content - Inside Samples
- Sensitivity and Specificity Needed
- Limitations Not Well Enough Defined

Sample Acceptance Criteria

Minimum Outside Sample Analyte Weight
(e.g., ng) Must Be at Least:

a) $APF \times \text{Mean Field Blank Analyte Weight}$

Better Acceptance Criteria Would Be:

b) $10 \times APF \times \text{Mean Field Blk Anl. Weight}$

Or

c) $100 \times APT \times \text{Mean Field Blk Anl. Weight}$

Sample Acceptance Criteria (Continued)

Dependent on Sample Loading, Not
Concentration

Acceptable Analytical Precision
Must Also Be Defined

Data Analysis Concerns

- Methodology Not Standardized
- WPFs from Individual Data Sets Not Meaningful
- WPF Estimates from Populations and TWA WPFs More Meaningful
- Much Reported Data May Not Be Meaningful as It is Currently Stated

Suggested Data Analysis Rules

- Invalidate Sample Sets Subject to Sampling Problems
- Invalidate Sample Sets with Inadequate Sample Loadings or Analytical Precision
- Use Mean Field Blank Value to Correct Inside and Outside Sample Loadings

Suggested Data Analysis Rules (Continued)

- Use Corrected Sample Loadings for Concentration and WPF Calculations
- Consider Need for Corrections Due to Humidity Effects or Other Factors
- Calculate Appropriate Measures of Distribution Such as Geometric Means and 5th Percentiles

Suggested Data Analysis Rules (Continued)

Identify and Investigate Potential
Outliers, Retain or Reject

Examine Data for Correlation Between
WPFs and Sample Loading, Consider
Validity of Data if Insufficient
Mass Has Been Collected

Suggested Data Analysis Rules (Continued)

- Test for Differences Among Respirators, Test Subjects, Days, Operations, Etc.
- Define Any Problems Encountered and Clearly Describe Conditions That May be Relevant to Others
- Avoid Overinterpretation of Results

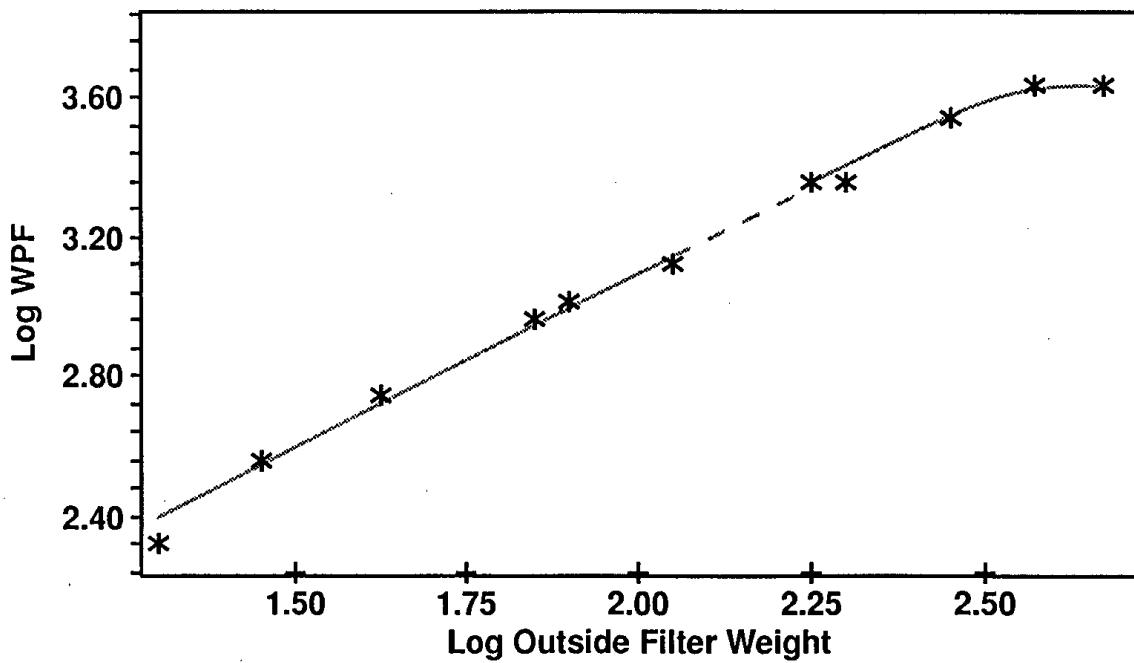
Sample Loading

- Should Not Affect Actual WPFs
- Can Affect WPF Measurements
- Relates to Reproducibility of Data
- Beneficial to Optimize
- Difficult to Do

No. Samples	Field Blank Multiple*	Geom. Mean WPF	Geom. Std. Dev.	5th.. %tile
Study 1:				
37	10X	2143	3.6	259
32	200X	2340	3.5	324
28	400X	3135	2.5	673
22	600X	4150	2.2	1167
17	1000X	4076	2.3	1038
15	1200X	4023	2.2	1096
Study 2:				
32	10X	220	5.3	14
24	25X	360	4.6	29
18	50X	482	3.1	75
14	100X	904	2.6	186
10	200X	1142	3.0	187
8	300X	1417	3.0	224

Workplace Protection Factor Vs. Outside Filter Weight

Two Different Supplied Air Respirator Studies



Observations

- No Test Subjects Overexposed
- Where High PF's Needed, High WPF's Have Been Observed
- Where Low WPFs Have Been Observed, They Were Still More Than Sufficient

Conclusions

- WPF Testing Can Be Useful Tool
- Standardized Methodology is Not Yet Definable
- Significant Concerns About Reproducibility of Data
- Not an Appropriate Certification Test

DOCKET OFFICE COPY

INDUSTRIAL SAFETY EQUIPMENT ASSOCIATION

**RESPIRATORY PROTECTION
PERFORMANCE CRITERIA DOCUMENT**

December 18, 1990

**DOCUMENT OUTLINE
DRAFT 9**

**RESPIRATORY PROTECTION PERFORMANCE CRITERIA DOCUMENT
TASK FORCE SCOPE**

1. **GOAL** - To develop a criteria document that establishes a framework for use in developing future respiratory protection performance standards aimed at testing and certifying the performance of respirators, including a definitions section.

2. **PHILOSOPHY** - To be performance driven rather than design restrictive while excluding use or application requirements wherever possible.

3. **RESPIRATOR CATEGORIES TO BE COVERED**
 - A. Air Purifying
 - (1) Negative Pressure Class
 - a. Particulates
 - b. Gases/Vapors

 - (2) Positive Pressure Class (PAPR's)
 - a. Particulates
 - b. Gases/Vapors

 - B. Atmosphere Supplying
 - (1) Airline
 - a. Positive Pressure Class
 - b. Negative Pressure Class

 - (2) Self-Contained Breathing Apparatus (SCBA's)
 - a. Open Circuit
 - b. Closed Circuit

4. **SEVEN SEPARATE STAND ALONE SECTIONS TO BE WRITTEN**
 - A. Air Purifying
 - B. Powered Air Purifying
 - C. Airline
 - D. Open Circuit SCBA
 - E. Closed Circuit SCBA
 - F. Open Circuit Escape SCBA (Not yet considered)
 - G. Closed Circuit Escape SCBA (Not yet considered)

FORMAT FOR SECTION OUTLINES BY RESPIRATOR CATEGORY

1. General Description
2. Styles and Classes
3. Modes of Operation
4. General Requirements
5. Internal Pressure and Breathing Resistance Requirements
6. Carbon Dioxide Accumulation Requirements
7. Simulated Work - Test Requirements
8. Rough Handling Requirements
9. Breathing Gas Quality Requirements
10. Miscellaneous Requirements
11. Labeling, Marking and Instruction
12. Inward Leakage Requirements
13. Special Requirements

Note: This is a criteria document, not a proposed standard.
The individual section outlines are not intended to read like a standard. They are not complete and thus contain notes, comments and descriptions which the committee views as important for the interpretation of the document. Many of these notations (possibly extraneous) are intended to provide guidance to the committee for future developmental work.

COMMENTS REGARDING PRESSURE PERFORMANCE CRITERIA

1. Pressure measurements are taken in the throat of a breathing machine headform in order to address the physiological aspects of breathing and thus relate to breathing resistance. The maximum and minimum pressures during the breathing cycle are maximum breathing pressure (MAX BP) and minimum breathing pressure (MIN BP).
2. Exhalation resistance is the same as MAX BP in that the total physiological burden of exhalation is the sum of the static pressure plus that portion of the BP curve above the static pressure. For negative pressure respirators, the static pressure is atmospheric pressure and for positive pressure respirators, the static pressure is higher than atmospheric pressure. In either case, however, the exhalation resistance is equal to the MAX BP measurement.
3. Inhalation resistance is the difference between the static pressure and the MIN BP. For negative pressure respirators, the inhalation resistance is equal to zero minus the MIN BP since the static pressure is atmospheric pressure. For positive pressure respirators, the inhalation resistance is the static pressure minus the MIN BP. However, inhalation resistance of positive pressure respirators is rarely burdensome since the MIN BP usually does not go below atmospheric pressure.
4. Pressure measurements are taken in close proximity to the primary sealing flange just inside the respiratory inlet covering. This is done so that the pressure differential, between the gas just inside the covering and the gas just outside the covering, can be assessed. It is assumed that a gas at atmospheric pressure will tend to flow towards areas of lower pressure and likewise a gas at higher pressure will tend to flow towards the atmospheric pressure. Positive pressure respirators operate on the principle that "clean" breathing gas inside the respiratory inlet covering tends to flow outward toward the surrounding atmosphere thus minimizing contaminant intrusion inside the covering since the pressure inside is greater than outside. Negative pressure respirators operate on the principle that a tight seal between the respiratory inlet covering and the wearer tends to prevent contaminant intrusion inside the covering since the seal acts as a physical barrier even though there is a tendency for the contaminated gas outside the covering to flow toward the lower pressure gas inside the covering. It is also assumed that for positive pressure respirators the greater this pressure differential the less is the tendency for gas to flow into the respiratory inlet covering and for negative pressure respirators the greater is the tendency for gas to flow into the covering. Measurements are indicated as minimum internal pressure (MIN IP) or maximum internal pressure (MAX IP).
5. Contaminant exclusion for positive pressure respirators as a function of pressure differential between just inside and outside the respiratory inlet covering is assumed to relate, in part, to the MIN IP and of course should be positive or above atmospheric pressure. Likewise, the MIN IP for negative pressure respirators should be kept as high or close to atmospheric as possible (low pressure differential) due to the potential for leaks to develop, during use, in the primary seal.
6. The pressure swing between MAX IP and MIN IP during the breathing cycle, if great enough, can be sensed by the ears and thus some limits should be placed on this pressure differential for hood style respiratory inlet coverings.

PRESSURE PERFORMANCE CRITERIA

- A Exhalation resistance (MAX BP)
- B Inhalation resistance (SP)-(MIN BP)
- C Maximum pressure swing (MAX IP)-(MIN IP)
- D Degree of positive pressure (MIN IP)

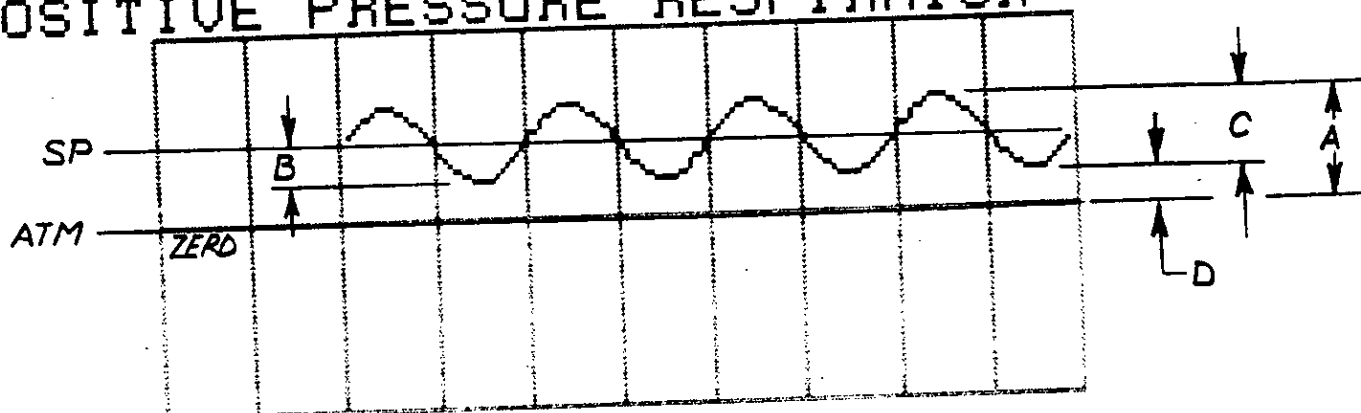
PHYSIOLOGICAL CRITERIA

- A Used for exhalation resistance
- B Used for inhalation resistance
- C Used for ear comfort with hoods

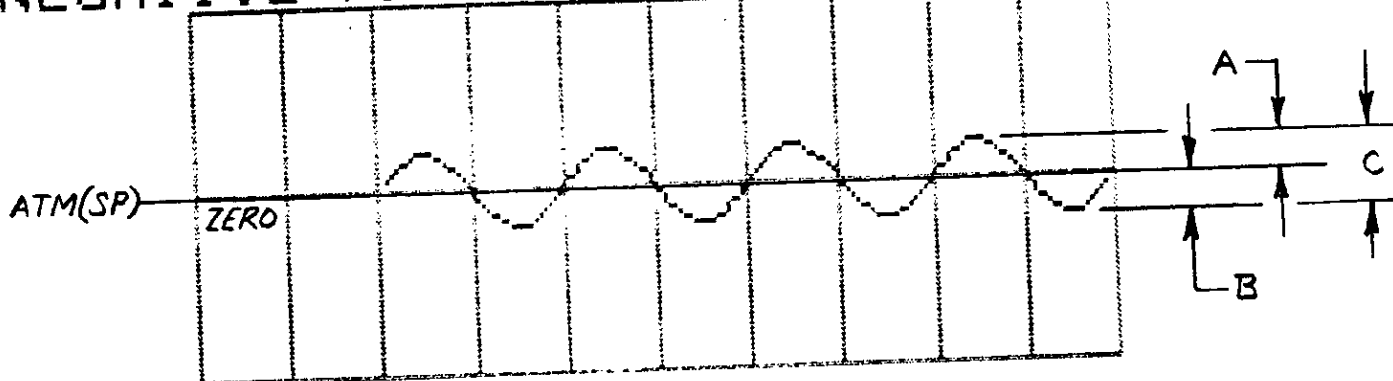
CONTAMINANT EXCLUSION

- D Used for amount of positive pressure

POSITIVE PRESSURE RESPIRATOR



NEGATIVE PRESSURE RESPIRATOR



December 18, 1990

TERMS AND DEFINITIONS

**RESPIRATORY PROTECTION
PERFORMANCE CRITERIA DOCUMENT**

**ISEA
DRAFT 9**

TERMS & DEFINITIONS

AIR CONTROL VALVE - a valve used to control the flow of respirable gas supplied ultimately to the respiratory inlet covering.

AIR LINE RESPIRATOR - a respirator which receives its breathing gas from a source other than the ambient atmosphere and the source of breathing gas is not carried on the user.

AIR PURIFYING ELEMENT - that portion of a respirator which removes contaminants from the ambient air.

AIR PURIFYING RESPIRATOR - a category of respirators in which ambient air is passed through an air purifying element(s) which removes the contaminant(s).

AIR SUPPLY LINE - the hose or combination of hoses and fittings of an airline respirator which conducts breathing gas to the wearer's respiratory inlet covering (via a breathing tube if necessary) from a source of respirable air (breathing gas) and is connected to the body via a strain relief device.

ATMOSPHERE SUPPLYING RESPIRATOR - a category of respirators that supply a respirable breathing gas independent of the ambient atmosphere.

BREAKTHROUGH CONCENTRATION - a specified level of test agent passing through a sorbent containing air purifying element.

BREATHING GAS - a gas suitable for breathing and typically (when compressed) meeting at least the requirements of the specification for Type I, Grade D breathing air or if liquid meeting at least the requirements for Type II, Grade B breathing air as described in ANSI Z86.1.

BREATHING PRESSURE (BP) - the instantaneous pressure within the throat of a breathing machine headform at any point during the breathing cycle.

BREATHING RESERVOIR - the portion of a closed circuit SCBA from which a user inhales and into which a user exhales and which serves as the mixing vessel for replacement breathing gas.

BREATHING RESISTANCE - the pressures caused by restrictions to air flow during inhalation and exhalation.

BREATHING TUBE - the hose or combination of hoses and fittings connecting the respiratory inlet covering to a source of respirable air (breathing gas) and is connected to the body via a strain relief device.

BYPASS VALVE - a valve to be used in emergencies which enables compressed breathing gas to bypass other valves or certain sources of respirator system failure.

CAPACITY - the amount of a specific gaseous or vapor contaminant that a sorbent containing air purifying element will remove prior to breakthrough under specified test conditions.

TERMS & DEFINITIONS

CARTRIDGE - that portion of an air purifying element which contains the filter.

CATEGORY - describes basic respiratory protective systems such as atmosphere supplying or air purifying as well as subsets thereof.

CLASS - a term to describe whether the internal pressure, within the respiratory inlet covering, of a respirator is positive or negative during inhalation.

CLOSED-CIRCUIT SCBA - a SCBA respirator which gets its breathing gas independent of the ambient atmosphere (self contained) and in which the exhaled gas is rebreathed by the wearer after the carbon dioxide has been removed from the exhalation and the oxygen content within the system has been restored from sources such as compressed breathing gas, chemical oxygen, and liquid oxygen.

CONTAMINANT - a harmful, irritating, or nuisance airborne material which may be in the form of gases, vapors or particulates.

CONTINUOUS FLOW - a mode of operation of respirators where the respirable gas flows into the respiratory inlet covering at an essentially constant rate during a breathing cycle.

DEMAND VALVE - a device which regulates the flow of breathing gas as a function of internal or breathing pressure during the breathing cycle (typically used in variable flow respirators).

ESCAPE SCBA - a SCBA to be used only for emergency egress from a hazardous atmosphere.

EXHALATION - the part of the breathing cycle where expired air and carbon dioxide is forced out of the respiratory system by contraction of the lungs.

EXHALATION RESISTANCE - the maximum breathing pressure (MAX BP).

FILTER - that portion of an air purifying element which extracts contaminants (particulates or gases/vapors) from the air passing through it.

FIT CHECK - a test conducted by the wearer to determine if a noticeable leakage of air exists between the respiratory inlet covering and his/her body.

FIT TEST - use of a test agent to determine a respiratory inlet covering's ability to prevent inward leakage of the test agent to the breathing zone of an individual as a means of qualifying that individual to wear a specific respirator.

FULL FACE MASK - a style of respiratory inlet covering which covers the nose, mouth and eyes and may offer eye and/or face protection.

GAS - the fluid form of a substance at standard temperature and pressure in which it can expand indefinitely and completely fill its container.

TERMS & DEFINITIONS

GROUP - particulates, gases or vapors with similar characteristics.

HALF MASK - a style of respiratory inlet covering which covers only the nose and mouth (includes quarter mask).

HARNESS - those portions of a respirator which support and may adjust the positioning of various components on the wearer.

HEADFORM - the mounting surface for the respiratory inlet covering used in testing.

HEAD HARNESS - the harness associated with the respiratory inlet covering.

HELMET - a hood comprised of a rigid or hard shell.

HIGH PRESSURE HOSE - the hose of an SCBA used to conduct breathing gas at cylinder pressure.

HOOD - a style of respiratory inlet covering which covers the head and neck and may cover portions of the shoulders and may offer eye, face, or head protection.

INHALATION - the part of the breathing cycle where air (breathing gas) is pulled into the respiratory system by expansion of the lungs.

INHALATION RESISTANCE - the difference between the static pressure and the minimum breathing pressure (SP-MIN BP).

INTERNAL PRESSURE (IP) - the instantaneous pressure within the respiratory inlet covering as measured in close proximity to the primary seal against the wearer at any point during the breathing cycle.

INTRINSIC SAFETY - the incapacity under test conditions specified in an intrinsic safety standard of a spark or thermal effect produced in a specified fault condition of causing ignition of a mixture of flammable or combustible material in air in the mixture's most easily ignited concentration.

INWARD LEAKAGE - see total inward leakage.

LENS - that portion of a respiratory inlet covering which provides the wearer with an area for vision.

LEVEL - a numerical rating at which a respirator will maintain a positive pressure within the respiratory inlet covering.

LOOSE FITTING RESPIRATORY INLET COVERING - a style of respiratory inlet covering that relies on positive pressure within the respiratory inlet covering to protect the wearer. It is not designed to prevent the passage of air through the space between the respiratory inlet covering and the wearer.

LOW PRESSURE HOSE - the hose of a SCBA used to conduct breathing gas at less than cylinder pressure.

TERMS & DEFINITIONS

MAXIMUM BREATHING PRESSURE (MAX BP) - the highest instantaneous breathing pressure in the breathing cycle during the operation of a respirator.

MAXIMUM INTERNAL PRESSURE (MAX IP) - the highest instantaneous internal pressure in the breathing cycle during the operation of a respirator.

MINIMUM BREATHING PRESSURE (MIN BP) - the lowest instantaneous breathing pressure in the breathing cycle during the operation of a respirator.

MINIMUM INTERNAL PRESSURE (MIN IP) - the lowest instantaneous internal pressure in the breathing cycle during the operation of a respirator.

MODE - describes the operating characteristics of a respirator in terms of variable or continuous flow.

MOUTH BIT (MOUTH PIECE) - a style of respiratory inlet covering which fits into the wearer's mouth and designed to prevent contaminated air entry into the wearer's nose.

NEGATIVE PRESSURE - pressure which is below ambient pressure.

OPEN-CIRCUIT SCBA - a SCBA respirator which gets its breathing gas independent of the ambient atmosphere (self contained) and in which the exhaled gas is vented to the atmosphere and not rebreathed.

PARTICULATES - fine solid or liquid particles (when suspended in air is commonly known as an aerosol).

PENETRATION - the amount of contaminant which is measured inside the respiratory inlet covering and is usually expressed as a percentage of the concentration outside the respiratory inlet covering.

POINT OF ATTACHMENT - the junction of an airline respirator's air supply line to the air (breathing gas) supply source.

POSITIVE PRESSURE - pressure which is above ambient pressure.

PRIMARY SEAL - the sealing interface between the respiratory inlet covering and the wearer's body which is exposed directly to the ambient atmosphere.

PROTECTION FACTOR - contaminant concentration outside of the respirator divided by total inward leakage of the contaminant.

PURGE VALVE - a valve usually found on or upstream of a demand valve to permit a temporary flow of breathing gas into the respiratory inlet covering for the length of time that the valve is manually engaged in the open position.

RESPIRATOR - a device which is worn that reduces the concentration of airborne contaminants to which the wearer's respiratory system is exposed.

TERMS & DEFINITIONS

RESPIRATORY INLET COVERING - that portion of a respirator which covers, as a minimum, the nose and mouth or fits into the mouth.

SELF-CONTAINED BREATHING APPARATUS (SCBA) - an atmosphere supplying respirator that supplies a respirable atmosphere to the wearer, where the source of breathing gas is either carried in or generated by the apparatus and is independent of the ambient environment.

STATIC PRESSURE (SP) - the constant equilibrium breathing or internal pressure without cyclic breathing during the operation of a respirator.

STRAIN RELIEF DEVICE - that portion of the respirator which prevents the dislodging of the respiratory inlet covering by the force exerted by other respiratory components.

STYLE - describes the respiratory inlet covering.

TIGHT FITTING RESPIRATORY INLET COVERING - a style of respiratory inlet covering designed to prevent the passage of air through the seal between the respiratory inlet covering and the wearer (primary seal).

TOTAL INWARD LEAKAGE - the contaminant concentration found within the respiratory inlet covering while the respirator is being worn by a user.

TYPE - a description of the efficiency or capacity of an air purifying element.

VAPOR - the gaseous form of any substance which is usually a liquid or solid at standard temperature and pressure.

VARIABLE FLOW - a mode of operation of respirators where the air or breathing gas flows into the respiratory inlet covering at a variable rate dependent on the breathing cycle.

December 18, 1990

SECTION A OUTLINE

**AIR PURIFYING RESPIRATORS
NEGATIVE PRESSURE CLASS (APR'S)**

**ISEA
DRAFT 9**

1. **GENERAL DESCRIPTION** - Provides protection by purifying air through the use of air purifying elements. These elements can be designed for protection against particulates and/or gases and vapors. This class of respirator exclusively uses tight fitting respiratory inlet coverings which are intended to seal against the wearer.
2. **STYLES AND CLASSES** - Tight fitting respiratory inlet coverings are provided as half masks, full face masks, hoods or mouth pieces. These respirators are classified only as negative pressure. Loose fitting respiratory inlet coverings are not allowed.
3. **MODES OF OPERATION** - Since the purified air is forced through the air purifying elements by use of the wearer's lungs, the respirator operates on the principle of variable flow.
4. **GENERAL REQUIREMENTS**
 - A. **Eye Protection** - All styles of respiratory inlet coverings that provide primary eye protection for impact and penetration shall meet the following requirements:

High Speed Impact - See ANSI Z87.1-1989 for Test Method Reference
High Mass Impact - See ANSI Z87.1-1989 for Test Method Reference

Full facepieces and hoods not providing eye protection shall be marked as such.
 - B. **Optical Requirements** - All lenses integral to the respiratory inlet covering, except those used for escape only, shall meet the following optical requirements:

Prism Imbalance - See ANSI Z87.1-1989 for Test Method Reference
Optical Definition - See ANSI Z87.1-1989 for Test Method Reference
 - C. **Shelf Life** - Wording needs to be developed for routine testing over specified "Estimated" shelf life period or duration.
 - D. **Fit Check Capability** - Negative pressure class respirators must provide the wearer with the ability to perform a routine fit check.
 - E. **Field of Vision** - Requirements to be similar to CEN Standards. The effective field of vision shall not be less than XX% of the unrestricted field available when the respiratory inlet covering is not used. The overlapping field shall not be less than XX%. Special purpose respirators designed for use in applications such as welding may exhibit effective and overlapping fields as low as XX% and XX% respectively. The respiratory inlet covering is mounted on a headform which is part of a Stoll Apertometer.

F. **Intrinsic Safety** - Requirements are not intended to apply to all respirators. However, if the manufacturer claims any form of intrinsic safety, the specific type (class/group referred to in the National Electric Code) shall be included in the labeling and marking (see Section 11). Said claim(s) shall be verified by a third party such as Factory Mutual, Underwriters Laboratories, MSHA, etc.

5. **INTERNAL PRESSURE AND BREATHING RESISTANCE REQUIREMENTS** - Breathing resistance is determined by use of a breathing machine. The respiratory inlet covering is mounted and sealed at the primary sealing flange on the breathing machine headform as worn by the user and the breathing machine is operated at a work rate (see table in Section 9) with a minute volume of 40 Liters (100 watts) for a duration of 10 full breathing cycles. During that period the MAX BP and the MIN BP for each cycle is recorded. The test value for MAX BP shall be the average of the recorded individual MAX BP measurements. The test value for the MIN BP is likewise the average of the recorded individual MIN BP measurements.

BP measurements to be made with an electronic transducer with specified response characteristics over a pressure range of ± 100 MM H₂O. Accuracy and resolution is also to be specified. Probe location to be at point of laminar flow inside the simulated throat of the headform.

The test breathing resistance values shall be within the limits specified as follows:

A. **Particulates**

Type	MAX BP Exhalation Resistance (MM H ₂ O)	Zero - MIN BP Inhalation Resistance (MM H ₂ O)
1		
2		
3		
4		

B. **Gases/Vapors**

Type	Exhalation Resistance (MM H ₂ O)	Inhalation Resistance (MM H ₂ O)
1		
2		
3		

C. Particulate and Gas/Vapor Combinations

Aerosol Type	Gases/Vapors (MM H ₂ O)					
	Type 1		Type 2		Type 3	
	Exhale	Inhale	Exhale	Inhale	Exhale	Inhale
1						
2						
3						
4						

For hood type respiratory inlet coverings, the internal pressure swing (MAX IP-MIN IP) shall not exceed XX MM H₂O.

6. **CARBON DIOXIDE ACCUMULATION REQUIREMENTS** - When tested with the respiratory inlet covering's primary sealing flange sealed to a headform on a breathing machine which exhales carbon dioxide at a concentration of 5% in the exhaled breath and at a work rate of 100 watts, the concentration of carbon dioxide inside the respiratory inlet covering shall not exceed a steady state concentration of XX% with an ambient face velocity of 0.5 M/S across the outside of the respiratory inlet covering.

7. **SIMULATED WORK, TEST REQUIREMENTS** - Respirators shall be tested to verify that they are capable of providing protection which equals or exceeds the requirements specified in the inward leakage section (see Section 12). Before the simulation of work begins respirators shall undergo a pre-screening process. Ten human test subjects shall be used, one representing each of the 10 Los Alamos fit test panel boxes. Each test subject will don and use the respirator according to the manufacturer's instructions provided with the respirator. The specified fit check procedures shall be performed before the test subjects enter the test chamber as part of the pre-screening procedure in order to maximize the respirator fit.

After conducting the applicable fit check, subjects shall undergo a quantitative fit test prior to the simulated work exercises. At least 9 of the 10 test subjects shall obtain fit test results which meet or exceed 10 times the protection factor calculated from the applicable maximum penetration value listed in Section 12.

If at least 9 of the 10 test subjects obtain acceptable fit test results they shall then undergo a simulated work test. The test chamber and equipment is to be specified but should be similar to an ATI corn oil polydispersed aerosol QFT apparatus with particle size and challenge agent consistent with the type of air purifying elements used. The test chamber has to be large enough to accommodate the simulation of work.

The simulated work protocol shall involve five different work regimes, some of which being performed under high "wind" conditions. The chamber shall also provide an elevated temperature and humidity environment. Each test subject shall simulate work for a period of one hour or for the service life of the respirator if said service life is less than one hour. During the simulation of work, the test subjects shall be continuously monitored for total inward leakage. The total inward leakage is compared to the chamber concentration to provide a percent penetration which is integrated over the entire test period to determine the average percent penetration for each of the 9 or 10 individual tests.

The 95th percentile of the individual average penetration values shall be equal to or less than the applicable maximum penetration value listed in Section 12.

In order to test gas/vapor respirators, the manufacturer shall supply "test" air purifying elements which simulate the weight, balance and breathing resistance of the gas/vapor air purifying elements used. The "test" elements shall meet the efficiency requirements of type 4 particulate air purifying elements.

(The work regime protocol is to be developed and will probably involve the use of a tread mill programmed for normal work activities, moving cinder blocks, running in place, hammering, crawling, etc.)

8. **ROUGH HANDLING REQUIREMENTS**

- A. Packaged respirators and/or components of respirators to be tested according to MIL-STD-810D Section II-3.2.
- B. Shaker table for complete respirators and air purifying elements (see CEN standards for reference).

After conditioning, respirators are to be evaluated according to the requirements of Section 9 for breathing air quality on a breathing machine (efficiency and/or penetration tests).

- 9. **BREATHING GAS QUALITY REQUIREMENTS** - Rough handling tests specified in Section 8 shall be performed prior to tests specified in this section. Air purification requirements for particulate groups use a NaCl test aerosol for solids and a DOP test aerosol for liquids. All respirators are tested on a breathing machine for efficiency or penetration with the respiratory inlet covering sealed to the test headform. Additionally, gas/vapor respirator air purifying elements will be tested for capacity using continuous flow methods at humidities of 25% and 80% at a temperature of 30°C. Particulate air purifying respirators will be tested for efficiency up to loads of 200 Mg.

RELEVANT BREATHING MACHINE WORK RATES:

Minute Volume (Liters)	Peak Inspiratory Flow Rate (LPM)	Respirations per Minute	Work Rate (Watts)	Tidal Volume (Liters)
10	30	21	25	0.7
40	120	24	100	1.6
60	180	26	150	2.2

- A. **Particulate Groups** - Challenge aerosol shall be charge neutralized and to be 0.1 to 0.3 micron count median diameter particle size with a geometric standard deviation less than 1.8 micron at a concentration of 50 to 150 Mg/M³. Respirators to be preconditioned in heat and humidity before testing (exact conditions to be determined).

Efficiency to be measured with the breathing machine operating at a work rate which develops a minute volume flow of 10 LPM and at a work rate which develops a minute volume flow of 60 LPM.

The breathing machine shall be equipped with a filter down stream of the sampling port in order to prevent the lung of the machine from pumping contaminated air back into the respirator.

Efficiency measurements will also be continuously monitored during the loading test which is performed at 60 LPM until the respirator has been challenged with 200 Mg of particulate, while on the breathing machine. At no time shall the efficiency drop below the specified minimum requirements.

The minimum efficiency for any given respirator under any of the above conditions shall exceed the following requirements:

(1) Solid Aerosol Group

Type	Efficiency
1	90%
2	95%
3	99%
4	99.97%

(2) Liquid Aerosol Group

Type	Efficiency
1	90%
2	95%
3	99%
4	99.97%

- B. **Gas/Vapor Groups** - Air purification requirements for gas/vapor groups use a variety of challenge contaminants at various concentrations. The challenge concentration increases with the air purifying element type (IE: Type 3 greater than Type 1).

Instantaneous penetration is measured using a breathing machine operating at minute volume flows of 10 LPM and 60 LPM. The applicable breakthrough concentration shall not be exceeded in the effluent air.

The breathing machine shall be equipped with a filter down stream of the sampling port in order to prevent the lung of the machine from pumping contaminated air back into the respirator.

Breakthrough times are measured in a continuous flow test run at 40 LPM with the challenge atmosphere at two separate humidities (25% and 80%).

(1) **Organic Gas/Vapor Group**

Type Element	Test Agent	Challenge Concentration (PPM)	Breakthrough Concentration (PPM)	Min. Break-through Time (Minutes)
1	CC14	1000	5	
2	CC14	5000	5	
3	CC14	20000	5	

(2) **Acid Gas/Vapor Group**
(to be determined)

(3) **Alkaline Gas/Vapor Group**
(to be determined)

(4) **Specific Gases and Vapors**
(to be determined)

- C. **Particulate and Gas/Vapor Combinations**
(To be determined)

10. **MISCELLANEOUS REQUIREMENTS**

- A. **Breathing Tubes** - Propose a pull test and a crush test requirement.
- B. **End of Service Life Indicators** - Requirements to be determined but not intended to apply to all respirators or filters, only if ESLI is provided for gas/vapor filter(s).

11. **LABELING, MARKING AND INSTRUCTIONS**

A. **Labeling and Markings** - Air purifying elements shall be color coded. Each major component is to be permanently marked with:

- (1) Manufacturer's identification
- (2) Date or lot number
- (3) Manufacturer's part number

(Those items listed on the "Approved Assembly List" are considered major components.) Each respirator shall have a label (on the product or package) listing the major components which make up the complete "approved" respirator. Air purifying elements shall be labeled with the group and type as well as any applicable approval agency limitations and the estimated shelf life/expiration date. Each respirator shall bear the following limitation marking:

"Approved use of this respirator is limited to respirator wearers having successfully completed an acceptable fit test as recommended by the manufacturer."

B. **Instructions** - Storage, use and maintenance instructions to be specified and clearly presented by the manufacturer.

12. **INWARD LEAKAGE REQUIREMENTS**

(to be determined)

Note: It is likely that full face masks will be assigned lower allowable values (% penetration) than half masks and that respirators with Type 3 or 4 air purifying elements will be assigned lower allowable values than those with Type 1 elements.

December 18, 1990

SECTION B OUTLINE

**AIR PURIFYING RESPIRATORS
POSITIVE PRESSURE CLASS (PAPR'S)**

**ISEA
DRAFT 9**

1. **GENERAL DESCRIPTION** - Provides protection by purifying air through the use of air purifying elements. The air is forced through the air purifying elements by a motive force other than use of the wearer's lungs. The motive force shall be sufficient to maintain internal pressure above ambient pressure at specified work rate levels. Respirators are rated according to work rate levels (IE level one is 100 watts, level 2 is 175 watts and level 3 is 250 watts).
2. **STYLES AND CLASSES** - Respiratory inlet coverings are provided as half masks, full face masks or hoods and may be either loose fitting or tight fitting. These types of respirators are classified as positive pressure only.
3. **MODES OF OPERATION** - Since air is forced through the air purifying elements by a motive force other than the use of the wearer's lungs, the air can be regulated to flow variably or continuously.
4. **GENERAL REQUIREMENTS**
 - A. **Eye Protection** - All styles of respiratory inlet coverings that provide primary eye protection for impact and penetration shall meet the following requirements:

High Speed Impact - See ANSI Z87.1-1989 for Test Method Reference
High Mass Impact - See ANSI Z87.1-1989 for Test Method Reference

Full facepieces and hoods not providing eye protection shall be marked as such.
 - B. **Optical Requirements** - All lenses integral to the respiratory inlet covering, except those used for escape only, shall meet the following optical requirements:

Prism Imbalance - See ANSI Z87.1-1989 for Test Method Reference
Optical Definition - See ANSI Z87.1-1989 for Test Method Reference
 - C. **Shelf Life** - Wording needs to be developed for routine testing over specified "Estimated" shelf life period or duration.
 - D. **Intrinsic Safety** - Requirements are not intended to apply to all respirators. However, if the manufacturer claims any form of intrinsic safety, the specific type (class/group referred to in the National Electric Code) shall be included in the labeling and marking (see Section 11). Said claim(s) shall be verified by a third party such as Factory Mutual, Underwriters Laboratories, MSHA, etc.
 - E. **Pressure/Flow Monitors** - Requirements to be determined (will apply to all respirators). Issues to be addressed include:
 - . Environmental Stability
 - . Accuracy/Resolution
 - . Rules for Automatic Integration

F. **Field of Vision** - Requirements to be similar to CEN Standards. The effective field of vision shall not be less than XX% of the unrestricted field available when the respiratory inlet covering is not used. The overlapping field shall not be less than XX%. Special purpose respirators designed for use in applications such as welding may exhibit effective and overlapping fields as low as XX% and XX% respectively. The respiratory inlet covering is mounted on a headform which is part of a Stoll Apertometer.

5. **INTERNAL PRESSURE AND BREATHING RESISTANCE REQUIREMENTS** - Pressure measurements are made by use of a breathing machine. The respiratory inlet covering is mounted on the breathing machine headform as worn by the user. Tight fitting respiratory inlet coverings to be sealed to headform at the primary seal. The respirator is operated according to the manufacturer's instructions.

Internal pressure and breathing pressure is then measured with the breathing machine operating at a work rate level appropriate to the respirator being tested according to the following specifications.

Work Level	Minute Volume (Liters)	Peak Inspiratory Flow Rate (LPM)	Respirations per Minute	Work Rate (Watts)	Tidal Volume (Liters)
1	40	120	24	100	1.6
2	70	210	27	175	2.5
3	100	300	30	250	3.4

The breathing machine is operated for a duration of 10 full breathing cycles. During that period the MAX IP and MIN IP for each cycle is recorded. The test value for MAX IP shall be the average of the recorded individual MAX IP measurements. The test value for MIN IP is likewise the average of the recorded individual MIN IP measurements. Breathing pressures are likewise treated.

IP measurements to be made with an electronic transducer with specified response characteristics over a pressure range of ± 100 MM H₂O. Probe location, accuracy and resolution are to be specified, but shall be in close proximity to the primary seal of the respiratory inlet covering.

BP measurements to be made with an electronic transducer with specified response characteristics over a pressure range of ± 100 MM H₂O. Probe location, accuracy and resolution are to be specified but shall be at a point of laminar flow inside the simulated throat of the headform.

The internal and breathing pressures shall be within the following limits:

A. Level 1 Work Rate

(MMH₂O)

Style Fit Configuration	MAX BP	MIN IP	MAX IP-MIN IP
Tight Mask			N/A
Tight Hood			
Loose Mask			N/A
Loose Hood			

B. Level 2 Work Rate

(MMH₂O)

Style Fit Configuration	MAX BP	MIN IP	MAX IP-MIN IP
Tight Mask			N/A
Tight Hood			
Loose Mask			N/A
Loose Hood			

C. Level 3 Work Rate

(MM H₂O)

Style Fit Configuration	MAX BP	MIN IP	MAX IP-MIN IP
Tight Mask			N/A
Tight Hood			
Loose Mask			N/A
Loose Hood			

If the MIN BP is less than zero at any of the specified work rates then a static pressure is to be measured and the inhalation resistance shall not exceed XX MM H₂O.

6. **CARBON DIOXIDE ACCUMULATION REQUIREMENTS** - When tested on a breathing machine which exhales carbon dioxide at a concentration of 5% in the exhaled breath and at a work rate of 100 watts, the concentration of carbon dioxide inside the respiratory inlet covering shall not exceed a steady state concentration of XX% with an ambient face velocity of 0.5 M/S across the outside of respiratory inlet covering. Tight fitting respiratory inlet coverings to be sealed to headform at the primary seal.
7. **SIMULATED WORK, TEST REQUIREMENTS** - Respirators shall be tested to verify that they are capable of providing protection which equals or exceeds the requirements specified in the inward leakage section (see Section 12). Before the simulation of work begins, respirators shall undergo a pre-screening process. Ten human test subjects shall be used, one representing each of the 10 Los Alamos fit test panel boxes. Each test subject will don and use the respirator according to the manufacturer's instructions provided with the respirator. The specified fit check procedures shall be performed for all tight fitting respiratory inlet coverings before the test subjects enter the test chamber as part of the pre-screening procedure in order to maximize the respirator fit.

After conducting the applicable fit check, subjects shall undergo a quantitative fit test prior to the simulated work exercises. At least 9 of the 10 test subjects shall obtain fit test results which meet or exceed 10 times the protection factor calculated from the applicable maximum penetration value listed in Section 12.

If at least 9 of the 10 test subjects obtain acceptable fit test results they shall then undergo a simulated work test. The test chamber and equipment is to be specified but should be similar to an ATI corn oil polydispersed aerosol QFT apparatus with particle size and challenge agent consistent with the type of air purifying elements used. The test chamber has to be large enough to accommodate the simulation of work.

The simulated work protocol shall involve five different work regimes, some of which being performed under high "wind" conditions. The chamber shall also provide an elevated temperature and humidity environment. Each test subject shall simulate work for a period of one hour or for the service life of the respirator if said service life is less than one hour. During the simulation of work, the test subjects shall be continuously monitored for total inward leakage. The total inward leakage is compared to the chamber concentration to provide a percent penetration which is integrated over the entire test period to determine the average percent penetration for each of the 9 or 10 individual tests.

The 95th percentile of the individual average penetration values shall be equal to or less than the applicable maximum penetration value listed in Section 12.

In order to test gas/vapor respirators, the manufacturer shall supply "test" air purifying elements which simulate the weight, balance and breathing resistance of the gas/vapor air purifying elements used. The "test" elements shall meet the efficiency requirements of type 4 particulate air purifying elements.

(The work regime protocol is to be developed and will probably involve the use of a tread mill, programmed for the appropriate work rate, moving cinder blocks, running in place, hammering, crawling, etc.)

8. **ROUGH HANDLING REQUIREMENTS**

- A. Packaged respirators and or components of respirators to be tested according to MIL-STD-810D Section II-3.2.
- B. Shaker table for complete respirators and air purifying elements (see GEN standards for reference).

After conditioning, respirators are to be evaluated according to the requirements of Section 9 for breathing air quality on a breathing machine (efficiency and/or penetration tests).

9. **BREATHING GAS QUALITY REQUIREMENTS** - Rough handling tests specified in Section 8 shall be performed prior to the tests specified in this section. Air purification requirements for particulate groups use a NaCl test aerosol for solids and a DOP test aerosol for liquids. All respirators are tested on a breathing machine for efficiency or penetration with the respiratory inlet covering mounted on the test headform as would be worn by the user. Additionally, gas/vapor respirator air purifying elements will be tested for capacity using continuous flow methods at humidities of 25% and 80% at a temperature of 30°C. Particulate air purifying respirators will be tested for efficiency up to loads of 2000 Mg.

- A. **Particulate Groups** - Challenge aerosol shall be charge neutralized and to be 0.1 to 0.3 micron count median diameter particle size with a geometric standard deviation less than 1.8 micron at a concentration of 50 to 150 Mg/M³. Respirators to be preconditioned in heat and humidity before testing (exact conditions to be determined).

Efficiency to be measured with the breathing machine operating at a work rate which develops a minute volume flow appropriate to the applicable work rate (IE 40, 70 or 100 LPM).

The breathing machine shall be equipped with a filter down stream of the sampling port in order to prevent the lung of the machine from pumping contaminated air back into the respirator.

Efficiency measurements will also be continuously monitored during the loading test which is performed at the applicable work rate (100, 175 or 250 Watts) until the respirator has been challenged with 2000 Mg of particulate, while on the breathing machine. At no time shall the efficiency drop below the specified minimum requirements.

The minimum efficiency for any given respirator under any of the above conditions shall exceed the following requirements:

(1) Solid Aerosol Group

Type	Efficiency
1	90%
2	95%
3	99%
4	99.97%

(2) Liquid Aerosol Group

Type	Efficiency
1	90%
2	95%
3	99%
4	99.97%

- B. Gas/Vapor Groups - Air purification requirements for gas/vapor groups use a variety of challenge contaminants at various concentrations. The challenge concentration increases with the air purifying element type (IE: Type 3 greater than Type 1).

Instantaneous penetration is measured with the breathing machine operating at a work rate which develops a minute volume flow appropriate to the applicable work rate (IE 40, 70, or 100 LPM).

The breathing machine shall be equipped with a filter down stream of the sampling port in order to prevent the lung of the machine from pumping contaminated air back into the respirator. The applicable break through concentration shall not be exceeded in the effluent air.

Breakthrough times are measured in a continuous flow test at 25% and 80% relative humidity at a temperature of 30°C. The test flow shall be equivalent to the minute volume of air passed through the air purifying element(s) when tested on a breathing machine as specified in Section 5. The work rate used shall depend on the level appropriate to the respirator. This equivalent flow shall be determined as follows:

(Test to be determined - May involve a dry gas test meter.)

(1) Organic Gas/Vapor Group

Type Element	Test Agent	Challenge Concentration (PPM)	Breakthrough Concentration (PPM)	Min. Break-through Time (Minutes)
1	CCl4	1000	5	
2	CCl4	5000	5	
3	CCl4	20000	5	

- (2) Acid Gas/Vapor Group
(to be determined)
- (3) Alkaline Gas/Vapor Group
(To be determined)
- (4) Specific Gases and Vapors
(To be determined)

- C. Particulate and Gas/Vapor Combinations
(To be determined)

10. **MISCELLANEOUS REQUIREMENTS**

- A. Breathing Tubes - Propose a pull test and a crush test requirement.
- B. Sound Levels - Sound level shall not exceed 80 dBA. Test method to be specified. Test to be performed in Anechoic chamber of specified characteristics (ask Paul Michael at Penn State for reference). Respiratory inlet covering to be mounted on a Bruel and Kjaer head/torso simulator (Type 4128). Microphone of specified type to be used and connected to a dosimeter of specified type. Test run at both ears of headform with microphone mounted in specified manner.
- C. End of Service Life Indicators - Requirement to be determined but not intended to apply to all respirators or filters, only if ESLI is provided for gas/vapor filter(s).

11. **LABELING, MARKING AND INSTRUCTIONS**

- A. Labeling and Markings - Air purifying elements shall be color coded. Each major component is to be permanently marked with:
 - (1) Manufacturer's identification
 - (2) Date or lot number
 - (3) Manufacturer's part number

Each respirator to be marked with the appropriate work rate level. (Those items listed on the "Approved Assembly List" are considered major components.) Each respirator shall have a label (on the product or package) listing the major components which make up the complete "approved" respirator. Air purifying elements shall be labeled with the group, type and work rate level, as well as any applicable approval agency limitations and the estimated shelf life/expiration date. Each respirator incorporating a tight fitting respiratory inlet covering shall bear the following limitation marking:

"Approved use of this respirator is limited to respirator wearers having successfully completed an acceptable fit test as recommended by the manufacturer."

B. Instructions - Storage, use and maintenance instructions to be specified and clearly presented by the manufacturer.

12. **INWARD LEAKAGE REQUIREMENTS**

(Values to be determined)

December 18, 1990

SECTION C OUTLINE

ATMOSPHERE SUPPLYING RESPIRATORS

AIRLINE (SAR'S)

**ISEA
DRAFT 9**

1. **GENERAL DESCRIPTION** - Provides protection by supplying breathing gas through the use of an air-supply line. Respirators include all items necessary to conduct the breathing gas from the point of attachment to the wearer's breathing zone. The breathing gas is supplied to the respiratory inlet covering and is available for the user to breathe.
2. **STYLES AND CLASSES** - Respiratory inlet coverings are provided as half masks, full face masks, hoods, or mouth pieces. Respirators are classified as negative pressure or positive pressure. Both loose fitting and tight fitting respiratory inlet coverings can be used with positive pressure class respirators. However, only tight fitting respiratory inlet coverings can be used with negative pressure class respirators.
3. **MODES OF OPERATION** - Since breathing gas is supplied to the respiratory inlet covering by a remote source, the gas can be regulated to flow variably or continuously. Continuous flow respirators shall be classified as positive pressure devices only. Demand valve operated respirators operate in the variable flow mode. Negative pressure class respirators are demand valve operated respirators. Demand valve operated respirators operate in a variable flow mode and can be classified as negative pressure or positive pressure.
4. **GENERAL REQUIREMENTS**
 - A. **Eye Protection** - all styles of respiratory inlet coverings that provide primary eye protection for impact and penetration shall meet the following requirements:

High Speed Impact - See ANSI Z87.1-1989 for Test Method Reference
High Mass Impact - See ANSI Z87.1-1989 for Test Method Reference

Full facepieces and hoods not providing eye protection shall be marked as such.
 - B. **Optical Requirements** - All lenses integral to the respiratory inlet covering shall meet the following optical requirements:

Prism Imbalance - See ANSI Z87.1-1989 for Test Method Reference
Optical Definition - See ANSI Z87.1-1989 for Test Method Reference
 - C. **Shelf Life** - Wording needs to be developed for routine testing over specified "Estimated" shelf life period or duration.
 - D. **Point of Attachment** - Instructions shall be provided to the user on how to adjust the source of breathing gas at the point of attachment so as to provide for proper operation of the respirator. This means shall take into account the specific air supply line being used (IE. could use flow indicator instead of pressure gage).
 - E. **Security** - Respirators shall be provided with a means to prevent the respiratory inlet covering from being dislodged by pulling on the air supply line. Effectiveness will be determined by the simulated work tests.

- F. **Pressure/Flow Monitors Requirements** to be determined (will apply to all respirators). Issues to be addressed include:
- . Environmental Stability
 - . Accuracy/Resolution
 - . Rules for Automatic Integration
- G. **Fit Check Capability** - Negative pressure class respirators must provide the wearer with the ability to perform a routine fit check.
- H. **Field of Vision** - Requirements to be similar to CEN Standards. The effective field of vision shall not be less than XX% of the unrestricted field available when the respiratory inlet covering is not used. The overlapping field shall not be less than XX%. Special purpose respirators designed for use in applications such as welding may exhibit effective and overlapping fields as low as XX% and XX% respectively. The respiratory inlet covering is mounted on a headform which is part of a Stoll Apertometer.
- I. **Intrinsic Safety** - Requirements are not intended to apply to all respirators. However, if the manufacturer claims any form of intrinsic safety, the specific type (class/group referred to in the National Electric Code) shall be included in the labeling and marking (see Section 11). Said claim(s) shall be verified by a third party such as Factory Mutual, Underwriters Laboratories, MSHA, etc.

5. **INTERNAL PRESSURE AND BREATHING RESISTANCE REQUIREMENTS** - Pressure measurements are made by use of a breathing machine. The respiratory inlet covering is mounted on the breathing machine headform as worn by the user. Tight fitting respiratory inlet coverings to be sealed to headform at the primary seal. The source of air is adjusted according to the manufacturer's instructions at the point of attachment.

Internal pressure and breathing pressure are then measured with the breathing machine operating at a work rate level appropriate to the respirator being tested according to the following specifications:

Work Rate Level	Minute Volume (Liters)	Peak Inspiratory Flow Rate (LPM)	Respirations per Minute	Work Rate (Watts)	Tidal Volume (Liters)
1	40	120	24	100	1.6
2	70	210	27	175	2.5
3	100	300	30	250	3.4

The breathing machine is operated for a duration of 10 full breathing cycles. During that period the MAX IP and MIN IP for each cycle is recorded. The test value for MAX IP shall be the average of the recorded individual MAX IP measurements. The test value for MIN IP is likewise the average of the recorded individual MIN IP measurements. Breathing pressures are likewise treated.

IP measurements to be made with an electronic transducer with specified response characteristics over a pressure range of ± 100 MM H₂O. Probe location, accuracy and resolution is also to be specified, but shall be in close proximity to the primary seal of the respiratory inlet covering.

BP measurements to be made with an electric transducer with specified response characteristics over a pressure range of ± 100 MM H₂O. Probe location, accuracy and resolution are to be specified but shall be at a point of laminar flow inside the simulated throat of the headform.

The internal and breathing pressures shall be within the following limits:

A. Level 1 Work Rate

(MM H₂O)

Style	MAX IP		MIN IP		MAX IP-MIN IP	
	Pos Press	Neg Press	Pos Press	Neg Press	Pos Press	Neg Press
Tight Mask					N/A	N/A
Tight Hood						
Loose Mask		N/A		N/A	N/A	N/A
Loose Hood		N/A		N/A		

B. Level 2 Work Rate

(MM H₂O)

Style	MAX BP		MIN IP		MAX IP-MIN IP	
	Pos Press	Neg Press	Pos Press	Neg Press	Pos Press	Neg Press
Tight Mask					N/A	N/A
Tight Hood						
Loose Mask		N/A		N/A	N/A	N/A
Loose Hood		N/A		N/A		

C. Level 3 Work Rate

(MM H₂O)

Style	MAX IP		MIN IP		MAX IP-MIN IP	
	Pos Press	Neg Press	Pos Press	Neg Press	Pos Press	Neg Press
Tight Mask					N/A	N/A
Tight Hood						
Loose Mask		N/A		N/A	N/A	N/A
Loose Hood		N/A		N/A		

If the MIN BP for positive pressure respirators is less than zero at any of the specified work rates, then a static pressure is to be measured and the inhalation resistance shall not exceed XX MM H₂O.

The MIN BP for negative pressure respirators shall not be less than Neg. XX MM H₂O.

6. **CARBON DIOXIDE ACCUMULATION REQUIREMENTS** - When tested on a breathing machine which exhales carbon dioxide at concentration of 5% in the exhaled breath and at a work rate of 100 watts, the concentration of carbon dioxide inside the respiratory inlet covering shall not exceed a steady state concentration of X% with an ambient face velocity of 0.5 M/S across the outside of respiratory inlet covering. Tight fitting respiratory inlet coverings to be sealed to headform at the primary seal.
7. **SIMULATED WORK, TEST REQUIREMENTS** - Respirators shall be tested to verify that they are capable of providing protection which equals or exceeds the requirements specified in the inward leakage section (see Section 12). Before the simulation of work begins, respirators shall undergo a pre-screening process. Ten human test subjects shall be used, one representing each of the 10 Los Alamos fit test panel boxes. Each test subject will don and use the respirator according to the manufacturer's instructions provided with the respirator. The specified fit check procedures shall be performed for all tight fitting respiratory inlet coverings before the test subjects enter the test chamber as part of the pre-screening procedure in order to maximize the respirator fit.

After conducting the applicable fit check, subjects shall undergo a quantitative fit test prior to the simulated work exercises. At least 9 of the 10 test subjects shall obtain fit test results which meet or exceed 10 times the protection factor calculated from the applicable maximum penetration value listed in Section 12.

If at least 9 of the 10 test subjects obtain acceptable fit test results they shall then undergo a simulated work test. The test chamber and equipment is to be specified but should be similar to an ATI corn oil polydispersed aerosol QFT apparatus. The test chamber has to be large enough to accommodate the simulation of work.

The simulated work protocol shall involve five different work regimes, some of which being performed under high "wind" conditions. The chamber shall also provide an elevated temperature and humidity environment. Each test subject shall simulate work for a period of one hour. During the simulation of work, the test subjects shall be continuously monitored for total inward leakage. The total inward leakage is compared to the chamber concentration to provide a percent penetration which is integrated over the entire test period to determine the average percent penetration for each of the 9 or 10 individual tests.

The 95th percentile of the individual average penetration values shall be equal to or less than the applicable maximum penetration value listed in Section 12.

(The work regime protocol is to be developed and will probably involve the use of a tread mill, programmed for the appropriate work rate, moving cinder blocks, running in place, hammering, crawling, etc.)

8. **ROUGH HANDLING REQUIREMENTS**

- A. Respirators to be tested less air supply lines according to MIL-STD-810D Section II-3.2.
- B. Air supply line coupling impact test to be devised to simulate repeated dropping on the floor.

After conditioning, respirators are to be evaluated on breathing machine for proper function.

- 9. **BREATHING GAS QUALITY REQUIREMENTS** - For testing, gas shall be at least grade D quality. However, air supply hoses should be tested for permeability and outgasing (requirements to be determined).

10. **MISCELLANEOUS REQUIREMENTS**

- A. **Breathing Tubes** - Propose pull test and crush test requirements.
- B. **Air Supply Lines**- Air-supply lines employed on airline respirators shall meet or exceed the following requirements:
 - (1) **Length** - 300 feet maximum
 - (2) **Strength** - Withstand 100 Lb. pull and 2X over pressurization (see NIOSH requirements).
 - (3) **Non-Kinkability** - Proposed NIOSH loop test

- (4) **Tightness** - Proposed NIOSH leakage test (coupling leak test)
- C. **Flow Control Valves** - Valves used to control the flow of breathing gas shall meet or exceed the following requirements:
 - (1) **Manual Flow Control** - Adjustment must not be affected by ordinary movements.
 - (2) **Demand Valves** - To be cycle tested on a breathing machine for 100,000 cycles per Section 5, level one and shall continue to meet the requirements of Section 5. Also valves to be subjected to over-pressurization and checked for function (requirements to be determined but must pass breathing machine test).
- D. **Strain Relief Harnesses** - To withstand XXX lb. pull of air supply line.
- E. **Sound Levels** - Sound level shall not exceed 80 dBA. Test method to be specified. Test to be performed in Anechoic chamber of specified characteristics (ask Paul Michael at Penn State for reference). Respiratory inlet covering to be mounted on a Bruel and Kjaer head/torso simulator (Type 4128). Microphone of specified type to be used and connected to a dosimeter of specified type. Test run at both ears of headform with microphone mounted in specified manner.

11. LABELING, MARKING AND INSTRUCTIONS

- A. **Labeling and Markings** - Each major component is to be permanently marked with:
 - (1) Manufacturer's identification
 - (2) Date or lot number
 - (3) Manufacturer's part number

Each respirator is to be marked with the appropriate work rate level. (Those items listed on the "Approved Assembly List" are considered major components.) Each respirator shall have a label (on the product or package) listing the major components which make up the complete "approved" respirator. Each respirator incorporating a tight fitting respiratory inlet covering shall bear the following limitation marking:

"Approved use of this respirator is limited to respirator wearers having successfully completed an acceptable fit test as recommended by the manufacturer."

- B. **Instructions** - Storage, use and maintenance instructions to be specified and clearly presented by the manufacturer.

12. INWARD LEAKAGE REQUIREMENTS

(Values to be determined)

Note: Positive pressure respirators will be assigned lower allowable values (% penetration) than negative pressure respirators.

December 18, 1990

SECTION D OUTLINE

**ATMOSPHERE SUPPLYING RESPIRATORS
OPEN CIRCUIT, SELF-CONTAINED BREATHING APPARATUS
(SCBA'S)**

**ISEA
DRAFT 9**

1. **GENERAL DESCRIPTION** - Provides protection by supplying a self-contained breathing gas (stored within the apparatus) to the respiratory inlet covering. This class of respirator uses tight fitting respiratory inlet coverings which are intended to seal against the wearer. Exhaled gas is exhausted to the atmosphere without recirculation. The source of breathing gas may be compressed air or liquid air. These respirators are designed for the possible use in IDLH atmospheres for entry into and egress.
2. **STYLES AND CLASSES** - Tight fitting respiratory inlet coverings are provided as full face masks or hoods. These respirators are classified only as positive pressure. The current requirements and tests have considered only tight fitting respiratory inlet coverings. The use of loose fitting respiratory inlet coverings shall require further consideration and may require additional tests.
3. **MODES OF OPERATION** - These respirators are demand valve operated devices and thus operate in a variable flow mode.
4. **GENERAL REQUIREMENTS**
 - A. **Eye Protection** - All styles of respiratory inlet coverings shall provide primary eye protection for impact and penetration. Lenses shall meet the following requirements:

High Speed Impact - See ANSI Z87.1.1989 for Test Method Reference
High Mass Impact - See ANSI Z87.1-1989 for Test Method Reference
 - B. **Optical Requirements** - Lenses shall meet the following requirements:

Prism Imbalance - See ANSI Z87.1-1989 for Test Method Reference
Optical Definition - See ANSI Z87.1-1989 for Test Method Reference
 - C. **Shelf Life** - Wording needs to be developed for routine testing over specified "Estimated" shelf life period or duration.
 - D. **Fit Check Capability** - The respirator must provide the wearer with the ability to perform a routine fit check.
 - E. **Field of Vision** - Requirements to be similar to CEN Standards. The effective field of vision shall not be less than XX% of the unrestricted field available when the respiratory inlet covering is not used. The overlapping field shall not be less than XX%. Special purpose respirators designed for use in applications such as welding may exhibit effective and overlapping fields as low as XX% and XX% respectively. The respiratory inlet covering is mounted on a headform which is part of a Stoll Apertometer.

F. **Service-Life Indicators/Alarms**

- (1) **Liquid Type** - Requirements to be determined.
- (2) **Gas Type** - Remaining service-life indicators or warning devices shall be provided in addition to a compressed gas pressure gage and shall operate automatically without preadjustment by the wearer.

Each remaining service life indicator or warning device shall give an alarm when the remaining service life or cylinder pressure of the apparatus is reduced to a level of 75% to 80% as specified in the following Section (4G). There shall be no degrading of performance by the remaining service life indicator. Audible remaining service life indicators shall be clearly and distinctly detectable and be between 80 dBA and 100 dBA at both ears. (See Section 10-F for reference regarding the sound measuring test method.) Remaining service life indicators or warning devices shall warn the wearer for a period of 30 seconds or more after the alarm is initiated.

- G. **Rated Gas Volume** - Since service time is greatly influenced by use conditions, manufactures shall provide a gas volume rating, in liters, instead of a service time rating. This rating shall be verified by the use of a breathing machine according to the characteristics described in Section 5. The breathing machine shall be operated for a period of time such that the total gas consumption of the machine equals 90% of the rated gas volume specified by the manufacturer. During this period of time the requirements of Section 5 shall be maintained by the respirator. The service life indicator/alarm shall activate when 75% to 80% of the rated gas volume has been consumed.

The rated gas volume shall not be less than 600 liters.

- H. **Intrinsic Safety** - Requirements are not intended to apply to all respirators. However, if the manufacturer claims any form of intrinsic safety, the specific type (class/group referred to in the National Electric Code) shall be included in the labeling and marking (see Section 11). Said claim(s) shall be verified by a third party such as Factory Mutual, Underwriters Laboratories, MSHA, etc.

- I. **Corrosion Resistance** - An SCBA with a fully charged cylinder and having the cylinder valve closed shall be tested in accordance with Method 509.2. Salt Fog, Section II, of MIL-STD-810D, Environmental Test Methods.

The SCBA shall be attached to a mannequin to simulate its typical wearing position as specified by the manufacturer. The mannequin shall then be placed in a test chamber. The test chamber temperature shall be adjusted to 95°F. The SCBA shall be placed in the chamber for 2 hours prior to the introduction of the salt solution.

The SCBA shall be exposed to a 5% salt fog for a period of 48 hours.

Finally, the SCBA shall be stored in an environment of 72°F with 50% relative humidity for a minimum of 48 hours.

The SCBA shall be subsequently evaluated relative to all sections of this standard and shall meet all stated requirements.

- J. **Particulate Resistance Requirements** - A fully charged SCBA shall be subjected to Method 510.2. Sand and Dust. Section II-3, of MIL-STD-810D, Environmental Test Methods.

The respiratory inlet covering of the SCBA being tested shall be secured to a test headform.

The test headform shall be joined to a mannequin with the remaining components of the SCBA attached to the mannequin to simulate its typical wearing position specified by the manufacturer.

The test headform shall be connected to a Breathing Machine or other respiration simulator capable of producing a Level 1 Work Rate.

The mannequin, including the test headform, shall be mounted upright and turned about its vertical axis 180° midway through the test. The test duration shall be one hour and the breathing machine shall be operating throughout the entire test. The test may be interrupted to change the SCBA breathing gas container.

The test conditions as outlined per Method 510.2. Sand and Dust, of MIL-STD-810D, Environmental Test Methods. Section I-3d shall be:

- (1) Air velocity: Refer to subparagraph I-3.2c (1).
- (2) Temperature: 72°F.
- (3) Test item configuration and orientation: mannequin upright and rotated 180° midway through the test.
- (4) Dust Composition: Refer to Section I-3.2d (1).
- (5) Dust concentration: Refer to Section I-3.2e (1).
- (6) Test duration: 1 hour

After the completion of the above test, the SCBA shall be removed from the test compartment; it shall be lightly shaken or brushed free of dust, and then shall meet all of the requirements of this standard.

- K. **Thermal Resistance Requirements** - The thermal resistance tests specified in this section may be conducted in any sequence. After performing each test, the SCBA shall be placed in an ambient environment of 72°F, with a relative humidity of 50% for a minimum 12-hour dwell period.

The SCBA shall be placed in an appropriate environmental chamber and positioned to simulate the normal wearing position of the SCBA as specified by the manufacturer. A test headform shall be equipped with a thermocouple or other temperature-sensing element to monitor SCBA test chamber temperature. The thermocouple or other temperature-sensing element used shall be attached to the test headform in a manner in which it will be directly exposed to the chamber atmosphere. The test headform shall be connected to a breathing machine appropriate to the device being evaluated. The breathing machine may be located either inside or outside the environmental chamber.

The dwell period between thermal tests shall be used for refilling the breathing gas container and visually inspecting the SCBA for any gross damage that could cause unsafe test conditions.

- (1) The SCBA shall be cold soaked at -25°F for a minimum of 12 hours. The SCBA shall be tested at an ambient of -25°F.
- (2) The SCBA shall be hot soaked at 160°F for a minimum of 12 hours. The SCBA shall then be tested at an ambient of 160°F.
- (3) The SCBA shall be hot soaked at 160°F for a minimum of 12 hours. The SCBA shall then be transferred to a chamber with an air temperature of -25°F. The SCBA shall then be tested at a chamber air temperature of -25°F.
- (4) The SCBA shall be cold soaked at -25°F for a minimum of 12 hours. The SCBA shall then be transferred to a chamber with an air temperature of 160°F. The SCBA shall then be tested at a chamber air temperature of 160°F.

L. **Low Temperature Operation Requirements** - The manufacturer shall specify the minimum temperature for safe operation and test subjects shall perform the tests described in this section wearing the apparatus according to manufacturer's instructions. At the specified temperature, the apparatus shall meet all the requirements described below.

The apparatus shall be cold soaked at the manufacturer's specified minimum temperature for 12 hours.

The apparatus shall be worn in the low temperature chamber for 30 minutes, or for the service time of the apparatus, whichever is less.

During the test period, alternate 1-minute periods of exercise and rest shall be required with the exercise periods consisting of stepping onto and off a box 8.5 inches high at a rate of 30 cycles per minute.

- (1) The apparatus shall function satisfactorily at the specified minimum temperature on duplicate tests.

- (2) The wearer shall have sufficient unobscured vision to perform The work and read an eye chart (see proposed NFPA).
- (3) The wearer shall not experience undue discomfort because of airflow restriction or other physical or chemical changes in the operation of the apparatus.

Auxiliary low-temperature parts which are commercially available to the user and recommended by the manufacturer may be used on the apparatus to meet these requirements.

M. **Communication Requirements** - Same as NFPA.

N. **System Safety Analysis Requirements** - A failure mode analysis shall be conducted relative to the SCBA design. Requirements to be determined with system reliability at 90% to at least 100,000 breathing cycles with at least 95% confidence.

5. **INTERNAL PRESSURE AND BREATHING RESISTANCE REQUIREMENTS** - Pressure measurements are made by use of a breathing machine. The respiratory inlet covering is mounted and sealed to the breathing machine headform as worn by the user. The respirator is operated according to the manufacturer's instructions.

Internal pressure and breathing resistance are then measured with the breathing machine operating as indicated below:

Work Rate Level	Minute Volume (Liters)	Peak Inspiratory Flow Rate (LPM)	Respirations per Minute	Work Rate (Watts)	Tidal Volume (Liters)
3	100	300	30	250	3.4

The breathing machine is operated for a period of time as indicated in Section 4G. During that period the MAX IP and MIN IP for each cycle is recorded starting with the second breathing cycle. Breathing pressures are likewise treated. Performance must be maintained during the entire test period including the alarm activation period.

IP measurements to be made with an electronic transducer with specified response characteristics over a pressure range of ± 100 MM H₂O. Probe location, accuracy and resolution is to be specified, but shall be in close proximity to the primary seal of the respiratory inlet covering.

BP measurements to be made with an electronic transducer with specified response characteristics over a pressure range of ± 100 MM H₂O. Probe location, accuracy and resolution are to be specified but shall be at a point of laminar flow inside the simulated throat of the headform.

The internal and breathing pressures shall be within the following limits:

(MM H₂O)

Style Fit Configuration	MAX BP	MIN IP	MaxIP-MinIP
Tight Mask			N/A
Tight Hood			
Loose Mask			N/A
Loose Hood			

If the MIN BP is less than zero, then a static pressure is to be measured and the inhalation resistance shall not exceed XX MM H₂O.

6. **CARBON DIOXIDE ACCUMULATION REQUIREMENTS** - When tested with the respiratory inlet covering's primary sealing flange sealed to a headform on a breathing machine which exhales carbon dioxide at concentration of 5% in the exhaled breath and at a work rate of 100 watts, the concentration of carbon dioxide inside the respiratory inlet covering shall not exceed a steady state concentration of XX% with an ambient face velocity of 0.5 M/S across the outside of respiratory inlet covering.

7. **SIMULATED WORK, TEST REQUIREMENTS** - Respirators shall be tested to verify that they are capable of providing protection which equals or exceeds the requirements specified in the inward leakage section (see Section 12). Before the simulation of work begins, respirators shall undergo a pre-screening process. Ten human test subjects shall be used, one representing each of the 10 Los Alamos fit test panel boxes. Each test subject will don and use the respirator according to the manufacturer's instructions provided with the respirator. The specified fit check procedures shall be performed for all tight fitting respiratory inlet coverings before the test subjects enter the test chamber as part of the pre-screening procedure in order to maximize the respirator fit.

After conducting the applicable fit check, subjects shall undergo a quantitative fit test prior to the simulated work exercises. At least 9 of the 10 test subjects shall obtain fit test results which meet or exceed 10 times the protection factor calculated from the applicable maximum penetration value listed in Section 12.

If at least 9 of the 10 test subjects obtain acceptable fit test results they shall then undergo a simulated work test. The test chamber and equipment is to be specified but should be similar to an ATI corn oil polydispersed aerosol QFT apparatus. The test chamber has to be large enough to accommodate the simulation of work.

The simulated work protocol shall involve five different work regimes, some of which being performed under high "wind" conditions. The chamber shall also provide an elevated temperature and humidity environment. Each test subject shall simulate work for a period of one hour or for the service life of the respirator if said service life is less than one hour. During the simulation of work, the test subjects shall be continuously monitored for total inward leakage. The total inward leakage is compared to the chamber concentration to provide a percent penetration which is integrated over the entire test period to determine the average percent penetration for each of the 9 or 10 individual tests.

The 95th percentile of the individual average penetration values shall be equal to or less than the applicable maximum penetration value listed in Section 12.

(The work regime protocol is to be developed and will probably involve the use of a tread mill, programmed for the appropriate work rate, moving cinder blocks, running in place, hammering, crawling, etc.)

8. **ROUGH HANDLING REQUIREMENTS** - The following tests shall be conducted in the order specified. After being subjected to the tests, the SCBA shall meet all the requirements of this standard.

The complete SCBA shall be tested in accordance with Method 514.3, Vibration, of MIL-STD-810D, Environmental Test Methods. The test shall be set up according to I-3.2.1c. The test procedure used shall be Section II-3.1, Procedure II, using the frequency curves 514.3-1, 514.3-2, and 514.3-3. The SCBA shall be secured using a suitable rigid mounting bracket and the SCBA shall be tested on each axis for three hours. The total duration shall be 9 hours; 3 hours for each frequency curve.

The complete SCBA less the respiratory inlet covering and less those components that attach directly to the respiratory inlet covering per the manufacturer's instructions for use shall be tested in accordance with Method 514.3, Vibration, of MIL-STD-810D, Environmental Test Methods, using Procedure II. The test shall be set up according to I-3.2.3c. The duration of the test shall be 3 hours. A vibration box with a one-inch circular motion shall be constructed in accordance with diagram 514.3-24 of Method 514.3, Vibration, of MIL-STD-810D, Environmental Test Methods.

The respiratory inlet covering with those components, not tested above, attached to the respiratory inlet covering shall be tested in accordance with Method 514.3, Vibration, Section II-3.2 of MIL-STD-810D, Environmental Test Methods, using Procedure II. The test shall be set up according to I-3.2.3c. The duration of the test shall be 3 hours. A vibration box with a one-inch circular motion shall be constructed in accordance with diagram 514.3-24 of Method 514.3, Vibration, of MIL-STD-810D, Environmental Test Methods.

9. **BREATHING GAS QUALITY REQUIREMENTS** - For testing, gas shall be at least Grade D quality. Plus, see new CGA 7.1 1989 requirements, with the exception of a maximum dew point requirement of -65 degrees F.

10. **MISCELLANEOUS REQUIREMENTS**

- A. **Breathing Tubes** - Propose pull test and crush test requirements.
- B. **Flow Control Valves** - Valves used to control the flow of breathing gas shall meet or exceed the following requirements:
 - (1) **Hand Operated Valves**
 - (a) Valves shall be designed and constructed to prevent removal of the stem from the valve body during normal usage to ensure against a sudden release of the full pressure of the container when the valve is opened.
 - (b) Valves shall be designed or positioned to prevent accidental opening and closing and damage from external forces.
 - (c) Valves operated during use of the apparatus shall be installed in locations where they can be readily operated by the wearer.
 - (d) Valves installed on apparatus shall be clearly distinguishable from one another by sight and touch.
 - (2) **Cylinder Valves**- Compressed breathing gas container valves or a separate charging system or adapter provided with each apparatus shall be equipped with outlet threads specified by the American National Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections. CGA V-1.1987 standard.
 - (3) **By-Pass Valves** - Hand-operated or automatic by-pass systems designed and constructed to permit the wearer to breathe and conserve the gas supply in the event of a pressure/flow regulator failure, shall be provided where necessary and provide a minimum air flow of XXX LPM. Hand-operated by-pass valve controls shall be colored red.
 - (4) **Purge Valves** - If provided, purge valves shall be designed to close automatically if not being held open by the wearer.
 - (5) **Shut-Off Valves** - Manual or automatic shut-off valves shall be provided to feed any remotely mounted air operated device such as pressure indicators or service time alarms unless a severed line leading to such device(s) restricts the flow of air such that the service time is not diminished more than 5%.
 - (6) **Relief Valves** - Automatically operated pressure relief valves shall be provided if the system safety analysis (see Section 4-N) indicates that a potential over pressurization malfunction could damage the apparatus or injure the wearer.

- (7) **Demand Valves** - Shall not be provided with any mechanism which would allow the user to manually impede the flow of breathing gas during normal use (i.e. donning devices).
- C. **Compressed Gas Containers** - Compressed breathing gas containers shall meet the minimum requirements of the Department of Transportation for interstate shipment of such containers when fully charged. Such containers shall be permanently and legibly marked to identify their contents. Containers which may be removed from apparatus for refilling shall be equipped with an indicating gauge which shows the pressure in the container.
- D. **Harnesses** - Requirements to be determined.
- E. **Compressed Gas Particulate Filters** - All self-contained breathing apparatus shall have a filter downstream of the gas source to remove particles which may adversely affect respirator performance.
- F. **Sound Levels** - Sound level, under normal operating conditions excluding that period during which audible alarms are actuated, shall not exceed 80 dBA. Test method to be specified. Test to be performed in Anechoic chamber of specified characteristics (ask Paul Michael at Penn State for reference). Respiratory inlet covering to be mounted on a Bruel and Kjaer head/torso simulator (Type 4128). Microphone of specified type to be used and connected to a dosimeter of specified type. Test run at both ears of headform with microphone mounted in specified manner.
- G. **Hoses** - Burst pressure to exceed 2X maximum normal operating pressure. Hose assemblies to withstand XXX pound pull test.
- H. **Quick Disconnect Hose Couplings** - Where provided, couplings designed for quick disconnect shall prevent accidental separation.
- I. **Pressure Indicators** - Gas pressure gages employed on compressed breathing gas containers shall be marked in force per unit area. Other gas pressure gages shall be marked in:
- (1) Force per unit area.
 - (2) Fractions of total container capacity, or
 - (3) Both in force per unit area and fractions of total container capacity.

Gages shall be accurate to within 5 percent of full scale when tested both up and down the scale at each of 5 equal intervals. The full scale graduation of dial-indicating gages shall not exceed 150 percent of the maximum rated cylinder pressures specified for the container in applicable Department of Transportation specifications or permits, or 150 percent of the maximum pressure specified by the manufacturer's user instructions, whichever is less.

- J. **Over Pressurization Requirements** - Demand valves shall be preconditioned to simulate intentional over pressurization by the user. The regulator shall be subjected to a 1 to 2 second simulated attempt to block the regulator flow with the regulator by-pass valve set at maximum flow. Such simulation shall be either manual or mechanical as appropriate to the respirator being evaluated. Each regulator shall be subjected to a sequence of 20 simulated blocking attempts. Following the simulation blocking cycles, the regulator diaphragm shall be inspected and shall be found free of damage.
- K. **Lenses** - Lens scratch resistance as developed by NFPA to be specified.

11. **LABELING, MARKING AND INSTRUCTIONS**

- A. **Labeling and Markings** - Each major component is to be permanently marked with:
 - (1) Manufacturer's identification
 - (2) Date or lot number
 - (3) Manufacturer's part number

Each respirator is to be marked with the rated gas volume. (Those items listed on the "Approved Assembly List" are considered major components.) Each respirator shall have a label (on the product) listing the major components which make up the complete "approved" respirator. Each respirator shall bear the following limitation marking:

"Approved use of this respirator is limited to respirator wearers having successfully completed an acceptable fit test as recommended by the manufacturer."

- B. **Instructions** - Storage, use and maintenance instructions to be specified and clearly presented by the manufacturer.

12. **INWARD LEAKAGE REQUIREMENTS**
(Values to be determined)

13. **SPECIAL REQUIREMENTS**

- A. **Apparatus for use in fire fighting**
 - (1) Flame Test Requirements - Same as NFPA
 - (2) Fabric Components - Same as NFPA
 - (a) Flame Resistance
 - (b) Heat Resistance
 - (3) Minimum use temperature shall be -25°F or colder
 - (4) Minimum rated gas volume shall be 1200 liters
- B. **Apparatus With "Buddy Breathing" Devices** - Requirements to be Determined. Goal is that both respiratory inlet coverings receive enough flow to meet the requirements of Section 5.

December 18, 1990

SECTION E OUTLINE

**ATMOSPHERE SUPPLYING RESPIRATORS
CLOSED CIRCUIT SELF-CONTAINED BREATHING APPARATUS
(SCBA's)**

**ISEA
DRAFT 9**

1. **GENERAL DESCRIPTION** - Provides protection by supplying a self-contained source of breathing gas (stored within the apparatus) to the respiratory inlet covering. This class of respirator uses tight fitting respiratory inlet coverings which are intended to seal against the wearer. Carbon dioxide is removed from the exhaled gas and the "scrubbed" gas is recirculated within the apparatus. The source of breathing gas can be oxygen, oxygen-enriched air (stored as a liquid or a gas) or an oxygen generating material. These respirators are designed for the possible use in IDLH atmospheres for entry into and egress.
2. **STYLES AND CLASSES** - Tight fitting respiratory inlet coverings are provided as full face masks or hoods. These respirators are classified only as positive pressure devices. The current requirements and tests have considered only tight fitting respiratory inlet coverings. The use of loose fitting respiratory inlet coverings shall require further consideration and may require additional tests.
3. **MODES OF OPERATION** - These respirators are in-effect demand valve operated devices and thus operative in a variable flow mode.
4. **GENERAL REQUIREMENTS**
 - A. **Eye Protection** - All styles of respiratory inlet coverings shall provide primary eye protection for impact and penetration. Lenses shall meet the following requirements:
 - High Speed Impact - See ANSI Z87.1-1989 for Test Method Reference
 - High Mass Impact - See ANSI Z87.1-1989 for Test Method Reference
 - B. **Optical Requirements** - Lenses shall meet the following requirements:
 - Prism Imbalance - See ANSI Z87.1-1989 for Test Method Reference
 - Optical Definition - See ANSI Z87.1-1989 for Test Method Reference
 - C. **Shelf Life** - Wording needs to be developed for routine testing over specified "Estimated" shelf life period or duration.
 - D. **Fit Check Capability** - The respirator must provide the wearer with the ability to perform a routine fit check.
 - E. **Field of Vision** - Requirements to be similar to CEN Standards. The effective field of vision shall not be less than XX% of the unrestricted field available when the respiratory inlet covering is not used. The overlapping field shall not be less than XX%. Special purpose respirators designed for use in applications such as welding may exhibit effective and overlapping fields as low as XX% and XX% respectively. The respiratory inlet covering is mounted on a headform which is part of a Stoll Apertometer.

F. **Service-Life Indicators/Alarms**

- (1) **Chemical or Liquid Oxygen Apparatus** - Timers are generally used to estimate the remaining service-life of the apparatus when in use. Timers shall be readable by sight and/or by touch during use and shall be equipped with automatically preset alarms which will warn the wearer for a period of 30 seconds or more when 20 to 30 percent of the service-life is remaining.
- (2) **Compressed Gas Apparatus** - Remaining service-life indicators or warning devices shall be provided in addition to a compressed gas pressure gage and shall operate automatically without preadjustment by the wearer.

Each remaining service life indicator or warning device shall give an alarm when the remaining service life or cylinder pressure of the apparatus is reduced to a level of 70% to 80% as specified in the following Section (4G). There shall be no degrading of performance by the remaining service life indicator. Audible remaining service life indicators shall be clearly and distinctly detectable and be between 80 dBA and 100 dBA at both ears. (See Section 10-F for reference regarding the sound measuring test method.) Remaining service life indicators or warning devices shall warn the wearer for a period of 30 seconds or more after the alarm is initiated.

- G. **Rated Gas Volume** - Since service time is greatly influenced by use conditions, manufacturers shall provide a gas volume rating, in liters, instead of a service time rating. This rating shall be verified by use of a metabolic simulator operating with consumption and ventilation rates equivalent to a work rate of 175 watts. The metabolic simulator shall be operated for a period of time such that the total gas consumption of the machine equals 90% of the rated gas volume specified by the manufacturer. During this period of time requirements of the following sections shall be maintained by the respirator:

- 4 Breathing Gas Temperature
- 5 Internal and Breathing Pressure
- 6 CO₂ Accumulation
- 9 Breathing Gas Quality

The service life indicator/alarm shall activate when 70% to 80% of the rated gas volume has been consumed.

The rated gas volume shall not be less than 600 liters.

- H. **Intrinsic Safety** - Requirements are not intended to apply to all respirators. However, if the manufacturer claims any form of intrinsic safety, the specific type (class/group referred to in the National Electric Code) shall be included in the labeling and marking (see Section 11). Said claim(s) shall be verified by a third party such as Factory Mutual, Underwriters Laboratories, MSHA, etc.

- I. **Corrosion Resistance** - An SCBA in the non-operational mode (shut-off) shall be tested in accordance with method 509.2. Salt Fog Section II, of MIL-STD-810D Environmental Test Methods.

The SCBA shall be attached to a mannequin to simulate its typical wearing position as specified by the manufacturer. The mannequin shall then be placed in a test chamber. The test chamber temperature shall be adjusted to 95°F. The SCBA shall be placed in the chamber for 2 hours prior to the introduction of the salt solution.

The SCBA shall be exposed to a 5% salt fog for a period of 48 hours.

Finally, the SCBA shall be stored in an environment of 72°F with 50% relative humidity for a minimum of 48 hours.

The SCBA shall be subsequently evaluated relative to all sections of this standard and shall meet all stated requirements.

- J. **Particulate Resistance Requirements** - A fully charged SCBA shall be subjected to Method 510.2. Sand and Dust. Section II-3, of MIL-STD-810D, Environmental Test Methods.

The respiratory inlet covering of the SCBA being tested shall be secured to a test headform.

The test headform shall be joined to a mannequin with the remaining components of the SCBA attached to the mannequin to simulate its typical wearing position specified by the manufacturer.

The test headform shall be connected to a metabolic simulator.

The mannequin, including the test headform, shall be mounted upright and turned about its vertical axis 180° midway through the test. The test duration shall be one hour and the metabolic simulator shall be operating throughout the entire test. The test may be interrupted to change the SCBA breathing gas containers.

The test conditions as outlined per Method 510.2. Sand and Dust, of MIL-STD-810D, Environmental Test Methods. Section I-3d. shall be:

- (1) Air velocity: Refer to subparagraph I-3.2c (1).
- (2) Temperature: 72°F.
- (3) Test item configuration and orientation: mannequin upright and rotated 180° midway through the test.
- (4) Dust Composition: Refer to Section I-3.2d (1).
- (5) Dust concentration: Refer to Section I-3.2e (1).
- (6) Test duration: 1 hour

After the completion of the above test, the SCBA shall be removed from the test compartment; it shall be lightly shaken or brushed free of dust, and then shall meet all of the requirements of this standard.

- K. **Thermal Resistance Requirements** - The thermal resistance tests specified in this section may be conducted in any sequence. After performing each test, the SCBA shall be placed in an ambient environment of 72°F, with a relative humidity of 50% for a minimum 12-hour dwell period.

The SCBA shall be placed in an appropriate environmental chamber and positioned to simulate the normal wearing position of the SCBA as specified by the manufacturer. A test headform shall be equipped with a thermocouple or other temperature-sensing element to monitor SCBA test chamber temperature. The thermocouple or other temperature-sensing element used shall be attached to the test headform in a manner in which it will be directly exposed to the chamber atmosphere. The test headform shall be connected to a metabolic simulator appropriate to the device being evaluated. The metabolic simulator should be located outside the environmental chamber.

The dwell period between thermal tests shall be used for refilling the breathing gas container(s) and visually inspecting the SCBA for any gross damage that could cause unsafe test conditions.

- (1) The SCBA shall be cold soaked at -25°F for a minimum of 12 hours. The SCBA shall be tested at an ambient of -25°F.
- (2) The SCBA shall be hot soaked at 160°F for a minimum of 12 hours. The SCBA shall then be tested at an ambient of 160°F.
- (3) The SCBA shall be hot soaked at 160°F for a minimum of 12 hours. The SCBA shall then be transferred to a chamber with an air temperature of -25°F. The SCBA shall then be tested at a chamber air temperature of -25°F.
- (4) The SCBA shall be cold soaked at -25°F for a minimum of 12 hours. The SCBA shall then be transferred to a chamber with an air temperature of 160°F. The SCBA shall then be tested at a chamber air temperature of 160°F.

While liquid air or oxygen devices are not exempt from these requirements, it may not be practical or feasible to condition the breathing gas source for a period of 12 hours. Therefore, the breathing gas container(s) may be charged/replaced between the soak and test operations.

- L. **Low Temperature Operation Requirements** - The manufacturer shall specify the minimum temperature for safe operation and test subjects shall perform the tests described in this section wearing the apparatus according to manufacturer's instructions. At the specified temperature, the apparatus shall meet all the requirements described below.

The apparatus shall be cold soaked at the manufacturer's specified minimum temperature for 12 hours.

The breathing gas container of liquid air or oxygen devices may be charged/replaced immediately after the 12 hour soak period, just prior to testing.

The apparatus shall be worn in the low temperature chamber for 30 minutes, or for the service time of the apparatus, whichever is less.

During the test period, alternate 1-minute periods of exercise and rest shall be required with the exercise periods consisting of stepping onto and off a box 8.5 inches high at a rate of 30 cycles per minute.

- (1) The apparatus shall function satisfactorily at the specified minimum temperature on duplicate tests.
- (2) The wearer shall have sufficient unobscured vision to perform the work and read an eye chart (see proposed NFPA)
- (3) The wearer shall not experience undue discomfort because of airflow restriction or other physical or chemical changes in the operation of the apparatus.

Auxiliary low-temperature parts which are commercially available to the user and recommended by the manufacturer may be used on the apparatus to meet these requirements.

- M. **Breathing Gas Temperature** - The SCBA is to be tested on a metabolic simulator which is operating in an ambient room environment of 24 ± 4 degrees celsius. The exhaled breath of the simulator shall be 33 ± 1 degrees celsius as measured in the throat of the headform. Test probe location for inspiration temperature shall be within the respiratory inlet covering immediately adjacent to the mouth of the test headform. The instantaneous inspiration temperature throughout the breathing cycle shall be monitored for the entire duration as specified in the rated gas volume Section (4G). The metabolic simulator is continually cycled through three discrete work rates (100, 175 & 250 watts) such that the average consumption and ventilation rates are equivalent to 175 watts of work rate. At no time shall the inspiration temperature exceed the following values after correction for deviation from 24°C.

Rated Service Time (Hours)	RH of Inspired Gas (%)	Max. Allowable Temperature (°C)
<.050	0-100	57
.050-.075	0-50	52
	51-100	43
1.0-2.0	0-50	46
	51-100	41
2.5-4.0	0-50	43
	51-100	38
>4.0	0-50	41
	51-100	35

N. **Communication Requirements** - Same as NFPA.

O. **System Safety Analysis Requirements** - A failure mode analysis shall be conducted relative to the SCBA design. Requirements to be determined with system reliability at 90% to at least 100,000 breathing cycles with at least 95% confidence.

5. **INTERNAL PRESSURE AND BREATHING RESISTANCE REQUIREMENTS** - Pressure measurements are made by use of a metabolic simulator operated in a cyclic fashion through three discrete work rates (100, 175, 250 watts) such that the average consumption and ventilation rates are equivalent to 175 watts of work rate. The respiratory inlet covering is mounted and sealed to the headform as worn by the user. The respirator is operated according to the manufacturer's instructions.

The ventilation rate performance of the metabolic simulator at the three discrete work rates is characterized as follows:

Work Rate Level	Minute Volume (Liters)	Peak Inspiratory Flow Rate (LPM)	Respirations per Minute	Work Rate (Watts)	Tidal Volume (Liters)	Duration Ratio
1	40	120	24	100	1.6	1/3
2	70	210	27	175	2.5	1/3
3	100	300	30	250	3.4	1/3

The metabolic simulator is operated for a period of time as indicated in Section 4G. During that period the MAX IP and MIN IP for each cycle is recorded starting with the second breathing cycle. Breathing pressures are likewise treated. Performance must be maintained during the entire test period including the alarm activation period except during a period while a pressure relief valve is actuated and in this case the MAX BP shall not increase more than XX MM H₂O beyond the "normal" MAX BP immediately prior to activation.

IP measurements to be made with an electronic transducer with specified response characteristics over a pressure range of ± 100 MM H₂O. Probe location, accuracy and resolution is to be specified, but shall be in close proximity to the primary seal of the respiratory inlet covering.

BP measurements to be made with an electronic transducer with specified response characteristics over a pressure range of ± 100 MM H₂O. Probe location, accuracy and resolution is to be specified, but shall be at a point of laminar flow inside the simulated throat of the headform.

The internal and breathing pressures shall be within the following limits:

(MM H₂O)

Style Fit Configuration	MAX BP	MIN IP	MaxIP-MinIP
Tight Mask			N/A
Tight Hood			
Loose Mask			N/A
Loose Hood			

If the MIN BP is less than zero at any point then a static pressure is to be measured and the inhalation resistance shall not exceed XX MM H₂O.

6. **CARBON DIOXIDE ACCUMULATION REQUIREMENTS** - When tested with the respiratory inlet covering's primary sealing flange sealed to a headform on a metabolic simulator, operating for a period of time as indicated in Section 4G, which exhales carbon dioxide at concentration of 5% in the exhaled breath and at consumption and ventilation rates equivalent to 175 watts, the concentration of carbon dioxide inside the respiratory inlet covering shall not exceed the steady state concentrations listed in the below table with an ambient face velocity of 0.5 M/S across the outside of respiratory inlet covering.

Rated Service Time (Hours)	Max. Allowable CO ₂ Accumulation (%)
<0.5	2.5
0.5-1.0	2.0
1.5-2.0	1.5
>2.0	1.0

In addition to the above criteria, the carbon dioxide content shall not exceed 0.5% at a point immediately downstream of the carbon dioxide sorbent.

7. **SIMULATED WORK, TEST REQUIREMENTS** - Respirators shall be tested to verify that they are capable of providing protection which equals or exceeds the requirements specified in the inward leakage section (see Section 12). Before the simulation of work begins, respirators shall undergo a pre-screening process. Ten human test subjects shall be used, one representing each of the 10 Los Alamos fit test panel boxes. Each test subject will don and use the respirator according to the manufacturer's instructions provided with the respirator. The specified fit check procedures shall be performed for all tight fitting respiratory inlet coverings before the test subjects enter the test chamber as part of the pre-screening procedure in order to maximize the respirator fit.

After conducting the applicable fit check, subjects shall undergo a quantitative fit test prior to the simulated work exercises. At least 9 of the 10 test subjects shall obtain fit test results which meet or exceed 10 times the protection factor calculated from the applicable maximum penetration value listed in Section 12.

If at least 9 of the 10 test subjects obtain acceptable fit test results they shall then undergo a simulated work test. The test chamber and equipment is to be specified but should be similar to an ATI corn oil polydispersed aerosol QFT apparatus. The test chamber has to be large enough to accommodate the simulation of work.

The simulated work protocol shall involve five different work regimes, some of which being performed under high "wind" conditions. The chamber shall also provide an elevated temperature and humidity environment. Each test subject shall simulate work for a period of one hour or for the service life of the respirator if said service life is less than one hour. During the simulation of work, the test subjects shall be continuously monitored for total inward leakage. The total inward leakage is compared to the chamber concentration to provide a percent penetration which is integrated over the entire test period to determine the average percent penetration for each of the 9 or 10 individual tests.

The 95th percentile of the individual average penetration values shall be equal to or less than the applicable maximum penetration value listed in Section 12.

(The work regime protocol is to be developed and will probably involve the use of a tread mill, programmed for the appropriate work rate, moving cinder blocks, running in place, hammering, crawling, etc.)

8. **ROUGH HANDLING REQUIREMENTS** - The following tests shall be conducted in the order specified. After being subjected to the tests, the SCBA shall meet all the requirements of this standard.

The complete SCBA shall be tested in accordance with Method 514.3, Vibration, of MIL-STD-810D, Environmental Test Methods. The test shall be set up according to I-3.2.1c. The test procedure used shall be Section II-3.1, Procedure II, using the frequency curves 514.3-1, 514.3-2, and 514.3-3. The SCBA shall be secured using a suitable rigid mounting bracket and the SCBA shall be tested on each axis for three hours. The total duration shall be 9 hours; 3 hours for each frequency curve.

The complete SCBA less the respiratory inlet covering and less those components that attach directly to the respiratory inlet covering per the manufacturer's instructions for use shall be tested in accordance with Method 514.3, Vibration, of MIL-STD-810D, Environmental Test Methods, using Procedure II. The test shall be set up according to I-3.2.3c. The duration of the test shall be 3 hours. A vibration box with a one-inch circular motion shall be constructed in accordance with diagram 514.3-24 of Method 514.3, Vibration, of MIL-STD-810D, Environmental Test Methods.

The SCBA respiratory inlet covering with those components, not tested above, attached to the respiratory inlet covering shall be tested in accordance with Method 514.3, Vibration, Section II-3.2 of MIL-STD-810D, Environmental Test Methods, using Procedure II. The test shall be set up according to I-3.2.3c. The duration of the test shall be 3 hours. A vibration box with a one-inch circular motion shall be constructed in accordance with diagram 514.3-24 of Method 514.3, Vibration, of MIL-STD-810D, Environmental Test Methods.

9. **BREATHING GAS QUALITY REQUIREMENTS** - For testing, compressed gases shall have a maximum dew point requirement of -65 degrees F. At no time during testing on a metabolic simulator with consumption and ventilation rates equivalent to a work rate of 175 watts shall the O₂ content of inspired breathing gas be less than 19.5 percent. Inspired breathing gas shall meet the requirements of United States Pharmacopeia (USP) specification at all times within the period indicated in Section 4G when the apparatus is operated on a metabolic simulator.

10. **MISCELLANEOUS REQUIREMENTS**

- A. **Breathing Tubes** - Propose pull test and crush test requirements.
- B. **Flow Control Valves** - Valves used to control the flow of breathing gas shall meet or exceed the following requirements:
- (1) **Hand Operated Valves**
 - (a) Valves shall be designed and constructed to prevent removal of the stem from the valve body during normal usage to ensure against a sudden release of the full pressure of the container when the valve is opened.
 - (b) Valves shall be designed or positioned to prevent accidental opening and closing and damage from external forces.

- (c) Valves operated during use of the apparatus shall be installed in locations where they can be readily operated by the wearer.
 - (d) Valves installed on apparatus shall be clearly distinguishable from one another by sight and touch.
- (2) **Cylinder Valves**- Compressed breathing gas container valves or a separate charging system or adapter provided with each apparatus shall be equipped with outlet threads specified by the American National Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections. CGA V-1.1987 standard.
 - (3) **By-Pass Valves** - Hand-operated by-pass systems designed and constructed to permit the wearer to breathe and conserve the gas supply in the event of a pressure/flow regulator failure, shall be provided where necessary and provide a minimum air flow of XXX LPM. The by-pass valve control shall be colored red.
 - (4) **Purge Valves** - Purge valves shall be designed to close automatically if not being held open by the wearer. A purge valve could also be considered a by-pass valve depending upon the SCBA design.
 - (5) **Shut-Off Valves** - Manual or automatic shut-off valves shall be provided to feed any remotely mounted air operated device such as pressure indicators or service time alarms unless a severed line leading to such device(s) restricts the flow of air such that the service time is not diminished more than 5%.
 - (6) **Relief Valves** - Automatically operated pressure relief valves shall be provided if the system safety analysis (see Section 4-0) indicates that a potential over pressurization could damage the apparatus or injure the wearer. Generally, closed-circuit SCBA's require a pressure relief valve(s) which operate in conjunction with a breathing reservoir(s) in order to maintain the requirements for internal pressure specified in Section 5.
 - (7) **Demand Valves** - Shall not be provided with any mechanism which would allow the user to manually impede the flow of breathing gas during normal use (i.e. donning devices).
- C. **Compressed Gas Containers** - Compressed breathing gas containers shall meet the minimum requirements of the Department of Transportation for interstate shipment of such containers when fully charged. Such containers shall be permanently and legibly marked to identify their contents. Containers normally removed from apparatus for refilling shall be equipped with an indicating gauge which shows the pressure in the container.
- D. **Harnesses** - Requirements to be determined.

- E. **Compressed Gas Particulate Filters** - All self-contained breathing apparatus using compressed gas containers shall have a filter downstream of the gas source to remove particles which may adversely affect respirator performance.
- F. **Sound Levels** - Sound level, under normal operating conditions excluding that period during which audible alarms or relief valves are actuated, shall not exceed 80 dBA. Test method to be specified. Test to be performed in Anechoic chamber of specified characteristics (ask Paul Michael at Penn State for reference). Respiratory inlet covering to be mounted on a Bruel and Kjaer head/torso simulator (Type 4128). Microphone of specified type to be used and connected to a dosimeter of specified type. Test run at both ears of headform with microphone mounted in specified manner.
- G. **Hoses** - Burst pressure to exceed 2X maximum normal operating pressure. Hose assemblies to withstand XXX pound pull test.
- H. **Quick Disconnect Hose Couplings** - Where provided, couplings designed for quick disconnect shall prevent accidental separation.
- I. **Pressure Indicators** - Gas pressure gages employed on compressed breathing gas containers shall be marked in force per unit area. Other gas pressure gages shall be marked in:
- (1) Force per unit area.
 - (2) Fractions of total container capacity, or
 - (3) Both in force per unit area and fractions of total container capacity.
- Gages shall be accurate to within 5 percent of full scale when tested both up and down the scale at each of 5 equal intervals. The full scale graduation of dial-indicating gages shall not exceed 150 percent of the maximum rated cylinder pressures specified for the container in applicable Department of Transportation specifications or permits, or 150 percent of the maximum pressure specified by the manufacturer's user instructions, whichever is less.
- J. **Lenses** - Lens scratch resistance as developed by NFPA to be specified.
- K. **Breathing Reservoirs** - (Breathing Bags) shall have sufficient volume to prevent gas waste during exhalation and to provide an adequate reserve for inhalation. Breathing reservoirs shall be installed in a location which will protect them from damage or collapse by external forces.

11. **LABELING, MARKING AND INSTRUCTIONS**

A. **Labeling and Markings** - Each major component is to be permanently marked with:

- (1) Manufacturer's identification
- (2) Date or lot number
- (3) Manufacturer's part number

Each respirator is to be marked with the rated gas volume. (Those items listed on the "Approved Assembly List" are considered major components.) Each respirator shall have a label (on the product) listing the major components which make up the complete "approved" respirator. Each respirator shall bear the following limitation marking:

"Approved use of this respirator is limited to respirator wearers having successfully completed an acceptable fit test as recommended by the manufacturer."

B. **Instructions** - Storage, use and maintenance instructions to be specified and clearly presented by the manufacturer.

12. **INWARD LEAKAGE REQUIREMENTS**

(Values to be determined)

13. **SPECIAL REQUIREMENTS**

A. **Apparatus for use in fire fighting**

- (1) Flame Test Requirements - Same as NFPA
- (2) Fabric Components - Same as NFPA
 - (a) Flame Resistance
 - (b) Heat Resistance
- (3) Minimum use temperature shall be -25°F or colder
- (4) Minimum rated gas volume shall be 1200 liters