Triosyn Corp.

March 11, 2003

NIOSH Docket Officer
Reference: NIOSH DOCKET -002
Robert A. Taft Laboratories, M/S C34
4676 Columbia Parkway
Cincinnati, Ohio 45226

Dear NIOSH Docket Officer:

Please accept the enclosed letter as comments for NIOSH Docket-002. These comments are being submitted in response to NIOSH's call for public comments regarding requirements for consideration in the Full Facepiece Air Purifying Respirator Concept Development and in the Full Facepiece Air Purifying Respirator Concept Development as posted on the NPPTL website.

Sincerely,

Smatha Myers (for Elaine O'Grady)

Elaine O'Grady
Regulator

Rec'd
3/12/03
KED

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March 10, 2003

Richard W. Metzler
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Wayne Davis
Product Director for Respiratory Protection, Project Manager for Nuclear, Biological and Chemical Defense Systems, SBCCOM
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SUBJECT: Development of CBRN Standards for Air-Purifying Respirators

Dear Sirs,

Following the review of the concept papers for the CBRN Full Facepiece Air-Purifying Respirators (APRs) for Emergency Responders and Air-Purifying Escape Respirator Standards Development, we wish to inform you of our comments in view of the sections on the protection against biological agents.

Within their identification of potential hazards, these documents underline the reality of biological threat in the event of terrorist attacks and support the need for personal respiratory protection which would shield the emergency responder community against the risk of such acts. However, as scientists engaged in the research and development of experimental models for testing the efficacy of filtration media for several years now, we cannot help but note the absence of concrete proposals within these documents in terms of methods necessary to adequately evaluate the actual level of protection against biological agents offered by respiratory protective equipment.

Traditionally, the filtration efficacy of air filters and masks has been determined through particulate testing methods such as in 42 CFR §§ 84.170 - 84.182 for the evaluation of non-powered APRs. Several scientific references as well as our personal experience tend to demonstrate that particulate methods can reflect real-life occurrences as far as bacteria models are concerned. On the other hand, considering their minute size (0.03 to 0.2 µm) and their weak electrical charge, the behavior of airborne viral particles differs from that of 0.3 µm inert particles used for filtration challenge in particulate methods and are likely to be underestimated when enumerated using such methods.

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Furthermore, certain airborne viruses possess high relative infectivity and the inhalation of only a few particles may be sufficient to develop infection (see attached Addendum: Minimal Infective Doses for Airborne Viruses of Pathogenic Concern). The 99.97% filtration efficiency offered by P100 membranes is then insufficient to protect users against many airborne viral pathogens responsible for causing diseases such as Smallpox or Hemorrhagic Fevers (not to mention genetically altered viruses) when challenged with high concentrations suggested by exposure during a crisis situation such as a terrorist act. In fact, a test method developed in parallel with Dr. Linda Stetzenbach[1] permitted to demonstrate that under experimental conditions, a C2A1 canister HEPA paper allowed 10^4 pfu (i.e. 10 000 viral particles) of a 10^7 pfu challenge of MS2 coliphage in the effluent. In light of these issues, the need to subject respiratory protection equipment to tests more representative of incurred risks and real use conditions becomes crucial.

We strongly believe that NIOSH CBRN standards for APRs should reflect this reality, and provide the scientific, manufacturing and end-user communities with a tool to assess the efficacy of respirators against a viral challenge.

The use of challenge concentrations of $\geq 1 \times 10^4$ PFU/L_{air} at 85 L/m for the expected duration of an APR is useful in discriminating between high efficacy filtration material demonstrating microbial reduction values of 99.9999% and above. Moreover, it permits a more accurate and needed assessment of the number of viral particles passing through tested media and resulting in exposure. Such a protocol can be drafted using MS2 coliphage as an accepted surrogate that renders such a test safe and cost-effective. We would be glad to provide our current protocol as a basis for discussion.

Sincerely,

Pierre Jean Messier
President & CEO

cc.: Julie Louise Gerberding, M.D., M.P.H., Director, Centers for Disease Control and Prevention; John Howard, M.D., M.P.H., J.D., LL.M., Director, NIOSH; NIOSH Docket Officer.

[1] Dr. Stetzenbach is Director, Microbiology division at the Harry Reid Center for Environmental Studies (University of Nevada, Las Vegas), chair of ASM's Environmental & General Applied Microbiology Division and editor of Applied and Environmental Microbiology

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ADDENDUM: MINIMAL INFECTIVE DOSES FOR AIRBORNE VIRUSES OF PATHOGENIC CONCERN

Many complexities are associated with the determination of Infective Dose which is based on multifaceted variables. Although one should keep in mind these considerations when using these numbers, the scientific community generally agrees in regarding the minimal infective dose (MID) as the smallest quantity of infective material that regularly produces infection.

Airborne viral pathogen	Associated diseases	Minimum infectious dose	Tested in	Reference
Adenovirus	Respiratory infections, tumors	HID50: 0.5 pfu	Human	No. 4
Coxsackie virus	Meningitis, myocarditis	ID50: <18 pfu	Human	No. 2, 5
Ebola virus	Human hemorrhagic fever	ID < 10 pfu	Non-human primates	No. 5
Encephalitis and encephalomyelitis viruses	Encephalitic diseases	MID: 10-100 pfu	Human	No.7
Equine influenza viruses	Influenza	ID50: 100 pfu/ml	Ponies	No.9
Foot-and-mouth disease virus	Aphtous fever	TCID50: 12.5 pfu	Cattle	No.3
Hantaan, Seoul, and Puumala virus	Hemorrhagic fever with renal syndrome (HFRS)	ID50: 0.5 pfu	Rats	No. 11
Influenza virus	Influenza	HID50: 1 pfu	Human	No. 4
Junin virus	Human hemorrhagic fever	LD50 <50 pfu	Non-human primates	No. 12
Lassa virus	Human hemorrhagic fever	LD50 < 500 pfu	Non-human primates	No. 12
Marburg virus	Human hemorrhagic fever	LD50 = 30 pfu	Non-human primates	No. 12
Norwalk-like virus	Gastroenteritis	MID: 10-100 pfu	Not determined	No. 10
Orthomyxovirus	Influenza	ID: 2-790 pfu	Human	No. 5, 1, 2
Respiratory Syncytial virus	Lower respiratory tract infections, colds	ID > 100-640 pfu	Not determined	No. 5
Rhinovirus	Colds	ID: 5 (estimated)	Not determined	No. 1
Rubella virus	Rubella	ID: 60 pfu	Not determined	No. 5
Rubeola virus	Measles	ID50: 0.2	Children (human)	No. 2, 5
Variola virus	Smallpox	MID: 10-100 pfu	Human	No. 6
Venezuelan Equine Encephalitis	Encephalitis	HID: 10-100 pfu	Not determined	No. 13

PFU: plaque forming unit
ID: Infective Dose
ID50: 50% Infective dose
HID50: 50% Human infectious dose
TCID50: 50%Tissue culture infectious dose
LD50: 50% Lethal dose

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