DRAFT

Proposed Concept:

Air-fed Ensembles (AFE) Standard

August 25, 2009

Concept Requirements, Air-fed Ensembles

1.0 Applicable Sections of 42 CFR Part 84:

Subpart A, General provisions (entire subpart)
Subpart B, Application for Approval (entire subpart)
Subpart D, Approval and Disapproval (entire subpart)
Subpart E, Quality Control (entire subpart)

2.0 Air-Fed Ensemble Requirements:

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3.0 Terms and Definitions

2.1 Air-fed ensembles, concept reference standards:

NIOSH introduced the development plan for the Air-Fed Protective Ensembles Respiratory Standard on December 2, 2008 at a public meeting held in Pittsburgh, PA. This concept, based on the development plan, includes references from the nationally and internationally recognized standards or draft standards:

1. Certification Criteria and Test Result Documents for the Propellant Handler's Ensemble, KSC-TA-9557, National Aeronautics and Space Administration (NASA), October 21, 2008.
2. The Department of Energy Respiratory Acceptance Program for Supplied-Air Suits, DOE-STD-1167-2003, U.S. Department of Energy, October 2003.
3. European Standard for Protective Clothing against Radioactive Contamination, EN 1073-1, January 1998.
4. European Standard Respiratory Protective Devices - Continuous Flow Compressed Air Line Breathing Apparatus, EN 14594, August 2005. (This standard replaced EN 270, dated February 1995, referenced throughout EN 1073).
4. International Standard for Protective Clothing for Protection against Chemical - Classification, Labeling and Performance Requirements, ISO 16602.3, June 2005.

5. Draft International Standard for Respiratory Protective Devices – Methods of test and test equipment, Part 1: Determination of Inward Leakage, ISO/DIS 16900-1.
6. Draft – American National Standard for Classification and Performance Requirements for Chemical Protective Clothing, American National Standards Institute (ANSI)/International Safety Equipment Association (ISEA), June 2005.

2.2. Air-fed ensembles; concept description:

Air ensembles, currently considered in this concept are, technically, either supplied-air respirators (SAR), or power air-purifying (PAPR) supplied respirators, full body garments, where the respiratory protection is an integral part of the design, construction and use of the ensemble. The ensemble must provide a flow of respirable air to the wearer and maintain a positive pressure in the suit in relation to the immediate environment during both inhalation and exhalation (NASA standard).

The use of positive pressure air ensembles may include environments where specific chemical, biological, or radiological (including nuclear) hazards exist. The ensemble may be a single use piece of PPE which can be used once, then discarded, or a reusable ensemble that can be decontaminated, maintained and reused. Because of the dermal protection potentially provided by an ensemble, this type of PPE is used in work environments that could typically be considered immediately dangerous to life or health (IDLH). Due to engineering controls used in these workplaces and often task oriented, limited durations of work, the ensembles may be currently used in potentially IDLH environments to provide both respiratory and dermal protection.

The ensemble shall allow for sufficient distribution of the breathing air from the externally coupled air hose to the internal air distribution manifold, or from a blower assembly. The air flow system and exhaust vent or vents shall provide sufficient air supply to the breathing zone, move exhaled air away, and prevent fogging. The internal design and construction shall also distribute air to the torso and limbs of the ensemble (NASA standard, section 5.5k, qualitative practical performance).

Currently, NIOSH is conducting benchmark testing of commercially available air-fed ensembles of the SAR type. NIOSH intends to conduct testing of PAPR air-fed ensembles as well. Additional non-respiratory performance requirements relating to PAPR air-fed ensembles may include: further harness requirements, power supply requirements, battery life, and end of service life (ESLI) criteria. Additional respiratory performance requirements relating to PAPR air-fed ensembles may include: determination of work rates, service time limitations, and PAPR cartridge and canister requirements.

2.3 Air-fed ensembles; general construction and performance requirements:

The materials, construction and design of the air-fed ensemble must meet the general construction requirements specified in 42 CFR Part 84, §84.61, §84.62, and test requirements in §84.63 (c and d).

2.4 Air-fed ensembles; non-respiratory performance requirements

Practical performance:

The practical performance of the ensemble shall evaluate human interface issues associated with the use of the ensemble. At a minimum, factors which shall be evaluated (if applicable based upon the ensemble design) are: the comfort of the body harness, the security of the couplings and/or connections, accessibility and ease of use of valves or controls, the range and clarity of vision, the comfort of the ensemble, and ease of speech transmission. Test subjects shall be trained on proper use of the ensemble in accordance with the applicant's user's instructions. The ensembles to be tested will be visually examined for imperfections, and evaluated for the use of the manufacturer's written instructions for donning and doffing.

EN standard 1073 calls for preconditioning prior to practical performance testing: 4 hours at -30 ±3˚C, followed by 4 hours at 60 ±3˚C at 95% relative humidity, returned to ambient temperature, using two test subjects (section 5.2 of EN 1073). NIOSH will consider the use of the EN 1073 preconditioning requirement (or similar) while completing bench mark practical performance tests of commercially available ensembles. NIOSH will also consider conditioning the test ensembles for 4 hours at both the minimum use and maximum use temperature or storage temperature, when specified by the manufacturer.

Preconditioned ensembles may be used for respiratory test requirements including the unmanned CO_2 testing, human subject breathing gas concentration determinations, total inward leakage testing, maintenance of positive pressure and exhaust vent evaluations, and the air regulating or flow control valve testing.

Preconditioning requirements for reusable air-fed ensembles will considered during benchmark testing as well.

Physical Properties of Materials used in construction; minimum requirements:

The manufacturer shall use nationally or internationally recognized standards to evaluate the physical properties of the materials used to construct the ensemble, including the visor. Properties to be evaluated may include tensile strength, tear resistance, puncture resistance, burst strength, abrasion resistance, flex cracking resistance and the resistance to ignition and flame. (ISO 16602.3, EN 1073) Seam penetration and permeation

resistance and seam strength shall also be determined. NIOSH may, at its discretion, conduct testing to confirm submitted test results. When this is done, the NIOSH results shall serve as the approval determining results.

Permeation Resistance of material used in construction; minimum requirements:

The manufacturer shall use nationally or internationally recognized standards to evaluate the permeation resistance of the materials used to construct the ensemble, including the visor. The certification may include permeation resistance, liquid penetration resistance and particulate penetration resistance to quantify the chemical, biological or radiological dermal protection provided by the ensemble. NIOSH may, at its discretion, conduct testing to confirm submitted test results. When this is done, the NIOSH results shall serve as the approval determining results.

Visor; minimum requirements:

The air-fed ensemble acts as the respirator and shall be designed and constructed to fit persons with various facial shapes and sizes, allow for the optional use of corrective eyewear and communication devices and insure against restriction of movement or vision by the wearer. The respiratory inlet shall be designed to fit the intended user as to generally align the covering with the mouth to facilitate unrestricted flow of breathing air to the user.

The visor shall provide adequate vision that is not distorted, shall be designed to resist fogging and shall obtain an average Visual Field Score (VFS) of 90 or greater following the VFS method described by the American Medical Association (AMA).

Ensembles intended for abrasive particulate blasting operations shall be designed and constructed to provide protection against impact and abrasion from rebounding abrasive materials from the wearer's head and neck.

Visors (lenses) shall meet the requirements of the impact and penetration sections of ANSI Z87.1-2003 or the lenses shall be prominently and permanently labeled to indicate that they are not impact resistant.

Fall arrest harness; minimum requirements:

If the ensemble includes a fall arrest harness, it must be integral to the design of the ensemble and shall meet the American National Standards Institute (ANSI) Z359.1 Fall Arrest Standard.

NIOSH is seeking information from stakeholders about the use of external fall arrest harnesses with air-fed ensembles.

Storage and use temperature; minimum requirements:

The materials of construction, connections, couplings, and assemblage shall be suitable to the storage life and use temperatures, minimum and maximum, stated by the manufacturer.

Breathing hose; minimum requirements:

External and internal breathing hoses shall be sufficiently flexible to enable the wearer to carry out all tasks and permit free head and body movement, evaluated in practical performance test (ISO 16602.3). The hoses shall demonstrate resistance to kinking and resistance to collapse, and external hoses shall not interfere with the respiratory protection provided by the ensemble.

The external hose shall not collapse or exhibit permanent deformation when a force of 90 kg (200lbs) is applied for five minutes between two planes 7.6 cm (3 inches) wide on opposite sides of the hose. This test will be conducted with the external breathing hose operated at the manufacturer's minimum design flow rate.

Couplings; minimum requirements:

All connections and/or couplings for all supplied-air hoses shall be constructed so that at least 2 different motions are required for disconnection of connected fittings to prevent unintentional disconnection. Inadequate connection shall be visually evident.

EN standard 14594 requires at least one swiveling coupling shall be fitted to the compressed air supply tube adjacent the wearer to prevent unintentional interruption of the air supply. The coupling is to be evaluated visual and in the practical performance test.

ISO standard 16602.3 states the equipment shall be constructed so that any twisting of the hoses does not affect the fit or performance of the suit or respiratory equipment, or cause the hoses or tubes to become disconnected. The design of the coupling shall be such as to prevent unintentional interruption of the air supply.

EN standard 270, included in EN 1073, was superseded by EN 14594, which requires the strength of the breathing hose at the facepiece and at the waist belt to withstand a force of 50N or 250 N depending on the class, A or B. Section 6.6.5 states the connection between the apparatus and the hood/helmet/suit shall be achieved by a permanent, special, or thread type connector (evaluated visually). Section 6.6.6 states it shall not be possible to connect the compressed air supply tube directly to the breathing hose or facepiece (also evaluated visually).

Noise levels; minimum requirements:

Noise levels generated by the respirator during normal operation shall be measured at maximum airflow obtainable within pressure and hose length requirements and shall be less than 80 dBA at both ear canals. Mannequin test requires 85 dBA or less. NIOSH will be completing benchmark testing to determine if specific sample preparations are required for testing the noise level. For example, manufacturers may be asked to provide an ensemble or ensembles with openings to accommodate test equipment.

2.5 Air-fed ensembles; respiratory performance requirements

SAR type air supply: minimum requirements:

Breathing gas used to supply SAR type air-fed ensembles shall be respirable breathing air of grade D quality or better as defined by the Compresses Gas association in publication G-7.1 and OSHA:

Oxygen content (v/v) of 19.5 to 23.5%
Hydrocarbon (condensed) content of 5 mg/m3 air or less
Carbon monoxide content of 10 ppm or less
Carbon dioxide content of 1,000 ppm or less
Lack of noticeable odor

SAR type air flow rate; minimum requirements:

The ensemble shall be tested prior to practical performance evaluation, at ambient conditions, with pressure on the supply-side of the ensemble's air supply connector, and the air flow inside the ensemble shall not be:

Less than the minimum stated by the manufacturer when the relative pressure of the air supply is set to the minimum value and;
Greater than the maximum stated by the manufacturer when the relative pressure of the air supply is set at the maximum value (EN 1073 section 4.8).

Pressure inside the ensemble shall remain above ambient at all times during testing.

PAPR type air flow rate; minimum requirements

The ensemble shall be tested prior to practical performance evaluation, at ambient conditions with pressure measurements recorded in the nose/mouth area of the respiratory inlet covering and on the suit inlet side of the ensemble. The pressure measured at both locations must remain above ambient during all testing and, for systems designed for different flow rates, at all flow rates.

SAR type breathing gas: Carbon Dioxide (CO_2) machine test:

NIOSH is currently conducting benchmark testing of several commercially available ensembles to develop the unmanned CO_2 test requirements. Benchmark testing will include using a sedentary work rate and a higher work rate (to be determined based on the current NIOSH test method capability). The ensembles will be tested using the manufacturer's minimum and maximum design flow rates.

NIOSH will consider using the following requirement for CO_2 machine testing, using the sedentary rate, from the NASA Standard (section 5.4, Physiological Tests):

Where the service time is	Max allowable average concentration of CO_2 in the inspired air % by volume
Not more than 30 minutes	2.5
One hour	2.0
Two hours	1.5
Three hours	1.0
Four hours	1.0

NIOSH will be conducting experiments to determine the feasibility of including a puncture test in this subpart. NIOSH conceptualizes a test method that intentionally punctures the ensemble and measures the respiratory protection, specifically the CO_2 concentration, following initiation and propagation of a puncture in one of three different locations on the ensemble (to include face and limb areas). The CO_2 machine test system will be used to complete the feasibility testing.

NIOSH will also consider testing that requires intentional wear of the material by abrasion, in a specific area (abdomen), followed by unmanned CO_2 testing.

Breathing gas concentration determinations: oxygen (O_2) and CO_2 human subject generated:

NIOSH is currently conducting benchmark testing of several commercially available ensembles to develop test methods for measuring human subject generated breathing gas concentrations. The number of test subjects, the exercises to be completed, the sampling method, and the quantity of ensembles required for testing will be proposed following completion of the benchmark testing.

The inhaled fractional CO_2 concentration during the inhalation portion of the breathing cycle shall not exceed 0.02 (or 2%).

The inhaled fractional O2 concentration shall be no less than 0.195 (or 19.5%).

The ensembles shall be tested at a temperature of 25 ± 5˚C.

Total Inward Leakage: aerosol penetration:

NIOSH intends to develop a test method for evaluating inward leakage of air-fed ensembles.

The DOE STD-1167-20003 Appendix C states the supplied air suit shall be acceptable in regard to providing respiratory protection if the average peak aerosol penetration into the helmet of the suit in the breathing zone of the suit tester does not exceed 0.02% for any individual exercise or does not exceed 0.01% for all exercises.

ISO 16602.3 states chemical protective suits shall not have an inward leakage greater than 0.05%, using either sulfur hexafluoride or salt aerosol.

EN 1073 states inward leakage requirements based on the class of the ensemble, as given in table below, using the minimum design air flow rate:

EN 1073 Class	Maximum value of mean inward leakage into the hood during exercise	
	One activity (%)	All activities (%)
5	0.004	0.002
4	0.01	0.005
3	0.02	0.01
2	0.04	0.02
1	0.10	0.05

Air regulating or air flow valves, minimum requirements:
If an air-regulating or continuous flow valve is provided to a SAR type ensemble, it shall be so designed that it shall be easily adjusted by the user and shall remain at a specific adjustment, and not be affected by the ordinary movement of the wearer. The valve must be so constructed such the air supply with the maximum length of hose and connections, at the minimum specified air-supply pressure, maintains positive pressure. The valve shall be tested in ambient air at the minimum use temperature specified by the manufacturer of the ensemble. NIOSH benchmark testing will evaluate the effects of workrate, if any, on the function of the air regulation or air flow valve.

Exhaust vents, minimum requirements:

The ensemble shall be provided with one or more exhaust vents or devices designed and positioned to maintain a positive pressure within the ensemble when the outfit is used in the environment specified. The function of the vent or vents shall not be interrupted by the movements and mobility of the ensemble user.

EN 1073 states exhaust devices shall continue to work correctly after the testing of the pressure in the suit, during practical performance and during the determination of the protection factor.

ANSI/ISEA 103-2005 (draft, section 6.12.8) and ISO 16602.3 (section 5.15.1) indicate the flow rate and distribution of the air into the suit shall not cause distress to the wearer by excessive local cooling evaluated as part of the practical performance test.

Both EN 1073 and ISO 16602.3 require the pressure in the suit shall not exceed 1000 Pa (4 inches water) mean and 2000 Pa (8 inches water) peak. A positive pressure shall be maintained, while testing with maximum flow rate during an activity sequence.

NIOSH may use the activity sequence given in EN 1073 during the TIL benchmarking study and may also include activities in the sequence to test the breathing resistance of the ensemble. Activities that simulate normal work activities that may interfere with the operation of the exhaust vents and allow for inward leakage or increased breathing resistance will be evaluated.

NIOSH will also consider using the exhaust device pull test, given in EN 1073:

Mount the suit on a dummy torso which can be adjusted so that the load can be applied axially to the exhaust device. A system of retaining straps or bands is fitted over the suit around the exhaust device so that the load is applied as directly as possible to the exhaust device in the suit.

Exert a force of (50 ± 2.5)N to the exhaust device and hold for 10s. Repeat 10 times.

Examine the exhaust device for signs of damage or failure.

3.0 Terms and Definitions: (Reference: Draft International Standard ISO/DIS 16972, respiratory Protective Devices – Terms, Definitions, Graphical Symbols and Units of Measurement.)

abrasion resistance
ability of an **RPD** and/or its components to withstand degradation from abrasive effects (e.g. scratch, scrape, scuff)
aerosol
suspension of solid, liquid or solid and liquid particles in a gaseous medium
air-purifying respiratory protective device
device in which ambient air is passed through an air-purifying element(s) that remove(s) the contaminant(s). Air is passed through the air purifying element by means of the breathing action or by a blower
ambient atmosphere
air surrounding the **RPD** wearer
ambient concentration
concentration of a compound in the air surrounding the **RPD** wearer
ambient laboratory conditions
atmosphere where the temperature is between 16 and 32 degrees C and the relative humidity is between 20 and 80 %
breathable gas
mixtures of gases that are suitable for respiration without adverse effects to health
body harness
means to enable a wearer to wear certain components of an **RPD** on the body
breathing machine
ventilation machine that uses waveforms to simulate air movement during inhalation and exhalation. See also metabolic simulator
breathing resistance
differential pressure caused by an **RPD** to the flow of breathable gas during inhalation (inhalation resistance) or exhalation (exhalation resistance)
CO2 concentration limits
maximum allowed concentration of carbon dioxide within inhaled **breathable gas**
char length
length of brittle residue found when a fabric or material is exposed to thermal energy
contaminant
undesirable solid, liquid or gaseous substance in the atmosphere
continuous flow valve
control valve which provides the wearer of a breathable gas-supplying **RPD** with **breathable gas** and allows the wearer to regulate a continuous air flow within prescribed limits
dead space
space in which exhaled gas has not been purged and is subject to being re-breathed
donning
process of putting on the **RPD** effectively
doffing

process of removing or taking off the **RPD** effectively

end of battery life

lowest capacity level of a battery which still allows a proper continuous function of the

ESLI (end of service life indicator)

system that warns the **RPD** wearer of the approach of the end of adequate respiratory protection

environment

workplace environment in which the **RPD** is to be used

field of vision

remaining fraction of the natural area of sight while wearing a **RPD**

fogging

reduction of the field of vision and visual acuity caused by condensation of humidity inside the **visor**

hose

hollow flexible conduit to carry **breathable gas** designated as **low, medium or high pressure**

IDLH (immediately dangerous to life or health)

atmosphere that poses an immediate threat to life, would cause irreversible adverse health effects, or would impair an individual's ability to escape from a dangerous atmosphere

inward leakage

leakage of the ambient atmosphere into the **respiratory interface** from all sources excluding filters of the device, when measured in the laboratory in the specific test atmosphere. It is expressed as a ratio of contaminant concentration inside an **RPD** and ambient atmosphere Inward leakage (%) = Ci/Co x 100

Ci = concentration of challenge agent inside the respiratory interface

Co = concentration of challenge agent outside inside the respiratory interface

leak-tightness

ability to withstand a loss of pressure inside an **RPD** over a given time

manufacturer's minimum design condition lowest level of operating conditions of the device as stated by the manufacturer at which the complete device will still meet the requirements for the designated class

manufacturer's minimum design flow rate MMDF

minimum air flow rate, as stated by the manufacturer, at which the class requirements are met

maximum flow condition

those factors appropriate to the design specified by the manufacturer which give rise to the highest flow rate

maximum use concentration MUC

maximum atmospheric concentration of a hazardous substance from which the **RPD** wearer can be expected to be protected when wearing an **RPD**, and is determined by the assigned protection factor of the **respiratory protective device** or class of respiratory protective devices and the **occupational exposure limit** of the hazardous substance. The MUC usually can be determined mathematically by multiplying the assigned protection factor specified for a respiratory protective device by the occupational exposure limit, used for the hazardous substance

mechanical strength of visor

ability of the device to withstand mechanical stress to the barrier in front of the eyes

practical performance

evaluation of **RPD** during simulation of typical activities during work or escape

positive pressure

pressure inside the **respiratory interface**, hose, etc. is higher than that of the **ambient**

resistance of materials to chemicals

durability of **RPD** material to resist permeation and degradation from external chemical stress

resistance to biological agents

ability of the RPD material not to be affected by biological agents

respiratory protective device RPD

personal protective equipment designed to protect the wearer's respiratory tract against inhalation of **hazardous** (contaminated) **atmospheres**

RPD manufacturer

natural or legal person, who:

• designs and/or manufactures an **RPD,** or who has an **RPD** designed and/or manufactured with view to its placing on the market or for other use, under his own name or trademark; or who:

• places an **RPD** on the market and/or puts it into service, under his own name or trademark

service life

period of time during which an **RPD** provides adequate protection to the wearer

shelf life

length of time an **RPD** or RPD component may be stored without deteriorating prior to use when stored in accordance with manufacturers instructions

TIL

leakage of the ambient atmosphere into the **respiratory interface** from all sources including filter, where present, or device, when measured in the laboratory in the specific test atmosphere. It is expressed as a ratio of contaminant concentration inside an **RPD** and ambient atmosphere

Total inward leakage (%) = Ci/Co x 100

Ci = concentration of challenge agent inside the respiratory interface

Co = concentration of challenge agent outside the respiratory interface

user

person or organization who makes use of **RPD**, e.g., those involved in selecting, maintaining, wearing, etc.

visor

part of the respiratory interface through which the wearer sees and can, in addition, provide eye and face protection

work rate

demand for **breathable gas** by the wearer per time due to work load