APPENDIX B

MATERIAL SAFETY DATA SHEET

The following items of information that are applicable to a product or material shall be provided in the appropriate block of the material safety data sheet (MSDS).

Insert the product designation in the block in the upper left corner of the first page to facilitate filing and retrieval. Print in upper case letters as large as possible. The MSDS should be printed to read upright with the sheet turned sideways. The product designation is the name or code that appears on the label, or the name by which the product is sold, or the name known by workers. The relative numerical hazard ratings and key statements are those determined by the rules in Chapter V, Part B, of the NIOSH publication entitled *A Recommended Standard: An Identification System for Occupationally Hazardous Materials* [NIOSH 1974b]. The company identification may be printed in the upper right corner if desired.

B.1 SECTION I. PRODUCTION IDENTIFICATION

Insert the manufacturer's name, address, and regular and emergency telephone numbers (including area code) in the appropriate blocks of Section I.

The company listed should be a source of detailed backup information on the hazards of the material(s) covered by the MSDS. The listing of suppliers or wholesale distributors is discouraged. The trade name should be the product designation or common name associated with the material. The synonyms are those commonly used for the product, especially formal chemical nomenclature. Every known chemical designation or competitor's trade name need not be listed.

B.2 SECTION II. HAZARDOUS INGREDIENTS

The "materials" listed in Section II shall be those substances that are part of the hazardous product covered by the MSDS and individually meet any of the criteria defining a hazardous material. Thus one component of a multicomponent product might be listed because of its toxicity, another component because of its flammability, and a third component could be included both for its toxicity and its reactivity. Note that the MSDS for a single component product must have the name of the material repeated in this section to avoid giving the impression that there are no hazardous ingredients.

Chemical substances should be listed according to their complete name derived from a recognized system of nomenclature. Where possible, avoid using common names and general class names such as "aromatic amine," "safety solvent," or "aliphatic hydrocarbon" when the specific name is known.

The "%" may be the approximate percentage by weight or volume (indicate basis) that each hazardous ingredient of the mixture bears to the whole mixture. This may be indicated as a range or maximum amount (i.e., 10% to 40% vol. or 10% max. wt.) to avoid disclosure of trade secrets.

Toxic hazard data shall be stated in terms of concentration, mode of exposure or test, and animal used (e.g., "100 ppm LC_{50}-rat," "25 mg/kg LD_{50}-skin-rabbit," "75 ppm LC man," "permissible exposure from 29 CFR 1910.1000") or, if not available, from other sources such as NIOSH RELs and publications of the American Conference of Governmental Industrial Hygienists (ACGIH) or the American National Standards Institute, Inc. (ANSI). Flashpoint, shock sensitivity, or similar descriptive data may be used to indicate flammability, reactivity, or similar hazardous properties of the material.

B.3 SECTION III. PHYSICAL DATA

The data in Section III should be for the total mixture and should include the boiling point and melting point in degrees Fahrenheit (Celsius in parentheses); vapor pressure, in conventional millimeters of mercury (mm Hg); vapor density of gas or vapor (air = 1); solubility in water, in parts per hundred parts of water by weight; specific gravity (water = 1); percent volatiles (indicated if by weight or volume) at 70°F (21.1°C); evaporation rate for liquids or sublimable solids, relative to butyl acetate; and appearance and odor. These data are useful for the control of toxic substances. Boiling point, vapor density, percent volatiles, vapor pressure, and evaporation are useful for designing proper ventilation equipment. This information is also useful for design and deployment of adequate fire and spill containment equipment. The appearance and odor may facilitate identification of spilled substances or substances stored in improperly marked containers.

B.4 SECTION IV. FIRE AND EXPLOSION DATA

Section IV should contain complete fire and explosion data for the product, including flashpoint and autoignition temperature in degrees Fahrenheit (Celsius in parentheses); flammable limits, in percent by volume in air; suitable extinguishing media or materials; special fire fighting procedures; and unusual fire and explosion hazard information. If the product presents no fire hazard, insert "NO FIRE HAZARD" on the line labeled "Extinguishing Media."

B.5 SECTION V. HEALTH HAZARD INFORMATION

The "Health Hazard Data" should be a combined estimate of the hazard of the total product. This can be expressed as a TWA concentration, as a permissible exposure, or by some other

indication of an acceptable standard. Other data are acceptable, such as lowest LD_{50} if multiple components are involved.

Under "Routes of Exposure," comments in each category should reflect the potential hazard from absorption by the route in question. Comments should indicate the severity of the effect and the basis for the statement if possible. The basis might be animal studies, analogy with similar products, or human experiences. Comments such as "yes" or "possible" are not helpful. Typical comments might be:

> Skin Contact—single short contact, no adverse effects likely; prolonged or repeated contact, possibly mild irritation.
>
> Eye Contact—some pain and mild transient irritation; no corneal scarring.
>
> "Emergency and First Aid Procedures" should be written in lay language and should primarily represent first-aid treatment that could be provided by paramedical personnel or individuals trained in first aid.

Information in the "Notes to Physician" section should include any special medical information that would be of assistance to an attending physician, including required or recommended preplacement and periodic medical examinations, diagnostic procedures, and medical management of overexposed workers.

B.6 SECTION VI. REACTIVITY DATA

The comments in Section VI relate to safe storage and handling of hazardous, unstable substances. It is particularly important to highlight instability or incompatibility to common substances or circumstances such as water, direct sunlight, steel or copper piping, acids, alkalies, etc. "Hazardous Decomposition Products" shall include those products released under fire conditions. It must also include dangerous products produced by aging, such as peroxides in the case of some ethers. Where applicable, shelf life should also be indicated.

B.7 SECTION VII. SPILL OR LEAK PROCEDURES

Detailed procedures for cleanup and disposal should be listed with emphasis on precautions to be taken to protect workers assigned to cleanup detail. Specific neutralizing chemicals or procedures should be described in detail. Disposal methods should be explicit, including proper labeling of containers holding residues and ultimate disposal methods such as "sanitary landfill" or "incineration." Warnings such as "comply with local, State, and Federal antipollution ordinances" are proper but not sufficient. Specific procedures shall be identified.

B.8 SECTION VIII. SPECIAL PROTECTION INFORMATION

Section VIII requires specific information. Statements such as "yes," "no," or "if necessary" are not informative. Ventilation requirements should be specific as to type and preferred

methods. Respirators shall be specified as to type and NIOSH or MSHA approval class (i.e., "supplied air," "organic vapor canister," etc.). Protective equipment must be specified as to type and materials of construction.

B.9 SECTION IX. SPECIAL PRECAUTIONS

"Precautionary Statements" shall consist of the label statements selected for use on the container or placard. Additional information on any aspect of safety or health not covered in other sections should be inserted in Section IX. The lower block can contain references to published guides or in-house procedures for handling and storage. Department of Transportation markings and classifications and other freight, handling, or storage requirements and environmental controls can be noted.

B.10 SIGNATURE AND FILING

Finally, enter the name and address of the responsible person who completed the MSDS and the date of completion. This will facilitate correction of errors and identify a source of additional information.

The MSDS shall be filed in a location readily accessible to workers exposed to the hazardous substance. The MSDS can be used as a training aid and basis for discussion during safety meetings and training of new workers. It should assist management by directing attention to the need for specific control engineering, work practices, and protective measures to ensure safe handling and use of the material. It will aid the safety and health staff in planning a safe and healthful work environment and in suggesting appropriate emergency procedures and sources of help in the event of harmful exposure of workers.

MATERIAL SAFETY DATA SHEET

Sections I - III

MATERIAL SAFETY DATA SHEET

I PRODUCT IDENTIFICATION	
MANUFACTURER'S NAME	REGULAR TELEPHONE NO EMERGENCY TELEPHONE NO
ADDRESS	
TRADE NAME	
SYNONYMS	

II HAZARDOUS INGREDIENTS		
MATERIAL OR COMPONENT	%	HAZARD DATA

III PHYSICAL DATA			
BOILING POINT, 760 MM HG		MELTING POINT	
SPECIFIC GRAVITY (H_2O=1)		VAPOR PRESSURE	
VAPOR DENSITY (AIR=1)		SOLUBILITY IN H_2O % BY WT	
% VOLATILES BY VOL		EVAPORATION RATE (BUTYL ACETATE=1)	
APPEARANCE AND ODOR			

MATERIAL SAFETY DATA SHEET (Continued)

Sections IV - V

IV FIRE AND EXPLOSION DATA					
FLASH POINT (TEST METHOD)		AUTOIGNITION TEMPERATURE			
FLAMMABLE LIMITS IN AIR, % BY VOL.	LOWER		UPPER		
EXTINGUISHING MEDIA					
SPECIAL FIRE FIGHTING PROCEDURES					
UNUSUAL FIRE AND EXPLOSION HAZARD					

V HEALTH HAZARD INFORMATION
HEALTH HAZARD DATA
ROUTES OF EXPOSURE
INHALATION
SKIN CONTACT
SKIN ABSORPTION
EYE CONTACT
INGESTION
EFFECTS OF OVEREXPOSURE
ACUTE OVEREXPOSURE
CHRONIC OVEREXPOSURE
EMERGENCY AND FIRST AID PROCEDURES
EYES
SKIN:
INHALATION:
INGESTION:
NOTES TO PHYSICIAN

MATERIAL SAFETY DATA SHEET (Continued)

Sections VI - VIII

VI REACTIVITY DATA
CONDITIONS CONTRIBUTING TO INSTABILITY
INCOMPATIBILITY
HAZARDOUS DECOMPOSITION PRODUCTS
CONDITIONS CONTRIBUTING TO HAZARDOUS POLYMERIZATION
VII SPILL OR LEAK PROCEDURES
STEPS TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED NEUTRALIZING CHEMICALS
WASTE DISPOSAL METHOD
VIII SPECIAL PROTECTION INFORMATION
VENTILATION REQUIREMENTS
SPECIFIC PERSONAL PROTECTIVE EQUIPMENT RESPIRATORY (SPECIFY IN DETAIL)
EYE
GLOVES
OTHER CLOTHING AND EQUIPMENT

MATERIAL SAFETY DATA SHEET (Continued)

Section IX

IX SPECIAL PRECAUTIONS
PRECAUTIONARY STATEMENTS
OTHER HANDLING AND STORAGE REQUIREMENTS

PREPARED BY _____

ADDRESS _____

DATE _____

APPENDIX C

BACKGROUND OF METHODS USED FOR ANALYSIS OF BAA IN URINE

Johanson et al. [1986] modified the method of Smallwood et al. [1984] to determine BAA in urine. An internal standard for pentoxyacetic acid was added to acidified urine. After extraction with methylene chloride, an alkaline solution of tetrabutylammonium hydrogen sulfate was added. Pentafluorobenzyl bromide (PFBB) was also added and the mixture shaken vigorously for 1 hr. Gas chromatography with a flame ionization detector (FID) was performed on a fused silica capillary column (BP-10, 12 m × 0.22 mm id) using a 1:100 split ratio. The limits of detection for BAA in urine and recovery data were not presented. Reproducibility was reported as 7.6%.

Johanson et al. [1988] modified the method used previously for BAA in urine by performing the phase transfer catalysis derivatization at pH 6 to avoid hydrolysis of potential conjugates and by using an electron capture detector to increase sensitivity. Urine (200 µl), tetrabutylammonium hydrogen sulfate, sodium phosphate buffer, pentoxyacetic acid (pH 6) (internal standard), methylene chloride, and PFBB were added to a screw-capped culture tube. The culture tube was vigorously shaken and then rotated for 1 hr at room temperature. The methylene chloride layer was evaporated to dryness and the residue taken up in hexane. A gas chromatograph equipped with an Ni^{63} electron capture detector and an autosampler was used for separation and quantitation of BAA. A fused silica capillary column (Oribond SE-30, 25 m × 0.32 mm id) was used in the split/splitless mode. The analytical range of the method was 5 to 500 µmol/liter (0.66 to 66 mg/liter). Although limits of detection were not given, they can be assumed to be lower than the standard (0.6 mg/liter). Reproducibility was stated as 14% (RSD) based on the analysis of 60 duplicate urine samples.

Groeseneken et al. [1989] further evaluated the existing methods for alkoxyacetic acids and concluded that the phase transfer catalysis procedures had the required specificity without the production of artifacts, but they lacked sufficient sensitivity to detect these metabolites at low occupational exposure concentrations. On the other hand, the methods utilizing diazomethane derivatization had the required sensitivity but lacked the specificity. Therefore, Groeseneken et al. [1989] developed an improved method that combined the best attributes of the two basic existing methods. Because background interference in urine samples can be troublesome when using the electron capture detector, the method published by Johanson et al. [1988] was not cited even though it has the required sensitivity and specificity for BAA.

The procedure developed by Groeseneken et al. [1989] was described as follows. Urine was adjusted to pH 7; 1 ml was placed in small vials with 3-chloropropionic acid (internal standard) and lyophilized overnight. The dry residue was redissolved in methanol containing PFBB, and the vials were capped. The vials were heated at 90°C for 3 hr. After cooling, sample cleanup was performed by adding distilled water and extracting the pentafluorobenzyl esters (PFB esters) with methylene chloride. The methylene chloride extract was analyzed by gas chromatography using FID. A fused silica capillary column was used (CP Sil 5, 25 m × 0.32 mm id, 0.21-μm film thickness) with a split ratio of 5.1. Temperature programming was employed. All PFB esters showed baseline resolution; retention times of 11.66 min (BAA) and 8.59 min (internal standard) were observed. A typical gas chromatographic run, including cool-down and equilibration times, required about 30 min.

Optimization studies were performed for reagent concentrations as well as for urinary pH and reaction time. After correction for the partial solubility of methylene chloride in the 50:50 methanol: urine phase, recovery of BAA from urine averaged 95.1%. The yield for the derivatization reaction averaged 101.3% for BAA. Standard curves were set up in urine and were linear over the range of 0.1 to 200 mg/liter. The limit of detection, at a signal to noise ratio of 5, was 0.03 mg/liter. Precision of the method, calculated from triplicate injections of 40 urine samples, averaged 3.5%, ranging from 1.1% at 25 mg/liter to 20% at 0.1 mg/liter.

The method of Groeseneken et al. [1989] is the preferred method for analysis of the alkoxyacetic acid metabolites in urine.

APPENDIX D

GUIDELINES FOR BIOLOGICAL MONITORING

Compliance with the NIOSH REL alone may not ensure that workers are protected from overexposure to EGBE and EGBEA. In addition to inhalation, dermal absorption is a significant route of entry for these chemicals. As a result, biological monitoring of workers should be done routinely on the basis of work practices.

D.1 MONITORING FOR BAA IN URINE

To conduct biological monitoring, urine samples should be evaluated for BAA using the method of Groeseneken et al. [1989] or an equivalent method. Expression of results as milligrams of metabolite per gram of creatinine (mg/m creatinine) is suggested. Factors that may affect the urinary concentration of BAA include ethanol consumption (which lowers urinary metabolite concentrations), dermal contact, heavy workloads, and nonoccupational exposures.

Urine samples should be collected at the end of the workshift following at least 2 days of typical exposure. Such specimens reflect absorption (dermal and inhalation) during the day and possibly some residual BAA from the previous day's exposure. In case of an accident or spill, urine samples should be collected 3 hr later, when peak BAA excretion occurs.

Measurable concentrations of BAA in the urine indicate uptake of EGBE or EGBEA by inhalation, skin exposure, or both. Urinary BAA reflects nonoccupational as well as occupational exposure and may not correlate with the NIOSH REL. If concentrations of BAA exceed the estimated guidelines below, excessive exposure to EGBE or EGBEA may have occurred even if airborne concentrations were not necessarily above the NIOSH REL. The source of exposure should be determined by thorough industrial hygiene evaluation, with emphasis on possible dermal absorption. The guidelines in the following subsection are suggested until better documented ones are developed.

D.2 DETERMINATION OF URINARY BAA CONCENTRATION CORRESPONDING WITH THE REL FOR EGBE

Four sources (presented in Sections 4.3 and 5.2) were investigated for quantitative data relating EGBE exposure to urinary excretion of BAA: Johanson et al. [1986], Van Vlem [1988], pp. 1-54, Van Vlem [1988], pp. 55-72, and Carpenter et al. [1956]. Because

Carpenter et al. used paper chromatography (which is not as quantitatively accurate as modern chromatographic techniques) and because these investigators did not give data for the peak urinary (end of shift) concentration of BAA, concentrations were calculated from the other three sources, as follows.

D.2.1 Johanson et al. [1986].

The estimated BAA in urine was determined after a 2-hr exposure to 20 ppm EGBE, with a 50-W workload (see Table D-1). BAA excretion rates for the seven subjects were taken from Johanson et al. [1986] (Figure 5). The y-axis values were measured in mm, converted into μmol/min, and then converted into mg BAA excreted per 2 hr, for each subject. Johanson et al. [1986] do not give the creatinine values for these subjects, so a physiologically "normal" value of 1.5 g creatinine/day was assumed [Davidson and Henry 1974].

Therefore, a 2-hr exposure to 20 ppm EGBE with a 50-W workload, is expected to yield urinary BAA concentrations of 64, 84, 114, and 90 mg BAA/g creatinine at 2, 4, 6, and 8 hr, respectively. The urinary BAA from an 8-hr exposure to 20 ppm EGBE with a 50-W workload can be estimated by "superpositioning" [Gibaldi and Perrier 1982] the urinary BAA profiles of four 2-hr exposures. For the 8-hr "end of shift" timepoint, the result is equal to the sum of the concentrations from the four 2-hr exposures given above; therefore, the expected urinary BAA concentration is 64 + 84 + 114 + 90 = 352 mg BAA/g creatinine. This can be extrapolated to a 5-ppm EGBE exposure by multiplying by 5/20 for a yield of 88 mg BAA/g creatinine.

D.2.2 Van Vlem [1988], pp. 1–54.

An estimate of BAA excretion from 4-hr EGBE exposures was determined from data by Van Vlem [1988], Appendix 3, Figure 2.10 (page 43). The exposures were 50 min/hr

Table D-1.—Excretion of BAA during various time intervals*,† (mg BAA/g creatinine)

Subject	Time interval (hr)			
	0 to 2	2 to 4	4 to 6	6 to 8
1	5.5956	5.9958	20.4336	25.1388
2	8.4693	16.1843	56.6037	30.9275
3	32.5721	20.9698	61.7085	73.3407
4	45.2215	49.2998	95.0266	112.9393
5	61.7085	52.8257	141.3661	115.9031
6	138.9457	187.9729	152.7901	123.1247
7	155.4516	252.1130	272.4866	146.3340
Average	63.9949	83.6230	114.3450	89.6726

*Adapted from Johanson et al. [1986].
†Assuming 1.5 g creatinine excreted per day. EGBE exposure = 2 hr, 20 ppm, 50-W workload.

for 4 hr, by facemask, to either 25.2 (experiment I) or 12.6 (experiments II and III) ppm EGBE. Because the subjects were exposed for only 50 minutes per hour, these are equivalent to 4-hr exposures to 21.0 (experiment I) or 10.5 (experiments II and III) ppm EGBE. Only three subjects were used; each subject was exposed once in each of the three experiments. Experiments I and II were performed with the subjects in a "resting" condition, while experiment III was done under a 30-W workload. Because of the very limited number of subjects, a separate estimate of BAA excretion was made for each of the three experiments, and the three estimates were averaged to give one overall estimate of BAA excretion.

The y-axis values in Figure 2.10 were measured (in mm) for the 4- and 8-hr time points and converted to μg BAA/min. Assuming a normal physiological level of creatinine excretion (1.5 g/day), BAA concentrations in urine at 4 and 8 hr after the beginning of an 8-hr EGBE exposure were calculated as shown in Table D-2.

The urinary BAA concentrations predicted (by "superpositioning" two 4-hr exposures) for an 8-hr end-of-shift urine sample are 87, 51, and 61 mg BAA/g creatinine for experiments I, II, and III, respectively. For a work setting, the values in experiments I and II should be approximately doubled to reflect the increased pulmonary uptake expected under nonresting conditions. Proportionally adjusting these values to a 5-ppm EGBE exposure results in predicted urinary BAA values of 41, 49, and 29 mg BAA/g creatinine for experiments I, II, and III, respectively. The arithmetic average of these three estimates is 39.6 mg BAA/g creatinine, or (rounding off) 40 mg BAA/g creatinine. The average estimate—40 mg BAA/g creatinine—is the best overall estimate of BAA excretion that can be prepared from this data set.

D.2.3 Van Vlem [1988], pp. 55–72.

These data were taken from Van Vlem [1988], Appendix 3, pp. 55–72. Van Vlem reports the average exposure to EGBE for the five women to be 3.1 mg/m^3 (0.65 ppm), resulting in a BAA value of 8.1 mg/liter at the end of the workday:

8.1 mg/liter × 1.2 liter urine/day × 1 day/1.5 g creatinine = 6.48 mg BAA/g creatinine

Adjusting this to a 5-ppm exposure yields:

6.48 × (5/0.65) = 49.8 mg BAA/g creatinine, or (rounded) 50 mg BAA/g creatinine

Table D–2.—BAA concentrations in urine after exposure to EGBE

Expt. No.	EGBE conc. (mg/m^3)	EGBE conc. (ppm)	Exercise (W)	mg BAA/g cr. 4-hr	mg BAA/g cr. 8-hr
I	120	21.0	0	48.12	38.88
II	60	10.5	0	34.38	16.50
III	60	10.5	30	38.40	22.92

D.3 OVERALL ESTIMATE OF BAA

The BAA estimates from Johanson et al. [1986] and Van Vlem [1988] can be averaged to provide a single "best" estimate as follows:

(88 + 40 + 50)/3 = 59.3, or (rounded) 60 mg BAA/g creatinine

D.4 LIMITATIONS OF ESTIMATING BAA

All of these studies have some limitations.

Johanson et al. [1986] is an excellent laboratory study; however, the seven subjects were male. The 50-W exercise level used in this study may exceed the actual workplace energy expenditure of many workers in "light" industries, leading to an overestimate of actual EGBE uptake (under working conditions). Furthermore, the experimental protocol utilized 2-hr exposures; this is a rather short exposure from which to extrapolate uptake during an 8-hr workday.

The Van Vlem [1988] laboratory studies used only three (male) subjects; this is far too few to compensate for individual variations in uptake and metabolism. Because the same three subjects were used for all three experiments, it is possible that the results of these experiments may be systematically biased (either high or low) by the presence of even one unusual EGBE metabolizer. In addition, the experiments were conducted using inhalation by face mask; this neglects any possible contribution from dermal absorption (caused by possible dermal deposition of EGBE vapor on the subject's skin). Because the subjects were exercising, and most likely sweating, the deposition of the highly water-soluble EGBE on the wet skin may conceivably be significant.

Urine samples from the Veulemans et al. study [1987] were analyzed for BAA by Van Vlem [1988]. They represent samples from five female workers under actual working conditions. The exposures were for five working days, so that the time of exposure was more than adequate. However, the average EGBE exposure concentration was only 0.65 ppm, and the exposure was to a mixture of solvents. Therefore, a substantial extrapolation is involved in using these data to project the results to a 5-ppm exposure to EGBE alone, and the possibility that the other solvents involved may have altered the metabolism of EGBE (most likely reducing BAA excretion) cannot be excluded. In addition, a dermal component of the EGBE uptake (under actual working conditions) cannot be ruled out.

In all, the published data on which this BAA estimation is based are not as complete and consistent as might be desired. It is clear that further studies of EGBE uptake (either laboratory or field studies) would be advantageous, and that the existing data do not allow an absolutely rigorous determination of a BAA concentration for corresponding to 5 ppm EGBE. However, publication of the estimated BAA concentration simply as a guideline may be of some use in situations where a mixed exposure (inhalation plus dermal) may occur. Under such conditions, a workplace standard based entirely on ambient air concentration may grossly underestimate the total uptake of EGBE (by neglecting the dermal

component), whereas biological monitoring for BAA will reflect both the pulmonary and the dermal exposure routes.

D.5 JUSTIFICATION FOR RECOMMENDING BIOLOGICAL MONITORING

The following factors justify NIOSH recommendations for biological monitoring:

- Biological monitoring for EGBE and EGBEA exposure is recommended even though no validated guidelines can be provided concerning the relationship between airborne exposure to these ethylene glycol ethers and their urinary metabolite, BAA. This metabolite is both an index of exposure or uptake of EGBE by the worker and an index of potential adverse health effects from this ethylene glycol ether.

- Dermal absorption may be a major route of exposure to EGBE or EGBEA. The potential also exists for absorption of their vapors through wet skin.

- The influence of workload is significant for inhalation exposure. Doubling the workload results in twice the uptake of EGBE and EGBEA.

APPENDIX E

MEDICAL ASPECTS OF WEARING RESPIRATORS*

In recommending medical evaluation criteria for respirator use, one should apply rigorous decision-making principles [Halperin et al. 1986]; tests used should be chosen for operating characteristics such as sensitivity, specificity, and predictive value. Unfortunately, many knowledge gaps exist in this area. The problem is complicated by the large variety of respirators, their conditions of use, and individual differences in the physiologic and psychologic responses to them. For these reasons, the following guidelines are to be considered as informed suggestions rather than established NIOSH policy recommendations. They are intended primarily to assist the physician in developing medical evaluation criteria for respirator use.

E.1 BACKGROUND INFORMATION

Brief descriptions of the health effects associated with wearing respirators are summarized below. More detailed analyses of the data are available in recent reviews by James [1977] and Raven et al. [1979].

E.1.1 Pulmonary Effects

In general, the added inspiratory and expiratory resistances and dead space of most respirators cause an increase in tidal volume and a decrease in respiratory rate and ventilation (including a small decrease in alveolar ventilation). These respirator effects have usually been small both among healthy individuals and, in limited studies, among individuals with impaired lung function [Gee et al. 1968; Altose et al. 1977; Raven et al. 1981; Hodous et al. 1983; Hodous et al. 1986]. This generalization is applicable to most respirators when resistances (particularly expiratory resistance) are low [Bentley et al. 1973; Love et al. 1977]. While most studies report minimal physiologic effects during submaximal exercise, the resistances commonly lead to reduced endurance and reduced maximal exercise performance [Craig et al. 1970; Raven et al. 1977; Stemler and Craig 1977; Myhre et al. 1979; Deno et al. 1981]. The dead space of a respirator (reflecting the amount of expired air that must be rebreathed before fresh air is obtained) tends to cause increased ventilation. At least one study has shown substantially increased ventilation with a full-face respirator, a type that can have a large effective dead space [James et al. 1984]. However, the net effect of a

*Adapted from *NIOSH Respirator Decision Logic* [NIOSH 1987b].

respirator's added resistances and dead space is usually a small decrease in ventilation [Craig et al. 1970; Hermansen et al. 1972; Raven et al. 1977; Stemler and Craig 1977; Deno et al. 1981; Hodous et al. 1983].

The potential for adverse effects, particularly decreased cardiac output, from the positive pressure feature of some respirators has been reported [Meyer et al. 1975]. However, several recent studies suggest that this is not a practical concern, at least not in healthy individuals [Bjurstedt et al. 1979; Arborelius et al. 1983; Dahlback and Balldin 1984].

Theoretically, the increased fluctuations in thoracic pressure caused by breathing with a respirator might constitute an increased risk to subjects with a history of spontaneous pneumothorax. Few data are available in this area. While an individual is using a negative-pressure respirator with relatively high resistance during very heavy exercise, the usual maximal-peak negative oral pressure during inhalation is about 15 to 17 cm of water [Dahlback and Balldin 1984]. Similarly, the usual maximal-peak positive oral pressure during exhalation is about 15 to 17 cm of water, which might occur with a respirator in a positive-pressure mode, again during very heavy exercise [Dahlback and Balldin 1984]. By comparison, maximal positive pressures such as those during a vigorous cough can generate 200 cm of water pressure [Black and Hyatt 1969]. The normal maximal negative pleural pressure at full inspiration is −40 cm of water [Bates et al. 1971], and normal subjects can generate −80 to −160 cm of negative water pressure [Black and Hyatt 1969]. Thus while vigorous exercise with a respirator does alter pleural pressures, the risk of barotrauma would seem to be substantially less than that of coughing.

In some asthmatics, an asthmatic attack may be exacerbated or induced by a variety of factors including exercise, cold air, and stress, all of which may be associated with wearing a respirator. While most asthmatics who are able to control their condition should not have problems with respirators, a physician's judgment and a field trial may be needed in selected cases.

E.1.2 Cardiac Effects

The added work of breathing from respirators is small and could not be detected in several studies [Gee et al. 1968; Hodous et al. 1983]. A typical respirator might double the work of breathing (from 3% to 6% of the total oxygen consumption), but this is probably not of clinical significance [Gee et al. 1968]. In concordance with this view, several other studies indicated that at the same workloads heart rate does not change with the wearing of a respirator [Raven et al. 1982; Harber et al. 1982; Hodous et al. 1983; Arborelius et al. 1983; Petsonk et al. 1983].

In contrast, the added cardiac stress due to the weight of a heavy respirator may be considerable. A self-contained breathing apparatus (SCBA) may weigh up to 35 lb. Heavier respirators can reduce maximum external workloads by 20% and similarly increase heart rate at a given submaximal workload [Raven et al. 1977]. In addition, it should be noted that many uses of SCBA (e.g., for firefighting and hazardous waste site work) also necessitate the wearing of 10 to 25 lb of protective clothing.

Raven et al. [1982] found statistically significant higher systolic and/or diastolic blood pressures during exercise for persons wearing respirators. Arborelius et al. [1983] did not find significant differences for persons wearing respirators during exercise.

E.1.3 Body Temperature Effects

Proper regulation of body temperature is primarily of concern with the closed circuit SCBA that produces oxygen via an exothermic chemical reaction. Inspired air within these respirators may reach 120°F (49°C), thus depriving the wearer of a minor cooling mechanism and causing discomfort. Obviously this can be more of a problem with heavy exercise and when ambient conditions and/or protective clothing further reduce the body's ability to lose heat. The increase in heart rate because of increasing temperature represents an additional cardiac stress.

Closed-circuit breathing units of any type have the potential for causing heat stress since warm expired gases (after exothermic carbon dioxide removal with or without oxygen addition) are rebreathed. Respirators with large dead spaces also have this potential problem, again because of partial rebreathing of warmed expired air [James et al. 1984].

E.1.4 Sensory Effects

Respirators may reduce visual fields, decrease voice clarity and loudness, and decrease hearing ability. Besides the potential for reduced productivity, these effects may result in reduced industrial safety. These factors may also contribute to a general feeling of stress [Morgan 1983a].

E.1.5 Psychologic Effects

This important topic is discussed in recent reviews by Morgan [Morgan 1983a, 1983b]. There is little doubt that virtually everyone suffers some discomfort when wearing a respirator. The large variability and the subjective nature of the psycho-physiologic aspects of wearing a respirator, however, make studies and specific recommendations difficult. Fit testing obviously serves an important additional function by providing a trial to determine if the wearer can psychologically tolerate the respirator. The great majority of workers can tolerate respirators, and experience in wearing them aids in this tolerance [Morgan 1983b]. However, some individuals are likely to remain psychologically unfit for wearing respirators.

E.1.6 Local Irritation Effects

Allergic skin reactions may occur occasionally from wearing a respirator, and skin occlusion may cause irritation or exacerbation of preexisting conditions such as pseudofolliculitis barbae. Facial discomfort from the pressure of the mask may occur, particularly when the fit is unsatisfactory.

E.1.7 Miscellaneous Health Effects

In addition to the health effects (described above) associated with wearing respirators, specific groups of respirator wearers may be affected by the following factors:

a. Perforated Tympanic Membrane

While inhalation of toxic materials through a perforated tympanic membrane (ear drum) is possible, recent evidence indicates that the airflow would be minimal and rarely if ever of clinical importance [Cantekin et al. 1979; Ronk and White 1985]. In highly toxic or unknown atmospheres, use of positive pressure respirators should ensure adequate protection [Ronk and White 1985].

b. Contact Lenses

Contact lenses are generally not recommended for use with respirators, although little documented evidence exists to support this viewpoint [daRoza and Weaver 1985]. Several possible reasons for this recommendation are noted below:

(1) Corneal Irritation or Abrasion

Corneal irritation or abrasion might occur with the exposure. This would, of course, be a problem primarily with quarter- and half-face masks, especially with particulate exposures. However, exposures could occur with full-face respirators because of leaks or inadvisable removal of the respirator for any reason. While corneal irritation or abrasion might also occur without contact lenses, their presence is known to substantially increase this risk.

(2) Loss or Misplacement of a Contact Lens

The loss or misplacement of a contact lens by an individual wearing a respirator might prompt the wearer to remove the respirator, thereby resulting in exposure to the hazard as well as to the potential problems noted above.

(3) Eye Irritation from Respirator Airflow

The constant airflow of some respirators, such as powered, air-purifying respirators (PAPRs) or continuous flow, air-line respirators, might irritate the eyes of a contact lens wearer.

E.2 SUGGESTED MEDICAL EVALUATION AND CRITERIA FOR RESPIRATOR USE

The following NIOSH recommendations allow latitude for the physician in determining a medical evaluation for a specific situation. More specific guidelines may become available as knowledge increases regarding human stresses from the complex interactions of worker

health status, respirator usage, and job tasks. While some of the following recommendations should be part of any medical evaluation of workers who wear respirators, others are applicable for specific situations.

- A physician should determine fitness to wear a respirator by considering the worker's health, the type of respirator, and the conditions of respirator use.

The recommendation above leaves the final decision of an individual's fitness to wear a respirator to the person who is best qualified to evaluate the multiple clinical and other variables. Much of the clinical and other data could be gathered by other personnel. It should be emphasized that the clinical examination alone is only one part of the fitness determination. Collaboration with foremen, industrial hygienists, and others may often be needed to better assess the work conditions and other factors that affect an individual's fitness to wear a respirator.

- A medical history and at least a limited physical examination are recommended.

The medical history and physical examination should emphasize the evaluation of the cardiopulmonary system and should elicit any history of respirator use. The history is an important tool in medical diagnosis and can be used to detect most problems that might require further evaluation. Objectives of the physical examination should be to confirm the clinical impression based on the history and to detect important medical conditions (such as hypertension) that may be essentially asymptomatic.

- While chest X-ray and/or spirometry may be medically indicated in some fitness determinations, these should not be routinely performed.

In most cases, the hazardous situations requiring the wearing of respirators will also mandate periodic chest X-rays and/or spirometry for exposed workers. When such information is available, it should be used in the determination of fitness to wear respirators.

Data from routine chest X-rays and spirometry are not recommended solely for determining if a respirator should be worn. In most cases, with an essentially normal clinical examination (history and physical) these data are unlikely to influence the respirator fitness determination; additionally, the X-ray would be an unnecessary source of radiation exposure to the worker. Chest X-rays in general do not accurately reflect a person's cardiopulmonary physiologic status, and limited studies suggest that mild to moderate impairment detected by spirometry would not preclude the wearing of respirators in most cases. Thus it is recommended that chest X-rays and/or spirometry be done only when clinically indicated.

- The recommended periodicity of medical fitness determinations varies according to several factors but could be as infrequent as every 5 years.

Federal or other applicable regulations shall be followed regarding the frequency of respirator fitness determinations. The guidelines for most work conditions for which respirators are required are shown in Table E-1.

Table E-1.—Suggested frequency of medical fitness determinations*

Type of working conditions	Worker age (years)		
	<35	35–45	>45
Most work conditions requiring respirators	Every 5 years	Every 2 years	1–2 years
Strenuous working conditions with a SCBA†	Every 3 years	Every 18 months	Annually

*Interim testing would be needed if changes in health status occur.
†SCBA = self-contained breathing apparatus.

These guidelines are similar to those recommended by ANSI, which recommends annual determinations after age 45 [ANSI 1984]. The more frequent examinations with advancing age relate to the increased prevalence of most diseases in older people. More frequent examinations are recommended for individuals performing strenuous work involving the use of a SCBA. These guidelines are based on clinical judgment and, like the other recommendations in this section, should be adjusted as clinically indicated.

- The respirator wearer should be observed during a trial period to evaluate potential physiological problems.

In addition to considering the physical effects of wearing respirators, the physician should determine if wearing a given respirator would cause extreme anxiety or claustrophobic reaction in the individual. This could be done during training while the worker is wearing the respirator and is engaged in some exercise that approximates the actual work situation.

Present OSHA regulations state that a worker should be provided the opportunity to wear the respirator "in normal air for a long familiarity period . . ." [29 CFR 1910.134(e)(5)]. This trial period should also be used to evaluate the ability and tolerance of the worker to wear the respirator [Harber 1984]. This trial period need not be associated with respirator fit testing and should not compromise the effectiveness of the vital fit testing procedure.

- Examining physicians should realize that the main stress of heavy exercise while using a respirator is usually on the cardiovascular system and that heavy respirators (e.g., SCBA) can substantially increase this stress. Accordingly, physicians may want to consider exercise stress tests with electrocardiographic monitoring when heavy respirators are used, when cardiovascular risk factors are present, or when extremely stressful conditions are expected.

Some respirators may weigh up to 35 lb and may increase workloads by 20%. Although a lower activity level could compensate for this added stress [Manning and Griggs 1983], a lower activity level might not always be possible. Physicians should also be aware of other added stresses, such as heavy protective clothing and intense ambient heat, that would increase the worker's cardiac demand. As an extreme example, firefighters who use a SCBA

inside burning buildings may work at maximal exercise levels under life-threatening conditions. In such cases, the detection of occult cardiac disease, which might manifest itself during heavy stress, may be important. Some authors have either recommended stress testing [Kilbom 1980] or at least its consideration in the fitness determination [ANSI 1984]. Kilbom [1980] has recommended stress testing at 5-year intervals for firefighters below age 40 who use SCBAs and at 2-year intervals for those aged 40 to 50. He further suggested that firemen over age 50 not be allowed to wear SCBAs.

Exercise stress testing has not been recommended for medical screening for coronary artery disease in the general population [Weiner et al. 1979; Epstein 1979]. It has an estimated sensitivity and specificity of 78% and 69%, respectively, when the disease is defined by coronary angiography [Weiner et al. 1979; Nicklin and Balaban 1984]. In a recent 6-year prospective study, stress testing to determine the potential for heart attacks indicated a positive predictive value of 27% when the prevalence of disease was 3.5% [Giagnoni et al. 1983; Folli 1984]. While stress testing has limited effectiveness in medical screening, it could detect individuals who may not be able to complete the heavy exercise required in some jobs.

A definitive recommendation regarding exercise stress testing cannot be made at this time. Further research may determine whether this is a useful tool in selected circumstances.

- An important concept is that "general work limitations and restrictions identified for other work activities also shall apply for respirator use" [ANSI 1984].

In most situations, a worker who can physically do an assigned job without a respirator can perform the same job without increased risk while wearing a respirator.

- Because of the variability in the types of respirators, work conditions, and workers' health status, many employers may wish to designate categories of fitness to wear respirators, thereby excluding some workers from strenuous work situations involving the wearing of respirators.

Depending on the various circumstances, several permissible categories of respirator usage are possible. One conceivable scheme would consist of three overall categories: full respirator use, no respirator use, and limited respirator use including "escape only" respirators. The latter category excludes heavy respirators and strenuous work conditions. Before identifying the conditions that would be used to classify workers into various categories, it is critical that the physician be aware that these conditions have not been validated and are presented only for consideration. The physician should modify the use of these conditions based on actual experience, further research, and individual worker sensitivities. He may also wish to consider the following conditions in selecting or permitting the use of respirators:

- History of spontaneous pneumothorax

- Claustrophobia/anxiety reaction

- Use of contact lenses (for some respirators)
- Moderate or severe pulmonary disease
- Angina pectoris, significant arrhythmias, recent myocardial infarction
- Symptomatic or uncontrolled hypertension, and
- Advanced age

Wearing a respirator would probably not play a significant role in causing lung damage such as pneumothorax. However, without good evidence that wearing a respirator would not cause such lung damage, the physician would be prudent to prohibit the individual with a history of spontaneous pneumothorax from wearing a respirator.

Moderate lung disease is defined by the Intermountain Thoracic Society [Kanner and Morris 1975] as being present when the following conditions exist—a forced expiratory volume in one second (FEV_1) divided by the forced vital capacity (FVC) (i.e., FEV_1/FVC) of 0.45 to 0.60, or an FVC of 51% to 65% of the predicted FVC value. Similar arbitrary limits could be set for age and hypertension. It would seem more reasonable, however, to combine several risk factors into an overall estimate of fitness to wear respirators under certain conditions. Here the judgment and clinical experience of the physician are needed. Many impaired workers would even be able to work safely while wearing respirators if they could control their own work pace, including having sufficient time to rest.

E.3 CONCLUSIONS

Individual judgment is needed to determine the factors affecting an individual's fitness to wear a respirator. While many of the preceding guidelines are based on limited evidence, they should provide a useful starting point for a respirator fitness screening program. Further research is needed to validate these and other recommendations currently in use. Of particular interest would be laboratory studies involving physiologically impaired individuals and field studies conducted under actual day-to-day work conditions.

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