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George C. Marshall Space Flight Center
Marshall Space Flight Center, Alabama 35812

EM50

MULTIPROGRAM/PROJECT COMMON-USE DOCUMENT

STANDARD DESIGN AND OPERATIONAL CRITERIA FOR CONTROLLED ENVIRONMENTAL AREAS

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DOCUMENT HISTORY LOG

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Baseline	Baseline	07/29/1966	Baseline release
Revision	A	04/06/1967	Update reflecting changes to FED-STD-209a.
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Revision	C	02/11/2005	Changes made to incorporate new document requirements, reorganization changes, and add information concerning clean work areas.

FOREWORD

The purpose of this Standard is to present data and information that relate to contamination control of MSFC environmentally controlled areas, clean rooms, and flow benches. It specifies environmental control operating standards to be used as minimum criteria for rooms and hardware requiring environmental control. This Standard lists guidelines for selecting environmental facilities and for achieving the operating conditions necessary to achieve contamination control of critical aerospace hardware during MSFC operations; it also lists quality control measures to assure compliance.

CONTENTS

1. SCOPE

1.1 Scope. This document establishes MSFC's standard design and operational criteria for controlled environmental areas including standard classes of air cleanliness for airborne particulate levels and condensables in clean rooms and clean work areas. It prescribes methods for class verification and monitoring of air cleanliness.

1.2 Authority. This Standard is prepared by MSFC for its internal use and that of its contractors. This document was derived from FED-STD-209, Air Force T.0. 00-25-203, and KSC KSTSM-14.2.1. It was prepared because the 209 Standard exceeds the requirements of MSFC operations.

1.3 Responsibility. The Marshall Space Flight Center is responsible for implementing this standard per MPR 5340.1. Each owner/operator of a clean facility shall be responsible for implementing the requirements indicated by this Standard. A single custodian designated for each facility shall be responsible for the implementation of this Standard. A separate authority from the Materials and Processes (M&P) Laboratory (EM01) shall be responsible for sampling to assure conformance and compliance. A Contamination Control Engineer (CCE) from M&P (EM50) shall be designated for each clean room with the responsibility to provide guidance to insure compliance with this Standard. Assistance is available for periodic audits and verification of programmatic requirements compliance.

1.4 Implementation. The designated custodian for each clean facility shall be responsible for implementing this Standard. Each facility shall have an operating procedure that implements this Standard, with the designated custodian being responsible for preparing such a procedure.

1.5 General Practices.

1.5.1 Personnel.

a. General Practices: When operating any type of environmentally controlled facility, the greatest source of particulate contamination comes directly from the personnel within the area. All personnel associated with the operation shall be thoroughly indoctrinated in the purpose and practices of facility operations. All the equipment installed to provide a clean atmosphere will be ineffective if the working personnel are not properly trained. Clean rooms are restricted areas - access shall be limited to authorized individuals. All personnel entering environmentally controlled areas shall wear garments as prescribed in Table 1 at all times and shall conform to prescribed pre-entry procedures and a clean room code of conduct.

ALL CLEAN ROOM VISITORS, *WITHOUT EXCEPTION*, MUST OBSERVE ALL CLEAN ROOM RULES.

b. Personnel Practices: Personnel with skin or upper respiratory diseases shall not be allowed to work in clean room areas if their condition could adversely affect the environment. Examples of physiological problems that are detrimental to clean atmospheres are as follows:

(1) Allergies

(2) Profuse nasal discharge

(3) Skin conditions which result in above normal skin shedding

(4) High amounts of acid found in moisture on hands

c. Personal Hygiene: All personnel shall receive periodic training and reviews on the importance of personal hygiene in clean room operations. The high degree of cleanliness required necessitates the development of the following habits:

(1) Wear clean under and outer garments

(2) Avoid scratching or rubbing one's head or exposed skin areas

(3) Do not wear or apply fingernail polish or cosmetics within the clean room (with the exception that lipstick may be worn)

(4) Keep hands, fingernails and face clean

(5) Exit clean room to comb or untangle hair

(6) Male personnel are to have clean shaven faces, otherwise, facial hair must be completely covered by a mask

d. Personnel Disciplines: Supervisor and employee discipline determine the quality of clean room products. All clean room personnel shall practice good clean room habits and observe clean room regulations. Supervisors shall enforce good housekeeping practices and assist in successful operation of clean rooms by requiring the following:

(1) Always wear prescribed garments

(2) These garments are to be worn only in the clean room

(3) Finger cots or gloves may be required. At no time are cotton or powdered gloves allowed in clean facility

(4) Hair shall be confined under a cap, hood or snood. Exposure of the tuft of hair on the back of the neck which cannot be covered by a cap (when properly worn) is acceptable. However, hair that is not covered on the front of the head at the foreline is not acceptable

(5) If jewelry is worn it shall be taped to the body or contained under garments or gloves

(6) Personal items such as cigarettes, matches, and tissues shall not be taken into an environmentally controlled area

(7) No eating or smoking shall be allowed in environmentally controlled areas

(8) No paper materials of any type shall be allowed in the clean room unless approved by the custodian

(9) Pencils and erasers shall not be used. Non-retractable ballpoint pens (without pocket clips) are acceptable

(10) Parts and tools at work stations shall be kept as clean and orderly as possible

(11) Any work, materials or tools dropped on the floor shall be considered contaminated

(12) Materials and parts that are not in use shall not be left exposed on workbench unless covered with an approved material

(13) Adverse changes in environmental conditions (particle generation or accumulation, marked changes in humidity or temperature) shall be reported to the custodian

(14) Storage in clean rooms shall not be permitted. Items shall be limited to those in direct support of daily operations in facility

(15) Operations such as lapping, filing, grinding and deburring are prohibited in environmentally controlled areas without special containment provisions approved by the custodian

e. Personnel Training: It is imperative that all personnel associated with environmentally controlled areas, including supervisors, technicians, and maintenance personnel, receive a thorough indoctrination in the purpose and practices of clean room operation. Because of the broad scope of this document and the many variables involved with contamination control, specific training shall be completed prior to processing

products and/or servicing operations for that specific program or project. This training shall be provided by EM50.

1.5.2 Cleaning Practices.

a. General: MIL-HDBK-406, "Cleaning Materials for Precision Precleaning and Use in Clean Rooms and Clean Work Stations" and MIL-HDBK-407, "Precision Cleaning Methods and Procedures" shall be used in determining clean materials and/or procedures. Consult with the CCE for specific cleaning practices or concerns.

b. Tools and Hardware: Various tools and other hardware items used in processing critical components require special cleaning techniques to maintain their cleanliness. Various solvents are used in cleaning tools, parts, and equipment. To be effective in critical applications, a final rinse solution shall be constantly filtered to ensure that particulates do not remain on items after they are immersed in that solution.

c. Workbench Surfaces: Working areas shall be cleaned periodically to ensure that all particulates are removed. Filtered solvents and clean lint-free cloths shall be used to wipe these working surfaces.

d. Process Materials: Only approved materials shall be used to wipe working surfaces. These materials shall be limited linting types, compatible with the solvent used, evaluated and approved by the responsible custodian. EM50 maintains a database of approved materials.

1.5.3 Garments.

a. General: The following applies for all facilities:

(1) Should a garment become soiled at any time while performing clean room duties it shall be changed immediately

(2) All extra garments shall be stored in facilities consistent with that class facility where the garment will be used

(3) Soiled garments shall be placed in proper containers

(4) Damaged garments shall be placed in a separate container for disposal/repair

b. Specifications: Garments required in facilities shall be functional and job oriented. Garments may be either washable and reusable or disposable (designed for single use). Garments shall be made of a CCE approved non-particulate generating fabric such as woven polyester. All garments shall form barriers between the human contamination

source and his work. All apparel shall be designed with a minimum of seams, no pockets, pleats, raw edges or dust collecting features. General types of garments are coveralls, smocks, frocks, hoods, snoods, caps, shoe covers, boots, and gloves. All new garments purchased to fulfill requirements of this Standard shall meet the requirements specified in Appendix II of this document.

c. Garment Changes: The following minimum change criteria are recommended:

(1) Class 300,000 Controlled Area: Uniforms not required. If reusable smocks, frocks, shirts, caps or snoods are used, they shall be changed once per week

(2) Class 100,000 Clean Work Areas: Smocks and caps/hoods recommended. Garments shall be changed every week

(3) Class 100,000 Clean Room: Garments shall be changed every five days

(4) Class 10,000 Clean Room: Garments shall be changed every three days

(5) Class 1,000 Clean Room: Garments shall be changed every other day

(6) Class 100 Facilities: Garments shall be changed every day

d. Clothing Cleanliness Requirements: Frequent laundering of clean room garments is required to minimize the spread of contamination. Custodians shall be responsible to ensure that clean room garments are clean, and meet limited linting requirements after washing. Sampling and monitoring procedures shall be as described in section 1.5.3 f.

e. Packaging of Garments: The laundry shall package and deliver all clean room garments in numbered lots which can be traced to a known wash load. The size of these lots should be carefully chosen since an entire lot may be rejected and returned for reprocessing. Specific packaging shall be as follows:

(1) All clean room garments and accessories shall be hermetically sealed in clean polyethylene bags having 2 mil minimum thickness

(2) Each garment shall be packaged individually except shoe covers and gloves, which may be packaged in pairs. Disposable garments may be substituted when issued at the point of use

(3) Each apparel package shall be marked as to size: S-M-L-XL, or packed such that garment size marking is clearly visible without opening package

f. Monitoring and Quality Control: Each custodian shall determine a sample size and monitor garments to ensure that they meet specifications. A garment exhibits proper cleanliness and limited linting properties if it has less than 2,000 particles per square foot 5.0 µm and larger; see Appendix II.

NOTE: Should the garment particle count exceed the allowable limit, tests shall be made to determine whether it is at fault or if it has been laundered improperly. Microscopy and/or microchemical methods may be employed. Should the garment itself be faulty and is shedding, it shall be discarded. If it has been improperly laundered, other garments from the same wash shall be rejected and returned to the laundry, as well.

1.6 Contamination Control.

This section describes the various types of facility contamination that are regularly monitored at MSFC. These include both airborne contaminants and surface deposits. Airborne contaminants are generally dependent on a facility's air conditioning and filtration system. However, processing operations within a facility have been shown to significantly increase airborne particle counts of sizes greater than or equal to 5.0 µm and volatile hydrocarbon levels. Deposits on surfaces are of greater concern to the hardware. Although deposits on samples or flight hardware are related to the facility air conditioning and filtration system, a strong correlation exists between surface deposition, operational activities and controls. It should be noted, however, that even in the cleanest of facilities with minimal activities and strict controls, particle fallout will occur and continue to accumulate on exposed surfaces with time (see Figure 1). For critical optics, fallout over time will obscure light transmission/reflection (surface obscuration), significantly impacting performance.

1.6.1 Types of Contamination.

a. Airborne Particulate Matter:

(1) Description: Airborne particulate is matter suspended in the ambient atmosphere. These particles are usually very small, i.e., submicrometer to perhaps 30 µm in size. This particulate can best be described as an "aerosol" - a dispersion of solid or liquid particles in a gaseous media.

(2) Sources: Airborne particles consist of environmental soils such as dust, smoke, and mists from both natural and man-made processes. Additional sources include skin and clothing from personnel as well as that generated by friction between surfaces or deterioration of materials in the area.

(3) Measurement: Airborne particulates are monitored with electronic particle counters to assure that a facility's air filtration system is fully functional.

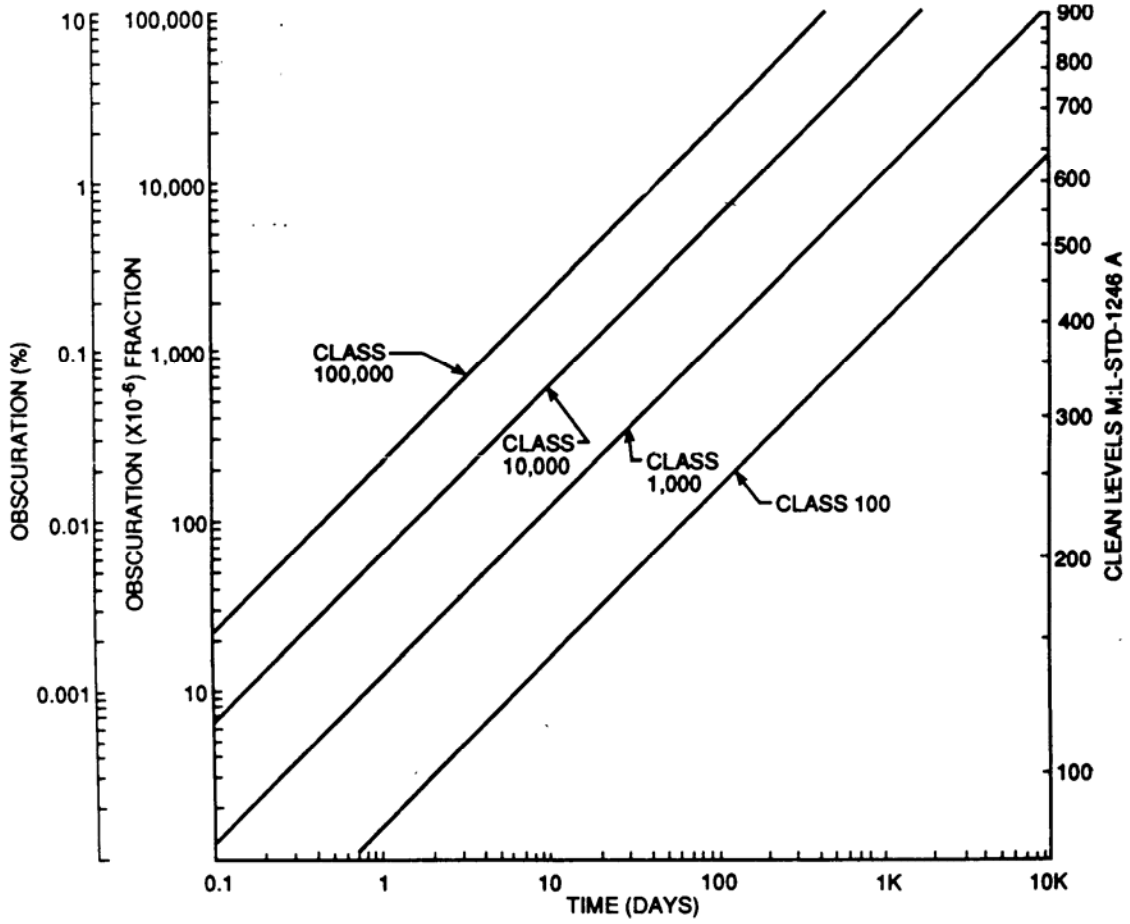

Figure 1: Particulate Fallout vs. Time for Clean Rooms

b. Surface Particulate Matter:

(1) Description: Surface particulate is matter deposited on the surface of an item or a part.

(2) Sources: Particles are generated by personnel, operations, and environmental soils introduced into a facility.

(3) Measurement: Surface particulate matter can be sampled by fallout plates and optical analysis or solvent flush or tape lift and analyzed per MSFC-PROC-1721. A level can be determined, if desired, by comparing the data to MIL-STD-1246.

c. Volatile Hydrocarbons:

(1) Description: Volatile hydrocarbons are those gaseous hydrocarbons dispersed in ambient air.

(2) Sources: Naturally occurring and man-made sources in the air are generated by decomposition, combustion, volatile solvents, paints, and internal combustion engines. Volatile hydrocarbons are not removed by High Efficiency Particulate Air (HEPA) filters but are reduced by passage of the air stream through activated charcoal and by control of its source.

(3) Measurement: A sample of facility atmosphere is drawn into an evacuated sample container or onsite analyzers. Results are reported in parts per million (ppm) methane equivalent. Analysis is typically done by MSFC-PROC-404 paragraph 6.5.3. Individual programs or projects with CCE consultation determine necessity and acceptable levels for volatile hydrocarbons.

d. Nonvolatile Residue (NVR):

(1) Description: Material remaining after filtration and temperature controlled evaporation of a volatile liquid (usually measured in milligrams per square foot).

(2) Source: Lubricants, leaks, and exposed organic materials from which volatile condensables may emanate and be transferred to a material surface, volatile condensable materials in the environment where contamination sensitive critical surfaces may be exposed.

(3) Measurement: NVR may be determined by using MSFC-PROC-1831 and MSFC-PROC-1832, or equal. Acceptable accumulated NVR, is program specific and will be determined by the program manager.

e. Microbial Contamination:

(1) Description: Microbial contamination includes microscopic biological materials such as bacteria (0.5 to 30 μm), fungal spores (0.5 to 60 μm) and viruses (<0.1 μm).

(2) Source: Microbial materials are introduced by airflow from external sources, personnel, and environmental soils carried into the facility on personnel and equipment.

(3) Measurement: Microbial monitoring of facilities will not be performed unless dictated by facility operations or program manager. Decayed or living matter deposited on surfaces within the facility will be classified as particulate matter and/or NVR. It will be monitored by the appropriate particulate and NVR tests.

2. APPLICABLE DOCUMENTS

Documents listed below provide requirements, specifications, standards, and procedures applicable to this specification. For each of these documents, the latest revision in effect at time of document approval shall apply.

ARP 743	Procedure for Determination of Particulate Contamination of Air Dust Controlled Spaces by Particle Count Method
ASTM-F-24	Measuring and Counting Particulate Contaminant on Surfaces
ASTM-F-312	Standard Methods For Microscopical Sizing and Counting Particles From Aerospace Fluids on Membrane Filters
ASTM-F-318	Standard Practice For Sampling Airborne Particulate Contamination in Clean Rooms For Handling Aerospace Fluids
FED-STD-209	Airborne Particulate Cleanliness Classes in Cleanrooms and Clean Zones
JSCM 5322B	Contamination Control Requirements
K-STSM-14.2.1	Kennedy Space Center Payload Facility Contamination Control Requirements/Plan
MIL-F-51068	HEPA Filters
MIL-HDBK-406	Cleaning Materials for Precision Precleaning and Use in Clean Rooms and Clean Work Stations
MIL-HDBK-407	Precision Cleaning Methods and Procedures
MIL-STD-1246	Military Standard Product Cleanliness Levels and Contamination Control Program Standard. This Standard covers surface cleanliness levels
MPR 5340.1	Controlled Work Area, Clean Room, and Flow Bench Operations
MSFC-PROC-404	Procedure for Gases, Drying and Preservation Cleanliness Level and Inspection Methods
MSFC-PROC-1721	Tape Lift Particle Counting Procedure
MSFC-PROC-1831	The Analysis of Nonvolatile Residue Content
MSFC-PROC-1832	The Sampling and Analysis of Nonvolatile Residue Content on Critical Surfaces

MSFC-SPEC-1443 Outgassing Test for Non-Metallic Materials Associated with Sensitive Optical Surfaces in a Space Environment

T.O. 00-25-203 Technical Order on Contamination Control of Aerospace Facilities, U.S. Air Force.

3. DEFINITIONS

3.1 Acronyms used in this standard. The acronyms used in this standard are defined as follows:

a. CCE Contamination Control Engineer

b. CFM Cubic feet per minute

c. CWA Clean Work Area

d. DOP Dioctyl Phthalate

e. EM10 Materials Test Branch

f. EM50 Environmental Effects Branch

g. GSE Ground Support Equipment

h. HEPA High Efficiency Particulate Air

i. KSC Kennedy Space Center

j. M&P Materials and Processes Laboratory

k. MSFC Marshall Space Flight Center

l. NVR Nonvolatile Residue

m. ppm parts per million

3.2 Glossary of Terms.

AIR CONDITIONING: A general term to describe the control and conditioning of air in an environmentally controlled facility to maintain specified standards of temperature and humidity.

AIR LOCK: An enclosed area between a clean room and the outside. An air lock should receive the same clean, filtered air as its clean room; it is designed to prevent contaminated outside air from infiltrating by pressure gradient. Not an air shower.

AIR SHOWER: An area between the entrance to a clean room and the entry from an air lock area. This room delivers a shower of clean air that removes most of the particulate from a person's garments.

AS-BUILT CLEAN ROOM (FACILITY): A clean room (facility) that is complete and ready for operation, with all services connected and functional, but without production equipment or personnel within the facility.

AT-REST CLEAN ROOM (FACILITY): A clean room (facility) that is complete; one which has the production equipment installed and operating, but without personnel within the facility.

CLEAN ROOM: An enclosed area employing control over the particulate matter in air with temperature, humidity, pressure and condensibles control as required. Clean rooms must not exceed the particle count specified in Table 1 (end of document) for the level involved.

CLEAN ROOM GARMENTS: Any part of or a complete uniform of special clothing that must be worn in environmentally controlled areas as specified in this Standard. These garments may include coveralls, boot type shoe covers, and hoods, etc.

CLEAN WORKSTATION: A workbench or similar working enclosure with its own HEPA filtered air supply exhausting over the work area in a laminar airflow pattern.

CONTAMINATION: The presence of any substance, material or energy that is unwanted and adversely affects the operation of system hardware.

CONTAMINATION CONTROL: The process of minimizing contamination in a work area by using environmentally controlled facilities, materials and procedures.

CONTAMINATION CONTROL ENGINEER: Individual from EM50 Contamination Team responsible for providing guidance in contamination control and prevention for MSFC clean facilities and to insure compliance with this Standard.

CONTROLLED AREA: An air conditioned work space or room in which the particle concentration is lower than that of normal air conditioned spaces. A controlled area is not to be classified as a clean room, but some special filtration is required as specified in this Standard. Such an area is required for overhaul of items which do not require the strict environmental controls of a clean room, but which should be segregated from less clean or contamination generating operations.

CUSTODIAN: Individual tasked with maintaining (1) controlled work area, clean room, or flow bench in operational order, (2) facility operational procedures and (3) insuring requirements of this document are met.

ENVIRONMENTAL CONTROL: A collective term for the positive control of atmospheric conditions within a designated area whereby particulate contamination, temperature, pressure, condensables, and humidity can be controlled and measured.

HIGH EFFICIENCY PARTICULATE AIR (HEPA) FILTER: An expendable, extended media dry type filter in a rigid frame having a minimum particle collection efficiency of 99.97 percent for 0.3 μm particles and larger and which shall not be DOP tested.

LAMINAR FLOW: An airflow pattern in which the entire body of air within a confined area moves with uniform velocity along parallel lines. The flow is essentially unidirectional and is non-turbulent.

LAMINAR FLOW CLEANROOM: A clean room in which laminar air flow characteristics predominate throughout the entire room with a minimum of eddies.

MICROMETER (μm): A unit of measurement equal to one-millionth of a meter or approximately 0.00003937 inch. (25 micrometers are approximately 0.001 inch.) Also referred to as a micron.

NONDIRECTIONAL AIRFLOW (COMMONLY KNOWN AS TURBULENT FLOW): Airflow which does not meet the definition of unidirectional airflow by having either multiple pass circulating characteristics or nonparallel flow directions.

NONVOLATILE RESIDUE (NVR): The material remaining after filtration and temperature controlled evaporation of a volatile liquid (usually measured in milligrams per unit volume).

OPERATIONAL CLEAN ROOM (FACILITY): A clean room (facility) in normal operation with all services functioning and with production equipment and personnel present and performing their normal work functions.

OPTICAL PARTICLE COUNTER: A light-scattering instrument with display and/or recording means to count and size discrete particles in air.

PARTICLE: A solid or liquid object generally between 0.001 and 1000 μm in size.
PARTICLE CONCENTRATION OR PARTICLE COUNT: Concentration expressed in terms of the number of particles per unit volume of air or other gas.

PARTICLE SIZE: The apparent maximum linear dimension of a particle in the plane of observation as observed with an optical microscope, or an equivalent diameter of a particle detected by automatic instrumentation. An equivalent diameter is the same as that of a reference

sphere having known properties and producing an identical response in a sensing instrument as the particle being measured.

PARTICULATE MATTER: A general term applied to particles of material suspended in gases or liquids, or resident as foreign matter on surfaces.

UNIDIRECTIONAL AIRFLOW (COMMONLY KNOWN AS LAMINAR FLOW): Air flowing in a single pass in a single direction through a clean room or clean zone with generally parallel streamlines.

4. REQUIREMENTS

4.1 Facilities.

4.1.1 General. There are four basic types of permanent environmentally controlled facilities that achieve and maintain contamination control of their air space while work is accomplished. They are, in order of cleanliness:

4.1.2 Types of Environmentally Controlled Facilities.

a. Controlled Areas (Class 300,000) – Section 4.3.

b. Clean Work Areas (Class 100,000) – Section 4.4.

c. Conventional Clean Facilities

(1) Class 100,000 – Section 4.5.

(2) Class 10,000 – Section 4.6.

(3) Class 1000 – Section 4.6.

d. Laminar Flow Clean Work Stations (Class 100) – Section 4.7.

There are a number of existing Conventional Clean Rooms at MSFC that are not classified as outlined in this standard (e.g. Class 30,000) or cannot meet particular requirements for a certain classification (e.g. humidity requirements during certain times of the year). Waivers shall be granted by the CCE on a case-by-case basis for each facility as warranted.

4.1.3 Environmental Control Requirements. Table 1 (end of this document) summarizes minimum standards required for each type of environmentally controlled facility.

4.1.4 Facility Identification. The following information shall be conspicuously posted at the main entrance of the environmentally controlled facility or posted immediately outside work area of a clean work station:

a. Type of facility (e.g. Class 300,000 Controlled Area)
b. Custodian and alternate name, office location, org. code and phone number
c. Maximum number of occupants (for conventional clean facilities only)
d. Most recent facility sampling results data
e. Copy of operating procedures
f. Operational status (Active or Deactivated)

4.2 Certifications.

4.2.1 General. Design certification shall be performed upon completion of facility construction and equipment installation. Recertification shall be performed after a facility fails to meet specified class standards and/or after any repairs or modifications. Consult a CCE for certification/re-certification criteria.

4.2.2 Sampling. Sufficient tests shall be made for particulate, temperature, relative humidity, airflow, positive pressure, and total hydrocarbons, as required, to establish clean room class (Appendix 1, Section 5).

4.2.3 Particulate. Procedures for certifying any room shall follow a general plan of placing an imaginary X across the room from corner to corner as pictured in Figure 11 in Appendix 1. Samples for particulate shall be taken as outlined in Appendix 1 using automatic counters or the manual method.

4.2.4 Total Hydrocarbons. If a room is to have an established hydrocarbon requirement, then refer to MSFC-PROC-404 paragraph 6.5.3 to determine the recommended procedure and analyses.

4.2.5 Fallout Rate. Cleanliness shall be evaluated by placing fallout plates at selected locations. Analysis of these plates will be for particulate and NVR. MIL-STD-1246 will be used to establish a fallout level for that room. Depending on facility class, exposure times could be as long as one month.

Figure 1 can be used for determining class versus surface cleanliness and time of exposure. These data can be used to plan critical activities in a clean room. These data are theoretical and were derived by a model.

NOTE: Rates shown in Figure 1 are for clean rooms at static conditions, i.e., no persons present nor processes in operation. The presence of personnel and/or activities in a clean room will drive time of exposure to a shorter period for a given cleanliness level.

4.2.6 Optical Witness Samples. Rooms may be rated for optical cleanliness by placing optical witness samples in selected locations, controlling their temperatures to that of near by critical items, then reading their results per optical acceptance criteria defined in MSFC-SPEC-1443 or as established by the optic designer. The responsible CCE shall determine exposure times.

4.3 Controlled Areas (Class 300,000).

A Controlled Area is intended to provide a semi-clean atmosphere for equipment and hardware that requires some degree of contamination control, but which does not require a high degree of temperature or humidity control. Controlled Areas contain vertical structures, portable ground support equipment, movable platforms, overhead cranes, forklifts, and other equipment not typically allowed in conventional clean rooms. Most existing manufacturing areas can be converted to controlled areas with relatively minor modifications.

4.3.1 Layout. No specific requirements exist for controlled areas. However, equipment and fixtures should be arranged to minimize contamination accumulation and promote cleaning operations.

4.3.2 Furniture and Fixtures. Furniture and fixtures shall be selected with care. Materials shall be chosen that will resist particle generation by chipping, flaking, oxidizing, or other deterioration. Most paints should not be used in controlled areas that are subject to repeated contact with personnel or other objects. Should such surfaces require painting, an epoxy, urethane or similar wear resistant surface coating shall be used.

4.3.3 Clothing Requirements. No special clothing is necessary, unless specific operations require it, then a smock and cap shall be sufficient in most cases. Gloves may be required, depending on end item requirements and type of work being done. Program management or facility custodian shall determine exact clothing requirements.

4.3.4 Operation. Operation of a controlled area is not as critical as clean room facilities. Special entering and exiting procedures are not required. Good housekeeping practices are essential. Frequent cleaning is required to prevent contamination accumulation that could cause concentrations of particulate to exceed that specified in Table 1. Utilities, fixtures, or any other equipment to be used in the controlled area shall be selected with cleanliness in mind. The room, floor, walls, and ceiling shall be painted or covered with materials that can withstand constant cleaning. Specific environmental conditions and other requirements for controlled areas are specified in Table 1. Comments on some of these requirements follow:

a. Air Conditioning: Air conditioning shall be a standard commercial design except that its filtration system shall be rated 80-85 percent efficient for 1.0 μm and larger particles. Its air-handling unit shall be designed to provide at least 2 air changes per

hour. Consideration shall be given to installing equipment with sufficient capacity (static pressure and CFM) where feasible, such that HEPA filters could be installed later if required. Air handling equipment shall run continuously. The facility custodian shall be notified and grant permission to conduct maintenance operations before they start.

b. Particle Count Tolerance: An operation tolerance for controlled areas shall be no more than 300,000 particles 0.5 μm and larger per cubic foot of air or no more than 1200 particles 5.0 μm and larger per cubic foot of air.

c. Pressure Differential: Sufficient pressure differential shall be maintained at all times to prevent contaminated air from flowing into a controlled area. An air lock is desirable, but is not required if room integrity can be maintained without it.

d. Environmental Conditions: Controlled areas may be very flexible regarding temperature and humidity. If a controlled area incorporates laminar flow clean workstations (class 100) for purposes of critical work, then temperature and humidity at the workstation shall meet class 100,000 clean room requirements as specified in Table 1.

4.3.5 Maintenance. Good housekeeping practices are essential. Clean floors weekly and other surfaces as required. GSE shall be cleaned monthly.

4.3.6 Monitoring. Controlled areas shall be sampled at least once a week by M&P for the particle count and environmental conditions as specified in Table 1. Sampling shall be in the immediate vicinity of the hardware in processing areas during normal operating conditions to insure a representative sampling of the environment. Certification shall be in accordance with Section 4.2. When laminar flow clean workstations are incorporated as stated above, temperature and humidity of controlled areas shall be monitored and certified or decertified to the same requirements as a class 100,000 clean room. Monitoring procedures are outlined in Section 4.8. Particulate shall be monitored continuously during critical operations while temperature and humidity shall be monitored at all times.

4.4 Clean Work Area (Class 100,000).

Clean Work Areas (CWA) contain vertical structures, portable ground support equipment, movable platforms, overhead cranes, forklifts, and other equipment not typically allowed in conventional clean rooms. Therefore, CWA's, while having similar environmental requirements of conventional clean rooms, are not clean rooms. Good housekeeping, procedures and personnel controls are required to maintain cleanliness. Clean Work Areas can be any part of a facility. Achieving and maintaining the required cleanliness level of a payload depends on the procedures, maintenance rules, and payload exposure time in the CWA. Since some facilities accommodate multiple payloads or serve many functions

simultaneously, facility housekeeping procedures, environmental monitoring and cleanliness level capabilities normally do not change from payload to payload. Variations in payload cleanliness can be affected by operational controls implemented in the vicinity of sensitive payloads. If individual payload controls are not possible or practical the entire facility shall be required to meet cleanliness requirements for the most sensitive payload.

4.4.1 Layout. As with Controlled Areas, Clean Work Areas have no specific layout requirements, but equipment and fixtures shall be arranged to minimize the accumulation of contamination and promote cleaning operations.

4.4.2 Furniture and Fixtures. Furniture and fixtures shall be selected with care. Materials shall be chosen that will resist particle generation by chipping, flaking, oxidizing, or other deterioration. Most paints that are subject to repeated contact with personnel or other objects should not be used in Clean Work Areas. Should such surfaces require painting, an epoxy, urethane or similar wear resistant surface coating shall be used.

4.4.3 Clothing Requirements. Complete clean room uniforms or special clothing are not required unless needed to maintain integrity of the facility. Special clothing may be required for work on special items, but in most cases, a smock and cap/hood are suggested. Program management and the facility custodian shall determine exact clothing requirements. Gloves may be required, depending on end item requirements and type of work being done.

4.4.4 Operation. Operational controls of a CWA are not as stringent as conventional clean-room facilities. Personnel entry and exit through an air shower is not required, but recommended. Specific environmental conditions and other requirements for CWA's are specified in Table 1. Comments on some of these requirements follow:

a. Air Conditioning: Air conditioning shall be a standard commercial design except that its filtration system shall have three stages: Stage 1 shall be a rough filter 50-60% efficient, Stage 2 shall be a medium efficiency filter (80-85%), and Stage 3 shall be a HEPA filter. The air-handling unit shall be designed to provide at least 4 air changes per hour. Air handling equipment shall run continuously. HVAC systems shall be maintained to endure compliance with CWA parameters. Preventative maintenance schedules shall be established for cooling, heating, air handling and filtration systems. The facility custodian shall be notified and grant permission to conduct maintenance operations before they start.

b. Particle Count Tolerance: An operation tolerance for Clean Work Areas shall be no more than 100,000 particles 0.5 μm and larger per cubic foot of air or no more than 700 particles 5.0 μm and larger per cubic foot of air.

c. Pressure Differential: A minimum pressure differential of 0.02 inches of water shall be maintained at all times to prevent contaminated air from flowing into a CWA. An

air lock is desirable, but is not required if facility integrity can be maintained without it.

d. Environmental Conditions: Clean Work Areas may be somewhat flexible regarding temperature and humidity. The temperature shall not exceed 80°F, and humidity shall be controlled between 30 and 55%. If a controlled area incorporates laminar flow clean workstations (class 100) for purposes of critical work, then temperature and humidity shall meet class 100,000 clean room requirements as specified in Table 1.

4.4.5 Maintenance. Good housekeeping practices are essential. Frequent cleaning is required to prevent contamination accumulation that could cause concentrations of particulate to exceed that specified in Table 1. Utilities, fixtures, furniture or any other equipment shall be selected with cleanliness in mind. The room, floor, walls, and ceiling shall be painted or covered with materials that can withstand constant cleaning. Clean floors weekly and other surfaces as required. GSE shall be cleaned monthly.

4.4.6 Monitoring. Clean Work Areas shall be sampled at least once a week by M&P for the particle count and environmental conditions as specified in Table 1. Sampling shall be in the immediate vicinity of the hardware processing areas during normal operating conditions to insure a representative sampling of the environment. Certification shall be in accordance with Section 4.2. When laminar flow clean workstations are incorporated as stated above, temperature and humidity shall be monitored and certified or decertified to the same requirements as a class 100,000 clean room. Monitoring procedures are outlined in Section 4.8. Particulate shall be monitored continuously during critical operations while temperature and humidity shall be monitored at all times.

4.5 Conventional Clean Room (Class 100,000).

Clean rooms require special construction materials, air conditioning, and filtration systems. As shown in Figure 2, turbulent airflow conditions are inherent in conventional clean rooms, and personnel are required to wear complete coverage uniforms in order to isolate human generated contamination from critical systems. Air locks are required at entrances and exits, and positive internal pressure is required to prevent contaminated air from flowing into the clean room.

4.5.1 Layout. A conventional clean room sample layout is presented in Figure 3. This illustration is used solely to facilitate a presentation of procedures, not to define an exact shape for clean rooms. Any layout shall consider the following:

a. Change/Locker Room: Change/locker rooms provide employees or visitors with a place to prepare themselves for entry into the clean room. A sample change/locker room is shown in Figure 3. These rooms are connected to the clean room by air locks. Change rooms shall receive clean filtered air equivalent to that supplied to the

clean room. Locker rooms need not be separate but merely places where overcoats, inclement weather garments, etc., can be stored prior to donning clean room garments. Locker rooms are considered an uncontrolled area. Effective shoe cleaners shall be provided at entrances to change/locker rooms and effective sole cleaners, tacky or sticky mats, shall be located between change rooms and entrances to clean rooms.

b. Wash Rooms: Washrooms, including toilet facilities, are normally provided. Wash facilities incorporate lavatories, liquid soap dispensers, and warm air hand dryers. Air hand dryers may be a contamination source so those used shall be specifically designed to produce warm, but relatively particle free air.

c. Equipment Air Locks: Equipment air locks are provided to accommodate most equipment that must be moved into or out of clean room. Air locks also serve as areas where final cleaning operations can be performed on equipment prior to its entry into clean rooms. For large, infrequently moved items, temporary air locks may be constructed of polyethylene or similar approved plastic sheeting.

d. Air Shower: This class facility shall have an air shower for personnel entry. Its air supply's cleanliness shall be the same as the clean room's. The system shower of air delivered shall be directional and with such force that most particulate adhering to the wearer's garment is removed.

e. Pass-through Windows: Pass through windows or pass-through boxes are small air locks through which hand tools or small parts can be transferred in or out of a clean room without carrying them through the larger air locks. They are for use during operating hours and will help minimize personnel traffic in and out, thus minimizing clean room contamination.

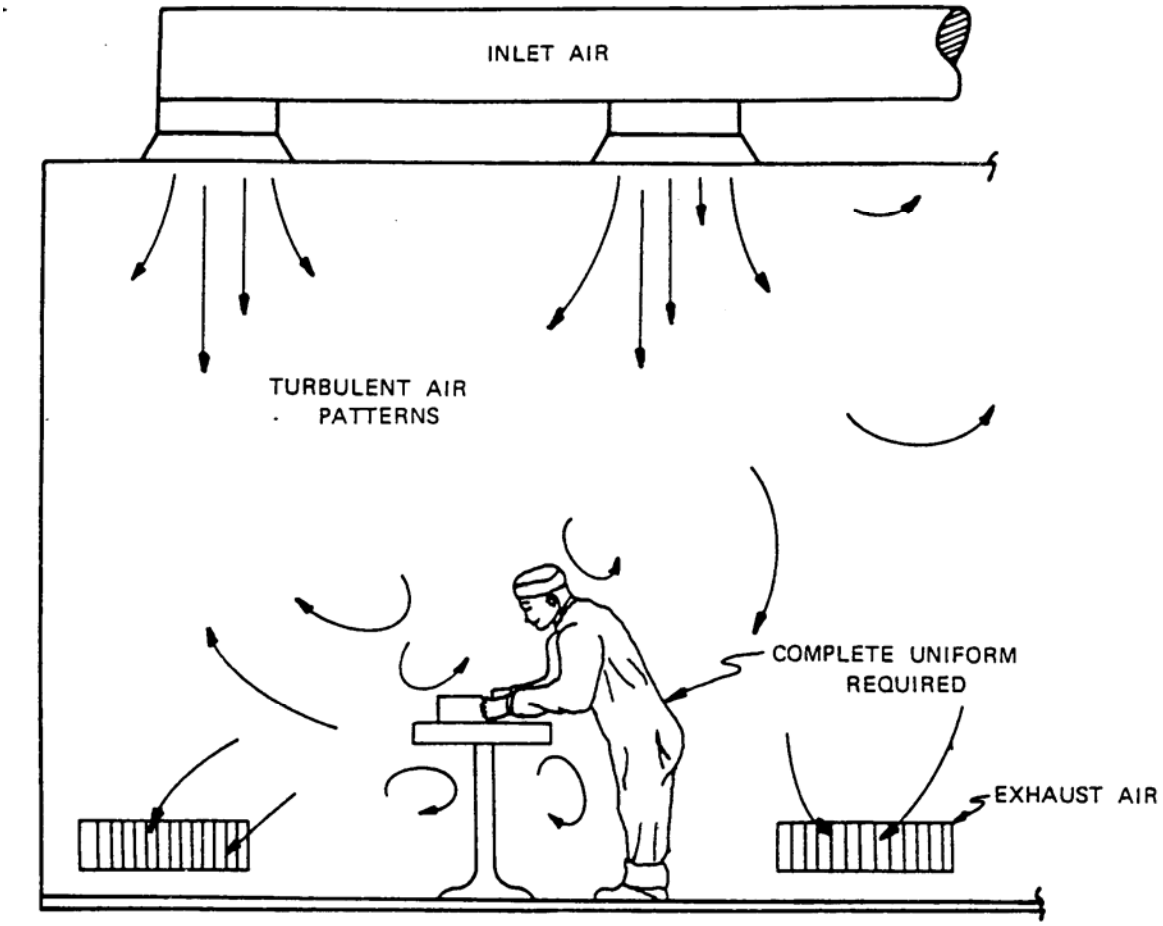

Figure 2: Typical Class 100,000 Clean Room Air Patterns

4.5.2 Furniture and Fixtures.

Furniture and fixtures for clean room use shall be selected with care. Materials shall be chosen that will resist particle generation by chipping, flaking, oxidizing, or other deterioration. Most paints should not be used on clean room surfaces that are subject to repeated contact with personnel or other objects. Should such surfaces require painting, an epoxy, urethane or similar wear resistant surface coating shall be used.

4.5.3 Clothing Requirements.

a. Minimum conventional clean room garments are coveralls, hoods and shoe covers. Gloves may be required, depending on end item requirements and type of work being done. Approved gloves are recommended anytime personnel handle sensitive

hardware. Program management or facility custodian shall impose additional clothing requirements as operations dictate.

b. Garment specifications are described in Section 1.5.3.b.

4.5.4 Operation.

a. Air Conditioning: Air conditioning shall be a standard commercial design except that its filtration system shall have three stages: Stage 1 shall be a rough filter 50-60% efficient, Stage 2 shall be a medium efficiency filter (80-85%), and Stage 3 shall be a HEPA filter. HEPA filters shall be non DOP tested when sensitive optics are in clean room. The air-handling unit shall be designed to provide at least 15 air changes per hour. Air handling equipment shall run continuously. HVAC systems must be maintained to endure compliance with parameters. Preventative maintenance schedules shall be established for cooling, heating, air handling and filtration systems. The facility custodian shall be notified and grant permission to conduct maintenance operations before they start.

b. Particle Count Tolerance: An operation tolerance for Conventional Clean Room shall be no more than 100,000 particles 0.5 μm and larger per cubic foot of air or no more than 700 particles 5.0 μm and larger per cubic foot of air.

c. Pressure Differential: A minimum pressure differential of 0.05 inches of water shall be maintained at all times to prevent contaminated air from flowing into a Conventional Clean Room. An air lock is required.

d. Environmental Conditions: The temperature and humidity shall be controlled to 72±5°F and 45±5%, respectively.

e. Entering Procedures: The following shall apply:

(1) Before entering a change/locker room from an environmentally uncontrolled area, remove weather protective clothing such as raincoats, overcoats, etc.; put them into a locker or storage place provided for storage (see Figure 3). Clean your shoes with a shoe cleaner as prescribed by manufacturer. Procedures shall prevent cleaned shoes from becoming re-contaminated upon removal. A cleaner should effectively clean each shoe's sole including the indented area in front of its heel. A visual check should be made to ensure that caked contaminants such as mud, dirt, sand, salt, cement, etc., have been removed from shoes and clothes. Then obtain a complete uniform from the issue room or garment lockers and proceed to the change room.

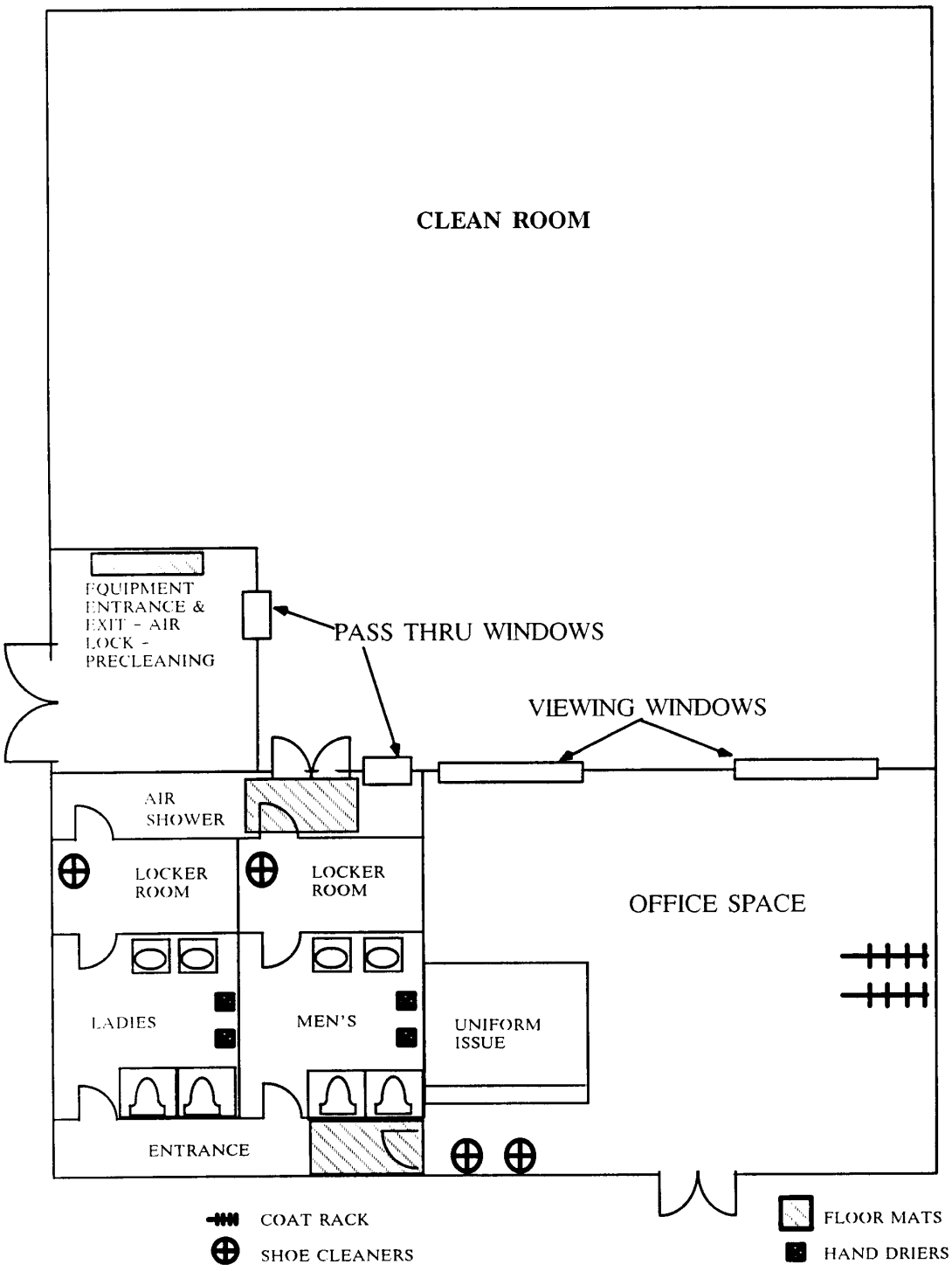

Figure 3: Conventional Class 100,000 Clean Room Layout

(2) Inspect issued uniform for holes or tears. Any damaged item shall be turned in and replaced with an undamaged garment. Uniforms shall be donned using care to minimize contamination. They shall be donned from the head down. Don hood then coveralls, being careful not to allow garments to contact the floor. Hood skirts shall be tucked into coveralls collar. Finally, place shoe covers or booties over coverall legs if possible. Care shall be taken to wear the uniform properly. Prior to entering clean rooms check the following:

(a) All zippers shall be closed completely.

(b) Caps shall cover all hair possible, particularly above the forehead. Only a small portion of sideburns and a tuft in back of the neck (when caps are worn) are allowed to be exposed.

(c) Hoods and snoods shall cover all hair possible, particularly above the forehead; their skirts shall be tucked inside each uniform's collar.

(d) If small shoe covers or clean room shoes are used, then coverall pants leg shall fit snugly.

(e) All personnel entering a clean room shall enter via its air shower.

NOTE: Clean room shoes or shoe covers may be required; they shall be donned last. Prior to entering a clean room, each employee shall walk over a sole cleaner, sticky or tacky mat.

f. Exiting Procedures. Upon leaving the clean room, remove uniforms in reverse order of donning, being careful not to allow garments to contact the floor. Garments shall be stored in an enclosed area. When lockers or shelves are not enclosed, garments shall be folded, enclosed in plastic bags, labeled and placed on a shelf. Clean room shoes or shoe covers shall be handled similarly and placed in separate plastic bags. Any disposable garment pieces (e.g. caps, gloves, shoe covers) shall be discarded after one use.

g. Parts, Tools, Equipment, and Material Cleaning. Cleaning practices for clean room work are described in Section 1.5.2 of this Standard.

(1) Prior to entry into clean rooms, all parts, tools, equipment, and material shall be cleaned. Selection of cleaning solvents and methods should depend on type of contaminant, materials of construction and degree of cleanliness required.

(2) Large items of equipment being moved into a clean room shall be thoroughly vacuumed prior to entry. Rough cleaning shall be accomplished in an uncontrolled area; however, final cleaning operations shall be done in an air

lock. Large items shall be moved into clean rooms when their operations are "shut down" or at a minimum.

(3) Small hand tools used in clean room shall be cleaned (ultrasonically when possible) prior to their entry and at scheduled intervals. The facility custodian, on a case by case basis, shall determine an exact cleaning schedule.

(4) General parts cleaning shall occur outside of clean rooms. Pass-through boxes shall be used to transfer clean parts into clean rooms. Where cleaning operations must be conducted inside clean rooms, adequate ventilation shall be provided or cleaning done in a reverse-flow booth. Location of cleaning operations within the clean room shall consider other operations and cross contamination potential.

(5) All tools shall be of approved types and meet required specifications for materials, corrosion resistance, and particle generation.

h. Material and Parts Handling.

(1) Material and parts shall be handled, in "tote boxes" or plastic bags. These containers surfaces shall be smooth to reduce generation of particulate matter. Cleanliness is of the utmost importance. Care exercised in container cleaning shall be as thorough as that given the part to be transported.

(2) Hardware that is very cold (below the dew point) shall be allowed to acclimate to clean room temperature prior to entry to avoid condensation.

(3) Parts that are sensitive to human contact shall never be handled by unprotected hands. Such precision components shall always be handled with tools or gloved hands. In most applications clean plastic, surgical gloves, or finger cots approved by the responsible EM50 CCE shall be used. EM50 maintains a database of approved materials for clean room use.

(4) Tools shall be maintained and stored in such a manner that they cannot transfer contaminants.

(5) Storage racks shall be easily cleaned, accumulate little dust, and be constructed of materials which resist deterioration. Meat racks consisting of open bars or mesh grills make excellent storage racks for clean rooms.

4.5.5 Room Maintenance.

a. Good housekeeping practices are of prime importance in clean rooms. Addition of personnel will increase contamination levels in the room. Therefore, room cleaning times shall be chosen with care. An important point to remember is that it will take some period of time for an increased contamination level caused by a cleaning operation to return to acceptable levels. Cleaning shall be done during non-critical activities, preferably during late day or night. Critical hardware shall be protected with an approved material or cover during cleaning operations. Floors shall be cleaned twice a week and other surfaces as required. GSE shall be cleaned monthly.

b. Cellulose mops and sponges shall be used with clean water. High-grade plastic buckets that are not subject to flaking shall be used, if necessary. A detergent can be used.

c. A central vacuum cleaning system or a portable vacuum cleaner with a HEPA filtered exhaust shall be employed for cleaning. This cleaning method shall be scheduled between shifts. Minor dry floor and bench vacuuming may be performed, if necessary, during room operation if equipment and procedures used insure a minimum of disturbance to settled particles.

d. Floors shall not be waxed.

e. Housekeeping equipment, utensils, etc., are sources of contamination. Care shall be exercised while using them so that room integrity is not adversely affected. These items shall be thoroughly cleaned and vacuumed prior to entering the clean room.

4.5.6 Monitoring.

a. General. M&P Laboratory shall be responsible for insuring compliance with this Standard by sampling all clean rooms at MSFC at least once a week for particulate, pressure, temperature and humidity as prescribed in Table 1. Hydrocarbon content shall also be measured weekly if project requires it. Detailed monitoring procedures are described in Section 4.8. Particulate, temperature and humidity shall be monitored continuously. This monitoring is for certification of facilities in accordance with Section 4.2. While the clean room is in operation, the facility custodian shall ensure that continuous monitoring takes place. An occasional peaking of contamination is permissible for a few minutes time. However, continued out-of-tolerance conditions indicate serious systems problems. These conditions are unacceptable and may be cause for decertification. The responsible EM50 CCE shall be notified with any issues and consulted for placing facility back in service.

b. Particulate Contamination. The contamination level varies throughout a conventional clean room, but shall always remain below the standard allowable during work shifts. This contamination variation is caused by turbulent air conditions and the varying amounts of particles being generated throughout the room. The important sections of

any class clean room are the workbenches and the areas surrounding the products or hardware.

c. Temperature. The temperature within a room varies. This temperature variance is sometimes referred to as a temperature gradient. The 3 to 5 feet elevation area is of prime importance for table top operations, and temperature control shall be maintained in this zone. No reading shall be taken within 2 feet of a heat-producing unit. Unless a product is very sensitive to the rate of temperature change, temperature can be monitored at any other convenient spot.

d. Humidity. Humidity can become troublesome if allowed to reach a low level where clean room personnel generate static charges or a high level where condensation or metallic oxidation may be a problem. A relative humidity level of not less than 30 percent and no more than 50 percent is desired.

e. Pressure. Positive pressure shall be maintained in conventional clean rooms to prohibit contaminated air from entering from outside sources. Airflow shall always be from the clean space outward to uncontrolled areas.

4.6 Conventional Clean Room (Class 10,000 and Class 1000).

Laminar flow clean rooms are preferred when desiring higher cleanliness levels. A higher cleanliness level can be maintained in these types of facilities because of their airflow patterns. Turbulent airflow patterns, characteristic of conventional clean rooms, keep internally generated contamination suspended in the air, making it more difficult to achieve lower airborne particulate levels. Laminar airflow is essentially unidirectional - parallel air streams from supply to exhaust grills. This type airflow is generally classified as cross-flow or down-flow and is capable of achieving a class 100 with the addition of very stringent controls.

4.6.1 Types. Although laminar cross-flow or down-flow clean rooms are generally considered the two basic configurations, other variations should be noted:

a. Cross-Flow. When airflow is essentially horizontal, flowing from one wall to an opposite exit wall, that area is called a cross-flow or horizontal laminar flow clean room. A typical cross-flow room is shown in Figure 4. Some degree of air cleanliness will be sacrificed toward the room's exhaust.

b. Down-Flow. When air moves from ceiling to floor and the laths serve as a return air grille, the room is called a down-flow or vertical laminar flow clean room. A down-flow design provides the greatest contamination control over an entire working area because airborne contamination is immediately carried down and out of the room as soon as it is generated. A down-flow room design takes advantage of gravity on larger particles for removal; therefore, its air velocity can be less (50 ft per min.) than

that of a cross-flow room (100 ft per min.). A typical down-flow room is shown in Figure 5.

c. Down-Flow Curtain Unit (Portable Clean Room). Down-flow curtain units are portable and a compromise between laminar down-flow rooms and individual down-flow clean workstation. Its air handling equipment and HEPA filters are located on an overhead framework supported by legs as shown in Figure 6. Filtered air flows downward and exits under the plastic curtain sidewalls. These units can be mounted on casters and rolled into any position with ease and allow the establishment of a cleaner work area within a clean room or controlled environment. Although Portable Clean Rooms are listed in this section, they are not limited to Class 10,000 or 1000. These facilities may be classified according to what particulate levels can be maintained during normal operations.

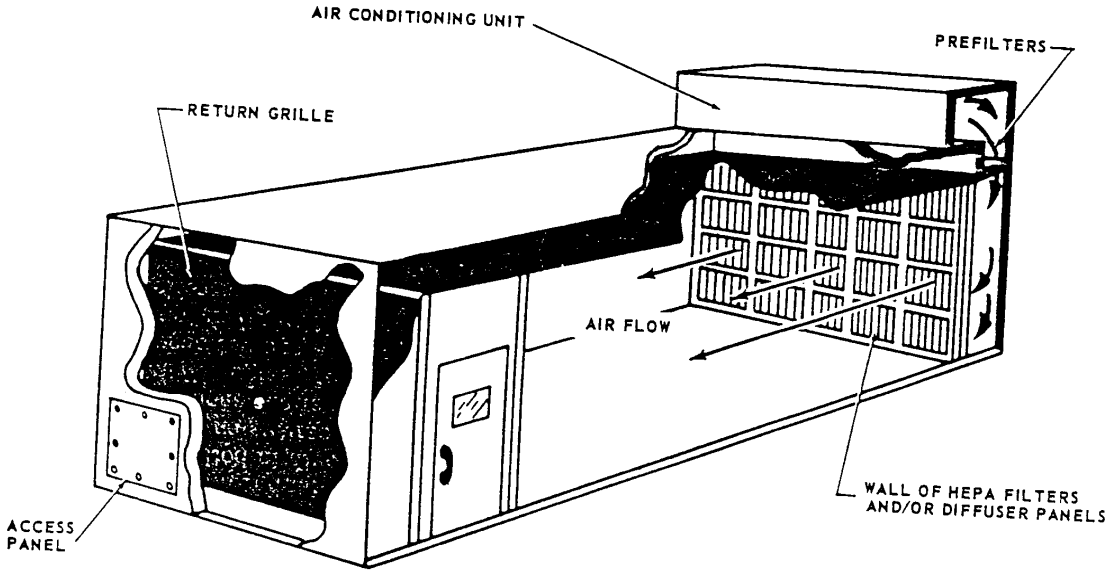

Figure 4: Cross-Flow Room

d. Tunnel Clean Room. Tunnel clean rooms combine features of cross-flow room and the down-flow curtain units. The tunnel is made of prefabricated modules that can be assembled and disassembled with relative ease, giving a high degree of portability. Its air handling equipment and HEPA filter bank are located at one end while the opposite end is open. These units can be extended in length and made to any width. A typical unit is shown in Figure 7. These units will provide cleanliness levels approaching those of cross-flow rooms.

4.6.2 Layout. Locating equipment within laminar flow rooms to minimize eddy currents or turbulent airflow patterns is very important. Any layout shall consider the following:

a. Change/Locker Room: Change/locker rooms provide employees or visitors with a place to prepare themselves for entry into the clean room. A sample change/locker room is shown in Figure 3. These rooms are connected to the clean room by air locks. Change rooms shall receive clean filtered air equivalent to that supplied to the clean room. Locker rooms need not be separate but merely places where overcoats, inclement weather garments, etc., can be stored prior to donning clean room garments. Locker rooms are considered an uncontrolled area. Effective shoe cleaners shall be provided at entrances to change/locker rooms and effective sole cleaners, tacky or sticky mats shall be located between change rooms and entrances to clean rooms.

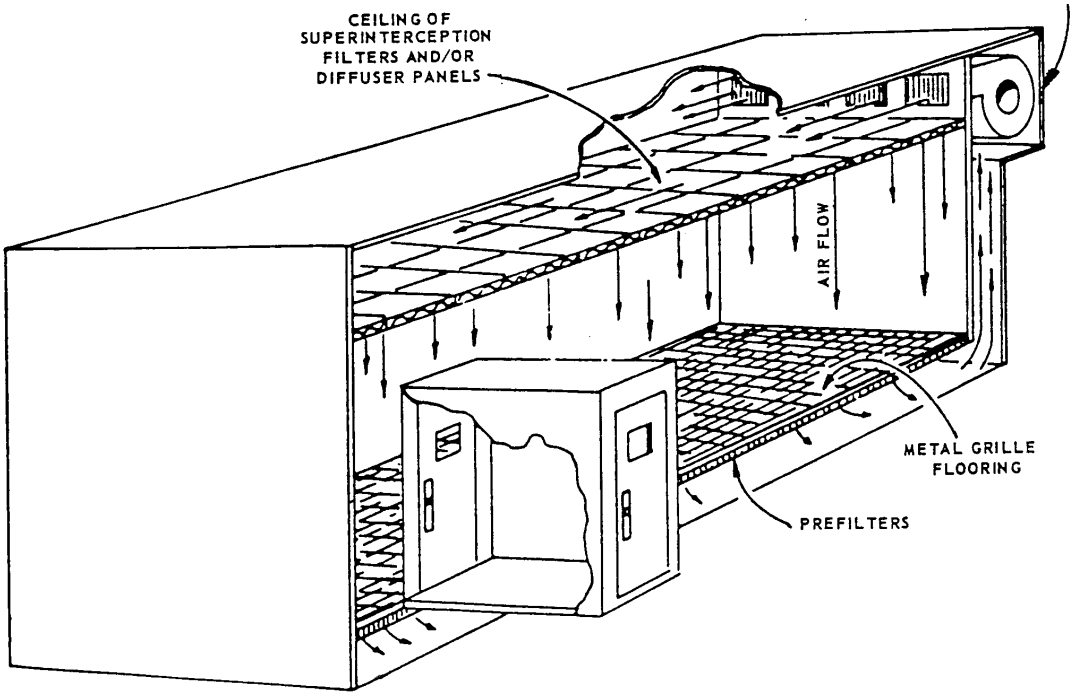

Figure 5: Down-Flow Room

b. Wash Rooms: Washrooms, including toilet facilities, are normally provided. Wash facilities incorporate lavatories, liquid soap dispensers, and warm air hand dryers. Air hand dryers may be a contamination source so those used shall be specifically designed to produce a warm, but relatively particle free air.

c. Equipment Air Locks: Equipment air locks are provided to accommodate most equipment that must be moved into or out of clean room. Air locks also serve as areas where final cleaning operations can be performed on equipment prior to its entry into clean rooms. For large, infrequently moved items, temporary air locks may be constructed of polyethylene or similar approved plastic sheeting.

d. Air Shower: This class facility shall have an air shower for personnel entry. Its air supply's cleanliness shall be the same as the clean room's. The system shower of air delivered shall be directional and with such force that most particulate adhering to the wearer's garment is removed.

e. Pass-through Windows: Pass through windows or pass-through boxes are small air locks through which hand tools or small parts can be transferred in or out of a clean room without carrying them through the larger air locks. They are for use during operating hours and will help minimize personnel traffic in and out, thus minimizing clean room contamination.

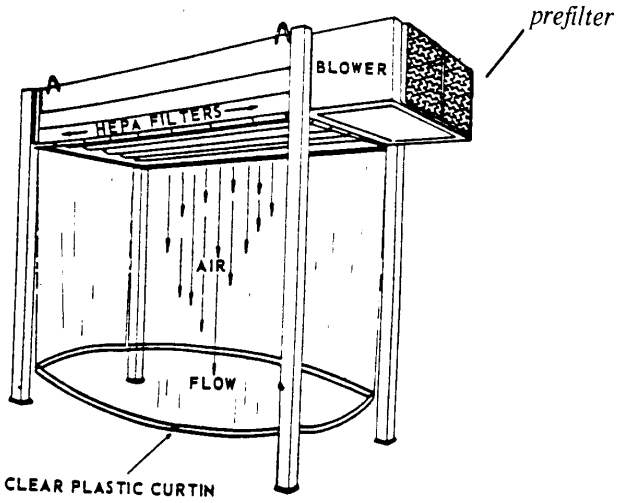

Figure 6: Down-Flow Curtain Unit

4.6.3 Furniture and Fixtures.

Furniture and fixtures for clean room use shall be selected with care. Materials shall be chosen that will resist particle generation by chipping, flaking, oxidizing, or other deterioration. Most paints should not be used on clean room surfaces that are subject to repeated contact with personnel or other objects. Should such surfaces require painting, an epoxy, urethane or similar wear resistant surface coating shall be used.

Equipment layout is important in laminar flow rooms in order to minimize turbulent air flow patterns, therefore, many things must be considered: type of work being done, end item flow, personnel flow, equipment sizes, emission patterns, etc. Objects size and placement control dead air spaces and eddy currents. For utmost utilization of a facility, steps shall be taken to determine the length, width, and depth of these patterns. Equipment in a cross flow room shall be perpendicular to air flow lines, and operations requiring the highest environmental control shall be located closest to filters. Operations

that require less stringent environmental control and those that produce contamination shall be located on the rooms exhaust side. Figure 8 shows a typical room layout where workbenches are placed upstream and larger consoles are located at the exhaust end, thus minimizing disruption of airflow. Staggering equipment and personnel will also help in minimizing disruption of airflow. After all layouts are complete and equipment is located, the airflow pattern shall be checked by the CCE for certification and, if necessary, equipment and personnel relocated to eliminate dead air spaces or poor flow patterns. In a down-flow room, less concern needs to be given to equipment layout since contamination at any workstation will exit through the floor as it is generated. Figure 9 illustrates a typical emission pattern and Figure 10 illustrates proper equipment layout in a down-flow clean room.

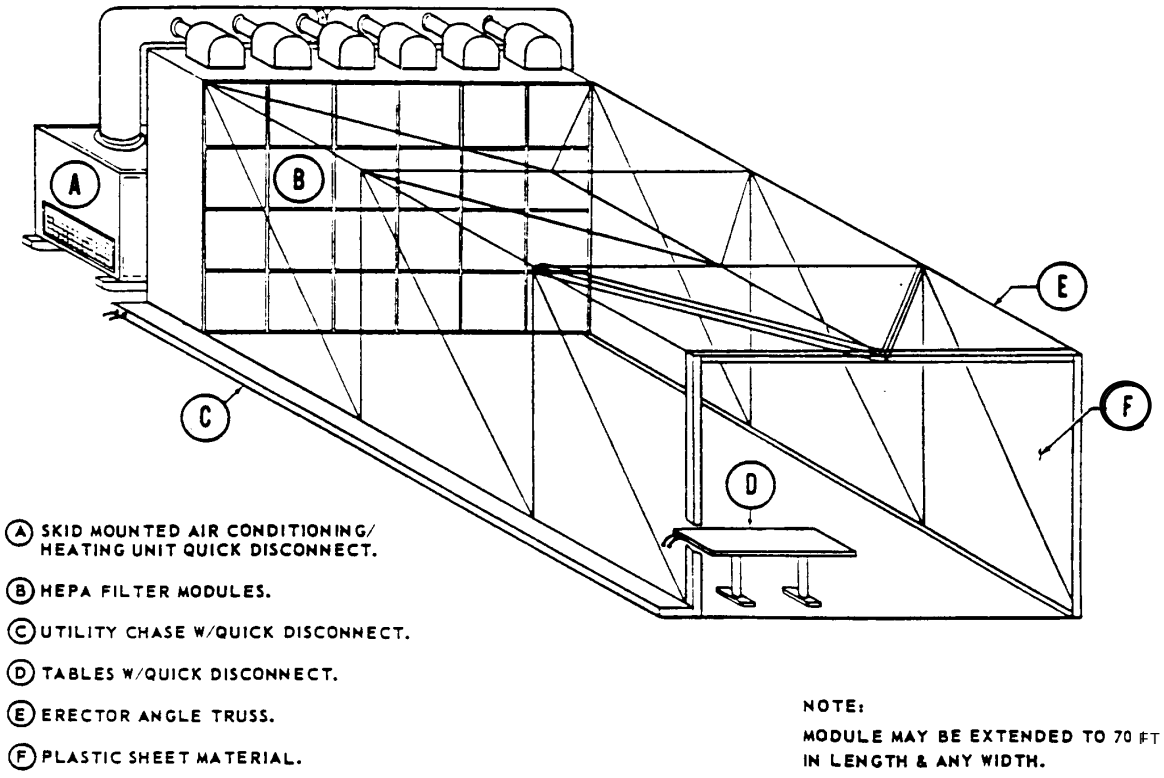

Figure 7: Tunnel Clean Room

4.6.4 Clothing Requirements.

a. Clean room clothing, such as coveralls, hoods and booties, is required. Refer to Table 1 for garment requirements of a specific class clean room. Additional clothing, as determined by the program manager, CCE or facility custodian, may be necessary to prevent contamination of work by skin oil, hair, dandruff, etc. Goggles and gloves are often required.

b. Garment specifications are described in Section 1.5.3.b.

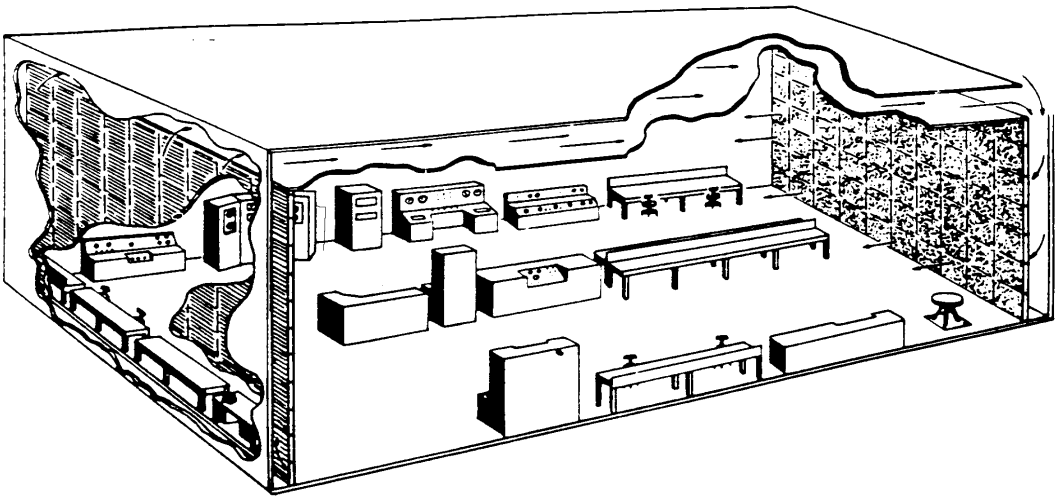

Figure 8: Cross-Flow Clean Room Layout with Various Bench and Console Operations

4.6.5 Operation.

a. Air Conditioning: Air conditioning shall be a standard commercial design except that its filtration system shall have three stages: Stage 1 shall be a rough filter 50-60% efficient, Stage 2 shall be a medium efficiency filter (80-85%), and Stage 3 shall be a HEPA filter. HEPA filters shall be non DOP tested. The air-handling unit shall be designed to provide at least 20 air changes per hour. Air handling equipment shall run continuously. HVAC systems shall be maintained to endure compliance with parameters. Preventative maintenance schedules shall be established for cooling, heating, air handling and filtration systems. The facility custodian shall be notified and grant permission to conduct maintenance operations before they start.

b. Particle Count Tolerance: An operation tolerance shall be no more than 10,000 particles 0.5 μm and larger per cubic foot of air for Class 10,000 rooms and for Class 1000 shall be no more than 1000 particles 0.5 μm and larger per cubic foot of air.

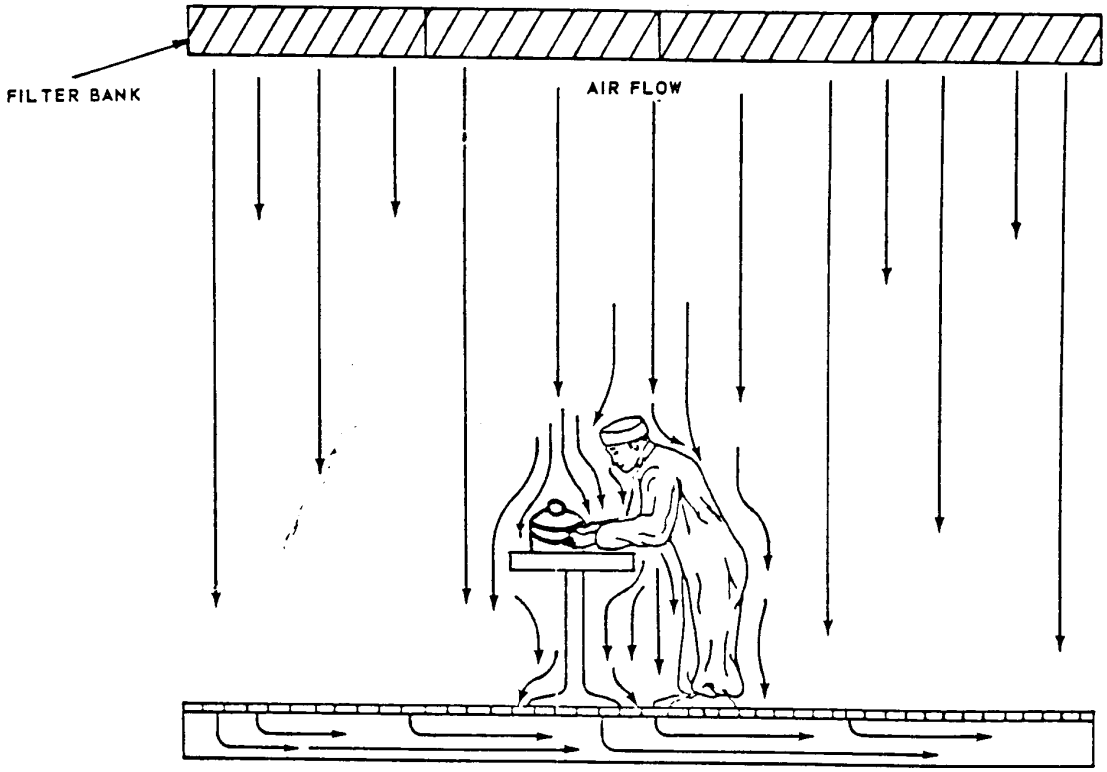

Figure 9: Airflow Pattern in a Down-Flow Clean Room

c. Pressure Differential: A minimum pressure differential of 0.05 inches of water shall be maintained at all times to prevent contaminated air from flowing into a clean room. An air lock is required.

d. Environmental Conditions: The temperature and humidity shall be controlled to 72±5°F and 45±5%, respectively.

e. Entering Procedures: The following shall apply:

(1) Before entering a change/locker room from an environmentally uncontrolled area, remove weather protective clothing such as raincoats, overcoats, etc.; put them into a locker or storage place provided for storage (see Figure 3, "Sample Clean Room"). Clean your shoes with a shoe cleaner as prescribed by manufacturer. Procedures shall prevent cleaned shoes from becoming re-contaminated upon removal. A cleaner shall effectively clean each shoe's sole including the indented area in front of its heel. A visual check shall be made to ensure that caked contaminants such as mud, dirt, sand, salt, cement, etc. have been removed from shoes and clothes. Then obtain a complete uniform from the issue room or garment lockers and proceed to the change room.

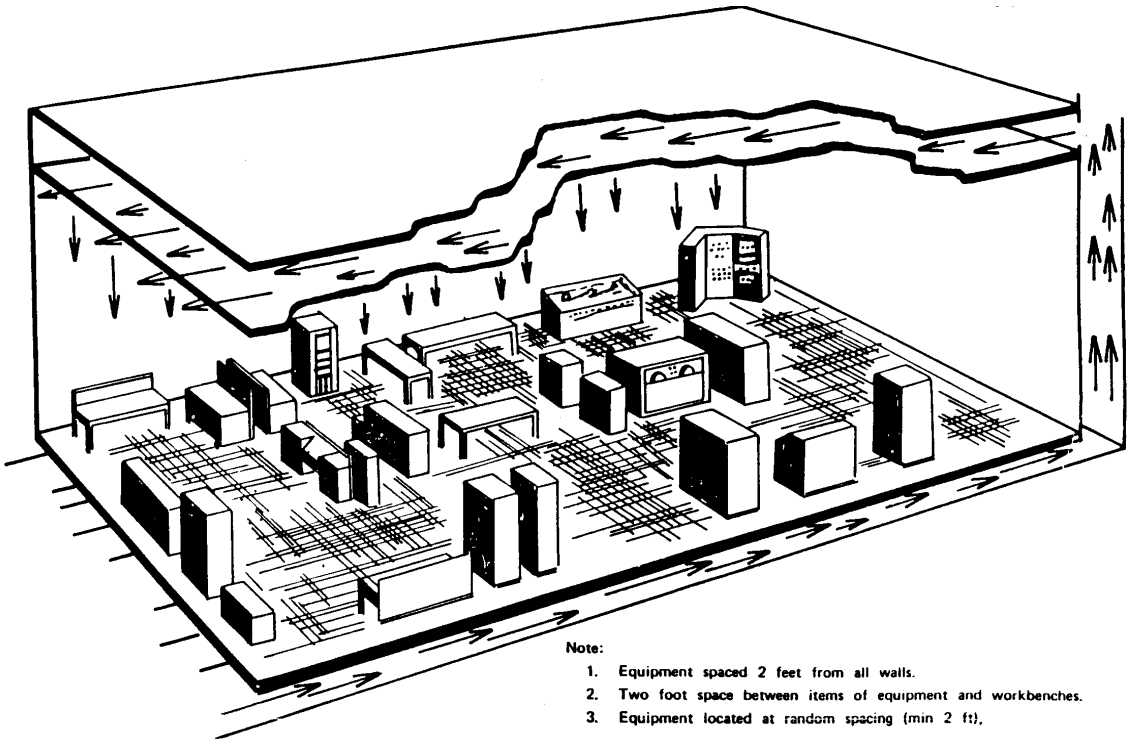

Figure 10: Down-Flow Clean Room Layout

(2) Inspect issued uniform for holes or tears. Any damaged item shall be turned in and replaced with an undamaged garment. Uniforms shall be donned using care to minimize contamination. They shall be donned from the head down. Don hood then coveralls, being careful not to allow garments to contact the floor. Hood skirts shall be tucked into coveralls collar. Finally, place booties over coverall legs if possible. Care shall be taken to wear the uniform properly. Prior to entering clean rooms check the following:

(a) All zippers shall be closed completely.

(b) Hoods and snoods shall cover all hair possible, particularly above the forehead; their skirts shall be tucked inside each uniform's collar.

(c) All personnel entering a clean room shall enter via its air shower.

NOTE: Booties are required; they shall be donned last. Prior to entering a clean room, each employee shall walk over a sole cleaner, sticky or tacky mat.

f. Exiting Procedures. Upon leaving the clean room, remove uniforms in reverse order of donning, being careful not to allow garments to contact the floor. They shall be

stored in an enclosed area. When lockers or shelves are not enclosed, garments shall be folded, enclosed in plastic bags, labeled and placed on a shelf. Booties shall be handled similarly and placed in separate plastic bags.

g. Parts, Tools, Equipment, and Material Cleaning. Cleaning practices for clean room work are described in Section 1.5.2 of this Standard.

(1) Prior to entry into clean rooms, all parts, tools, equipment, and material shall be cleaned. Selection of cleaning solvents and methods depends on type of contaminant, materials of construction and degree of cleanliness required.

(2) Large items of equipment being moved into a clean room shall be thoroughly vacuumed prior to entry. Rough cleaning shall be accomplished in an uncontrolled area; however, final cleaning operations shall be done in an air lock. Large items shall be moved into clean rooms when operations are "shut down" or at a minimum.

(3) Small hand tools shall be cleaned (ultrasonically when possible) prior to their entry and at scheduled intervals. Local management and the CCE, on a case by case basis, shall determine an exact cleaning schedule.

(4) General parts cleaning shall occur outside of clean rooms. Pass-through boxes shall be used to transfer clean parts into clean rooms. Where cleaning operations must be conducted inside clean rooms, adequate ventilation shall be provided, or cleaning done in a reverse-flow booth (See Section 4.7). Location of cleaning operations within the clean room shall consider other operations and cross contamination potential.

(5) All tools shall be of approved types and meet required specifications for materials, corrosion resistance, and particle generation.

h. Material and Parts Handling.

(1) Material and parts shall be handled, in "tote boxes" or plastic bags. These container surfaces shall be smooth to reduce generation of particulate matter. Cleanliness is of the utmost importance. Care exercised in container cleaning shall be as thorough as that given the part to be transported.

(2) Hardware that is very cold (below the dew point) shall be allowed to acclimate to clean room temperature prior to entry to avoid condensation.

(3) Parts that are sensitive to human contact shall never be handled by unprotected hands. Such precision components shall always be handled with tools or gloved hands. In most applications clean plastic, surgical gloves, or finger cots

approved by the responsible EM50 CCE shall be used. EM50 maintains a materials database for reference.

(4) Tools shall be maintained and stored in such a manner that they cannot transfer contaminants.

(5) Storage racks shall be easily cleaned, accumulate little dust, and be constructed of materials which resist deterioration. Meat racks consisting of open bars or mesh grills make excellent storage racks for clean rooms.

4.6.6 Room Maintenance.

a. Good housekeeping practices are of prime importance in clean rooms. Addition of personnel will increase contamination levels in the room. Therefore, room cleaning times shall be chosen with care. Rooms shall be cleaned in accordance with local schedules established to be consistent with the class of clean room. Critical hardware shall be protected with an approved material or cover during cleaning operations. An important point to remember is that it will take some period of time for an increased contamination level caused by a cleaning operation to return to acceptable levels. Clean up time of the air within a laminar flow type room will be rapid due to its laminar flow characteristics. Cleaning shall be done during non-critical activities, preferably during late day or night. Floors shall be cleaned daily, walls weekly, and ceilings as required. GSE shall be cleaned weekly. For Class 10,000 facilities, structures shall be cleaned monthly. Structures in Class 1,000 facilities shall be cleaned weekly.

b. Cellulose mops and sponges shall be used with clean water. High-grade plastic buckets that are not subject to flaking shall be used, if necessary. A detergent can be used.

c. A central vacuum cleaning system or a portable vacuum cleaner with a HEPA filtered exhaust shall be employed for cleaning. This cleaning method shall be scheduled between shifts. Minor dry floor and bench vacuuming may be performed, if necessary, during room operation if equipment and procedures used insure a minimum of disturbance to settled particles.

d. Floors shall not be waxed.

e. Housekeeping equipment, utensils, etc., are sources of contamination. Care shall be exercised while using them so that room integrity is not adversely affected. These items shall be thoroughly cleaned and vacuumed prior to entering the clean room.

4.6.7 Monitoring.

a. General. The M&P Laboratory shall be responsible for insuring compliance with this Standard by sampling all clean rooms at MSFC at least once a week for particulate, pressure, temperature and humidity as prescribed in Table 1. Detailed monitoring procedures are described in Section 4.8. Particulate, temperature and humidity shall be monitored continuously. This monitoring is for certification of facilities in accordance with Section 4.2. While clean room is in operation, the facility custodian shall ensure that continuous monitoring takes place. An occasional peaking of contamination is permissible for a few minutes time. However, continued out-of-tolerance conditions indicate serious systems problems. These conditions are unacceptable and may be cause for decertification. The responsible EM50 CCE shall be notified and consulted for placing facility back in service.

b. Particulate Contamination. The contamination level varies throughout a clean room, but shall always remain below the standard allowable during work shifts. This contamination variation is caused by turbulent air conditions and the varying amounts of particles being generated throughout the room. In cross-flow rooms, levels of particulate contamination will vary in proportion to the distance from the filter bank wall. Work areas that are downstream of other work areas are susceptible to higher contamination levels. Contamination levels may be higher around particular workbench operations, and are highest during peak operations when the room is fully manned. Levels of particulate contamination in down-flow rooms are generally consistent throughout the room. In either case, the workbenches and areas surrounding the work area are critical, and particle counts shall be made in those areas.

c. Temperature. The temperature within a room varies. This temperature variance is sometimes referred to as a temperature gradient. The 3 to 5 feet elevation area is of prime importance for table top operations, and temperature control shall be maintained in this zone. No reading shall be taken within 2 feet of a heat-producing unit. Unless a product is very sensitive to the rate of temperature change, temperature can be monitored at any other convenient spot.

d. Humidity. Humidity can become troublesome if allowed to reach a low level where clean room personnel generate static charges, or a high level where condensation or metallic oxidation may be a problem. A relative humidity level of 45±5% is desired.

e. Pressure. Positive pressure shall be maintained in clean rooms to prohibit contaminated air from entering from outside sources. Airflow shall always be from the clean space outward to uncontrolled areas.

f. Air Velocity. Air velocity shall be checked for compliance with the requirements specified in Table 1. In cross-flow rooms, air velocity shall not vary more than 20 ft/min throughout the facility, and shall not drop below 75 ft/min at any workstation. In down-flow rooms, air velocity should not drop below 50 ft/min at any workstation.

4.7 Laminar Flow Bench/Clean Work Stations (Class 100).

4.7.1 Description.

a. General. Laminar flow bench workstations offer a high degree of flexibility to operations that must be performed where clean rooms are not available or practical. In such situations the ambient contamination level of the room may be very high in comparison to the environment within the laminar flow bench workstations. Laminar flow bench workstations operate on the principle of removing contamination from the workspace as soon as it is generated. It accomplishes this by blowing clean air from HEPA filters over the work area at a velocity of 100 ft per minute. The laminar airflow is unidirectional; therefore, it carries contamination away from the work. Laminar flow workstations are available as modular units and are likened to building blocks that can be arranged in various configurations to handle many different product lines. Increased clean room flexibility can be achieved by using modular units that permit various arrangements within the room. The size and shape of these flow benches may vary, depending on the type of work being performed.

   Laminar flow benches are designed to achieve the highest class cleanliness (Class 100) specified in this Standard, but they may also be used to achieve Class 1,000. If a laminar flow workstation is used to achieve a cleanliness condition less than class 100, then it shall be labeled for that class and be monitored for the higher particulate count.

b. Material. A smooth, durable material not susceptible to flaking shall be used, e.g., glass, Plexiglas, laminated panels, stainless steel, or equivalent material.

c. Particle Count. For Class 100, air filtration shall provide no more than 100 particles per cubic foot of air 0.5 μm and larger. This condition shall prevail throughout the entire workbench, upstream of the work piece, unless the workbench is labeled for a lesser cleanliness level (class 1,000).

d. Filters. The final filters shall be of 99.97 percent efficiency. The filters shall conform to MIL-F-51068 and shall be tested before installation. Pre-filters can be disposable or of a material capable of being cleaned and reused. HEPA filters shall be sealed and shall not be DOP tested.

e. Airflow. A minimum velocity of 100 ft per minute shall be maintained throughout the bench area. It is very important that airflow be essentially laminar. Clean benches are enclosed on the insides and tops to ensure laminar flow and prevent recirculation air currents from contaminating the work area.

f. Illumination. Shadowless illumination with a minimum intensity of 100 foot candles is suggested at bench level. Precautions shall be taken to avoid glare and excessive illumination.

4.7.2 Types. The sizes and/or shapes of the clean bench workstations may vary depending on the type of work being performed. The flow of air may be horizontal or vertical as long as it is essentially laminar and achieves the cleanliness level desired. Various configurations of clean bench workstations are available to adapt to most requirements. Some of these units are floor mounted, while others can be placed directly on top of standard workbenches. Basic configurations are as follows:

a. Horizontal. This bench brings the air in from underneath and exhausts in a horizontal direction across the workbench.

b. Vertical. This bench brings the air from the front lower side and exhausts in a downward, vertical fashion.

c. Reverse Flow. This bench contains the same accessories as the other types except their filters and airflows are reversed. This bench can be used for soldering operations and to disassemble components that would otherwise contaminate the room. It is important to note that all work accomplished within reverse flow benches shall be strictly controlled. All reverse flow benches shall be provided with adequate vacuum attachments that will be used to clean bench surfaces and pre-filters as work progresses.

NOTE: Laminar flow workstations/flow benches may be placed as a group in an existing conventional clean room, a controlled area, or an air-conditioned room. Such a layout will use the recirculation capacity of the benches to clean the room's air. A room utilizing 20 percent of its floor area with workstations can expect approximately 100 room air changes per hour through the workstation's HEPA filters. If the air supply to the room also passes through HEPA fitters, such recirculation and filtration of air through workstations will cause the room's contamination level to approach that of the workstation. If the air supply to the room does not pass through HEPA filters, its contamination level should approach that of a class 100,000 clean room or better.

4.7.3 Clothing Requirements. Clean room clothing shall be in accordance with the class clean room/controlled area being occupied. Smocks with snug fitting wristbands are recommended when laminar flow workstations are used outside of the clean room confines. When added control is necessary due to close proximity or direct contact with critical parts, gloves, finger cots, or other hand coverings shall be used. Finger cots or gloves used to handle parts shall not be used to handle material outside the flow bench and then returned to the station to handle clean parts. Care shall also be taken not to use the finger cots to rub face or hair. If close inspection of the work piece is required where

the worker must lean over the part, a properly worn head covering is essential. EM50 can assist with any processing related questions.

4.7.4 Operation.

a. General. Laminar flow workstations/flow benches are designed to filter contamination from air in the environment in which they are placed. The recovery rate (time for the first input air to reach the last work station exit point) of the clean workstation will be only a matter of minutes. It is not necessary to operate these units 24 hours a day unless required for supplemental help in controlling the contamination level within the room. Operation during normal operating hours will usually be sufficient. The education of workers regarding possible contamination sources and techniques for their control is of prime importance. Proper personnel operating techniques are required to control contaminants carried into the bench on hands, tools, fixtures, etc. This is even more critical for benches located in uncontrolled areas because there is greater susceptibility to carry more contamination on all items transported in and out of the workstation. A general flow bench operating procedure is provided in Appendix III.

b. Evaluation of the Work Area. Although some workstations are designated to operate in uncontrolled areas, the immediate area around the bench should be surveyed to determine whether heavy particles are being generated above the bench. Heavy particles may penetrate the air stream or follow a worker's arms into the workstation and degrade its effectiveness. In this case the top of the bench shall be extended to or beyond the edge of the bench to protect that area from heavy fallout sources. The work area shall also be checked for any operations producing high velocity particles that could penetrate the air stream and get into the clean work area. Such conditions shall be avoided or corrected.

c. Station Control. If a protective screen is provided in front of the filters, it shall be cleaned to remove any captured particles before work begins. A vacuum device with a plastic intake nozzle is recommended for this cleaning. All sensitive material shall be removed from the station or be properly covered during this operation. After the screen has been cleaned and the air supply is operating, the work surface shall be wiped thoroughly with approved materials at least once per shift. More frequent wiping may be required depending on the quantity of material carried in and out of the station.

d. Work Piece and Equipment Control. It should be recognized that, although the workstation atmosphere is clean, the air around the workstation might be heavily contaminated. Care shall be taken to prevent this contamination from reaching critical work parts.

(1) All critical operations shall be accomplished within the confines of the workstations (particularly in reverse flow benches).

(2) At no time shall there be any critical work performed within a workstation without it being operational.

(3) All material (work pieces, tools, containers, jigs, etc.) shall be cleaned to remove particulate matter before being placed inside a workstation.

(4) In bench type work devices, the bench section shall be kept as free as possible of any material not being used immediately. Any material kept inside the station shall be stored along workstation sides. Nothing shall be placed along the bench back edge or between the work piece and the filters. Positioning objects between the filter and work piece will disturb the laminar airflow pattern and may contribute particulate matter to the airflow.

(5) Papers and paper products are not allowed inside a workstation with the exception of a reverse flow bench.

(6) Lead pencils are not allowed inside a workstation.

(7) Nothing shall be placed or stored on top of a bench type clean workstation. If such objects were removed, particles large enough to penetrate the air stream would be brushed off the cabinet or the bottom of these objects.

(8) The clean workstation shall be turned on at least 10 minutes before any shop operation is accomplished within its confines. For critical operations, verify workstation meets requirements before work proceeds. Ideally, workstations should run 24 hours per day.

(9) Additional cleaning shall be necessary to keep working surfaces, work pieces, tools, etc. free of particulate contamination if they are unprotected when the bench is turned off.

e. Personnel Controls. Personnel requirements shall be in accordance with Section 1.5.1. Proper personnel operating techniques are required to control contamination transfer from hands, tools, fixtures, etc., into the workstation. Care shall be taken to assure that hands, forearms, etc., are clean and free of loose dirt and lint before placing them inside workstation.

f. Operational Techniques and Procedures.

(1) Clean parts shall be placed in the unobstructed clean airflow from HEPA filters. Work on critical parts shall be performed with the hands downstream from the part as much as possible.

(2) Clean parts transported in protective containers shall be removed from containers only inside the bench or in the unobstructed air stream directly outside of the station. Containers shall be kept inside the workstation or in the unobstructed air stream directly outside of the station until the part is replaced and the container re-closed. Locate items inside workstation so that airflow is unobstructed. Long term storage is prohibited. Containers may be removed and stored elsewhere if precautions are taken to maintain their cleanliness.

(3) Clean parts containers shall be placed to one side and downstream from the work piece.

(4) Parts containers carry a certain amount of contamination that can be transferred to horizontal surfaces in the workstation. Critical parts shall not be placed on the same surfaces on which parts containers are placed.

(5) To eliminate the problem of carrying contamination from parts containers onto horizontal surfaces of the bench a small shelf may be located downstream of the work piece.

(6) Another solution for keeping critical parts away from contamination on horizontal work surfaces is to place them on a jig, fixture, or work stand. This will keep the part in the clean air stream.

(7) Storage for tools not in use shall be provided. A separate tray or wire mesh container is recommended.

(8) Objects brought into the workbench from the outside carry a shadow of contaminated air behind them into the devices. Care must be taken that critical parts are not exposed to this contamination. Exposure can be minimized with slow movement of objects into workstation.

(9) The transfer of material, including the worker's hands, in and out of the bench section, shall be kept at a minimum.

(10) Transfer of contaminants directly to the part from hands or misused gloves or finger cots, due to poor technique, may be many times greater than contamination resulting from airborne sources.

(11) The working area and all surfaces shall be kept clean and orderly.

g. Special Considerations.

(1) Laminar flow benches/clean workstations offer a high degree of flexibility to operations that must be performed in locations where a standard clean room is neither available nor practical. In such locations the ambient contamination level will be very high in comparison to the environment within the device. Therefore, any work to be performed within a device outside of clean room confines shall follow a sequence such as: item brought into the bench in a sealed container, opened, worked upon, and resealed in the container while in the clean environment. Failure to follow such a procedure will result in contamination of the item.

(2) Laminar flow benches/clean workstations operate on the principle of removing contamination from the workspace as soon as it is generated. This is accomplished with an airflow of 100 feet per minute exiting from the filters. If a workbench with an open front is placed in the outdoors in a wind condition of 50 feet per minute or more, windborne contamination will be forced into the device, defeating its design purpose. Therefore, unless a temporary, effective wind shelter is provided for the device, it will not be able to control airborne contaminants outdoors.

4.7.5 Maintenance.

a. General. The use of proper techniques for operating and maintaining a workstation is necessary to obtain maximum benefits. All personnel concerned with its operation shall understand these procedures, which include initial check-out, clean operation, and proper maintenance. Inspections to determine that HEPA filters are properly sealed and that air velocity meets the requirements of Table 1 are of prime importance.

b. Air Velocity Inspection. Air velocity across the work area shall be checked periodically to determine that proper airflow is being maintained across the filter face (see Section 4.7.6). If airflow is below 75 ft/min. or extremely uneven (20 ft/min. variation), check blowers and/or filters to determine the cause of the trouble. Extremely high localized readings indicate leaks.

c. Filter Inspection. Filters can be inspected for leaks by measuring the particle contamination level of air passing through them. A few pinhole leaks will contribute a high percentage of contamination to the filtered air. If a leak is detected, determine by closer inspection whether the leak is coming around the filter (indicating a poor seal) or if the leak is in the filter itself (indicating a ruptured filter). Replace the filter or tighten pressure on the seal, as necessary.

d. Filter Replacement. When air velocity across a bench's work area falls below 75 ft/min., its pre-filter shall be inspected and replaced if required. Pre-filters typically accumulate dirt faster than HEPA filters so in most cases changing or cleaning the pre-filter will bring outlet air velocity to 75 ft/min. or greater. HEPA filters shall be changed only when damaged or when air velocity remains below 75 ft/min. after new pre-filters have been installed and the HEPA filters have been vacuum cleaned on their upstream sides. Inspection of pre-filters approximately once every two months is recommended, but this interval may vary depending on environmental cleanliness in the facility where the bench is located.

(1) When replacing HEPA filters, it is important that care be taken to assure that the filters are properly sealed in their supporting frames and are not bypassing contaminated air.

(2) After a HEPA filter is replaced, it shall be inspected by the custodian, and monitored per Section 4.7.6 prior to placing it in service.

4.7.6 Monitoring. The M&P Lab/EM10 shall sample all of MSFC's clean workstations at least once a month for their particle counts, air velocities, and other environmental conditions as specified in Table 1. Detailed monitoring procedures are described in Section 4.8. Certification shall be in accordance with Section 4.2.

4.8 Monitoring Practices.

Monitoring of a clean room can present many problems if those performing this function lack an understanding of the factors influencing its environment. These factors must be considered in order to properly interpret the monitoring data.

Monitoring shall be performed as close to the active work area as possible. Facility monitoring equipment calibration and service records shall be maintained near the facility and made available to inspectors.

The M&P Laboratory, with responsibilities defined in Section 1.3, shall sample all environmentally controlled facilities, as defined by this Standard, to determine whether they meet specified requirements.

4.8.1 Particulate Monitoring.

a. Contamination levels will vary throughout a clean room.

b. The highest level of contamination is not necessarily at the air exhaust area since air from a highly contaminated area may be diluted with cleaner air prior to exiting the room.

c. The areas that are of most concern are those immediately surrounding the work.

d. Facility monitoring for various classes is defined in Table 1. Contamination levels can be determined by statistically sampling the room. An exact procedure for sampling and certification can be determined locally using Section 4.2 as a guide.

e. Continuous particulate monitoring for the purpose of evaluating facility and processing health as well as certification/decertification of a clean room shall be accomplished with an automatic particle counter whose calibration has been performed in accordance with the manufacturer's specifications and is current. The automatic method is the only one approved for counting particles smaller than 5.0 µm. This means that automatic particle counters are required for all class 100,000 or cleaner facilities. Since there are many models available on the market, the manufacturer's instructions shall be followed in calibration and use of the instrument.

4.8.2 Temperature Monitoring.

a. Temperature monitoring for the purpose of certification/decertification shall be achieved by using a standard thermometer or a similar portable measuring device. More automated devices may be used to supplement or replace this thermometer, but these devices shall be checked periodically to assure accuracy.

b. Temperature readings shall also be made by the M&P Lab and records kept for weekly examination. Frequency of readings shall be determined locally. Certain class facilities or those containing products extremely sensitive to temperature fluctuations shall be monitored with a continuous temperature recorder. In such cases its temperature probe shall be placed in close proximity to the product.

c. The following comments apply to all temperature monitoring procedures:

d. The temperature will vary from point to point throughout a conventional clean room, particularly at different elevations. Temperature variations are practically nonexistent in laminar flow rooms.

e. The temperature at a 3 to 5 ft. elevation in an area surrounding the work is of prime importance and shall be maintained within established limits.

f. No readings shall be taken within 2 ft. of a heat producing unit.

4.8.3 Humidity Monitoring. Conventional wet and dry-bulb thermometers shall be used for certification/decertification. If automated devices are used, they shall be calibrated periodically. Humidity readings shall also be made by shop quality control personnel and records kept for the CCE's monthly examination. Frequency of readings are defined in Table 1 or if more frequent monitoring is desired the schedule may be determined locally.

4.8.4 Pressure Monitoring. Pressure monitoring can be achieved by using a manometer with each opening vented in such a manner that the pressure differential is measured between the clean room and its outside surroundings. The instrument shall be capable of reading 0.01 inch of water pressure clearly. A gauge that indicates pressure differential in increments of 0.01 inch of water may be substituted for the manometer. Failure to meet minimum pressure specifications of a room shall not in itself be cause for decertification. It indicates a problem that shall be investigated to determine whether corrective action is necessary. Monitoring frequency is defined in Table 1.

4.8.5 Airflow Monitoring. Air velocity in laminar flow rooms and laminar flow clean workstations shall be measured with an air velocity meter. This meter should be small and easily handled with approximate velocity ranges of 30 to 300 ft/min. and 100 to 1,000 ft/min. It shall be used in accordance with its manufacturer's instructions.

4.8.6 Garment Monitoring. Garment monitoring shall be used to determine whether they have been laundered properly or if they are faulty and shedding fabric. A garment is acceptable if it exhibits limited linting properties of not more than 2,000 particles/ft^2 5.0 μm and larger in size.

a. Manual Procedure. The detailed, manual procedure for monitoring clean room garments is presented in Appendix II.

b. Automatic Procedure. Faster and better results will be obtained by using automatic light-scattering particle counters to measure particulate contamination on clean room garments. Monitoring shall be accomplished in a laminar flow workstation or equivalent. The filter assembly and adapter referred to in Appendix II are fitted to the air intake of an automatic counter with a short length of Teflon or urethane tubing. The flow rate shall be set as determined by the operator and recorded for calculation purposes. Garment areas to be tested shall be selected as illustrated in Figure 14 of Appendix II. The area to be tested is placed in the assembly while the automatic counter is operating. A sampling time shall be determined by the operator for each area for a best combination of accuracy and speed. At least 1 minute shall be allowed for each area with a minimum sample flow rate of 1 cfm. Close observation will acquaint the operator with a sampling time in which more than 95 percent of the total count is recorded. The results shall be computed using appropriate factors and expressed as particles/ft^2 of garment.

APPENDIX I

MANUAL METHOD FOR SIZING AND COUNTING AIRBORNE PARTICULATE CONTAMINATION IN CLEAN ROOMS AND OTHER DUST-CONTROLLED AREAS

NOTE: These methods shall be used if automatic particle counters are not available or to verify automatic counter calibration.

1. SCOPE

This method covers a procedure for counting and sizing airborne particulate matter 5.0 micrometers (μm) and larger. The sampling areas are specifically those with contamination levels typical of clean rooms and dust-controlled areas designed for electronic and aerospace work. It is not a method for dust counting where isokinetic sampling is a factor.

2. OUTLINE OF METHOD.

This method is based on the microscopic examination of particles impinged upon a membrane filter with the aid of a vacuum. The number of sampling points is proportional to floor area being checked. An apparatus and facilities required are typical of a laboratory for the study of micro-particle contamination. Each operator shall have adequate basic training in microscopy and the techniques of particle sizing and counting.

3. DEFINITIONS

a. A particle's major dimension is designated as its size.

b. The standard unit of length for sizing purposes is the μm, which is 0.001 mm or 0.00004 in.

c. Only particles with a measurable dimension greater than 5.0 μm are to be counted.

d. A particle is considered a fiber when its length/width ratio of is 10/1 or more.

4. APPARATUS

a. Aerosol open type filter holder.

b. Vacuum pump or aspirator capable of producing a vacuum of 500 torr.

c. Flowmeter with 10 L/min capacity or 10 L/min orifice.

d. Membrane filters, contrasting, 0.80 μm or smaller pore size, with imprinted grid.

e. Glass microscope slides, 50x75 mm, or 47 mm plastic disposable Petri dishes.

f. Forceps with unserrated tips.

g. Binocular microscope with ocular-objective combinations to obtain 40/45X and 90/150X magnifications. The latter objective shall have a numerical aperture of 0.15 mm.

h. Manual counter.

i. Microscope lamp.

j. Micrometer eyepiece with movable scale or ocular micrometer reticle.

k. Stage micrometer, standard 0.01 to 0.1 mm scale.

5. SAMPLING

a. Samples shall be collected by a vacuum induction of airborne particles on a membrane filter that has a known effective area. The filter surface shall be horizontal with respect to the floor.

b. A standard sample for this procedure shall be 10 ft^3 (283 liters); however, sample size may be adjusted for specific conditions.

c. Samples shall be taken at waist level (36 to 40 inches from the floor) or at bench level unless area is limited. General sampling points are as designated on the sampling plan in Figure 11. The number of samples for averaging is a function of the floor area (See paragraph 5.d.).

d. Samples shall be taken at locations as illustrated on the sampling plan in Figure 11. (Also see paragraph 5.f.) Sample at 1 and 2 ft for areas less than 150 ft^2. Sample at 1, 2, 3, 4 and 5 for areas to 1,000 ft^2 increase sampling by 4 locations per 1,000 ft^2.

e. Locations are approximate. Location 1 is area center, 1 and 2 ft are centers of triangles on respective bases. Locations 2, 3, 4 and 5 are half distances from center to respective corners on area diagonals, as shown in sampling plan.

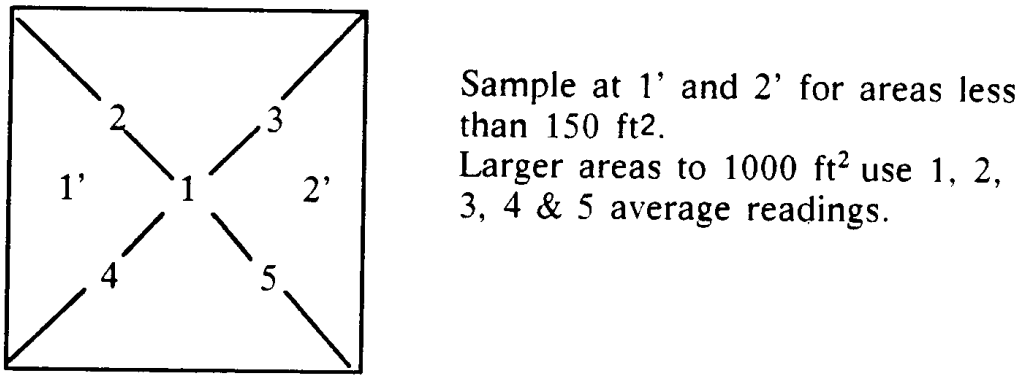

Figure 11: Clean Room Sampling Plan

f. Operating conditions shall dictate number and location of samples. Each critical work position within a clean room shall be monitored. Past experience has shown that these work positions shall be checked daily, or more often, and during periods of most activity.

6. PREPARATION OF APPARATUS

a. Prior to sampling, dirt and dust shall be removed from the filter holder by washing it in a free-rinsing detergent: ketone-free isopropyl alcohol and reagent grade petroleum ether (30-60°C boiling range).

b. All laboratory equipment and area used for counting and sizing airborne particulate shall be maintained in a condition of cleanliness paralleling or superior to the area sampled.

c. Personnel performing sizing and counting operations shall be equipped with garments consistent with good practice.

d. Microscope slides and Petri dishes shall be cleaned and prepared before samples are taken. Wiping with lens tissue or rinsing with 0.3 μm filtered cleaning fluids is satisfactory for this purpose.

e. Hazardous chemicals employed in the method shall be handled with recognized precautions.

f. A background particle count shall be made of each membrane filter that is to be used in the certification of a clean room facility. Examination at 40 to 50X through bench or stereo microscope will reveal low or high background count.

g. For routine work, an average background count requirement may be satisfied by sampling 4 filters per box of 100. However, if the background count of the samples is approximately 10 percent of the particle limit or greater, each individual filter shall have a background count established. This background count shall be subtracted from the sample count.

NOTE: If the background count is estimated to be greater than 10 percent of the total particle count from a 10 ft^3 specimen, a larger sample (15 or 20 ft^3 volume) may be used.

h. Acceptable filters shall be stored in clean Petri dishes labeled with background particle count.

7. PROCEDURE

a. With clean unserrated forceps, carefully remove membrane filter from Petri dish and place, with grid side up, on screen support of filter holder. Twist locking ring in place to secure filter.

b. Connect the assembly to a vacuum source that will cause at least 10 L/min airflow to occur.

NOTE: For mildly contaminated areas, a flowmeter with a 28 liters/min capacity may prove more satisfactory for taking a larger sample in less time.

c. When in the sampling area, place the filter holder in a horizontal position, filter surface vertical, 36 to 40 inches from floor level for purposes of sampling. Apply vacuum and adjust flow to 10 L/min or other desired flow. A standard vacuum gauge will not suffice for maintaining correct flow. Either a rotometer (flowmeter) or limiting orifice with manometer is required. When using an orifice, no adjustment is necessary. However, the pump should be checked with a manometer to assure its ability to maintain a vacuum of 500 torr or better while sampling.

d. The filter shall be removed from the holder with forceps and placed on a clean glass slide in preparation for particle counting. If the filter cannot be counted immediately, it shall be placed in a clean Petri dish for transport to the microscope counting area.

e. MICROSCOPIC ANALYSIS PROCEDURE:

(1) Place the ocular micrometer in one eyepiece. Using a stage micrometer, calibrate the measuring eyepiece (ocular micrometer) for each magnification.

(2) Place the microscope slide or Petri dish containing the filter under the microscope. The Petri dish cover must be removed.

(3) Adjust the microscope lamp intensity and direct it on the specimen from an oblique position to obtain maximum definition for sizing and counting. High intensity illumination is a critical requirement. The light beam's angle is very significant for defining different types of contamination.

(4) A magnification of approximately 100X will be required for counting particles 5.0 µm and larger. Greater magnification may be advantageous for identification of particles.

(5) Particles shall be counted and tabulated in three size ranges:

- All particles between 5 to 15 µm.
- All particles between 15 to 25 µm.
- All particles greater than 25 µm
- Number of fibers

NOTE: Fibers are counted as particles. Fibers shall be included in their particle size range for computing particles per cubic foot. Particles smaller than 5.0 µm shall not be counted by this method. The size of a particle is determined by its greatest projected dimension.

f. METHOD OF COUNTING PARTICLES

(1) Adjust microscope's focus and lamp position and angle so that maximum clarity of the filter surface and particle definition is obtained.

(2) The largest projected dimension of a particle determines its size.

(3) Count 10 grid squares or unit areas within the shaded area as indicated use the counting plan of Figure 12.

(4) If the total number of particles in each size range does not equal or exceed 50 after counting 10 squares or unit areas, count additional squares or unit areas until the following statistical requirement is met: $F_N \times N_T > 500$, where N_T is the total number of particles counted in F_N areas. If this requirement is not met for all size ranges after counting 50 areas, or 50 percent of the total effective filtering area, it will be necessary to increase the sample volume. Extreme caution must be used when examining filters because there is no visual evidence of effective area boundaries.

NOTE: The equation $F_N \times N_T > 500$ shall be met for each size range. It may, thereafter, be necessary to tabulate the three separate ranges (5 to 15 µm, 15 to 25 µm and > 25 µm) in the first 10 areas to satisfy the equation for each range, and then count only the particles greater than 25 µm in additional areas to get valid results for the third range.

A lower magnification may be used to count the particles greater than 25 µm, but this is not recommended.

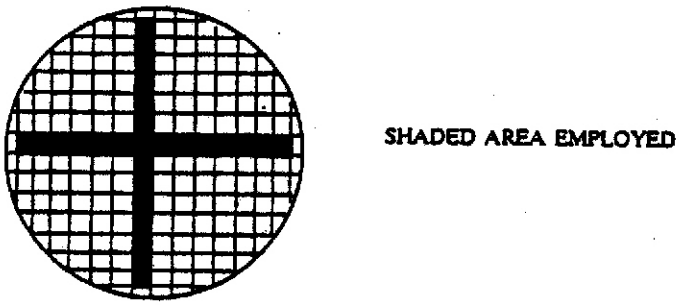

Figure 12: Double Diameter Counting Plan

(5) To obtain the total number of particles, 10 or more grid squares or unit areas on the filter disc shall be counted. From this count, the total number of particles that would be present on the total effective filtration area of grid squares is calculated.

(6) Unit areas for counting shall be selected so that the average total number of particles in a unit area does not exceed 50 to 60 particles. See Figure 13 for alternate unit areas.

(7) If a particle lies on the upper or left boundary line of a counting area, count that particle as if it were within the counting area.

(8) Start and finish a selected grid square or unit area sizing by counting from the left edge of a grid line, scanning exactly 1 grid square width as the operation continues from left to right. Optional unit areas are:

(a) A grid square.

(b) A rectangle defined by the width of a grid square and by the calibrated length of the ocular micrometer scale.

(c) A unit defined by the width of a grid square and a portion of the length of the ocular micrometer scale.

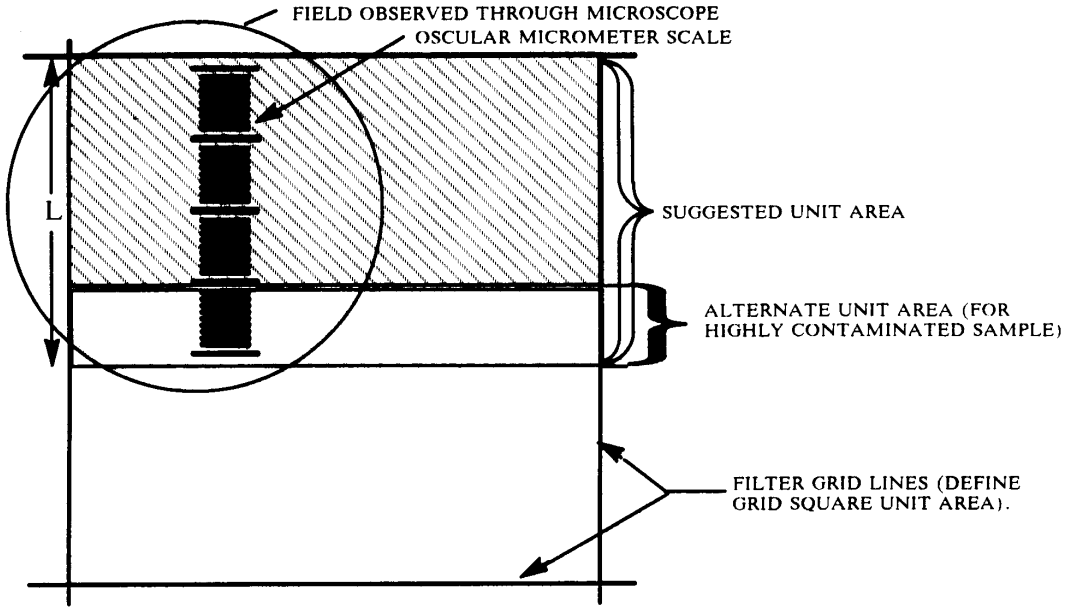

Figure 13: Alternate Unit Areas

(9) Scan a unit area for particles by manipulating the stage so that particles to be counted pass under the ocular micrometer scale. Only the maximum dimension of a particle is regarded as significant, and for particles improperly oriented relative to the ocular micrometer scale, an estimate of its maximum dimension is made. The ocular micrometer eyepiece should not be rotated to size specific particles. Using a manual counter, count all particles in the selected areas which are in the 5.0 µm and larger as indicated by the ocular micrometer scale. Record the number of particles of each size range in each unit area counted, to meet requirements of Appendix I, Section 7.f.(6).

8. CALCULATIONS

Calculate the total number of particles in a given size range on the filter, in accordance with the formula:

$$P_T = N_T \times \frac{E}{N \times A_F}$$

WHERE:

P_T is the total number of particles of a size range on the filter.

N_T is the total number of particles counted in N unit areas.

N is the number of unit areas counted.

E is the effective total filter area in mm^2.

A_F is the unit area in mm^2.

Results should be expressed for each size range in particles per cubic foot of sample by dividing the P_T by the sample size (10 ft^3 standard):

$$P/ft^3 = \frac{P_T}{10}$$

Final results are in particles per ft^3 of sampled atmosphere, separated into size ranges.

9. PRECISION AND ACCURACY

a. The precision and accuracy of this method can be no higher than the sum total of variables. In order to minimize variables attributable to an operator, a trained microscopist technician is required. Variables in equipment are recognized by the experienced operator, thus further reducing possible error.

b. A periodic check of the microscopist with a check-slide* shall be accomplished by individual laboratories to obtain quality results.

* A commercially available pre-counted membrane filter mounted in a glass slide.

c. For training personnel, low to medium concentration specimens may be prepared on a grid filter and preserved between micro slides as standard for a given laboratory.

d. This method can be adapted for projection microscopic analysis by the use of white filter, transmitted light, and a properly marked projection screen. However, projection techniques should be checked against a direct microscope count because the optics of projection equipment are sometimes inadequate for resolution of small particles.

APPENDIX II

MANUAL MONITORING PROCEDURE (COUNTING PARTICULATE CONTAMINANTS ON CLEAN ROOM GARMENTS)

1. SCOPE

This method is used for determining detachable particulate contaminant 5 µm or larger, in and on the fabric of clean room garments. It may also be used to determine whether a fabric exhibits limited linting characteristics. The greatest number of particles allowed is 2000/ft^2 of garment.

2. SUMMARY OF METHOD

Filtered air is drawn through five designated 0.01 ft^2 areas of single thickness of the garment fabric at a rate of 14 L/min for one minute per area. Air drawn through the garment subsequently passes through a membrane filter disk, impinging entrained particles upon its surface. The filter disk is then examined microscopically to determine numbers of particles larger than 5 µm.

3. DEFINITIONS

a. The major projected dimension of a particle is designated as its size.

b. The standard unit of length for sizing purposes is a µm, which is 0.001 mm or 0.00004 inches.

c. Only particles with a measurable length greater than 5.0 µm shall be counted.

d. Fibers are particles longer than 100 µm with length to width ratios exceeding 10 to 1.

4. APPARATUS

a. Filter assembly and adapter.

b. Vacuum pump or aspirator capable of producing a vacuum of 500 torr.

c. Flowmeter or orifice having a capacity of 14 liters per minute.

d. Membrane filters (black, blue, or green), 0.80 µm pore size, 47 mm diameter with 3.08 mm imprinted grid (for fabric particles), and white, 5.0 µm pore size, 47 mm diameter (air pre-filter).

e. Microscope and counting apparatus (refer to Appendix I).

5. SAMPLING REQUIREMENTS

a. Samples shall be collected by drawing 5 µm filtered air through test garments, impinging garment-borne particles on membrane filters. A gridded filter mounted in an open-type aerosol filter holder shall be placed on the outer surface of a garment to be tested. Test garments shall be firmly clamped to the filter holder by means of its air filter adapter. During sampling, garments shall be hung or carefully positioned to minimize extraneous contamination.

b. A standard sample for this method will have been acquired with the passage of 14 liters of air through the test fabric during a 1 minute period at each of five sampling areas as shown in Figure 14. One sampling area is adequate for caps, helmets, towels, wipers, and booties with plastic soles. Two sampling areas are suggested for all-fabric booties.

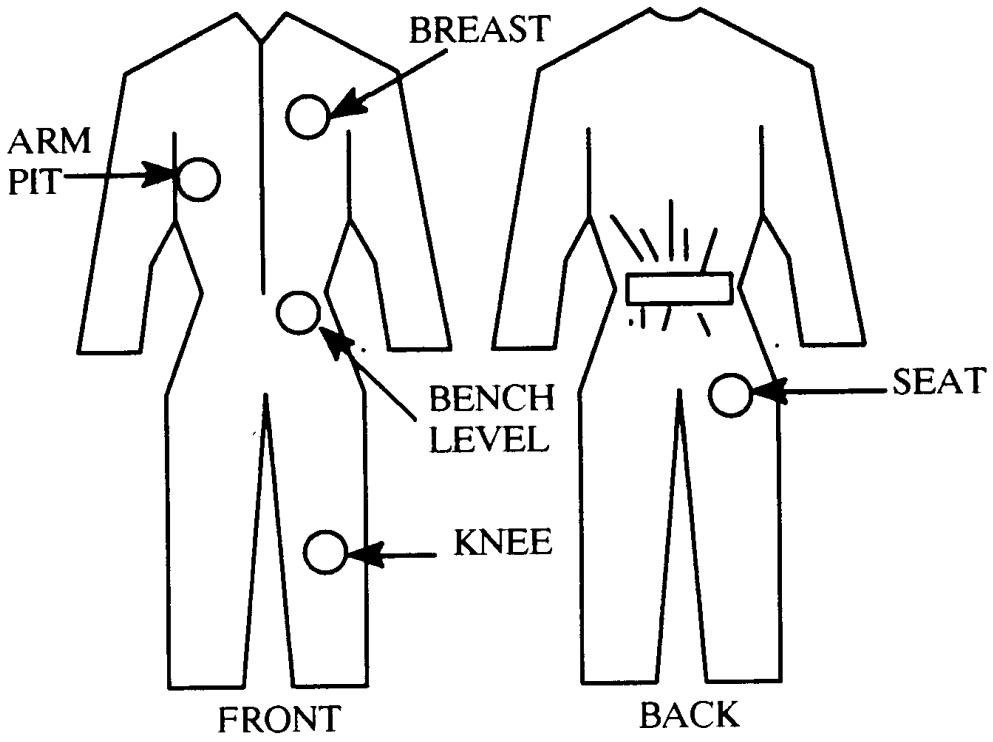

Figure 14: Clean Room Garment Sampling Locations

c. Locations are approximate and may, by agreement, be modified to suit a specific design factor.

6. PREPARATION OF APPARATUS

a. Prior to sampling, dirt and dust shall be removed from filter holders by washing them in a free-rinsing detergent: ketone-free isopropyl alcohol and reagent grade petroleum ether (30-60°C boiling range).

b. Laboratory equipment and areas used for counting and sizing airborne particulate shall be maintained in a condition of cleanliness paralleling or superior to that of the area sampled.

c. Personnel performing sizing and counting operations shall be equipped with garments consistent with conventional clean room procedures.

d. Microscope slides and Petri dishes shall be cleaned and prepared before samples are taken. Wiping with lens tissue or rinsing with 0.3 μm filtered cleaning fluids is satisfactory for that purpose.

e. Hazardous chemicals employed in this procedure shall be handled with proper precautions.

f. A background particle count shall be made of each membrane filter that is to be used in the certification of each clean room facility. Examination at 40 to 50X through bench or stereo microscope will reveal low or high background counts.

g. For routine work, an average background particle count may be obtained and used by counting 4 filters per box of 100. However, if the background count approximates 10 percent or greater of the sample count, each individual filter should have a background count established. This background count shall be subtracted from the sample count.

NOTE: If the background count is estimated to be greater than 10 percent of the total count from a 10 ft^3 specimen, a larger sample (15 to 20 ft^3 volume) may be used.

h. Acceptable filters shall be placed in clean, identified, covered Petri dishes for later use.

7. SAMPLING PROCEDURE

a. With the aid of laboratory pressure tubing, connect filter holders to a source of vacuum verified adequate to produce a flow rate of 14 L/min, at vacuum conditions of test (350 torr). Filter holder may be open, may contain a flow-limiting orifice, or may be connected to flowmeter. If flowmeters are used between filter holders and vacuum sources, corrections to standard temperature and pressure shall be made.

b. With clean forceps, carefully remove a 0.8 μm, dark background, membrane filter from its container and place it, with grid side up, on the filter holder screen support. Twist the

locking ring in place after placing the tapered adapter in position. Similarly, place a 5.0 µm air filter in top portion of adapter by removing "O" ring. (This filter may be used for many tests.)

c. When ready to sample, place the outer surface of a test garment over the tapered (male) adapter. Firmly lock it into test position by placing air filter tapered (female) adapter over test portion of fabric.

d. Apply vacuum at predetermined 14 L/min flow rate for a period of one minute on each garment area. Sample required areas (Figure 14) by repeating preceding paragraph c.

e. Remove the filter from the holder with forceps and place it between clean microscope slides or in a clean Petri dish and cover it for transport to the microscope counting area.

f. The garment to be tested shall be sampled in an area having a contamination level less than that of a conventional clean room. The sample (garment) should not be removed from its sealed plastic package until the test is ready to be performed. Care must be taken to ensure that limited sample handling occurs after its removal from the sealed bag. All sampling apparatus shall be thoroughly cleaned before this analysis is performed.

8. MICROSCOPE ANALYSIS PROCEDURE

a. Calibration of Ocular Micrometer Scale: Using a stage micrometer, determine the µm spacing of its ocular micrometer scale. Using a 10X eyepiece and 10X objective, its minor divisions (100 in scale) should equal approximately five µm.

b. Remove a filter from its Petri dish and place it, with filtering surface up, on a 2 by 3 inch microscope slide. Greasing the slide lightly with silicone stop-cock lubricant, prior to filter mounting, will assist in holding it flat in place.

c. Adjust an external light source to obtain maximum particle definition, with an illumination angle of approximately 45°.

d. By means of the mechanical stage, scan individual grid squares. With a gating technique, count and tabulate particles in two categories:

(1) Particles with major dimension greater than 5 µm. (Particles smaller than 5 µm shall not be counted by this method).

(2) Fibers (see Definitions, Section 3.d).

e. Count particles in a number of grid squares selected at random until the statistical requirements below are met: $F_N \times N_T > 500$, where F_N is the number of grid squares counted, and N_T is the total number of particles counted in F_N squares.

f. A background shall could be run on a new filter from that same box from which the sample filter was obtained. This background count shall be subtracted from the sample count. For best results, the exact filter used for testing purposes shall have its background count established. If its background count is 10 percent of the estimated sample count, a larger sample volume shall be established.

9. CALCULATIONS

a. To calculate the total number of particles > 5 µm and fibers on the filter, multiply the count of each category by $100/F_N$, where F_N is the number of grid squares counted. (There are 100 effective grid squares on filter). To compute a number of particles per square foot of garment fabric, multiply the total filter count obtained above by 20, providing that five areas of garment were sampled. (Let the total number of areas sampled be $F_{A.}$)

NOTE: Each garment sample area is 1/100 ft^2. Five sampling areas provide a garment sample of 1/20 ft^2.

b. Report results in terms of total particles per square foot in the two categories:

(1) Particles > 5 µm.

(2) Fibers.

These represent the particles and fibers, per square foot of fabric, removed from representative areas of a garment.

10. FACTORS AFFECTING PRECISION AND ACCURACY

a. The precision and accuracy of this method can be no higher than the sum total of its variables. In order to minimize those variables attributable to an operator, a trained microscopist is required. Variables in equipment shall be recognized by an experienced microscopist, thus further reducing possible error.

b. For training personnel, low to medium concentration specimens may be prepared on a grid filter and preserved between microscope slides as standards for a given laboratory. Standard specimens are also commercially available.

11. EXAMPLE

Sixty 5.0 µm and larger particles were collected on 30 grid squares when five 0.01 ft^2 areas were sampled on a clean room garment.

F_N = 30 grid squares
N_T = 60 particles
F_A = 5 areas sampled

F_N x N_T = 30 x 60 = 1800 > 500

Total particles x 100/F_N x 1.00/F_A x .01 = particles/ft^2

60 x 100/30 x 1.00/(5)(.01) = 6,000/1.5 = 4,000 particles/ft^2

APPENDIX III

FLOW BENCH GENERAL OPERATING PROCEDURES

NOTE: For detailed instructions, requirements, and definitions refer to MPR 5340.1 and MSFC-STD-246. Users of established clean areas shall be familiar and in compliance with these documents. Flow bench custodian's name and contact information shall be conspicuously posted on or near flow bench.

1. Verify bench certification card is current and bench meets cleanliness requirements.
2. Verify airflow and lighting meet requirements. The bench shall be on at least 10 minutes before operations commence. Ideally, bench should run 24 hours/day.
3. Remove all unnecessary items from bench top.
4. Take all reasonable steps to adequately clean items to be used in bench before placing them in the clean environment.
5. Never use hazardous solvents while working in flow bench. Use a fume hood for harmful vapors.
6. Always wear appropriate protective gear (gloves, smock, cap, etc.) when working inside clean environment.
7. Always work downstream of items in clean air flow and minimize hand movement over items.
8. Never lean over items in clean area.
9. If necessary for operations, use only high purity, filtered gases.
10. Replace gloves if they are removed from clean environment or come in contact with exposed skin.
11. Never place paper or paper products in clean bench environment.
12. Use caution when selecting and using materials within flow bench. Avoid using any materials that may be a potential source of contamination.
13. Move slowly and keep movement to a minimum.
14. Periodically check and replace, as necessary, air system pre-filters. Turn blower motor off before replacement of pre-filters.

Table 1: Environmental Standards (Guidelines for Clean Room Classes), page 1

	PARTICLE COUNT (0.5 µm and larger per ft^3 of air)	PARTICLE MONITORING Equipment Requirements	AIR CONDITIONING Systems shall be run continuously.	AIR FILTRATION For entire facility
Class 300,000 Controlled Area	300,000 1,200 for ≥5.0 µm when using manual method	Continuous monitoring by automatic particle counter during critical operations. CCE shall check. MP&M shall sample at least weekly.	Max. Temperature: 80°F Max. Humidity: 60% Min. Humidity: 30%	Stage #1: Rough filter, 50-60% efficient (NBS). Stage #2: Medium efficiency filter, 80-85% efficiency for ≥1.0 µm particles (NBS).
Class 100,000 Clean Work Area	100,000 700 for ≥5.0 µm when using manual method	Continuous monitoring by automatic particle counter during critical operations. CCE shall check. MP&M shall sample at least weekly.	Max. Temperature: 80°F Max. Humidity: 55% Min. Humidity: 30%	Stage #1 and Stage #2 same as Class 300,000. Stage #3: HEPA filter, 99.97% efficient for removing ≥1.0 µm particles per MIL-F-51068. Non DOP tested.
Class 100,000 Clean Room	100,000 700 for ≥5.0 µm when using manual method	Continuous monitoring by automatic particle counter. CCE shall check. MP&M shall sample at least weekly.	Temperature: 72±5°F Humidity: 45±5%	Stage #1 and Stage #2 same as Class 300,000. Stage #3: HEPA filter, 99.97% efficient for removing ≥1.0 µm particles per MIL-F-51068. Non DOP tested.
Class 10,000 Clean Room	10,000	Continuous monitoring by automatic particle counter. CCE shall check. MP&M shall sample at least weekly.	Temperature: 72±5°F Humidity: 45±5%	Stage #1 and Stage #2 same as Class 300,000. Stage #3: HEPA filter, 99.97% efficient for removing ≥1.0 µm particles per MIL-F-51068. Non DOP tested.
Class 1,000 Clean Room	1,000	Continuous monitoring by automatic particle counter. CCE shall check. MP&M shall sample at least weekly.	Temperature: 72±5°F Humidity: 45±5%	Stage #1 and Stage #2 same as Class 300,000. Stage #3: HEPA filter, 99.97% efficient for removing ≥1.0 µm particles per MIL-F-51068. Non DOP tested.
Class 100 Facility	100 or less	Continuous monitoring by automatic particle counter. CCE shall check. MP&M shall sample at least weekly. Flow benches shall be sampled at least every month	Temperature: 72±5°F Humidity: 45±5%	Stage #1 and Stage #2 same as Class 300,000. Stage #3: HEPA filter, 99.97% efficient for removing ≥1.0 µm particles per MIL-F-51068. Non DOP tested.

Table 1: Environmental Standards (Guidelines for Clean Room Classes), page 2

	PRESSURE DIFFERENTIAL Highest pressure within cleanest area.	AIR FLOW Air changes per hour or velocity	ENVIRONMENTAL CONTROLS Temperature & Humidity	ENVIRONMENTAL MONITORING Temperature, humidity, pressure and air velocity
Class 300,000 Controlled Area	Positive pressure to eliminate or minimize infiltration of contaminated outside air.	Minimum of 2 air changes per hour.	Temperature and humidity controls located within the facility, and no manual control within the facility.	Continuous monitoring of temp. and humidity required. Temp, humidity and pressure shall be recorded weekly. Air velocity shall be recorded monthly.
Class 100,000 Clean Work Area	Positive pressure (minimum of 0.02 inches of water) between clean area and the outside atmosphere.	Minimum of 4 air changes per hour.	Temperature and humidity controls located within the facility, and no manual control within the facility.	Continuous monitoring of temp. and humidity required. Temp, humidity and pressure shall be recorded weekly. Air velocity shall be recorded monthly.
Class 100,000 Clean Room	Positive pressure (minimum of 0.05 inches of water) between clean area and the outside atmosphere.	Minimum of 15 air changes per hour.	Temperature and humidity controls located within the facility, and no manual control within the facility.	Continuous monitoring of temp. and humidity required. Temp, humidity and pressure shall be recorded weekly. Air velocity shall be recorded monthly.
Class 10,000 Clean Room	Positive pressure (minimum of 0.05 inches of water) between clean area and the outside atmosphere.	Minimum of 20 air changes per hour. For laminar flow room, filter face velocity of 100 ft/min not to drop below 75 ft/min or vary more than 20 ft/min throughout facility.	Temperature and humidity controls located within the facility, and no manual control within the facility.	Continuous monitoring of temp. and humidity required. Temp, humidity and pressure shall be recorded daily. Air velocity shall be recorded monthly.
Class 1,000 Clean Room	Positive pressure (minimum of 0.05 inches of water) between clean area and the outside atmosphere.	Minimum of 20 air changes per hour. For laminar flow room, filter face velocity of 100 ft/min not to drop below 75 ft/min or vary more than 20 ft/min throughout facility.	Temperature and humidity controls located within the facility, and no manual control within the facility.	Continuous monitoring of temp. and humidity required. Temp, humidity and pressure shall be recorded daily. Air velocity shall be recorded monthly.
Class 100 Facility	Positive pressure (minimum of 0.05 inches of water) between clean area and the outside atmosphere. Not applicable to flow benches.	Minimum of 20 air changes per hour. For laminar flow facility, filter face velocity of 100 ft/min not to drop below 75 ft/min or vary more than 20 ft/min throughout facility.	Temperature and humidity controls located within the facility, and no manual control within the facility. Flow benches are controlled by the room where the bench is located	Continuous monitoring of temp. and humidity required. Temp, humidity and pressure shall be recorded daily. Air velocity shall be recorded monthly. Pressure N/A for flow benches.

Table 1: Environmental Standards (Guidelines for Clean Room Classes), page 3

	GARMENT REQUIREMENTS	SHOE CLEANERS	AIR SHOWER For personnel entry	EQUIPMENT AIR LOCKS Temporary air locks fabricated from approved materials is acceptable.
Class 300,000 Controlled Area	Not required. If garments are used, they shall be changed once per week.	Tacky mats at all entrances.	Not required.	Desirable, but not required.
Class 100,000 Clean Work Area	Not required, but recommend smock and cap as minimum unless operations dictate more strict requirements. Change once per week.	Vacuum shoe cleaners (brushes) recommended at all entrances to work area. Tacky mats at all entrances.	Not required, but desired.	Desirable, but not required.
Class 100,000 Clean Room	Smock or coveralls, cap/hood required; booties (optional), additional clothing as required. Change every 5 days.	Vacuum shoe cleaners (brushes) required at all entrances to clean room. Tacky mats at all entrances.	Required.	Air locks are required at all entrances and exits (except emergency). One shall be large enough to clean end items within air lock before entry into clean room.
Class 10,000 Clean Room	Coveralls, hood & booties required, and additional clothing as needed. Change every 3 days.	Vacuum shoe cleaners (brushes) required at all entrances to clean room. Tacky mats at all entrances.	Required.	Air locks are required at all entrances and exits (except emergency). One shall be large enough to clean end items within air lock before entry into clean room.
Class 1,000 Clean Room	Coveralls, hood, booties & gloves required and additional clothing as needed. Change every other day.	Vacuum shoe cleaners (brushes) required at all entrances to clean room. Tacky mats at all entrances.	Required.	Air locks are required at all entrances and exits (except emergency). One shall be large enough to clean end items within air lock before entry into clean room.
Class 100 Facility	Coveralls, hood, booties, gloves and additional clothing as needed. Change every day. For flow benches, smock, cap and gloves as required.	Vacuum shoe cleaners (brushes) required at all entrances to clean room. Tacky mats at all entrances. N/A for flow benches.	Required.	Air locks are required at all entrances and exits (except emergency). One shall be large enough to clean end items within air lock before entry into clean room. N/A for flow benches.

Table 1: Environmental Standards (Guidelines for Clean Room Classes), page 4

	VACUUM CLEANING SYSTEM	COMMUNICATIONS SYSTEM	CONTAMINATING OPERATIONS	CLEANING SCHEDULE
Class 300,000 Controlled Area	Central vacuum system or portable vacuum cleaner with HEPA filter on output available at workstations.	Not required, but desired.	Exhaust as required to maintain room integrity.	Floors: weekly Walls: As required Ceilings: As required Structures: As required GSE: As required
Class 100,000 Clean Work Area	Central vacuum system or portable vacuum cleaner with HEPA filter on output available at workstations.	A two-way communication system shall be installed between the controlled area and outside area in convenient locations as required.	Exhaust as required to maintain room integrity.	Floors: weekly Walls: As required Ceilings: As required Structures: As required GSE: Monthly
Class 100,000 Clean Room	Central vacuum system or portable vacuum cleaner with HEPA filter on output available at workstations, air locks and pass-throughs.	A central communications system shall be installed for addressing personnel within clean room. A two-way system shall be installed at convenient locations.	Exhaust as required to maintain room integrity or use reverse flow bench.	Floors: Twice weekly Walls: As required Ceilings: As required Structures: Monthly GSE: Monthly
Class 10,000 Clean Room	Central vacuum system or portable vacuum cleaner with HEPA filter on output available at workstations, air locks and pass-throughs.	A central communications system shall be installed for addressing personnel within clean room. A two-way system shall be installed at convenient locations.	Use reverse flow workstation.	Floors: Daily Walls: Weekly Ceilings: As required Structures: Monthly GSE: Weekly
Class 1,000 Clean Room	Central vacuum system available at workstations, air locks and pass-throughs.	A central communications system shall be installed for addressing personnel within clean room. A two-way system shall be installed at convenient locations.	Use reverse flow workstation.	Floors: Daily Walls: Weekly Ceilings: As required Structures: Weekly GSE: Weekly
Class 100 Facility	Central vacuum system available at workstations, air locks and pass-throughs. Portable vacuum with HEPA filter on output for flow benches.	A central communications system shall be installed for addressing personnel within clean room. A two-way system shall be installed at convenient locations. N/A for flow benches.	Not allowed.	Floors: Daily Walls: Weekly Ceilings: Monthly Structures: Weekly GSE: Daily Flow benches: As Required

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