

INSTRUCTIONS FOR PROGRAM MANAGERS

Don't forget to Delete this Instruction Section from your final Order!

A) This Boilerplate Order contains Instructional Notes to Program Managers throughout the text. The notes are in red and bold type in the text to make them easy to find. When the Order is completed make certain that all these notes have been deleted. To ensure that all notes are deleted, use "Edit, Find and Replace" to perform a global search for "[**Note to Program Managers:**".

B) **Respirator Table Appendices**

This Boilerplate Order has two Appendices containing Respirator Tables.

Appendix 1: Protection in the Workplace Respirators

Appendix 1 contains tables of respirators for inclusion in the Protection in the Workplace section of the Order.

1. **Copy** the appropriate individual respirator(s) from Appendix 1.
2. **Paste** the respirator(s) in the Protection of the Workplace section of the Order (a Note to Program Managers shows you where).
3. **Delete** the remainder of Appendix 1.

Appendix 2: NCELS Respirators

Appendix 2 contains tables for the NCELS section of the Order.

1. **Copy** the appropriate complete respirator table from Appendix 2.
2. **Paste** the respirator tabe in the NCELS section of the Order (a Note to Program Managers shows you where).
3. **Delete** the remainder of Appendix 2.

Do **Not** Delete Attachements A, B, and C.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:

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Premanufacture Notice Number:

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Consent Order for Contract Manufacturer

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. _____ (“the Contract Manufacturer”) has entered into a contract with _____ (“the Company”) to manufacture or import exclusively for the Company the chemical substance: _____ (P-__ - ____)(“the PMN substance”). The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the PMN substance in the United States by the Contract Manufacturer, except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the PMN

substance is exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Order.

(1) Export. Until the Contract Manufacturer begins commercial manufacture of the PMN substance for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substance solely for export in accordance with TSCA §12(a) and (b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Contract Manufacturer begins to manufacture the PMN substance for use in the United States, no further activity by the Contract Manufacturer involving the PMN substance is exempt as “solely for export” even if some amount of the PMN substance is later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substance while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substance that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

(2) Research & Development (R&D). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36.

(3) Byproducts. The requirements of this Order do not apply to the PMN substance when it is

produced, without separate commercial intent, only as a “byproduct” as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(4) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substance when it is manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h), with no commercial purpose separate from the substance, mixture, or article of which it is a part.

(c) Automatic Sunset. If the Contract Manufacturer has obtained for the PMN substance a Test Market Exemption (TME) under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption (LVE) or Low Release and Exposure Exemption (LoREX) under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

**II. TERMS OF MANUFACTURE, IMPORT, PROCESSING,
DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL
PENDING SUBMISSION AND EVALUATION OF INFORMATION**

PROHIBITION

As a condition of manufacturing or importing the PMN substance for the Company, the Contract Manufacturer is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the PMN substance for any non-exempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the health effects **[Note**

to Program Managers: Edit as appropriate.] of the substance, and the completion of EPA's review of, and regulatory action based on that information, except in accordance with the conditions described in this Order.

TESTING

Triggered Testing Requirements. The Contract Manufacturer is prohibited from manufacturing or importing the PMN substance beyond the following aggregate manufacture and import volumes ("the production limits"), unless the Company conducts the following studies on the PMN substance and submits all final reports and underlying data in accordance with the conditions specified in the Testing section of the Consent Order for the Company.

Production Limit

Study

Guideline

PROTECTION IN THE WORKPLACE

(a) Establishment of Program. During manufacturing, processing, and use of the PMN substance at any site controlled by the Contract Manufacturer (including any associated packaging and storage and during any cleaning or maintenance of equipment associated with the PMN substance), the Contract Manufacturer must establish a program whereby:

(1) General Dermal Protection. Each person who is reasonably likely to be dermally exposed

in the work area to the PMN substance through direct handling of the substance or through contact with equipment on which the substance may exist, or because the substance becomes airborne in a form listed in subparagraph (a)(5) of this section, is provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with OSHA dermal protection requirements at 29 CFR 1910.132, 1910.133, and 1910.138.

[Note to Program Managers: Use Paragraph (a)(2) when the PMN substance may present a high dermal risk and you want to specifically require certain types of dermal protective equipment. If the dermal risk is only moderate or general, paragraph (a)(1) alone may suffice and you can delete (a)(2).]

(2) Specific Dermal Protective Equipment. The dermal personal protective equipment required by subparagraph (a)(1) of this section must include, but is not limited to, the following items:

- (i) Gloves.
- (ii) Full body chemical protective clothing.
- (iii) Chemical goggles or equivalent eye protection.
- (iv) Clothing which covers any other exposed areas of the arms, legs and torso.

(3) Demonstration of Imperviousness. The Contract Manufacturer is able to demonstrate that each item of chemical protective clothing selected, including gloves, provides an impervious barrier to prevent dermal exposure during normal and expected duration and conditions of exposure within the work area by any one or a combination of the following:

(i) Permeation Testing. Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area. Permeation testing shall be conducted according to the American Society for Testing and Materials (ASTM) F739 "Standard Test Method for Resistance of Protective Clothing materials to Permeation by Liquids or Gases." Results shall be recorded as a cumulative permeation rate as a function of time, and shall be documented in accordance with ASTM F739 using the format specified in ASTM F1194-89 "Guide for Documenting the Results of Chemical Permeation Testing on Protective Clothing Materials." Gloves may not be used for a time period longer than they are actually tested and must be replaced at the end of each work shift during which they are exposed to the PMN substance.

(ii) Manufacturer's Specifications. Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the PMN substance alone and in likely combination with other chemical substances in the work area.

(4) Respiratory Protection. Each person who is reasonably likely to be exposed by inhalation in the work area to the PMN substance in the form listed in subparagraph (a)(5) of this section, is provided with, and is required to wear, at a minimum, a NIOSH-certified respirator with an APF of _____, from the respirators listed in subparagraph (a)(6) of this section, and the respirator is used in accordance with OSHA and NIOSH respiratory protection requirements at 29 CFR 1910.134 and

42 CFR Part 84. All respirators must be issued, used, and maintained according to an appropriate respiratory protection program under the Occupational Safety and Health Administration (OSHA) requirements in 29 CFR 1910.134.

(5) Physical States. The following physical states of airborne chemical substances are listed for subparagraphs (a)(1) and (4) of this section:

(i) Particulate (including solids or liquid droplets),

(ii) Gas/vapor (all substances in the gas form), or

(iii) Combination Gas/Vapor and Particulate (gas and liquid/solid physical states are both present; a good example is paint spray mist, which contains both liquid droplets and vapor).

(6) Authorized Respirators. The following NIOSH-certified respirators meet the minimum requirements for subparagraph (a)(4) of this section:

[Note to Program Managers: Copy the appropriate individual respirator(s) from the list in Appendix 1 of this document, past them here, then delete Appendix 1.]

NEW CHEMICAL EXPOSURE LIMIT

(a) Alternative to Requirements of Respirator Section.

(1) EPA recommends and encourages the use of pollution prevention, source reduction, engineering controls and work practices, rather than respirators, as a means of controlling inhalation exposures whenever practicable.

(2) Whenever a person is reasonably likely to be exposed to the PMN substance by inhalation, as an alternative to compliance with the respirator requirements in the Protection in the Workplace

section of this Order, the Contract Manufacturer may comply with the requirements of this New Chemical Exposure Limit section. However, before the Contract Manufacturer may deviate from the respirator requirements in the Protection in the Workplace section of this Order, the Contract Manufacturer or the Company must:

(i) submit to EPA a copy of the Contract Manufacturer's or the Company's sampling and analytical method for the PMN substance, verified in accordance with subsection (c)(3) of this New Chemical Exposure Limit section;

(ii) obtain exposure monitoring results in accordance with this New Chemical Exposure Limit section; and

(iii) based on those exposure monitoring results, select, provide, and ensure use if necessary of the appropriate respiratory protection specified in paragraph (e)(2) of this New Chemical Exposure Limit section by persons who are reasonably likely to be exposed to the PMN substance by inhalation.

(3) After appropriate respiratory protection has been selected at a workplace based on the results of actual exposure monitoring conducted in accordance with this New Chemical Exposure Limit section, the Contract Manufacturer shall not, at that workplace, use the respiratory protection required in the Protection in the Workplace section of this Order (unless it is the same as required by this New Chemical Exposure Limit section).

(b) Exposure Limit.

(1) General. The following new chemical exposure limit (NCEL) for the PMN substance is an

interim level determined by EPA based on the limited information available to the Agency at the time of development of this Order. The NCEL for the PMN substance is as follows:

(i) Time-Weighted Average (TWA) Limit. The Contract Manufacturer shall ensure that no person is exposed to an airborne concentration of the PMN substance in excess of _____ (the NCEL) as an 8-hour time-weighted average, without using a respirator in accordance with subsection (e) of this New Chemical Exposure Limit section.

(ii) Non-8-Hour Work-shifts. For non-8-hour work-shifts, the NCEL for that work-shift (NCEL_n) shall be determined by the following equation: $NCEL_n = NCEL \times (8/n) \times [(24-n)/16]$, where n = the number of hours in the actual work-shift.

(iii) Short-Term Exposure Limit (STEL). The Contract Manufacturer shall ensure that no person is exposed to an airborne concentration of the PMN substance in excess of _____ as averaged over any 15 minute period, without using a respirator in accordance with subsection (e) of this New Chemical Exposure Limit section. **[Note to Program Managers: Delete this paragraph if there is no STEL.]**

(2) Automatic Sunset. If, subsequent to the effective date of this Order, the Occupational Safety and Health Administration (OSHA) promulgates, pursuant to §6 of the Occupational Safety and Health Act, 29 U.S.C. 655, a final chemical-specific permissible exposure limit (PEL) specifically applicable to this PMN substance and the OSHA PEL is not challenged in court within 60 days of its promulgation, then any respirator requirements in the Protection in the Workplace section of this Order and any requirements of this New Chemical Exposure Limit section applicable to workers and situations subject to the OSHA PEL shall automatically become null and void. However, the

requirements of this Consent Order are not negated by any pre-existing OSHA PEL applicable to the PMN substance.

(c) Performance-Criteria for Sampling and Analytical Method.

(1) Applicability. For initial development and validation of the sampling and analytical method for the PMN substance, all the requirements of this subsection (c) apply. For subsequent exposure monitoring conducted pursuant to subsection (d) of this New Chemical Exposure Limit section, only the following requirements apply: (c)(4)(i), (4)(ii), (4)(iv)(B), (4)(v)(B), (8), (9) and (10). Any deviation from the requirements of this subsection (c) must be approved in writing by EPA.

(2) Submission of Verified Method and Certification Statement. The Contract Manufacturer or the Company shall submit to EPA a copy of a validated sampling and analytical method for the PMN substance which satisfies the criteria specified in this subsection (c). The method description shall expressly state how the method compares with each quantitative requirement specified in this subsection (c). The submission must include a written statement, signed by authorized officials of the Contract Manufacturer or the Company and the Laboratory, certifying the truth and accuracy of the independent laboratory verification conducted pursuant to subsection (c)(3). To assist EPA in identifying the document, it shall state in a conspicuous, underlined subject-line at the top of the first page: "NCEL Sampling and Analytical Method for PMN # _____," after-which the correct PMN number for this chemical substance shall be stated.

(3) Verification of Analytical Method by Independent Third-Party Laboratory.

(i) Verification. The Contract Manufacturer or the Company shall have an

independent reference laboratory ("Laboratory") verify the validity of the analytical method for the PMN substance, in accordance with the other requirements in this subsection (c)(3). It is the Contract Manufacturer's responsibility to ensure that the Laboratory complies with all the requirements specified in this subsection (c)(3).

(ii) Independent Reference Laboratory. The independent reference laboratory must be a separate and distinct person (as defined at 40 CFR 720.3(x)) from the Contract Manufacturer or the Company and from any other person who may have developed the method for the Contract Manufacturer or the Company.

(iii) Accreditation. The Laboratory must be accredited by a formally recognized government or private laboratory accreditation program for chemical testing and/or analysis.

(iv) Good Laboratory Practice Standards. The Laboratory verification of the analytical method for the PMN substance must comply with TSCA Good Laboratory Practice Standards (GLPS) at 40 CFR Part 792. [Certain provisions of the TSCA GLPS applicable to toxicity testing in laboratory animals, such as 40 CFR 792.43 ("Test system care facilities"), 792.45 ("Test system supply facilities") and 792.90 ("Animal and other test system care"), are clearly inapplicable to the NCEL requirements.] However, compliance with TSCA GLPS is not required under this New Chemical Exposure Limit section where the analytical method is verified by a laboratory accredited by either: (A) the American Industrial Hygiene Association (AIHA) Industrial Hygiene Laboratory Accreditation Program (IHLAP); or (B) another comparable program approved in advance in writing by EPA.

(v) Analysis of Duplicate Samples. The Contract Manufacturer or the Company shall

collect six duplicate samples (a total of 12) at the TWA concentration. The samples shall be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the PMN substance onto a sample collection device. The duplicate samples shall be collected on identical collection media, at the same time, and under the same conditions. One set of six samples shall immediately be analyzed by the Contract Manufacturer or the Company, the other set of six samples shall be analyzed by the Laboratory using the method developed by or for the Contract Manufacturer or the Company.

(vi) Sample Storage Study. If the results of the analysis of duplicate samples pursuant to paragraph (c)(3)(v) do not satisfy the requirements in paragraph (c)(3)(vii), the Contract Manufacturer or the Company must perform a sample storage study as follows:

(I) Triplicate Samples. The Contract Manufacturer or the Company shall collect six triplicate samples (a total of 18) at the TWA concentration. The samples shall be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the PMN substance onto a sample collection device. The triplicate samples shall be collected on identical collection media, at the same time, and under the same conditions. One set of six samples shall immediately be analyzed by the Contract Manufacturer or the Company.

(II) Analysis After Sample Storage. A sample storage evaluation shall be performed with the two remaining sets of six samples. One set of six samples shall be analyzed by the Laboratory using the method developed by or for the Contract Manufacturer or the Company, and the

other shall be analyzed by the Contract Manufacturer or the Company on the same day as the Laboratory analyzes its six samples. Specialized storage conditions for the samples including extraction conditions, time from sampling to extraction, time from collection or extraction (if applicable) to analysis and storage conditions must be specified in the method description.

(vii) Comparison of Results. The difference between the results of the two sets of six samples analyzed by the Laboratory and the Contract Manufacturer or the Company as required in either paragraph (c)(3)(v) or (c)(3)(vi)(II) shall be evaluated using a two-sample t-test with unequal variances, and the two sides of the critical regions shall not exceed a 5% significance level. (See Attachment B - Statistical Analysis of NCELS Analytical Method Verification Results.) The average of each set of six samples must be within 10% of the true value. If the average of each set of six samples is not within 10% of the true value, then the sample storage time between collection and analysis must be reduced until the average of each set of six samples is within 10% of the true value.

(4) Accuracy. The sampling and analytical method must clearly demonstrate the following:

(i) General. The sampling and analytical method, and all exposure monitoring data relied on by the Contract Manufacturer, shall be accurate to within $\pm 25\%$ at a 95% confidence level for concentrations of the PMN substance ranging from one half the NCEL to twice the NCEL.

(ii) NCEL Quantitation Limits. The analytical method should be capable of reliably quantifying the PMN substance across the full range of reasonably likely exposures. At a minimum, the analytical method must be capable of reliably quantifying from a lower quantitation limit ("LQL") of one half the NCEL to an upper quantitation limit ("UQL") of at least twice the NCEL. If the Contract Manufacturer obtains an exposure monitoring sample that is more than 10% above the actual UQL of

the analytical method, the Contract Manufacturer must comply with paragraph (e)(4)(i).

(iii) Lower Quantitation Limit Signal-To-Noise Ratio. The analytical method shall be capable of quantifying the PMN to a concentration of one half the NCEL with a signal that is at least five times the baseline noise level. Baseline noise must be amplified to a measurable level when possible, even if the required amplification is beyond that used in routine analysis of samples. (If baseline noise cannot be obtained, another reference must be selected. This may be a peak considered to be noise caused by the reagent matrix.) The sampling preparation method must be specified and the detection limit for the analytical procedure must be reported as mass per injection for chromatographic techniques.

(iv) Instrument Calibration.

(I) Initial Calibration. For method development and validation (but not subsequent exposure monitoring), the initial calibration shall at a minimum consist of five (5) calibration standards with a linear correlation of 0.95 -- these five (5) calibration standards must consist of one standard at each of the following concentrations: one half the NCEL (0.5 x NCEL); between one half and one times the NCEL ($0.5 \times \text{NCEL} < > 1 \times \text{NCEL}$); one times the NCEL (1 x NCEL); between one and two times the NCEL ($1 \times \text{NCEL} < > 2 \times \text{NCEL}$), and twice the NCEL (2 x NCEL).

(III) Continuing Calibration. During each week of both method development/validation and subsequent exposure monitoring, the Contract Manufacturer shall conduct both an initial instrument calibration and a continuing calibration. The Contract Manufacturer shall perform at least one continuing calibration sample at the NCEL concentration, and at least one additional calibration sample per every 10 samples analyzed. The continuing calibration sample shall fall

within $\pm 25\%$ of the initial calibration value. If not, then the initial calibration must be repeated, and any samples associated with that outlying calibration check must be re-analyzed.

(v) Calculated Percent Recovery.

(I) Initial Calculation. For method development and validation, the Contract Manufacturer or the Company must calculate the percent of the PMN substance recovered by the analytical method from a sample containing a known quantity of the PMN substance. The sample shall be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the PMN substance onto a sample collection device. (Such a sample is referred to as a "matrix spike"). The calculated percent recovery for each matrix spike shall be greater than or equal to 75% and less than or equal to 125%. Spike concentrations for the PMN substance must be included in the sampling and analytical method submitted to EPA.

(II) Subsequent Calculation. During each subsequent exposure monitoring episode or campaign, at least 1 matrix spike, prepared by injecting the PMN substance onto a sample collection device, shall be analyzed. (This matrix spike must be prepared at the NCEL concentration.)

(vi) Sampling Device Capacity. The capacity of the sampling device must be tested and results reported to show under a known and well-defined set of conditions that the device is capable of collecting the new chemical in solid, liquid or vapor phase with minimal loss. The sampling device's capacity (air volume and collected analyte mass) must be specified. For methods that use adsorbent tubes as the collection medium, evidence of the capacity must be provided in the form of breakthrough testing. This testing must be done at a concentration twice the NCEL and under

conditions similar to those expected in the workplace. Breakthrough is defined to have occurred when the concentration of the PMN substance in the effluent stream is equal to 5% of the concentration of the influent stream, or when 20% of the PMN substance is detected in the backup section of the sampler.

(vii) Sampling Device Desorption Efficiency. Where applicable, the desorption efficiency must be evaluated for the air sampling device. A minimum of six air samples spiked with the PMN substance at least the NCEL concentration must be prepared. A recovery of at least 75% must be obtained for each of the six samples.

(5) Precision. The estimate of the coefficient of variation of each set of six samples from the controlled atmosphere test (spiked at 1.0 NCEL, per paragraphs (c)(3)(v) or (vi)) must be less than 0.105, including allowance of 0.05 for error due to sampling.

(6) Interpretation of Accuracy and Precision Data.

(i) If a single matrix spike recovery is less than 75% recovery or greater than 125% or the estimated precision is greater than 0.105, then the Contract Manufacturer or the Company must re-prepare the matrix spike, re-sample, and re-analyze all samples associated with such matrix spike or triplicate samples.

(ii) For percent recoveries less than 90% but greater than 75%, correction for low recovery is required. Correct for recovery first by dividing the observed amount by the proportion recovered before determining if measurements fall below the NCEL. For example, if the observed level is 30 mg/m^3 and the percent recovery is 75%, use the value $30 \text{ mg/m}^3 / (0.75) = 40 \text{ mg/m}^3$ when determining whether the levels are below the exposure limit.

(7) Representativeness. All sample conditions used to develop the methodology shall mimic

the actual workplace environment expected to be monitored. Conditions such as the temperature, humidity, lighting, and presence of other chemicals, etc. must mimic the conditions in the workplace to be monitored.

(8) Changes Affecting Validity. If the workplace environment changes from the initial conditions described in the verified sampling and analytical method in a way reasonably likely to invalidate the accuracy of the method, then the Contract Manufacturer must comply with the respirator requirements in the Protection in the Workplace section of this Order, unless the Contract Manufacturer or the Company re-validates the method to confirm that the requirements for accuracy and precision in paragraphs (c)(4) and (5) are met. Examples of possible changes include but are not limited to: introduction of a new chemical substance to the workplace which may interfere with the analysis of the new chemical; introduction of light to the workplace which may interfere with a light-sensitive PMN substance; or introduction of water/increased humidity to the workplace which could react with the PMN substance and cause difficulties in collection and analysis.

(9) Comparability. All data and results shall be reported in the same units of measurement as the NCEL.

(10) Responsibility for Method Validity. The independent laboratory verification and EPA receipt of the sampling and analytical method pursuant to this subsection (c) do not ensure that the method will produce valid exposure monitoring data. The Contract Manufacturer is ultimately responsible for ensuring the validity of its exposure monitoring data.

(d) Monitoring Potential Exposure.

(1) General.

(i) Action Level. The "action level" is defined as an airborne concentration of the PMN substance, calculated as an 8-hour time-weighted average, equal to one half the NCEL TWA specified in subparagraph (b)(1). For non-8-hour work shifts, the action level is equal to one half the NCELn. (The NCELn is described in subparagraph (b)(1)(ii).) The Contract Manufacturer may exceed the action level without penalty. The purpose of the action level is solely to determine the requisite monitoring frequency.

(ii) Representative Exposure Groups. Whenever exposure monitoring is required by this New Chemical Exposure Limit section, the Contract Manufacturer shall take representative samples of what the potential exposure of each person who is reasonably likely to be exposed to airborne concentrations of the PMN substance would be if respirators were not worn. The Contract Manufacturer shall do so by sampling the breathing zone air of at least one person that represents, and does not underestimate, the potential exposure of every person performing the same or substantially similar operations in each work shift, in each job classification, in each work area (hereinafter identified as an "exposure group") where inhalation exposure to the PMN substance is reasonably likely to occur. The exposure of each person need not be itself directly sampled if that exposure is represented by sampling the exposure of another person in the same exposure group.

(iii) Good Laboratory Practice Standards. Determinations of potential inhalation exposure shall be made according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and the sampling and analytical method developed pursuant to subsection (c) of this New Chemical Exposure Limit section. [Certain provisions of the TSCA GLPS applicable to toxicity testing in

laboratory animals, such as 40 CFR 792.43 ("Test system care facilities"), 792.45 ("Test system supply facilities") and 792.90 ("Animal and other test system care"), are clearly inapplicable to the NCEL requirements.] However, compliance with TSCA GLPS is not required where exposure monitoring samples are analyzed by a laboratory accredited by either: (A) the American Industrial Hygiene Association (AIHA) Industrial Hygiene Laboratory Accreditation Program (IHLAP); or (B) another comparable program approved in advance in writing by EPA.

(iv) Full Shift Exposure Samples. Representative 8-hour TWA airborne concentrations shall be determined on the basis of samples representing the full shift exposure for each exposure group.

(v) STEL Samples. Determinations of compliance with the STEL shall be made from 15 minute breathing zone samples measured at operations where there is reason to believe that the maximum short-term exposures will occur, such as during, but not limited to, the following operations:

_____. **[Note to Program Managers: Delete this paragraph if there is no STEL.]**

(2) Initial Monitoring. Before the Contract Manufacturer may deviate from the respirator requirements of the Protection in the Workplace section, the Contract Manufacturer shall conduct initial exposure monitoring to accurately determine the airborne concentration of the PMN substance for each exposure group in which persons are reasonably likely to be exposed to the PMN substance.

(3) Periodic Monitoring.

(i) If any representative samples taken during the initial exposure monitoring reveal an airborne concentration at or above the action level but at or below the TWA, the Contract Manufacturer shall repeat the exposure monitoring for that exposure group at least every 6 months. If the PMN substance is not manufactured, processed, or used at all during a given 6 month calendar

period, the Contract Manufacturer or the Company is not required to conduct exposure monitoring until manufacture, processing, or use of the PMN substance is resumed. However, cessation of manufacturing, processing and use of the PMN substance for less than the 6 month period does not constitute grounds for postponement of the 6 month deadline to conduct exposure monitoring.

(ii) If any representative samples taken during the initial exposure monitoring reveal an airborne concentration above the TWA, the Contract Manufacturer shall repeat the exposure monitoring for that exposure group at least every 3 months. If the PMN substance is not manufactured, processed, or used at all during a given 3 month calendar period, the Contract Manufacturer is not required to conduct exposure monitoring until manufacture, processing, or use of the PMN substance is resumed. However, cessation of manufacturing, processing and use of the PMN substance for less than the 3 month period does not constitute grounds for postponement of the 3 month deadline to conduct exposure monitoring.

(iii) The Contract Manufacturer may alter the exposure monitoring schedule from every 3 months to every 6 months for any exposure group for whom two consecutive measurements taken at least 7 days apart indicate that the potential exposure has decreased to the TWA or below, but is at or above the action level. Where the PMN substance is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(4) Termination of Monitoring.

(i) If representative samples taken during the initial exposure monitoring reveal an

airborne concentration below the action level, the Contract Manufacturer may discontinue monitoring for that exposure group, except when additional exposure monitoring is required by paragraph (d)(5) of this New Chemical Exposure Limit section.

(ii) If representative samples taken during the periodic monitoring reveal that an airborne concentration, as indicated by at least 2 consecutive measurements taken at least 7 days apart, are below the action level, the Contract Manufacturer may discontinue the monitoring for that exposure group, except when additional monitoring is required by paragraph (d)(5) of this New Chemical Exposure Limit section. Where the PMN substance is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(5) Additional Monitoring.

(i) For a previously monitored exposure group, the Contract Manufacturer shall, within 7 days of any of the events listed below in this paragraph (d)(5)(i), conduct the initial exposure monitoring followed by any periodic or additional exposure monitoring required by subsection (d) of this New Chemical Exposure Limit section:

(I) change in the production volume, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the PMN substance;

(II) spills, leaks, ruptures or other breakdowns occur that may reasonably cause new or additional exposures to the PMN substance; and

(III) whenever else the Contract Manufacturer has any reason to suspect a

change that may reasonably result in new or additional exposures to the PMN substance.

(ii) In no event is the additional exposure monitoring requirement in paragraph (d)(5)(i) intended to delay implementation of any necessary cleanup or other remedial action. During any cleanup or remedial operations that may occur before commencing additional exposure monitoring, the Contract Manufacturer shall ensure that potentially exposed persons use at least the respiratory protection specified in subsection (e) for the measured airborne concentration, or more protective respiratory equipment deemed appropriate by the best professional judgment of a qualified expert.

(6) Notification of Monitoring Results.

(i) Within 15 working days after receipt of the results of any exposure monitoring required by this Order, the Contract Manufacturer shall notify each person whose exposure is represented by that monitoring. The notice shall identify the NCEL, the exposure monitoring results, and any corresponding respiratory protection required by subsection (e). Affected persons shall be notified in writing either individually or by posting the information in an appropriate and accessible location.

(ii) Whenever the NCEL is exceeded, the written notification required by the preceding paragraph shall describe the action being taken by the Contract Manufacturer to reduce inhalation exposure to or below the NCEL, or shall refer to a document available to the person which states the actions to be taken to reduce exposure.

(7) Exemption based on Objective Data. Where the Contract Manufacturer has documented and reliable objective data demonstrating that, even under worst-case conditions, employee exposure to the PMN substance will not exceed the action level (defined in paragraph (d)(1)(i)) under the

expected handling procedures and conditions for a specific "exposure group" (defined in paragraph (d)(1)(ii)), then that exposure group is exempt from this New Chemical Exposure Limit section (except paragraph (d)(5) "Additional Monitoring" and subsection (f) "NCEL Record-keeping") and the respirator requirements in the Protection in the Workplace section of this Order. Any such objective data must accurately characterize actual employee exposures to the PMN substance and must be obtained under conditions closely resembling the types of materials, processes, control methods, work practices, and environmental conditions in the Contract Manufacturer's current workplace operations with the PMN substance. Examples of objective data that may be used to demonstrate that employee exposure will not exceed the action level, even under worst case conditions, include information on the physical and chemical properties of the PMN substance, industry-wide studies, and/or laboratory test results.

(e) Respiratory Protection.

(1) General. Whenever the Contract Manufacturer has conducted exposure monitoring at a workplace in accordance with subsection (d) of this New Chemical Exposure Limit section and the measured airborne concentration of the PMN substance for any person who is reasonably likely to be exposed to the PMN substance by inhalation exceeds the NCEL, the Contract Manufacturer shall provide those persons the respirators specified in this subsection (e) (rather than the respirator(s) identified in the Protection in the Workplace section of this Order), and shall ensure that the respirators are used (including training, fit testing, and maintenance) in accordance with OSHA and NIOSH respiratory protection requirements at 29 CFR 1910.134 and 42 CFR Part 84. When the Contract

Manufacturer has not yet measured the airborne concentration of the PMN substance at a workplace in accordance with this New Chemical Exposure Limit section, the Contract Manufacturer shall comply with the respirator requirements in the Protection in the Workplace section of this Order at that workplace.

(2) Selection of Appropriate Respiratory Protection. After the Contract Manufacturer has conducted exposure monitoring in accordance with subsection (d) of this New Chemical Exposure Limit section, the Contract Manufacturer shall select, provide, and ensure that persons who are reasonably likely to be exposed to the PMN substance by inhalation use, at a minimum, the respiratory protection which corresponds in the following table to the measured airborne concentration (or a more protective respirator which corresponds to a concentration higher than measured).

[Note to Program Managers: Copy the appropriate complete table from the Table of Respirators for NCEs in Appendix 2, and paste it here, then delete Appendix 2.]

(3) Reductions in Respiratory Protection. After appropriate respiratory protection has been selected based on the results of actual exposure monitoring conducted at a workplace in accordance with subsection (d) of this New Chemical Exposure Limit section, the Contract Manufacturer shall not, at that workplace, use the respiratory protection required by the Protection in the Workplace section of this Order (unless it is the same as required by this New Chemical Exposure Limit section). Before the Contract Manufacturer may make any reduction in any respiratory protection selected pursuant to this New Chemical Exposure Limit section, the Contract Manufacturer must verify, by 2 consecutive measurements taken at least 7 days apart, that the new respiratory protection is appropriate in accordance with paragraph (e)(2). Where the PMN substance is manufactured, processed, or used in

batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(4) Special Situations.

(i) Measurements Outside Quantitation Limits. When a value less than the lower quantitation limit ("LQL") of the analytical method (as described in paragraph (c)(4)(ii)) is measured, the Contract Manufacturer or the Company shall estimate potential exposure using generally established and accepted statistical methods. If the Contract Manufacturer or the Company obtains an exposure monitoring sample that is more than 10% above the actual upper quantitation limit (UQL) of the analytical method, the Contract Manufacturer must ensure that its workers wear at least a NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece. Any reductions in this respiratory protection must comply with paragraph (e)(3). The Contract Manufacturer or the Company may submit an improved analytical method provided that it complies fully with subsection (c) of this New Chemical Exposure Limit section, including the verification required by subsection (c)(3).

(ii) Cleanup and Remedial Actions. During any special cleanup or other remedial actions that may occur before commencing additional exposure monitoring (as discussed in paragraph (d)(5)(ii)), the Contract Manufacturer shall ensure that potentially exposed persons use at least the respiratory protection specified above in this subsection (e) for the measured airborne concentration, or more protective respiratory equipment deemed appropriate by the best professional judgment of a qualified expert.

(f) NCEL Recordkeeping.

(1) Whenever the Contract Manufacturer elects to comply with this New Chemical Exposure Limit section rather than the respirator requirements in the Protection in the Workplace section of this Order, the Contract Manufacturer shall maintain the following records until 30 years after the date they are created, and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(i) A copy of the sampling and analytical methods used and continuing evidence of their accuracy over time as required by section (c);

(ii) Records documenting compliance with the analytical method verification requirements of subsection (c)(3), including copies of the signed certification statement and the verification results obtained by both laboratories;

(iii) Records documenting either compliance with the Good Laboratory Practice Standards at 40 CFR Part 792, or use of a laboratory accredited by the American Industrial Hygiene Association (AIHA) or another comparable program approved in advance in writing by EPA. Where the Contract Manufacturer elects to not comply with TSCA GLPS, such records shall include the written accreditation from the AIHA or the written approval from EPA.

(iv) Records documenting all exposure monitoring dates, duration, and results of each sample taken;

(v) Records documenting the name, address, work shift, job classification, and work area of the person monitored and of all other persons whose exposures the monitoring is intended to

represent;

(vi) Any conditions that might have affected the monitoring results;

(vii) Notification of exposure monitoring results required by paragraph (d)(6);

(viii) Records documenting any changes in the production, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the PMN substance;

(ix) Records documenting any spills, leaks, ruptures or other breakdowns that may cause new or additional exposure;

(x) The type of respiratory protective devices worn by the monitored person, if any;

(xi) Records documenting any actions taken to mitigate exposures to the PMN substance;

(xii) Records documenting reliance on the objective data exemption in paragraph (d)(7), including: (A) the source of the data, (B) protocols and results of any relevant testing or analysis, (C) a description of the operation exempted and how the data demonstrate that employee exposures will not exceed the action level, (D) other data relevant to the operations, materials and employee exposures covered by the exemption.

HAZARD COMMUNICATION PROGRAM

(a) Written Hazard Communication Program. The Contract Manufacturer shall develop and implement a written hazard communication program for the PMN substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, MSDSs,

and other forms of warning material will be satisfied. The Contract Manufacturer must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The Contract Manufacturer may rely on an existing hazard communication program, including an existing program established under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1910.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this section. The written program shall include the following:

(1) A list of chemical substances known to be present in the work area which are subject to a TSCA section 5(e) consent order signed by the Contract Manufacturer or to a TSCA section 5(a)(2) SNUR at 40 C.F.R. Part 721, subpart E. The list must be maintained in each work area where the PMN substance is known to be present and must use the identity provided on the MSDS for the substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the Contract Manufacturer is required either by another Order issued under section 5(e) of TSCA, or by a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, to maintain a list of substances, the lists shall be combined with the list under this subparagraph.

(2) The methods the Contract Manufacturer will use to inform employees of the hazards of non-routine tasks involving the PMN substance (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substance contained in unlabeled pipes in their work area.

(3) The methods the Contract Manufacturer will use to inform contractors of the presence of the PMN substance in the Contract Manufacturer's workplace and of the provisions of this Order if employees of the contractor work in the Contract Manufacturer's workplace and are reasonably likely

to be exposed to the PMN substance while in the Contract Manufacturer's workplace.

(b) Labeling.

(1) The Contract Manufacturer shall ensure that each container of the substance in the workplace is labeled in accordance with this subparagraph (b)(1).

(i) The label shall, at a minimum, contain the following information:

(I) A statement of the health hazards(s) and precautionary measure(s), if any, identified in paragraph (f) of this section or by the Contract Manufacturer, for the PMN substance.

(II) The identity by which the PMN substance may be commonly recognized.

(III) A statement of the environmental hazard(s) and precautionary measure(s), if any, identified in paragraph (f) of this section, or by the Contract Manufacturer, for the PMN substance.

(IV) A statement of exposure and precautionary measure(s), if any, identified in paragraph (f) of this section, or by the Contract Manufacturer, for the PMN substance.

(ii) The Contract Manufacturer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by subparagraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The Contract Manufacturer need not label portable containers into which the PMN substance is transferred from labeled containers, and which are intended only for the immediate use of

the employee who performs the transfer.

(iv) The Contract Manufacturer shall not remove or deface an existing label on containers of the PMN substance obtained from persons outside the Contract Manufacturer unless the container is immediately re-labeled with the information specified in subparagraph (b)(1)(i) of this section.

(2) The Contract Manufacturer shall ensure that each container of the substance leaving its workplace for distribution in commerce is labeled in accordance with this subparagraph (b)(2).

(i) The label shall, at a minimum, contain the following information:

(I) The information prescribed in subparagraph (b)(1)(i) of this section.

(II) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(ii) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, shall be legible and prominently displayed. (4)

The label, or alternative forms of warning, shall be printed in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing the PMN substance in combination with any other substance that is either subject to another TSCA section 5(e) Order applicable to the Contract Manufacturer, or subject to a TSCA section 5(a)(2) SNUR at 40

CFR Part 721, subpart E, or defined as a "hazardous chemical" under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1900.1200), the Contract Manufacturer may prescribe on the label, MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the Contract Manufacturer determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Order, the Contract Manufacturer must seek a determination of equivalency for such alternative control measures pursuant to 40 CFR 721.30 before prescribing them under this subparagraph (b)(5).

(6) If the Contract Manufacturer becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the label within 3 months from the time the Contract Manufacturer becomes aware of the new information. If the PMN substance is not being manufactured, imported, processed, or used in the Contract Manufacturer's workplace, the Contract Manufacturer must add the new information to the label before the PMN substance is reintroduced into the workplace.

(c) Material Safety Data Sheets.

(1) The Contract Manufacturer must obtain or develop an MSDS for the PMN substance.

(2) The MSDS shall contain, at a minimum, the following information:

(i) The identity used on the container label of the PMN substance under this section, and, if not claimed confidential, the chemical and common name of the PMN substance. If the chemical and common name are claimed confidential, a generic chemical name must be used.

(ii) Physical and chemical characteristics of the substance known to the Contract Manufacturer, (e.g., vapor pressure, flash point).

(iii) The physical hazards of the substance known to the Contract Manufacturer, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in paragraph (f) of this section.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the PMN substance known to the Contract Manufacturer.

(vi) The primary routes of exposure to the PMN substance.

(vii) Precautionary measures to control worker exposure and/or environmental release required by this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide substantially the same degree of protection as the identified control measures. The MSDS must identify any New Chemical Exposure Limits specified in paragraph (b) of the New Chemical Exposure Limit section of this Order and must contain the information specified in the graduated respirator table in paragraph (e)(2) of the New Chemical Exposure Limit section.

(viii) Any generally applicable precautions for safe handling and use of the PMN substance which are known to the Contract Manufacturer, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the Contract Manufacturer, such as appropriate engineering controls, work practices, or personal protective

equipment.

(x) Emergency first aid procedures known to the Contract Manufacturer.

(xi) The date of preparation of the MSDS or of its last revision.

(xii) The name, address, and telephone number of the Contract Manufacturer or another responsible party who can provide additional information on the chemical substance and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the MSDS, the Contract Manufacturer must mark the MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the PMN substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Contract Manufacturer may prepare one MSDS to apply to all of these multiple mixtures.

(5) If the Contract Manufacturer becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the MSDS within 3 months from the time the Contract Manufacturer becomes aware of the new information. If the PMN substance is not being manufactured, imported, processed, or used in the Contract Manufacturer's workplace, the Contract Manufacturer must add the new information to the MSDS before the PMN substance is reintroduced into the workplace.

(6) The Contract Manufacturer must ensure that persons receiving the PMN substance from the Contract Manufacturer are provided an appropriate MSDS with their initial shipment and with the first shipment after an MSDS is revised. The Contract Manufacturer may either provide the MSDS

with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The Contract Manufacturer must maintain a copy of the MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for the PMN substance and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The MSDS must be printed in English; however, the information may be repeated in other languages.

(d) Employee Information and Training. The Contract Manufacturer must ensure that employees are provided with information and training on the PMN substance. This information and training must be provided at the time of each employee's initial assignment to a work area containing the PMN substance and whenever the PMN substance is introduced into the employee's work area for the first time.

(1) The information provided to employees under this paragraph shall include:

- (i) The requirements of this section.
- (ii) Any operations in the work area where the PMN substance is present.
- (iii) The location and availability of the written hazard communication program required

under paragraph (a) of this section, including the list of substances required by subparagraph (a)(1) of this section and MSDSs required by paragraph (c) of this section.

(2) The training provided to employees shall include:

(i) Methods and observations that may be used to detect the presence or release of the PMN substance in or from an employee's work area (such as exposure monitoring conducted by the Contract Manufacturer, continuous monitoring devices, visual appearance, or odor of the substance when being released).

(ii) The potential human health and environmental hazards of the PMN substance as specified in paragraph (f) of this section.

(iii) The measures employees can take to protect themselves and the environment from the PMN substance, including specific procedures the Contract Manufacturer has implemented to protect employees and the environment from exposure to the PMN substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release required under this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the Contract Manufacturer under this section, including an explanation of the labeling system and the MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) Existing Hazard Communication Program. The Contract Manufacturer need not take additional

actions if existing programs and procedures satisfy the requirements of this section.

(f) Human Health, Environmental Hazard, Exposure, and Precautionary Statements. The following human health and environmental hazard and precautionary statements shall appear on each label as specified in paragraph (b) and the MSDS as specified in paragraph (c) of this section:

(1) Human health hazard statements. This substance may cause:

- (i) skin irritation.
- (ii) respiratory complications.
- (iii) central nervous system effects.
- (iv) internal organ effects.
- (v) birth defects.
- (vi) reproductive effects.
- (vii) cancer.
- (viii) immune system effects.
- (ix) developmental effects.

(2) Human hazard precautionary statements. When using this substance:

- (i) avoid skin contact.
- (ii) avoid breathing the substance.
- (iii) avoid ingestion.
- (iv) use respiratory protection, or maintain workplace airborne concentrations at or

below an 8-hour time-weighted average of _____. **[Note to Program Managers: Add STEL if**

applicable.]

(v) use skin protection.

(3) Environmental hazard statements. This substance may be:

(i) toxic to fish.

(ii) toxic to aquatic organisms.

(4) Environmental hazard precautionary statements. Notice to users:

(i) disposal restrictions apply.

(ii) spill clean-up restrictions apply.

(iii) do not release to water.

(5) The human and environmental hazard and precautionary statement on the label prepared pursuant to paragraph (b) of this section must be followed by the statement: "See the MSDS for details."

MANUFACTURING

(a)(1) Prohibition. The Contract Manufacturer shall not begin manufacture or import of the PMN substance until the Contract Manufacturer or the Company receives a fully executed copy of the Consent Order for Contract Manufacture from EPA.

(2) The Contract Manufacturer shall not cause, encourage, or suggest the manufacture or import of the PMN substance by any other person.

(3) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substance under section 5(a)(2) of TSCA

unless the Contract Manufacturer is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Contract Manufacturer is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Contract Manufacturer in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(4) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substance and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Contract Manufacturer shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substance of the existence of the SNUR.

(b) The Contract Manufacturer shall not manufacture the PMN substance:

- (1) In non-enclosed processes;
- (2) In the United States;
- (3) Beyond an aggregate manufacture and importation volume of _____;
- (4) Beyond an annual manufacture and importation volume of _____;
- (5) In the form of a powder;
- (6) In the form of a solid;
- (7) In the form of a liquid;
- (8) In the form of a gas; or
- (9) Other: _____.

PROCESSING

(a) The Contract Manufacturer shall not process the PMN substance:

- (1) In non-enclosed processes;
- (2) Beyond the site of manufacture or import;
- (3) In the form of a powder;
- (4) In the form of a solid;
- (5) In the form of a liquid;
- (6) In the form of a gas; or
- (7) Other:_____.

USE

(a) The Contract Manufacturer shall not use the PMN substance:

- (1) In non-enclosed processes;
- (2) Beyond the site of manufacture or import;
- (3) Other than as an intermediate;
- (4) Other than as a site-limited intermediate;
- (5) As an intermediate where the concentration of the PMN substance in the product intended for distribution in commerce exceeds ____ percent;
- (6) Other than as described in the PMN;
- (7) For non-industrial applications;
- (8) For commercial applications;
- (9) For non-commercial applications;

- (10) In consumer products;
- (11) In the form of a powder;
- (12) In the form of a solid;
- (13) In the form of a liquid;
- (14) In the form of a gas;
- (15) Involving an application method that generates a vapor, mist, or aerosol;
- (16) Involving an application method that generates a dust; or
- (17) Other: _____.

DISTRIBUTION

(a) Distribution Requirements. Except after the PMN has been completely reacted (or _____) **[Note to Program Managers: If applicable to the specific PMN substance, identify a state or states in which exposure to the PMN substance no longer presents a significant risk, e.g., “incorporated into a polymer matrix”, “adhered onto film”, or similar.]** or as provided in paragraph (b), the Contract Manufacturer shall distribute the PMN substance outside the Contract Manufacturer, other than for disposal, only to a person who has agreed in writing prior to the date of distribution, to:

(1) Not further distribute the PMN substance to any other person, other than for disposal, until after the PMN substance has been completely reacted (cured) or _____. **[Note to Program Managers: If applicable to the specific PMN substance, identify a state or states in which exposure to the PMN substance no longer presents a significant risk, e.g., “incorporated into**

a polymer matrix”, “adhered onto film”, or similar.]

(2) Comply with the same requirements and restrictions, if any, required of the Contract Manufacturer in the Protection in the Workplace and the New Chemical Exposure Limit sections of this Order, or _____.

(3) Comply with the same requirements and restrictions, if any, required of the Contract Manufacturer in the Hazard Communication Program section of this Order, or_____.

(4) Comply with the same environmental release restrictions, if any, required of the Contract Manufacturer in the Disposal and Release to Water sections of this Order, or _____.

(5) Not process the PMN substance:

- (i) In non-enclosed processes;
- (ii) At a site not in that person's control;
- (iii) Except as described in the PMN;
- (iv) In the form of a powder;
- (v) In the form of a solid;
- (vi) In the form of a liquid;
- (vii) In the form of a gas; or
- (viii) Other:_____.

(6) Not use the PMN substance:

- (i) At a site not under the person's control;
- (ii) In non-enclosed processes;
- (iii) Other than as an intermediate;

(iv) Other than as a site-limited intermediate; or

(v) As an intermediate where the concentration of the PMN substance in the product intended for distribution in commerce exceeds ____ percent;

(vi) Other than as described in the PMN;

(vii) For non-industrial applications;

(viii) For commercial use;

(ix) For non-commercial use;

(x) In consumer products;

(xi) In the form of a powder;

(xii) In the form of a solid;

(xiii) In the form of a liquid;

(xiv) In the form of a gas;

(xv) Involving an application method that generates a vapor, mist, or aerosol;

(xvi) Involving an application method that generates a dust; or

(xvii) Other: _____.

(b) Temporary Transport and Storage. Notwithstanding paragraph (a), the Contract Manufacturer may distribute the PMN substance outside the Contract Manufacturer for temporary transport and storage in sealed containers (labeled in accordance with paragraph (b)(2) of the Hazard Communication Program section of this Order) provided the following two conditions are met:

(1) Subsequent to any such exempt temporary transport or storage of sealed containers, the

PMN substance may be distributed only to the Company or a person who has given the Contract Manufacturer the written agreement required by paragraph (a).

(2) Any human exposure or environmental release resulting from opening the sealed containers and removing or washing out the PMN substance may occur only while the PMN substance is in the possession and control of the Contract Manufacturer or a person who has given the Contract Manufacturer the written agreement required by paragraph (a).

(c) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the PMN substance, the Contract Manufacturer obtains knowledge that a recipient of the substance has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section or, after paragraph (a)(1) expires in accordance with subparagraph (d)(1), has engaged in a significant new use of the PMN substance (as defined in 40 CFR Part 721, Subpart E) without submitting a significant new use notice to EPA, the Contract Manufacturer shall cease supplying the substance to that recipient, unless the Contract Manufacturer is able to document each of the following:

(1) That the Contract Manufacturer has, within 5 working days, notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA.

(2) That, within 15 working days of notifying the recipient of the noncompliance, the Contract Manufacturer received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (a) of this Distribution section and will comply with those terms, or is aware of

the terms of the significant new use rule for the PMN substance and will not engage in a significant new use without submitting a significant new use notice to EPA.

(3) If, after receiving a statement of assurance from a recipient under subparagraph (c)(2) of this Distribution section, the Contract Manufacturer obtains knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA, the Contract Manufacturer shall cease supplying the PMN substance to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substance to that recipient only upon written notification from the Agency.

(d) Sunset Following SNUR. (1) Paragraph (a)(1) of this Distribution section shall expire 75 days after promulgation of a final SNUR for the PMN substance under section 5(a)(2) of TSCA, unless the Contract Manufacturer is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Contract Manufacturer is so notified, paragraph (a)(1) of this Distribution section shall not expire until EPA notifies the Contract Manufacturer in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(2) When EPA promulgates a final SNUR for the PMN substance and paragraph (a)(1) of this Distribution section expires in accordance with subparagraph (d)(1), the Contract Manufacturer shall notify each person to whom it distributes the PMN substance of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the

PMN substance. Such notice must also reference the publication of the SNUR for this PMN substance in either the Federal Register or the Code of Federal Regulations. After promulgation of a SNUR and expiration of subparagraph (a)(1), such notice may substitute for the written agreement required in the introductory clause of paragraph (a); so that, if the Contract Manufacturer provides such notice to the persons to whom it distributes the PMN substance, then the Contract Manufacturer is not required to obtain from such persons the written agreement specified in paragraph (a).

DISPOSAL

(a) The Contract Manufacturer shall dispose of the PMN substance and any waste stream containing the PMN substance only as follows. This provision does not supersede or preempt any applicable federal, state, and local laws and regulations if those laws are more stringent than the requirements below.

- (1) The PMN substance must be disposed of only by:
 - (i) incineration;
 - (ii) landfill;
 - (iii) deep well injection;
 - (iv) other: _____

- (2) Waste streams from manufacture must be disposed of only by:
 - (i) incineration;
 - (ii) landfill;
 - (iii) deep well injection;
 - (iv) other: _____

- (3) Waste streams from processing must be disposed of only by:
- (i) incineration;
 - (ii) landfill;
 - (iii) deep well injection;
 - (iv) other: _____
- (4) Waste streams from use must be disposed of only by:
- (i) incineration;
 - (ii) landfill;
 - (iii) deep well injection;
 - (iv) other: _____
- (5) The Contract Manufacturer shall not dispose of or release the PMN substance into the environment.

RELEASE TO WATER

(a) This provision does not supersede or preempt any applicable federal, state, and local laws and regulations. (Those other laws may be more stringent than the requirements below.) The Contract Manufacturer is prohibited from any predictable or purposeful release of the PMN substance, or any waste stream from _____ (manufacturing/processing/use) containing the PMN substance:

- (1) Into the waters of the United States;
- (2) Into the waters of the United States without application of one or more of the following specified treatment technologies either by the discharger or, in the case of a release through publicly-

owned treatment works, by a combination of treatment by the discharger and the publicly-owned treatment works:

- (i) Chemical precipitation and settling;
- (ii) Biological treatment (activated sludge or equivalent) plus clarification;
- (iii) Stream stripping;
- (iv) Resin or activated carbon adsorption;
- (v) Chemical destruction or conversion;
- (vi) Primary wastewater treatment;

(3) Into the waters of the United States without primary wastewater treatment, and secondary wastewater treatment as defined in 40 CFR Part 133.

(4)(i) Into the waters of the United States if the quotient from the formula:

$$\frac{\text{number of kilograms/day/site released}}{\text{receiving stream flow (million liters/day)}} \times 1000 = N \text{ parts per billion}$$

exceeds _____, when calculated using the methods described in 40 CFR 721.91. However, 40 CFR 721.91(a)(4) does not apply. Instead, if the waste stream containing the PMN substance will be treated using _____, then the amount of PMN substance reasonably likely to be removed from the waste stream by such treatment may be subtracted in calculating the number of kilograms released. No more than ___ percent removal efficiency may be attributed to such treatment. **[Note to Program Managers:**

Use this language, starting from “However, 40 CFR 721.91(a)(4) does not...” only when EPA has received and reviewed removal rate data..]

(ii) In lieu of calculating the quotient in subparagraph (4)(i), monitoring or alternative

calculations may be used to predict the surface water concentration expected to result from the intended release of the substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on a written request to approve monitoring procedures or alternative calculations within 90 days after such a request is received. The Agency will inform the Contract Manufacturer of the disposition of such requests in writing and, where a request is denied, will explain the reasons therefor.

III. RECORDKEEPING

(a) Records. The Contract Manufacturer shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substance did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Contract Manufacturer. Any amounts or batches of the PMN substance eligible for the Export exemption in Section I, Paragraph (b)(3) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Contract Manufacturer maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substance eligible for the Research and Development exemption in Section I, Paragraph (b)(4) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Contract Manufacturer maintains, for 5 years from the

date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substance claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Contract Manufacturer shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) Records documenting the manufacture and importation volume of the PMN substance and the corresponding dates of manufacture and import;

(3) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Contract Manufacturer directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(4) Records documenting the address, of all sites of manufacture, import, processing, and use;

(5) Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required pursuant to the Protection in the Workplace section of this Order;

(6) Records documenting the determinations required by the Protection in the Workplace section of this Order that chemical protective clothing is impervious to the PMN substance;

(7) Records required by paragraph (f). of the New Chemical Exposure Limits section of this Order, if applicable;

(8) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Order;

(9) Copies of labels required under the Hazard Communication Program section of this Order;

(10) Copies of material safety data sheets required by the Hazard Communication Program section of this Order;

(11) Records documenting compliance with any applicable manufacturing, processing, use, and distribution restrictions in the Manufacturing, Processing, Use, and Distribution sections of this Order, including distributees' written agreement to comply with the Distribution section of this Order;

(12) Records documenting compliance with any applicable disposal requirements under the Disposal section of this Order, including method of disposal, location of disposal sites, dates of disposal, and volume of PMN substance disposed. Where the estimated disposal volume is not known to the Contract Manufacturer and is not reasonably ascertainable by the Contract Manufacturer, the Contract Manufacturer must maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements;

(13) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitation in the Release to Water section of this Order;

(14) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and

(15) The Contract Manufacturer shall keep a copy of this Order at each of its sites where the PMN substance is manufactured or imported.

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities of the Contract Manufacturer and its Contract Manufacturer, if applicable, and not to activities of the Contract

Manufacturer's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Contract Manufacturer is not required to respond to this “collection of information” unless this Order displays a currently valid control number from the Office of Management and Budget (OMB), and EPA so informs the Contract Manufacturer. The “collection of information” required in this TSCA §5(e) Consent Orders has been approved under currently valid **OMB Control Number 2070-0012**.

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA’s Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may occasionally conduct on-site compliance inspections of Contract Manufacturer facilities and conveyances associated with the PMN substance. To facilitate such inspections, EPA personnel may contact the Contract Manufacturer in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request may include, but are not limited to, the following:

(i) Expected dates and times when the PMN substance will be in production within the subsequent 12 months;

(ii) Current workshift schedules for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(iii) Current job titles or categories for workers who are involved in activities associated with the

PMN substance and may reasonably be exposed to the PMN substance;

(iv) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(v) Records required by the Recordkeeping section of this Order; and/or

(vi) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Contract Manufacturer's Response. The Contract Manufacturer shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Contract Manufacturer's response shall be in writing. To the extent the information is known to or reasonably ascertainable to the Contract Manufacturer at the time of the request, the Contract Manufacturer's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information (CBI) that the Contract Manufacturer submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

V. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Contract Manufacturer may petition EPA at any time, based upon new information on the health effects of, or human exposure to, the PMN substance, to modify or revoke substantive provisions

of this Order. The exposures and risks identified by EPA during its review of the PMN substance and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.

In addition, the Contract Manufacturer may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VI. EFFECT OF CONSENT ORDER

By consenting to the entry of this Order, the Contract Manufacturer waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Contract Manufacturer as to, the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Contract Manufacturer may have under TSCA.

Date

Wardner G. Penberthey, Acting Director
Chemical Control Division
Office of Pollution Prevention and Toxics

Date

Name:

Title:

Contract Manufacturer:

ATTACHMENT A

DEFINITIONS

[Note: The attached Order may not contain some of the terms defined below.]

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

"Company" means the person who submitted the pre-manufacture notice (PMN) and who is subject to the Consent Order to which this Consent Order for Contract Manufacturer is an attachment.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture and import the PMN substance under the conditions specified in this Consent Order for Contract Manufacturer and in Part II. of the Company's Consent Order.

"Identity" means any chemical or common name used to identify a chemical substance or a

mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labelled container.

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"PMN substance" means the chemical substance described in the Premanufacture notice submitted by the Company relevant to this Order.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN substance during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Work area" means a room or defined space in a workplace where the PMN substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B

STATISTICAL ANALYSIS OF NCELS ANALYTICAL METHOD VERIFICATION RESULTS

This Attachment describes the statistical technique (with examples) for comparing the analytical results obtained by two laboratories pursuant to paragraph (c)(3)(vii) of the New Chemical Exposure Limit section of this Order.

STATISTICAL TECHNIQUE

To obtain two-sample t test with unequal variances, perform the following operations:

- ! Compute means of the data measured by two laboratories.
- ! Compute mean squares

$$S_i^2 = \frac{\sum (\bar{X}_{ij} - X_i)^2}{(n_i - 1)}, i=1, 2$$

- ! Form the ratio

$$T = \frac{(\bar{X}_1 - \bar{X}_2)}{(W_1 + W_2)^{1/2}}$$

- ! Compute degrees of freedom

$$f = (W_1 + W_2)^2 / [W_1^2 / (n_1 - 1) + W_2^2 / (n_2 - 1)]$$

where,

$$W_i = S_i^2 / n_i, i = 1, 2$$

\bar{X}_1 = Average of the results from the Contract Manufacturer laboratory

\bar{X}_2 = Average of the results from the independent laboratory

n_1 = Number of samples analyzed by the Contract Manufacturer laboratory

n_2 = Number of samples analyzed by the independent laboratory.

Then compare the absolute value of T to the 97.5 percentile point of a t distribution with f degrees of freedom. If the absolute value exceeds the 97.5 percentile point, the results measured by two laboratories are significantly different at 95% level. Otherwise, they are not significantly different. In general, f may not be a integer. Use interpolation to obtain the 97.5 percentile point of a t distribution with f degrees of freedom.

EXAMPLES -- The following examples (based on simulated data) illustrate the method:

Example 1

<u>Data Set 1</u>		<u>Data Set 2</u>	
	80.56		97.11
	100.01		102.13
	86.04		99.83
	52.61		97.83
	84.85		105.44
	95.75		100.04
$\bar{X}_1 = 83.30$	$n_1 = 6$	$\bar{X}_2 = 100.40$	$n_2 = 6$
$S_1^2 = 278.72$	$W_1 = 46.25$	$S_2^2 = 9.26$	$W_2 = 1.54$
Absolute value of T = 2.467		f = 5.33	

The t table shows that the 97.5 percentile point is 2.571 and 2.447 for 5 and 6 degrees of freedom, respectively. For 5.33 degrees of freedom, the 97.5 percentile point will be approximately 2.530 which is greater than the absolute value of T, 2.467. Hence, the means of two data sets are not significantly different at the 5% level.

However, if this problem had been treated as an ordinary two-sample t test, the means would be significantly different at the 5% level because the absolute of T is greater than 2.228, the 97.5 percentile point for the t distribution with 10 degrees of freedom.

Example 2

<u>Data Set 1</u>	<u>Data Set 2</u>
82.87	108.05
101.85	96.51
87.44	100.04
99.68	104.33

101.15
99.21

110.32
107.00

$$\bar{X}_1 = 95.37 \quad n_1 = 6 \quad \bar{X}_2 = 104.37 \quad n_2 = 6$$

$$S_1^2 = 65.59 \quad W_1 = 10.93 \quad S_2^2 = 27.25 \quad W_2 = 4.54$$

Absolute value of $T = 2.290$ ~~8.54~~

The t table shows that for 8 and 9 degrees of freedom the 97.5 percentile point is 2.306 and 2.262, respectively. For 8.54 degrees of freedom the 97.5 percentile point will be approximately 2.282 which is less than the absolute value of T , 2.290. Hence, the means of two data sets are significantly different at the 5% level.

APPENDIX 1

LIST OF RESPIRATORS

Note to Program Managers: Copy the respirators in the appropriate exposure category below, then paste that information into the Protection in the Workplace section (a)(6) of the Consent Order (found in the boilerplate on page 13). For example, if the exposure to the PMN substance is expected to be in particulate form, copy all of the information in the “Particulate/Aerosol/Mist Exposure” category for the APF you need below. **After you have inserted the information into the Consent Order, delete this Appendix 1.**

Delete irrelevant respirators by unit, e.g. Particulate, APF of 2 to 10. Each unit is separated by a line divider (_____) and has a heading in red bold. Do *not* copy the line dividers or red bold headings into the body of the Order. Adjust numbering as necessary in the Order. Each unit does not require any editing unless specified.

Particulate, APF of 2 to 10

(i) Particulate/Aerosol/Mist Exposures, APF of 2 to 10:

(I) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters. **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, delete this respirator.]**

(II) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters.

(III) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters.

(IV) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters. **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

(V) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

Particulate, APF of 11 to 25

(i) Particulate/Aerosol/Mist Exposures, APF of 11 to 25:

(I) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters.

(II) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and HEPA filters.

(III) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters. **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

(IV) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

Particulate, APF of 26 to 50

(i) Particulate/Aerosol/Mist Exposures, APF of 26 to 50:

(I) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters.

(II) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters. **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

(III) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece (either half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

Particulate, APF of 51 to 2000

(i) Particulate/Aerosol/Mist Exposures, APF of 51 to 2000:

(I) NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece.

Gas/Vapor, APF of 2 to 10

(ii) Gas/Vapor Exposures, APF of 2 to 10:

If Data on Cartridge Service Life Testing has been Reviewed and Approved by

EPA:

(I) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, this option should be deleted.]**

(II) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

(III) NIOSH-certified powered air-purifying respirator equipped with a loose fitting hood or helmet and equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

(IV) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (half-face or full-face) and equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

(V) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

If No Cartridge Service Life Testing is Available:

(VI) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a loose fitting hood or tight-fitting facepiece (either half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous**

membranes, or skin, the half-face piece should be deleted.]

Gas/Vapor, APF of 11 to 25

(ii) Gas/Vapor Exposures, APF of 11 to 25:

If Data on Cartridge Service Life Testing has been Reviewed and Approved by

EPA:

(I) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

(II) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

(III) NIOSH-certified powered air-purifying respirator with a tight-fitting facepiece (half-face or full-face) and equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

(IV) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

If No Cartridge Service Life Testing is Available:

(V) NIOSH-certified supplied-air respirator operated in pressure demand or

continuous flow mode and equipped with a loose-fitting hood or helmet or a tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

Gas/Vapor, APF of 26 to 50

(ii) Gas/Vapor Exposures, APF of 26 to 50:

If Data on Cartridge Service Life Testing has been Reviewed and Approved by

EPA:

(I) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

(II) NIOSH-certified powered air-purifying, tight-fitting respirator (either half-face or full-face) equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

(III) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

If No Cartridge Service Life Testing is Available:

(IV) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting full facepiece.

Gas/Vapor, APF of 51 to 2000

(ii) Gas/Vapor Exposures, APF of 51 to 2000:

(I) NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece.

Combination Gas/Particulate, APF of 2 to 10

(iii) Combination of Gas/Vapor and Particulate (paint spray, etc.), APF of 2 to 10:

If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:

(I) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include a particulate filter (N100 if oil aerosols are absent, R100, or P100). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, this option should be deleted.]**

(II) NIOSH-certified air-purifying, tight-fitting full facepiece respirator equipped with the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include a particulate filter (N100 if oil aerosols are absent, R100, or P100).

(III) NIOSH-certified powered air-purifying respirator equipped with a loose fitting hood or helmet and the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and

should include HEPA filters.

(IV) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters. **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

(V) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

If No Cartridge Service Life Testing is Available:

(VI) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

Combination Gas/Particulate, APF of 11 to 25

(iii) Combination of Gas/Vapor and Particulate (paint spray, etc.), APF of 11 to 25:

If Data on Cartridge Service Life Testing has been Reviewed and Approved by

EPA:

(I) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include a particulate filter (N100 if oil aerosols are absent, R100, or P100).

(II) NIOSH-certified powered air-purifying respirator equipped with a loose fitting hood or helmet and the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters.

(III) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters. **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

(IV) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

If No Cartridge Service Life Testing is Available:

(V) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-

face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

Combination Gas/Particulate, APF of 26 to 50

(iii) Combination of Gas/Vapor and Particulate (paint spray, etc.), APF of 26 to 50:

If Data on Cartridge Service Life Testing has been Reviewed and Approved by

EPA:

(I) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include a particulate filter (N100 if oil aerosols are absent, R100, or P100).

(II) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters. **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

(III) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

If No Cartridge Service Life Testing is Available:

(IV) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

Combination Gas/Particulate, APF of 51 to 2000

(iii) Combination of Gas/Vapor and Particulate (paint spray, etc.), APF of 51 to 2000:

(I) NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece.

APPENDIX 2

NCELS RESPIRATOR TABLES Measured Concentrations of PMN Substance and Corresponding Acceptable Respiratory Protection

Note to Program Managers: Copy the appropriate respirator table below and paste into the NEW CHEMICAL EXPOSURE LIMIT section (e)(2) of the Consent Order. After copying the table into the Order, adjust the line spacing so that the table is single spaced and the rest of the Order is double spaced. **After you have copied and pasted the table into the Consent Order, delete this Appendix 2.**

PARTICULATE RESPIRATOR TABLE

Measured Concentration of PMN Substance

Required Respiratory Protection

NCEL

< No respiratory protection is required.

10 x NCEL

< NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters. **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

< NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters.

< NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters.

< NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters. **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

< NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

25 x NCEL

< NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters.

< NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and HEPA filters.

< NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters. **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

< NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

50 x NCEL

< NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters.

< NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters. **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

< NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece (either half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

2000 x NCEL

< NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece.

> 2000 x NCEL

< Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode.

< Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode.

GAS/VAPOR RESPIRATOR TABLE

**Measured
Concentration
of PMN Substance**

Required Respiratory Protection

NCEL

< No respiratory protection is required.

10 x NCEL

If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:

< NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

< NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

< NIOSH-certified powered air-purifying respirator equipped with a loose fitting hood or helmet and equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

< NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (half-face or full-face) and equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

< NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

If No Cartridge Service Life Testing is Available:

< NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a loose fitting hood or tight-fitting facepiece (either half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

25 x NCEL

If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:

< NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

< NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

< NIOSH-certified powered air-purifying respirator with a tight-fitting facepiece (half-face or full-face) and equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

< NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

If No Cartridge Service Life Testing is Available:

< NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a loose-fitting hood or helmet or a tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

50 x NCEL

If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:

< NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

< NIOSH-certified powered air-purifying, tight-fitting respirator (either half-face or full-face) equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

< NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

If No Cartridge Service Life Testing is Available:

< NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting full facepiece.

2000 x NCEL

< NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece.

> 2000 x NCEL

< Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode.

< Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode.

COMBINATION PARTICULATE AND GAS/VAPOR RESPIRATOR TABLE

**Measured
Concentration
of PMN Substance**

Required Respiratory Protection

NCEL

< No respiratory protection is required.

10 x NCEL

If Data on Cartridge Service Life Testing has been Reviewed and Approved

by EPA:

< NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include a particulate filter (N100 if oil aerosols are absent, R100, or P100). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

< NIOSH-certified air-purifying, tight-fitting full facepiece respirator equipped with the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include a particulate filter (N100 if oil aerosols are absent, R100, or P100).

< NIOSH-certified powered air-purifying respirator equipped with a loose fitting hood or helmet and the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters.

< NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters. **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

< NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

If No Cartridge Service Life Testing is Available:

< NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

25 x NCEL

If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:

< NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include a particulate filter (N100 if oil aerosols are absent, R100, or P100).

< NIOSH-certified powered air-purifying respirator equipped with a loose fitting hood or helmet and the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters.

< NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters. **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

< NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

If No Cartridge Service Life Testing is Available:

< NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**
[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]

50 x NCEL

If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:

< NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include a particulate filter (N100 if oil aerosols are absent, R100, or P100).

< NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and the appropriate combination

cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters. **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

< NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

If No Cartridge Service Life Testing is Available:

< NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

2000 x NCEL

< NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece.

> 2000 x NCEL

< Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode.

< Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode.