

MIL-STD-1246B  
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MILITARY STANDARD  
PRODUCT CLEANLINESS LEVELS  
AND  
CONTAMINATION CONTROL PROGRAM



AMSC No. A4180

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MIL-STD-1246B

DEPARTMENT OF DEFENSE  
Washington, DC 20301

Product Cleanliness Levels and Contamination Control Program

- \* 1. This military standard is approved for use by all Departments and Agencies of the Department of Defense.
- \* 2. Beneficial comments (recommendations, additions, deletions) and any pertinent data which may be of use in improving this document should be addressed to: Commander, U.S. Army Missile Command, ATTN: AMSMI-RD-SE-TD-ST, Redstone Arsenal, AL 35898-5270 by using the self-addressed Standardization Document Improvement Proposal (DD Form 1426) appearing at the end of this document or by letter.

MIL-STD-1246B

FOREWARD

- \* 1. This standard contains requirements for the establishment of a uniform method for specifying product cleanliness levels and contamination control program requirements.
- \* 2. The Data Item Description (DID) applicable to this standard is listed in Section 6.

## MIL-STD-1246B

## CONTENTS

| Paragraph |   | Page |
|-----------|---|------|
| 1         | SCOPE-----  | 1    |
| 1.1       | Scope-----  | 1    |
| 1.2       | Use-----  | 1    |
| 1.3       | Applicability-----  | 1    |
| 2.        | REFERENCED DOCUMENTS-----   | 1    |
| 2.1       | Government documents-----   | 1    |
| 2.1.1     | Standards-----  | 1    |
| 2.2       | Other publications-----   | 1    |
| 2.3       | Order of precedence-----  | 3    |
| 3.        | DEFINITIONS-----  | 3    |
| 3.1       | Cleanliness level-----  | 3    |
| 3.2       | Contamination-----  | 3    |
| 3.3       | Contamination control-----  | 3    |
| 3.4       | Micron-----   | 3    |
| 3.5       | Non-volatile residue-----   | 3    |
| 3.6       | Particle size-----  | 3    |
| 3.7       | Significant surface-----  | 3    |
| 4.        | GENERAL REQUIREMENTS-----   | 3    |
| 4.1       | Responsibility-----   | 3    |
| 4.1.1     | Prescribing product cleanliness-----  | 3    |
| 4.1.2     | Achieving and maintaining product<br>cleanliness-----                             | 3    |
| 4.1.3     | Assuring the integrity and continuity<br>of the contamination control effort----- | 4    |
| 4.1.4     | Contamination control plan-----   | 4    |
| 4.1.4.1   | Design requirement-----   | 4    |
| 4.1.4.2   | Product design review-----  | 4    |
| 4.1.4.3   | Processes and controls-----   | 4    |
| 4.1.4.4   | Clean room facilities and work stations-----                                      | 4    |
| 4.1.4.5   | Sub-tier contractors-----   | 4    |
| 4.1.4.6   | Calibration procedures-----   | 4    |
| 4.1.4.7   | Quality control-----  | 4    |
| 4.1.4.8   | Product protection-----   | 4    |
| 4.1.4.9   | Personnel-----  | 4    |
| 5.        | DETAILED REQUIREMENTS-----  | 5    |
| 5.1       | Cleanliness levels-----   | 5    |
| 5.1.1     | Application of cleanliness levels-----  | 5    |
| 5.1.2     | Measurement of cleanliness levels-----  | 5    |
| 5.1.3     | Methods for specifying product cleanliness<br>levels-----                         | 6    |
| 6.        | NOTES-----  | 6    |
| 6.1       | Intended use-----   | 6    |
| 6.2       | Data requirements-----  | 6    |
| 6.3       | Subject term (key word) listing-----  | 7    |
| 6.4       | Changes from previous issue-----  | 7    |

MIL-STD-1246B

TABLES

|       |    |                                       | Page |
|-------|----|---------------------------------------|------|
| Table | 1a | Derivation of Cleanliness Levels----- | 8    |
|       | 1b | Non-Volatile Residue-----             | 8    |

CHART

|       |   |                                 |   |
|-------|---|---------------------------------|---|
| Chart | I | Product Cleanliness Levels----- | 9 |
|-------|---|---------------------------------|---|

APPENDIX

|          |   |                                     |    |
|----------|---|-------------------------------------|----|
| Appendix | A | Cleaning Methods and Materials----- | 10 |
|----------|---|-------------------------------------|----|

## MIL-STD-1246B

## APPENDIX A

## CLEANING METHODS AND MATERIALS

| Paragraph |   | Page |
|-----------|---|------|
| 10        | CLEANING METHODS AND MATERIALS-----                     | 10   |
| 10.1      | Gross cleaning-----                                     | 10   |
| 10.1.1    | Gross cleaning types-----                               | 10   |
| 10.1.1.1  | Acid cleaners-----                                      | 10   |
| 10.1.1.2  | Alkaline cleaners-----                                  | 10   |
| 10.1.1.3  | Mild Alkaline cleaners and detergents-----              | 10   |
| 10.1.1.4  | Organic solvent cleaners-----                           | 11   |
| 10.1.1.5  | Tap water and deionized water-----                      | 11   |
| 10.1.1.6  | Neutralizing and passivating solutions-----             | 11   |
| 10.1.1.7  | Mechanical cleaning-----                                | 11   |
| 10.1.1.8  | Gross cleaning processes-----                           | 11   |
| 10.2      | Precision cleaning-----                                 | 11   |
| 10.2.1    | Precision cleaning solutions/fluids-----                | 11   |
| 10.2.2    | precision cleaning methods/processes-----               | 13   |
| 10.2.2.1  | Solution cleaning-----                                  | 13   |
| 10.2.2.2  | Spray cleaning-----                                     | 13   |
| 10.2.2.3  | Ultrasonic cleaning-----                                | 13   |
| 10.2.2.4  | Vapor cleaning-----                                     | 13   |
| 10.2.2.5  | Flush cleaning-----                                     | 13   |
| 10.3      | Solution controls-----                                  | 13   |
| 10.4      | A detailed process plan-----                            | 13   |
| 10.5      | Monitoring precision cleanliness of the<br>product----- | 14   |
| 10.6      | Handling during cleaning-----                           | 14   |
| 20.       | PROTECTION-----   | 14   |
| 20.1      | Cleanliness protection-----                             | 14   |
| 20.2      | Precision clean packaging-----                          | 14   |
| 20.3      | Storage-----  | 15   |
| 30.       | INSPECTION-----   | 15   |
| 30.1      | Inspection-----   | 15   |

## TABLE

|       |    |   |    |
|-------|----|---|----|
| Table | II | Selection Chart for Gross Cleaning Processes--- | 12 |
|-------|----|---|----|

## MIL-STD-1246B

## 1. SCOPE .

1.1 Scope. This standard provides a basis and a uniform method for specifying product cleanliness levels and contamination control program requirements.

1.2 Use. These requirements are unusual and are not required for all products but are intended for use in military procurement and design contracts for only those items that contamination control, by measurement for parts, components, or fluids, is necessary to ensure reliability.

1.3 Applicability. When this standard is made a part of a procurement contract, the procuring activity shall be responsible for identifying the applicable requirements contained herein that apply to the particular contract.

## 2. REFERENCE DOCUMENTS

- \* 2.1 Government documents.
- \* 2.1.1 Standards. Unless otherwise specified, the following standards of the issue listed in that issue of the Department of Defense Index of Specifications and Standards (DODISS) specified in the solicitation form a part of this standard to the extent specified herein.

## STANDARDS

Federal

FED-STD-209

Clean Room and Work Station  
Requirements, Controlled  
Environment

- \* (Copies of standards required by contractors in connection with specific acquisition functions should be obtained from the contracting activity or as directed by the contracting officer.)
- \* 2.2 Other publications. The following document(s) form a part of this standard to the extent specified herein. Unless otherwise specified, the issue of the documents which are DOD adopted shall be those listed in the issue of the DODISS specified in the solicitation. The issues of documents which have not been adopted shall be those in effect on the date of the cited DODISS.

MIL-STD-1246B

AMERICAN SOCIETY FOR TESTING AND MATERIALS (ASTM)

|   |            |  |
|---|------------|--|
|   | ASTM F 24  | Measuring and Counting<br>Particulate Contamination<br>on Surfaces   |
|   | ASTM F 25  | Sizing and Counting Airborne<br>Particulate Contamination in<br>Clean Rooms and Other Dust Controlled<br>Areas Designed for Electronic and<br>Similar Applications |
| * | ASTM F 303 | Sampling Aerospace Fluids from<br>Components   |
| * | ASTM F 307 | Sampling Pressurized Gas for<br>Gas Analysis   |
| * | ASTM F 311 | Processing Aerospace Liquid Samples<br>for Particulate Contamination<br>Analysis Using Membrane Filters  |
| * | ASTM F 312 | Microscopical Sizing and Counting<br>Particles from Aerospace Fluids<br>on Membrane Filters  |

(Application for copies should be addressed to the American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pennsylvania 19103.)

SOCIETY OF AUTOMATIVE ENGINEERS

|  |         |   |
|--|---------|---|
|  | ARP 598 | The Determination of Particulate<br>Contamination in Liquids by the<br>Particle Count Method  |
|  | ARP 743 | Procedure for the Determination of<br>Particulate Contamination of Air in<br>Dust Controlled Spaces by the Particle<br>Count Method |

(Application for copies should be addressed to the Society of Automotive Engineers, Inc., 485 Lexington Avenue, New York, New York 10017.)

- \* (Nongovernment standards are generally available for reference from libraries. They are also distributed among nongovernment standards bodies and using Federal agencies.)



## MIL-STD-1246 B

- \* 2.3 Order of precedence. In the event of a conflict between the text of this standard and the references cited herein, the text of this standard shall take precedence.

## 3. DEFINITIONS

The following definitions apply to terms used in this standard:

- 3.1 Cleanliness level. An established level of maximum allowable contamination based on size, distribution, or quantity in a given area or volume.
- 3.2 Contamination. Any foreign material.
- 3.3 Contamination control. Organized action to control the level of contamination.
- 3.4 Micron. A unit of measurement equal to one-millionth of a meter, or thirty-nine millionths of an inch (0.000039 inch), e.g., 25 microns is approximately 0.001 inch.
- \* 3.5 Non-Volatile Residue (NVR). Soluble material remaining after evaporation of a volatile liquid or determined by special purpose analytical instruments, usually measured in milligrams per unit volume.
- 3.6 Particle size. Particle size is expressed as the apparent maximum linear dimension or diameter of the particle.
- 3.7 Significant surface. Any surface of an item or product which is required to meet established cleanliness level requirements.

## 4. GENERAL REQUIREMENTS

4.1 Responsibility.

- 4.1.1 Prescribing product cleanliness. The responsibility for selecting or determining the degree of product cleanliness shall rest with the DOD design activity initially responsible for the product to be produced or processed.
- 4.1.2 Achieving and maintaining product cleanliness. The responsibility for achieving and maintaining product cleanliness shall rest with the responsible activity whose function is to process or produce the product from the design criteria and related specification requirements.

MIL-STD-1246B

4.1.3 Assuring the integrity and continuity of the contamination control effort. The responsibility for ensuring a continuing contamination control effort shall rest with quality control or similar activity whose function is to ensure that the product meets design criteria and specification requirements.

\* 4.1.4 Contamination control plan. A contamination control program plan and its methods for implementation shall be submitted to meet the product requirements for cleanliness as specified. When specified in the contract or order, a contamination control plan shall be prepared (see 6.2).

4.1.4.1 Design requirement. The cleanliness level of the product and its sensitivity to contamination shall be determined by the product design activity unless otherwise specified. Contamination limits are to be prescribed by design drawings or specifications consistent with the product requirements. When the product design activity cannot predetermine the cleanliness level, a proposed method for determining this level through investigation, experimentation or assessment shall be included.

4.1.4.2 Product design review. A product design review in terms of contamination sensitivity shall be included.

4.1.4.3 Processes and controls. Those processes and controls applicable to the product, at each state of manufacture or processing, including parts, components, assemblies, and materials, that will affect the cleanliness of the product shall be included.

4.1.4.4 Clean room facilities and work stations. The clean room facilities and work stations shall meet the requirements of FED-STD-209.

4.1.4.5 Sub-tier contractors. A method shall be outlined for imposing contamination control requirements on sub-tier contractors.

4.1.4.6 Calibration procedures. Facility and equipment calibration procedures that are to be followed shall be defined.

4.1.4.7 Quality control. Quality control procedures, sampling plans, etc., shall be detailed to ensure surveillance and compliance.

4.1.4.8 Product protection. Methods for product protection shall be provided to maintain the required product cleanliness level.

4.1.4.9 Personnel. Personnel training, motivation and control methods shall be outlined.

## MIL-STD-1246B

## 5. DETAILED REQUIREMENTS

5.1 Cleanliness levels. Table Ia and Ib prescribe the cleanliness levels established to provide a uniform set of criteria for specifying product cleanliness, based on contaminant size, distribution, and count. Use of these cleanliness levels provides a basis for specifying and determining conformance to cleanliness requirements.

5.1.1 Application of cleanliness levels. The cleanliness levels of Table Ia and Ib shall apply to surfaces, assemblies, components, or fluids. The following units of measure shall be used:

(a) Surfaces - Particles categorized by size and count per square foot of significant surface area.<sup>1/</sup> Non-volatile residue in milligrams per square foot of significant surface area.<sup>1/</sup>

\* (b) Assemblies and components - Particles categorized by size and count per square foot of significant surface area.<sup>1/</sup> Non-volatile residue (NVR) measured in milligrams per square foot of significant surface area.<sup>1/</sup>

(c) Liquid - Particles categorized in size and count per 100 milliliters of fluid. Non-volatile residue measured in milligrams per 100 milliliters of fluid sample.

(d) Gas - Particles categorized by size and count per cubic foot of gas.

5.1.2 Measurement of cleanliness levels. Measurements to determine cleanliness shall be accomplished as follows, or by demonstrated equivalents:

\* (a) Surfaces - According to ASTM F 24, ASTM F 303 (sampling), ASTM F 311 (processing sample), ASTM F 312 or SAE ARP 598 (sizing and counting).

(b) Assemblies and components - Same as surfaces (a).

\* (c) Liquids - According to ASTM F 303 (sampling), ASTM F 311 (processing sample), ASTM F 312 or SAE ARP 598 (sizing and counting).

\* (d) Gases - According to SAE ARP 743, ASTM F 25, ASTM F 307 (sampling), ASTM F 312 (sizing and counting).

<sup>1/</sup> Areas less than one square foot shall be calculated on the basis of one square foot.

Area may be estimated.

## MIL-STD-1246B

NOTE: For measurement conditions not covered, acceptable methods shall be negotiated between the contracting parties.

5.1.3 Method for specifying product cleanliness levels. Product cleanliness levels shall be specified in the following manner:

MIL-STD-1246 (Level 200), refers to particulates only.

MIL-STD-1246 (Level 200F), refers to particulates and NVR.

MIL-STD-1246 (Level NVR-F), refers to requirement for NVR only.

## 6. NOTES

6.1 Intended use. This standard is intended to be used as a basis and a uniform method for establishing product cleanliness and contamination control.

6.2 Data requirements. When this standard is used in an acquisition which incorporates a DD Form 1423, Contract Data Requirements List (CDRL), the data requirements identified below shall be developed as specified by an approved Data Item Description (DD Form 1664) and delivered in accordance with the approved CDRL incorporated into the contract. When the provisions of the DOD FAR Supplement, Part 27, Sub-Part 27.475-1 (DD Form 1423) are invoked and the DD Form 1423 is not used, the data specified below shall be delivered by the contractor in accordance with the contract or purchase order requirements. Deliverable data required by this standard is cited in the following paragraphs.

| <u>Paragraph no.</u> | <u>Data requirement title</u> | <u>Applicable DID</u> | <u>Options</u> |
|----------------------|-------------------------------|-----------------------|----------------|
| 4.1.4                | Contamination Control Plan    | DI-MISC-80411         | ---            |

(Data item descriptions related to this standard, and identified in section 6 will be approved and listed as such in DOD 5010.12-L, AMSDL. Copies of data item descriptions required by the contractors in connection with specific acquisition functions should be obtained from the Naval Publications and Forms Center or as directed by the contracting officer.)

MIL-STD-1246B

6.3 Subject term (key word) listing.

Cleanliness  
Contamination  
Control, contamination  
Micron  
Residue, non-volatile  
Particle  
Product

- \* 6.4 The margins of this document are marked with an asterisk to indicate where changes (additions, modifications, corrections, deletions) from the previous issue were made. This was done as a convenience only and the Government assumes no liability whatsoever for any inaccuracies in these notations. Bidders and contractors are cautioned to evaluate the requirements of this document based on the entire content irrespective of the marginal notations and relationship to the last previous issue.

Custodians:

Army-MI  
Navy-YD  
Air Force-99  
DLA-GS

Preparing activity:

Army-MI

(Project No. 3694-0031)

Review activities:

Army-AV, AT, GL, AL, AR  
Navy-AS  
Air Force-70, 71, 84  
DLA-GS

User activities:

Army-ME  
Navy-OS, SH  
Air Force-79  
DLA-ES

## MIL-STD-1246B

CLASSIFICATION OF PRODUCT CLEANLINESS LEVELS

\* Table Ia  
Derivation of Cleanliness Levels<sup>1/</sup>

| Cleanliness Level | Range Surface and Fluids | Quantity of Particulates |
|-------------------|--------------------------|--------------------------|
| 1                 | 1                        | 1                        |
| 5                 | 1                        | 3                        |
|                   | 2                        | 2                        |
| 10                | 5                        | 1                        |
|                   | 5                        | 3                        |
| 25                | 5                        | 23                       |
|                   | 15                       | 3                        |
|                   | 25                       | 1                        |
| 50                | 5                        | 165                      |
|                   | 15                       | 25                       |
|                   | 25                       | 7                        |
|                   | 50                       | 1                        |
| 100               | 15                       | 265                      |
|                   | 25                       | 78                       |
|                   | 50                       | 11                       |
|                   | 100                      | 1                        |
| 200               | 15                       | 4190                     |
|                   | 25                       | 1240                     |
|                   | 50                       | 170                      |
|                   | 100                      | 16                       |
| 300               | 25                       | 7450                     |
|                   | 50                       | 1020                     |
|                   | 100                      | 95                       |
|                   | 250                      | 2                        |
| 500               | 50                       | 11800                    |
|                   | 100                      | 1100                     |
|                   | 250                      | 26                       |
|                   | 500                      | 1                        |
| 750               | 100                      | 8900                     |
|                   | 250                      | 210                      |
|                   | 500                      | 7                        |
|                   | 750                      | 1                        |
| 1000              | 250                      | 1020                     |
|                   | 500                      | 40                       |
|                   | 750                      | 5                        |
|                   | 1000                     | 1                        |

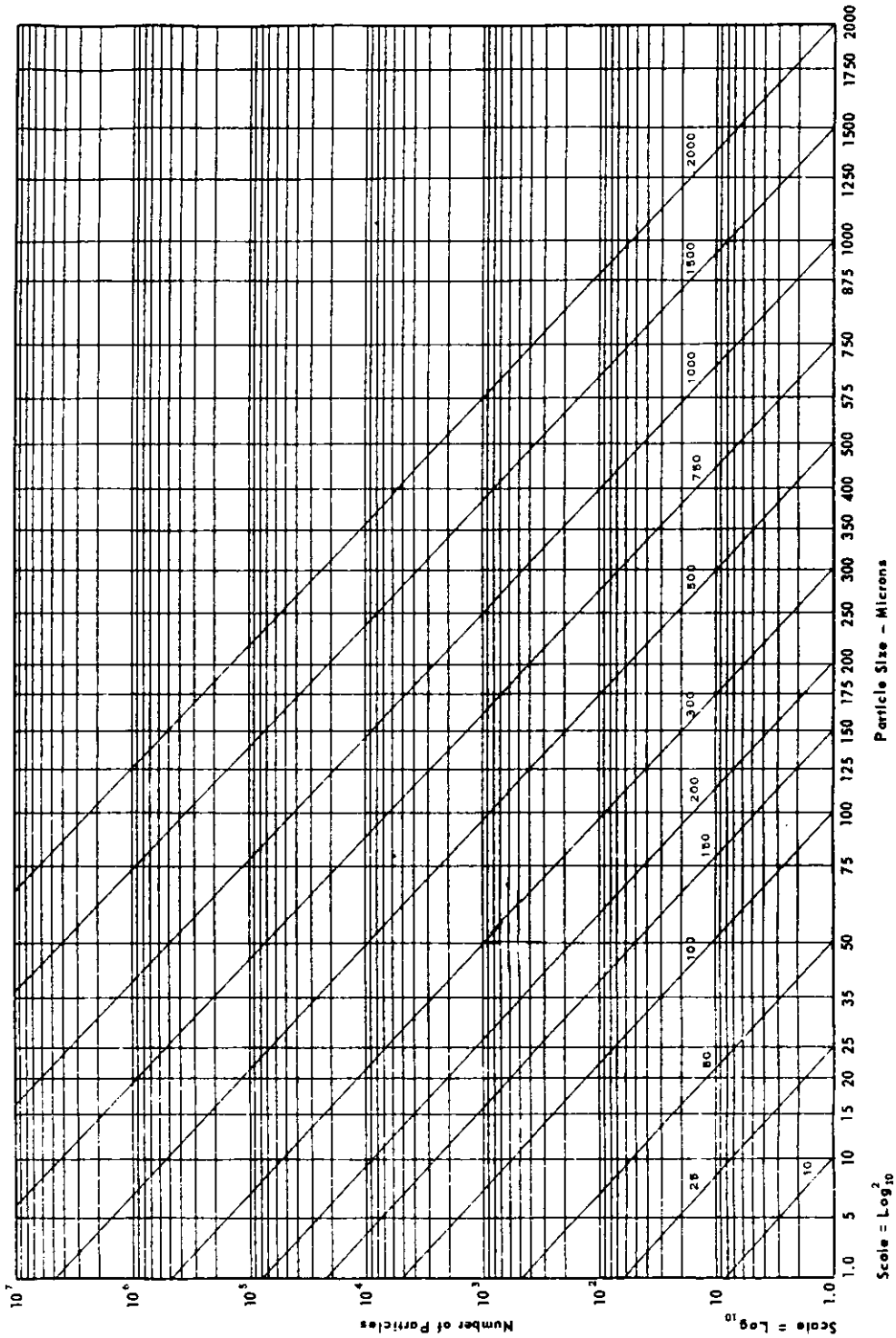
Table Ib  
Non-Volatile Residue

| Level | Quantity NVR             |
|-------|--------------------------|
| A     | Less than 1.0 mg         |
| B     | 1.0 mg<br>to<br>2.0 mg   |
| C     | 2.0 mg<br>to<br>3.0 mg   |
| D     | 3.0 mg<br>to<br>4.0 mg   |
| E     | 4.0 mg<br>to<br>5.0 mg   |
| F     | 5.0 mg<br>to<br>7.0 mg   |
| G     | 7.0 mg<br>to<br>10.0 mg  |
| H     | 10.0 mg<br>to<br>15.0 mg |
| J     | 15.0 mg<br>to<br>25.0 mg |

<sup>1/</sup>Derivation of Cleanliness Levels. The cleanliness levels and range within each level of Table Ia were established by plotting the curves in Chart I. Chart I plot point is number of total particles above given size versus particle size.

MIL-STD-1246B

CHART I  
PRODUCT CLEANLINESS LEVELS



Research shows that naturally occurring particulate contamination follows a log-normal distribution with a geometric mean of near one (1) micron particle. This distribution follows a straight line when plotted on a log x log<sup>2</sup> scale graph. The grid is derived from the log-normal Gaussian distribution function which provides a close fit to real contamination data. The lines on the chart represent the maximum contamination permitted for each level and the plot point is the number of particles above given size versus particle size. The curves can be expressed as  $\log n = 0.9260 (\log^2 X_1 - \log^2 X)$ , where  $n$  is the number of particles,  $X$  is the particle size, and  $X_1$  is the cleanliness level.

## MIL-STD-1246B

## APPENDIX A

## FOREWARD

The purpose of this appendix is to provide nonmandatory supplemental guidance information for the preparation of documents relating to contamination control programs.

## 10. CLEANING METHODS AND MATERIALS

\* 10.1 Gross cleaning. This method is used to achieve visibly clean articles. Gross cleaning removes contaminants such as weld scale, heat treat scale, corrosion, oxide films, oils, grease, shop soil, fuel and carbon deposits. The cleanliness level achieved by gross cleaning does not normally require verification beyond visual inspection. (Wipe test, waterbreak test, ultraviolet inspection, special lights and mirrors, are considered aids to visual inspection.) Gross cleaning is considered a normal shop process and usually does not require special environmental controls, packaging, handling, or storage beyond accepted good practice.

10.1.1 Gross cleaning types. The following types of cleaners, or their equivalents, may be used for removing gross forms of contamination.

NOTE: Chemical cleaning agents must be compatible to prevent excessive attack or latent degradation.

10.1.1.1 Acid cleaners. Used to remove the contamination, e.g., weld scale, corrosion, and oxide films not removable by other solutions. Use: nitric acid, chromic acid, inhibited hydrochloric acid, inhibited sulfuric acid, inhibited phosphoric acid, mixed acid deoxidizers, and alcoholic-phosphoric acid.

10.1.1.2 Alkaline cleaners. Used for removal of organic and inorganic contamination, e.g., grease, shop soil, scale, and soluble metal oxides. Alkaline cleaners dissolve (etch) certain metals such as aluminum or zinc. Use: alkaline rust strippers, heavy duty alkaline cleaners, molten alkalines, alkali, and alkali with nitrate or phosphate.

10.1.1.3 Mild alkaline cleaners and detergents. Used for the removal of organic and inorganic contamination, e.g., oils, fats, shop soil, and grease. Use: inhibited alkaline cleaners (mild alkaline cleaner), soaps, and detergents.



## MIL-STD-1246B

10.1.1.4 Organic solvent cleaners. Used to remove some forms of organic contamination, e.g., oils, grease, and hydrocarbon fuels. Use: halogenated solvents (except carbon tetrachloride), alcohol, xylene, and toluene.

10.1.1.5 Tap water and deionized water. Used to remove the residual material left by cleaning solutions and as a final flushing or rinsing medium.

- \* 10.1.1.6 Neutralizing and passivating solutions. Used as a supplementary treatment to acid, alkaline and mechanical cleaning, the neutralizing and passivating solutions prevent corrosion and acid etching. Use: nitrate, phosphate, alkali with nitrate or phosphate to neutralize; nitric acid or nitric acid and chromate solutions to passivate.

10.1.1.7 Mechanical cleaning. Removes contamination by abrasive action. Used only when physical damage to the item being cleaned will not occur. Includes: wire brushing, shot blasting (wet and dry), grinding, sand blasting (wet or dry), the use of aluminum oxide, abrasive coated papers and cloths, and related methods.

NOTE: Mechanical cleaning often leaves foreign deposits which may require additional cleaning for their removal. Compatibility of dissimilar metals is an important consideration when selecting a mechanical cleaning method.

10.1.1.8 Gross cleaning processes. Table II shows recommended gross cleaning processes and sequences.

- \* 10.2 Precision cleaning. This method is used to achieve a level of product cleanliness greater than the level normally detected by visual means. Articles should be visibly clean prior to precision cleaning. Precision cleaning is performed in a controlled environment, and is intended to remove particles, films, biological forms, fibers and other forms of contaminants that are usually not visible, but which could degrade the product or process. The level of precision cleanliness should be verified and evidence of inspection and acceptance provided. Precision cleaned articles shall be packaged immediately after verification of cleanliness, or suitably protected prior to leaving the controlled environment.
- \* 10.2.1 Precision cleaning solutions/fluids. Precision cleaning solutions or material shall not react with, combine with, etch, or otherwise cause immediate or latent degradation of the item being cleaned. Precision cleaning fluids should be filtered, and controlled. Their cleanliness level should be verified as being sufficient to achieve the specified product cleanliness. Use of the following fluids is recommended:

## MIL-STD-1246B

Table II

## \* Selection chart for gross cleaning processes

| NOTE<br>Symbols in the block denote a recommended process for the surface condition indicated, and will normally be accomplished in consecutive order from left to right. |  | Gross Cleaning Processes |                          |                |                 |                 |                 |             |                 |                          |                 |                       |        |
|---|--|--------------------------|--------------------------|----------------|-----------------|-----------------|-----------------|-------------|-----------------|--------------------------|-----------------|-----------------------|--------|
|   |  | Mechanical Descale/Clean | Organic Solvent Degrease | Alkaline Clean | Tap Water Rinse | Detergent Clean | Tap Water Rinse | Acid Pickle | Tap Water Rinse | Neutralize and Passivate | Tap Water Rinse | Deionized Water Rinse | Drying |
| Material  | Surface Condition                        |                          |                          |                |                 |                 |                 |             |                 |                          |                 |                       |        |
| Aluminum  | Bare or machined, free of heat oxidation |                          | X                        | X              |                 |                 |                 |             |                 |                          | X               | X                     | X      |
|   | Conversion or chemical film coating      |                          | X                        |                |                 | X               |                 |             |                 |                          | X               | X                     |        |
|   | Weld scale, corrosion, or heat oxidation | X                        | X                        | X              | X               |                 |                 |             |                 |                          | X               | X                     | X      |
| Copper, brass, bronze   | Bare or machined, free of heat oxidation |                          | X                        | X              |                 |                 |                 |             |                 |                          | X               | X                     | X      |
|   | Conversion or chemical film coating      |                          | X                        |                |                 | X               |                 |             |                 |                          | X               | X                     |        |
|   | Weld scale, corrosion, or heat oxidation |                          | X                        | X              | X               |                 |                 | X           |                 |                          | X               | X                     | X      |
| *Stainless steel  | Free of scale                            |                          | X                        | X              | X               |                 |                 | X           | X               | X                        | X               | X                     | X      |
|   | Weld scale, corrosion, or heat oxidation | X                        | X                        | X              | X               |                 |                 | X           | X               | X                        | X               | X                     | X      |
| Carbon steel  | Free of scale                            |                          | X                        | X              | X               |                 |                 |             |                 | X                        | X               | X                     | X      |
|   | Weld scale, corrosion, or heat oxidation | X                        | X                        | X              | X               |                 |                 | X           | X               | X                        | X               | X                     | X      |
| * Non-metallic parts, elastomers  | As received                              |                          |                          |                |                 | X               |                 |             |                 |                          | X               | X                     | X      |
| Electroplated parts and dissimilar metals   | As received                              |                          | X                        | X              |                 |                 |                 |             |                 |                          | X               | X                     | X      |

\*ASTM-A380 describes in detail recommended methods for descaling and cleaning stainless steel.

## MIL-STD-1246B

- (a) Halogenated solvents
- (b) Ketones
- (c) Alcohols
- (d) Detergent (must be followed by deionized water rinse)
- (e) Deionized water
- (f) Air or inert gas (for drying or removal of volatile fluids)

- \* 10.2.2 Precision cleaning methods/processes. Equipment and various methods suitable for precision cleaning are available. The appropriate process and equipment shall be selected on the basis of product configuration, compatibility with cleaning fluids, type and quantity of contaminants, desired cleanliness level, economic factors, and safety considerations. The following equipment and methods should be considered when selecting the appropriate process for a particular product.

10.2.2.1 Solution cleaning. The item is washed in suitable clean solvent or detergent solution followed by successive rinsing. Normally it requires agitation in the solution or use of a soft bristle brush to assure removal of contaminants.

- \* 10.2.2.2 Spray cleaning. A suitable filtered solvent or detergent solution is sprayed on the item to be cleaned.

- \* 10.2.2.3 Ultrasonic cleaning. The item to be cleaned is immersed in a bath of cleaning solution that is energized with an ultrasonic device. The cleaning solution and the frequency of the ultrasonic energy must be compatible and effective. This method should not be used on items which may be degraded by sonic energy, unless effective protection is provided.

10.2.2.4 Vapor cleaning. The item to be cleaned is exposed to heated solvent vapors which condense on the part and wash away contaminants.

10.2.2.5 Flush clean. The item to be cleaned is filled, flooded, or rinsed with a suitable cleaning solution. The item is agitated thoroughly to wash all surfaces and the solution is drained.

10.3 Solution controls. Solution controls should be used.

10.4 Process plan. A detailed process plan should be developed to specify requirements of the selected precision cleaning process for a particular part, assembly or product. The process plan should include the following elements:

## MIL-STD-1246B

- (a) Product description
- (b) Cleaning equipment to be used
- (c) Operating instructions for the equipment
- (d) Cleaning fluid specifications
- (e) Cleaning/rinse/drying cycle and sequence
- (f) Provisions for control of cleanliness of cleaning and rinse fluids
- (g) Inspection/monitoring requirements
- (h) Interim protection requirements including storage handling and temporary or permanent packaging
- (i) Layout plan of work area
- (j) Safety and health precautions
- (k) Others as applicable

10.5 Monitoring precision cleanliness of the product. The results of precision cleaning are not normally visible to the unaided eye. Special detection and measurement techniques are necessary and should be implemented to monitor and verify the achievement of the required level of precision cleanliness.

- \* 10.6 Handling during cleaning. Disassembly, cleaning, reassembly, in-process handling, packaging and other operations involved in cleaning should be conducted in a manner to preserve critical tolerances, finishes, calibration, or other sensitive attributes of the product. Adequate tooling, fixtures, handling devices, and product protection should be provided. Written instructions for sensitive or critical activities or procedures should be provided.

## 20. PROTECTION

20.1 Cleanliness protection. All precision cleaned items should be provided with cleanliness protection prior to leaving the controlled environment.

20.2 Precision clean packaging. The precision clean package shall maintain the cleanliness level specified for the product.

## MIL-STD-1246B

20.3 Storage. Storerooms or inventory control areas should provide adequate protection to the package and the product for the intended storage period.

## 30. INSPECTION

\* 30.1 Inspection. Inspection of precision cleaned and packaged products should be performed as required on a regular or cyclic basis to assure continued maintenance of the integrity of the package and the item. The following criteria shall constitute cause for rejection of the precision cleaned and packaged item.

(a) Identification label or decalcomania missing, broken, illegible, or incomplete.

(b) Tamper-proof seal missing, broken or incorrectly applied.

(c) Improper seal, open seal or closure, lifted tape, etc.

(d) Apparently damaged (including pinholes, etc.) or violated package or closure.

(e) Visibly entrapped moisture (or a change in a humidity indicator) or other unwanted material.

(f) Any apparent defect that may interfere with the proper function or use of the item.

30.1.1 Breaking of a closure. If it is necessary to break a closure or open a package for inspection, the item shall be opened in a controlled environment and repackaged to the same condition as the original.

30.1.2 Inspection requiring opening of a package. Inspection requiring opening of a package or closure shall be reduced to a minimum of occurrences consistent with good practice.

\* 30.1.3 Traceability. To assure traceability of contamination sources, a record shall be maintained of all incidents of opening or closure of the packages. The record shall show the date, responsible person, the reason for opening, and the disposition of the product.

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