

A person in a white cleanroom suit is adjusting their goggles in a cleanroom setting. The person is standing on a metal grate floor, and there are metal benches in the background. The cleanroom has a white ceiling with recessed lighting and a white wall with a door and a window. The text "Prudential Cleanroom Services®" is overlaid on the image in a blue and orange font.

# *Prudential Cleanroom Services®*

**CLEANROOM LAUNDRY SERVICES**  
**ISO 9001 CERTIFIED QUALITY MANAGEMENT SYSTEM**

*COMPLETE REUSABLE GARMENT - MOP - GOGGLE RENTAL PROGRAMS*

A Division of Prudential Overall Supply

# PRUDENTIAL CLEANROOM SERVICES

## PCS REUSABLE CLEANROOM LAUNDRY SERVICES GARMENTS - MOPS - GOGGLES

**Prudential  
Cleanroom  
Services®**

### WE ARE DEDICATED TO CRITICAL ENVIRONMENTS

Since 1960, Prudential Cleanroom Services (PCS) has provided cleanroom apparel services.

From these beginnings, Prudential has developed into an internationally recognized source for bio-science, pharmaceutical, medical device, semi-conductor, aerospace, and other companies manufacturing and operating in controlled environments.

PCS specializes in cleanroom garment processing services for aseptic, particulate & ESD controlled environments. All PCS plants fold, package and hermetically seal each finished item in an ISO Class 3 cleanroom.

PCS remains committed to satisfying our customers' evolving requirements throughout North America and Puerto Rico.

TO LEARN MORE:

[www.PrudentialUniforms.com/services/cleanroom/](http://www.PrudentialUniforms.com/services/cleanroom/)





John Clark, CEO  
Third Generation

Dan Clark, COB  
Second Generation

## OUR MISSION

Prudential Overall Supply is committed to excellence in:

1. Delivering quality service and products that meet or exceed customer requirements and earn customer satisfaction.
2. Developing all team members to achieve their full potential.
3. Providing a safe, clean and efficient work environment.
4. Conducting all business relationships with integrity.

*As we accomplish this, we will grow, retain our customers and prosper.*



# The Prudential Advantage

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# ABOUT PRUDENTIAL CLEANROOM SERVICES



## TRUSTED BY LEADERS AS THEIR FIRST CHOICE!

Since 1960 Prudential Cleanroom Services has remained first in Cleanroom Laundry Processing Services for critically controlled environments.



### BUILDING RELATIONSHIPS

- Prudential people work with your teams to develop and modify your unique requirements throughout your business process cycles. Many Prudential customer relationships span decades.



### ACCOUNTABILITY

- Exclusive Validated Garment Tracking System (GTS) RFID/Barcode Technology
- RFID/Barcode Technology: Our Validated GTS RFID/Barcode Technology was developed in coordination with our customers. Our ongoing evaluation of this system, and the consistent input from its users ensures the GTS RFID/Barcode Tracking System represents the latest technology.
- GTS RFID/Barcode Tracking System provides our customers with a complete account history report for each garment from installation to any repairs. It also tracks usage analysis by RFID/Barcode unique tracking number, department and distribution point.



### COMMITMENT TO THE CONTAMINATION CONTROL INDUSTRY

- Committed to IEST standards' development and participation, cleanroom laundry processing technology advances and innovative service offerings.
- Prudential is also invested in the success of technology companies. This is our business and not a small division like some other industry operators.



### EXPERIENCE

- Prudential has provided uninterrupted cleanroom laundry service to our customers.
- Prudential customers have NEVER experienced a cleanroom plant production service failure.
- Prudential's service team is the most experienced in the industry since 1960.



### STERILITY ASSURANCE

- Provides sterilized cleanroom garments, mops and goggles to customers with aseptic environments.
- Ensures the sterility of its products through strict compliance to cGMPs and through validation of the sterilization process in accordance with current ANSI/AAMI/ISO11137 guidelines to a SAL of 10<sup>-6</sup>.



### CAPACITY & CAPABILITIES

- Unmatched National network of direct service cleanroom laundry service facilities.
- This network represents the largest domestic throughput and capacity capabilities.
- All of Prudential's domestic cleanroom laundry processing facilities have a ISO 9001 certified Quality Management System.
- All are strategically located to augment each other in the event of a catastrophic event



## AVAILABILITY

- The high-quality services Prudential delivers each week are thanks in part to our one-of-a-kind Distribution Center. It is the heart of our operations that ensures we remain the leading uniform service, cleanroom and facility services provider in North America.
- Our Distribution Center processes millions of garments annually. Our Distribution team of dedicated employees can easily fulfill garment order requirements. The team also applies name tags, company emblems, direct embroidery, and RFID/barcodes as required by each customer's specific order.
- We offer centralized stock for industrial and cleanroom garment customers. Our Distribution Center receives and processes new customer garment orders as well as reusable garment orders for all existing client requirements.

### CUSTOMER BENEFITS:

- Centralized inventory for quick replacements upgrades and new accounts
- Stock garments, comprised of industry recognized fabrics, allow for quick installation.
- This helps to eliminate the long lead times that are common from cleanroom garment manufacturers.
- Wide variety of sizes and industry accepted styles will be stocked.
- Prudential Cleanroom Services' automatic ordering level quickens the fulfillment cycle, and ensures complete and timely deliveries.



## ENVIRONMENTALLY FRIENDLY

- Prudential has demonstrated a commitment to the environment with our TRSA Clean Green certification.
- Based on a Life Cycle Assessment (LCA) comparing reusable cleanroom apparel to disposable alternatives demonstrated:
  - 23-57% reduction in natural resource energy and CO<sup>2</sup> emissions
  - 77% reduction in 'blue water'
  - 96% reduction in solid waste
  - 47% cost reduction on average
  - Estimated U.S. cost savings of \$100 million per year for the cleanroom manufacturers bottom line!

**OUR TEAM IS  
DEDICATED TO  
CREATING THE BEST  
CLEANROOM  
LAUNDRY  
SERVICE PROGRAM  
FOR YOU.**



# INVENTORY MANAGEMENT

## GARMENT TRACKING SYSTEM (GTS)

Ensures correct inventory levels and cost containment

Prudential Cleanroom Services' validated GTS RFID/Barcode Tracking System was developed in coordination with our customers. Our ongoing evaluation of this system, and the consistent input from its users ensures the GTS RFID/Barcode Tracking System represents the latest technology.

GTS RFID/Barcode Tracking System provides our customers with a complete account history report for each garment from installation to any repairs. It also tracks usage analysis by wearer, department and distribution point.

- Improves garment inventory allocation
- Enhances efficiencies
- Real-time reporting
- Excel compatible reports
- Reduces costs
- Developed in coordination with our customers
- Utilizes the latest technology
- Provides our customer with a complete account history report for each garment
- Tracks usage analysis by department and distribution point



## ACCURATE GARMENT INVENTORY CONTROL BY DEPARTMENT

If garments are used in a different location other than where they were assigned, they will be delivered to the correct location once processed by PCS. Our GTS system ensures this process.

## BENEFITS OF RFID:

- Efficient and Instant Inventory Tracking
- Accurate and Sustainable Technology
- Greater Visibility on Merchandise Location
- Allows for more Data collection
- Multiple readings without line of sight
- Improves accuracy throughout the process
- Improves Customer Satisfaction

*"Prudential's technological innovation will continue to set us apart from our competition. RFID is the most modern method of uniform tracking, giving our customers far superior insight into the location of uniforms and history of use."*

*John Clark*  
Chief Executive Officer

## CLEANROOM IT CAPABILITIES

### CUSTOMER PORTAL:

Enhances our communication between our customers and service team.

- **ABS ROUTE ASSIST DEVICE:**  
The device captures service requests and downloads requests into Prudential's account management system.
- NetSuite's Customer Relationship Management (CRM) software is the only cloud solution offering a real-time, holistic customer view across the entire customer life cycle—from lead generation through opportunity, sales, fulfillment, renewal, cross-sell and support.
- Enterprise resource planning (ERP) is a type of software system that helps organizations automate and manage core business processes for optimal performance.

## GTS IDENTIFIES

- Customer name
- Type of fabric
- Date installed
- Style of garment
- Size of garment
- History of garment

## GTS REPORTS

- Account inventory average usage
- Soiled count pick up
- Wash count reports
- Detailed packing slip
- Inventory activity summary
- Cancel log
- Repair log by date summary
- Missing items by last process date



ORACLE NETSUITE

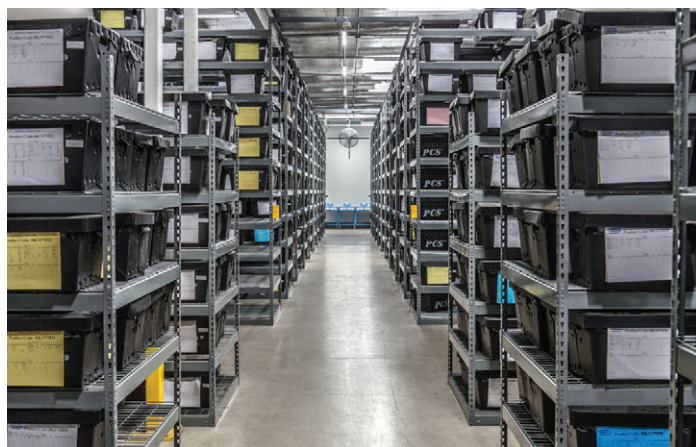
## STOCK GARMENT PROGRAM

Our STOCK program provides a service that is unique to the industry. The high-quality services Prudential delivers each week are thanks in part to our one-of-a-kind distribution center. It is the heart of our operations that ensures we remain the leading uniform service, cleanroom and facility services provider in North America.

We offer centralized stock for industrial and cleanroom garment customers. Our facility team receives and processes new garment customer programs, as well as reusable garment modifications for all existing client requirements and requests.

The STOCK garment program utilizes industry recognized fabrics that allow for quick installations. Thus, eliminating long lead times that are common from cleanroom garment manufacturers. A wide variety of sizes and industry accepted styles will be STOCKED for industry specific requirements.

Prudential Cleanroom Services' automatic ordering level quickens the reaction time to our customers' needs and ensures a complete and timely delivery.



## ADVACARE DISINFECTANT WASH FORMULA

Prudential wash formulas utilize AdvaCare disinfectant that meets EPA registration guidelines for requirements for disinfection. AdvaCare disinfectant utilized at a disinfection level of 4 oz per hundred pounds of laundry, the formulation meets the EPA requirements for laundry disinfection (complete kill) for ten different microorganisms:

- Staphylococcus aureus
- Klebsiella pneumoniae
- Pseudomonas aeruginosa
- Methicillin-resistant Staphylococcus aureus (MRSA)
- Methicillin-resistant Staphylococcus aureus (CA-MRSA)
- Acinetobacter baumannii
- Listeria monocytogenes
- Escherichia coli O157:H7
- Salmonella enterica
- HIV-1 Virus

## STERILIZATION VALIDATION PROGRAM

The validation activities contained in our validation manual and subsequent reports are based on ANSI/AAMI/ISO 11137:2015 (Sterilization of Health Care Products - Radiation - Part 1 Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices). Please note: these items are not health care products and the report does not imply that they should be considered as such. This validation of the sterilization process includes a qualification of materials, equipment, and processes, and the study of naturally-occurring bioburden on the product to be sterilized. The validation is performed to ensure that the products meet PCS sterility requirements. The selection of the dose to achieve  $10^{-6}$  SAL was based on bioburden test results using an exhaustive recovery method, product weight and density. The sterility dose is confirmed quarterly by the performance of verification dose audits.



## PRUDENTIAL'S STERILIZATION VALIDATION SAL $10^{-6}$

Applies to reusable polyester cleanroom garments and ancillary items.

- Laundered and packaged at Prudential Cleanroom Services Plants
- Always in accordance with plant procedures
- Gamma irradiated using a Cobalt 60 Radio Nuclide source
- $10^{-6}$  SAL (Sterility Assurance Level)

## "The ZEN of Cleanroom Laundry."



改善 KAIZEN

## SUSTAINABLE GOWNING PROTOCOL

### REUSABLE VS. DISPOSABLE

Help drive sustainability programs by reducing consumable products (disposable coveralls, hoods, boots, masks, goggles, mops and sleeve covers) all items you throw away, and convert them to a reusable solution.

#### DISPOSABLE GARMENT AND RELATED SUPPLIES SAVING

Projected Annual Savings >47% when switching to reusable supplies.

#### PROCUREMENT SAVINGS

Time and overall cost reduction.

#### CAPITAL INVESTMENT SAVINGS

We stock it for you; unlike a disposable program, where you have to purchase and frequently manage inventories.

#### INVENTORY MANAGEMENT SAVINGS

Validated Garment Tracking System.

#### FREIGHT SAVINGS

PCS routed deliveries.

#### REDUCTION OF WASTE COST

Disposable garments and related supplies.



VISIT US:

**PRUDENTIALUNIFORMS.COM**

to learn more about green initiatives

# SUSTAINABLE GOWNING PROTOCOL

Surface View at 200X:



High Density ESD

vs.



Tyvek

Cross Section View at 200X:



High Density ESD

vs.



Tyvek

		Maxima ESD 4043-60	Tyvek
Weight	oz/yd <sup>2</sup>	2.53	1.21
Tensile Strength (lb)	warp	154	24
ASTM D5034	fill	93	20
Tongue Tear (lb)	warp	2.86	3.32
ASTM D2261	fill	1.76	2.14
Body Box - Study 1: Maxima ESD v. Tyvek	# particles ≥ 0.3µm	201	243
IEST-RP-CC003.3	% difference	Tyvek released 21% more particles than Maxima ESD	
Mean Pore Size (Pill porometer)			
ASTME1294	µm	4.56	2.07
Air Porosity (Comfort)	cfm/ft <sup>2</sup>	3.9	0.17
ASTM D737			
Suter Hydrostatic ISO 811 (Fluid Resist.)			
AATCC 127/ISO811 (cm/sec)	mm	850	4030
Spray Test			
AATCC 22		100	100
Moisture Vapor Transmission (Comfort)			
ASTME96 D	g/m <sup>2</sup> 24h	2047	1504
Surface Resistivity			
AATCC 76	ohms/unit <sup>2</sup>	1.28 x 10 <sup>8</sup>	(1) 3.35 x 10 <sup>8</sup>
Static Decay 5000 - 500 volts			
FTMS 4046-101C	secs	0.01	0.01
Flammability			
16 CFR 1610 Not NFPA 70E Compliant		Class 1	Class 1
Non-linting		Yes	No
Approximate Cost per Use		\$0.97	\$5.00

1) Tyvek's ESD result is by virtue of non-durable anti-static finish rather than inherent in the fabric through use of carbon yarns  
 2) Because Tyvek is a single-use garment, using Tyvek negatively impacts the environment by creating unnecessary waste. Garments are made of HD ESD and Ultra ESD are reusable through over 100 launderings and are the environmentally friendly choice.  
 \*Test results are actual lab test data and are not to be used as specifications

		Maxima ESD 4043-60	Tyvek
Weight	oz/yd <sup>2</sup>	2.53	1.21
Tensile Strength (lb)	warp	154	24
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Static Decay 5000 - 500 volts			
FTMS 4046-101C	secs	0.01	0.01
Flammability			
16 CFR 1610 Not NFPA 70E Compliant		Class 1	Class 1
Bacteria Filtration Efficiency (2)		76.20%	99.20%
ASTM F2101			
Non-linting		Yes	No
Antimicrobial		available upon request	No
Approximate Cost per Use			

1) Tyvek's ESD result is by virtue of non-durable anti-static finish rather than inherent in the fabric through use of carbon yarns  
 2) The BFE test is a quantitative method that measures filtration efficiency against a bacterial challenge. The BFE test was conducted at Nelson Laboratories using Staphylococcus aureus, which has an approx. diameter of 0.8µm, as the challenge organism. A liquid suspension of S. aureus is dispersed into small aerosol droplets, and the aerosol is then drawn through the test sample. The bacterial aerosol is consistently maintained to provide a mean particle size of 3 µm.  
 3) Because Tyvek is a single-use garment, using Tyvek negatively impacts the environment by creating unnecessary waste. Garments are made of HD ESD and Ultra ESD are reusable through over 100 launderings and are the environmentally friendly choice.

## HIGH DENSITY ESD VS. TYVEK

### Tensile Strength

HD ESD has a much higher tensile strength than the Tyvek. Testing shows that HD ESD is a significantly stronger fabric.

### Body Box

At 0.3 microns, Tyvek released 21% more particles than HD ESD. The Body Box test is the best real world test to show filtration and particulation characteristics of a fabric.

*Explanation of Body Box: Personnel engaged in predetermined exercise per IEST-RP-CC003. This test challenges the entire garment system for particle containment capabilities. The particles are collected at two different levels, the knee and the sub floor.*

### Comfort

Air porosity and Moisture Vapor Transmission tests show HD ESD to be much more comfortable than Tyvek.

Employees who are more comfortable produce better work.

### Non-Linting

HD ESD is a non-linting fabric made of continuous filament polyester. Tyvek has a propensity to lint.

Gamma irradiated Tyvek also tends to out gas.

## THE RIGHT CHOICE!

Beyond Tyvek conversions there is a significant opportunity to reduce costs and your company's carbon footprint by converting your disposable mops and goggles into PCS reusable goggle and mop programs.

Scan to learn more...



Prudential BFE  
Information  
Reusable vs.  
Disposable



Particle  
Dispersion Test  
Reusable vs.  
Disposable

# PRUDENTIAL'S CUSTOMERS ACHIEVE ENVIRONMENTAL AND ECONOMIC BENEFITS

## Prudential Cleanroom Services®



PDA Journal of Pharmaceutical Science and Technology

### PUBLISHED LIFE CYCLE ASSESSMENT (LCA) STUDY FOR AMERICAN REUSABLE TEXTILE ASSOCIATION

LCA study for comparing reusable and disposable cleanroom coveralls, led to publication in PDA Journal of Pharmaceutical Science and Technology



23-57% reduction in natural resource energy and CO<sub>2</sub> emissions



77% reduction in 'blue water'



96% reduction in solid waste



### U.S. NATIONAL ECONOMIC STUDY FINDS THAT CUSTOMERS BENEFIT FROM SELECTING TEXTILE REUSABLES FOR THEIR CLEANROOM FACILITIES

47% cost reduction on average

Estimated U.S. cost savings of \$100 million per year for the cleanroom manufactures bottom line!

# PRUDENTIAL'S CUSTOMERS RECEIVE THE GREEN SHEET TO MEASURE ENVIRONMENTAL SAVINGS WHEN COMPARING REUSABLES TO DISPOSABLE PRODUCTS

## GREEN SHEET - BASICS

- Shows environmental benefits comparing reusable coveralls, boots, hoods and/or frocks to disposable alternatives
- Report output is available in the semi-annual Customer Visitation (CV) process
- Report specific to customers scan usage information

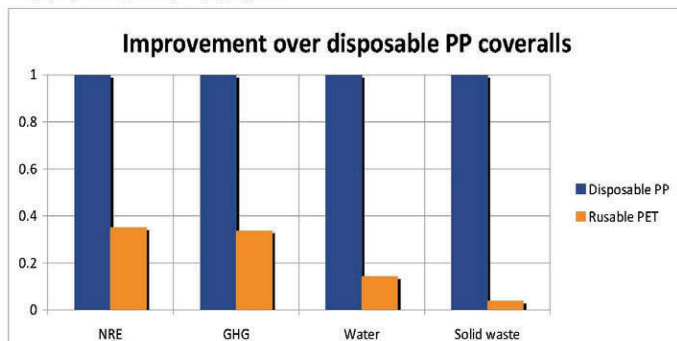
Example



Sustainability Improvement Document  
for My favorite customer

	Reusable PET Total	Disposable PP Total	Improvement	Environmental benefit from choosing reusables	Total as Percent Reduction
Natural resource energy consumption, MJ NRE	245,568,899	697,776,139	452,207,240	less MJ NRE consumed	65%
Greenhouse gas emissions, kg CO2 eq	14,262,982	42,205,774	27,942,792	less kg CO2 eq emitted	66%
Water consumption, kg blue water	1,793,747	12,553,842	10,760,094	less kg blue water consumed	86%
Solid waste generation, kg solid waste	333,384	8,674,319	8,340,935	less kg solid waste generated	96%

PET = polyethylene terephthalate; PP = polypropylene



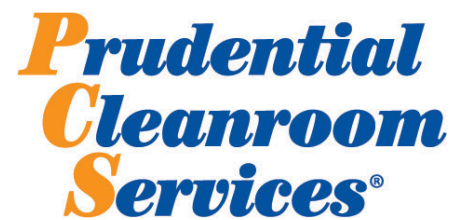
**Natural resource energy (NRE)** – Total energy consumed in a given process. Includes energy metered to plants (i.e. kWh electricity, m<sup>3</sup> natural gas) plus energy required to generate and deliver this energy.

**Greenhouse gas (GHG) emissions** – Includes GHG emissions at plants plus emissions from energy production. Expressed in units of carbon dioxide equivalent (CO2 eq) (methane = 24, nitrous oxide = 320, carbon monoxide = 2, carbon dioxide = 1).

**Blue water** – Includes water evaporated during production plus water incorporated into products.

**Solid waste** – Includes coveralls, biological waste, and packaging sent to landfills.

Data are derived from ARTA report (Life Cycle Analysis of Cleanroom Coveralls: Reusable and Disposable, 2015). Calculations for



Our Customers help protect the environment by using reusable textile products

PROVIDING AND PROTECTING WHAT IS VITAL



Clean Water



Abundant Energy



Carbon Footprint Reduction



Reducing Waste Stream

# GARMENT PROCESSING SERVICE CYCLE

The following flow chart illustrates the steps involved in processing your cleanroom garments.



Scan to learn more.

## Prudential Cleanroom Services®

CART IDENTIFICATION  
PLACED INTO SCAN MACHINE  
IN-SCANNED



### PICK UP

Our STOCK program provides a service that is unique to the industry. STOCKED garments utilizing industry recognized fabrics that will allow for quick installation. This eliminates the long lead times that are common from cleanroom garment manufactures. A wide variety of sizes and industry accepted styles will be STOCKED for industry specific requirements.

Prudential Cleanroom Services' automatic ordering level quickens the reaction time to our customers' needs and ensures a complete and timely delivery.



STARTS HERE

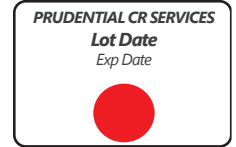
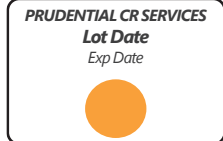
### CUSTOMER DISTRIBUTION

Garments distributed to end user gowning area as needed. PCS customers have never experienced an interruption in production due to a PCS delivery incursion.



### OUT-SCAN

RFID/Barcode Scanning outgoing cleaned, packaged and tested garments into the validated garment tracking system (GTS). The cart that is filled with cleaned customer garments is placed into the final RFID scan machine. Final RFID scan confirms that 100% of customer's garments are in the cart ready to be returned to customer's facility.



### FINAL DISTRIBUTION

Packaged garments are sorted for delivery in an ISO Class 7 environment.



### TESTING

All PCS facilities have an ISO Class 3 Garment System Test Chamber (Body Box). The Body Box is available for our customers to use. During Body Box testing personnel engage in predetermined exercise. This test challenges the entire garment system for particle containment capabilities.



# CLEAN TO CLEANEST PROGRESSION

## RFID IN-SCAN / SOIL INSPECTION

The cart is placed into the bulk RFID portal to record pick-up quantity, 100% inspection for any necessary repairs and sorted by customers' specified processing needs (RFID/Barcode scanned-in process) in ISO Class 8 controlled environment. Process performed on light tables to help inspector quickly identify actionable items.

## PRIORITY REPAIR STATION

Prudential is committed to maximizing garment inventory life. PCS' documented repair process fulfills this commitment, and repairs are tracked through GTS.

## WASH

PCS developed a customized pass through washing machine design which moves garments into the ISO Class 4 controlled environment after laundering. Washer internal drum surface areas are 316L stainless steel with Teflon seals and bearings. Deionized water is delivered through PVDF system. Computerized liquid injection system. Special processing requirements with segmented loads.

## DRY

Exclusively developed PCS customized pass through dryer design allows garments to move garments directly into ISO Class 3 cleanroom controlled environment.

Dryer internal drum surfaces are 316L stainless steel with Teflon seals and bearings.

Temperature & humidity controlled ULPA filtered @ 99.9995%.

## PACKAGE

Folding and Packaging is performed in ISO Class 3 environment.

Clean garments are folded, packaged, and sealed in preparation for testing and final distribution. Bags are hermetically sealed with easy open bags.

## QUALITY ASSURANCE PERSONNEL

Overview of ISO Class 3 Quality Assurance Test Lab.

All process data collected within the lab is entered into a statistical process control (SPC) data base. Monthly SPC charts are maintained on all critical plant processes. Quality Assurance Personnel perform ASTM F-51 testing using microscopic inspection technique; washloads are sampled and tested for particles and fibers; perform incoming product inspection; perform Helmke Drum Test. This method tests the total releasable particles on a garment.

## STERILITY ASSURANCE

Aseptic customers are provided with validated sterile product dosimetrically released with a SAL  $10^{-6}$ .

# CERTIFICATIONS



*"The entire organization is extremely proud of our ISO 9001:2015 certification for all operating locations and our corporate headquarters. This reinforces Prudential's ongoing commitment to providing Best-in-Class quality products and services."*

*Dan Clark*  
Chairman of the Board

## Prudential Cleanroom Services®

### ISO 9001:2015 CERTIFICATION

Prudential Cleanroom Services, the world leader in cleanroom laundry service systems is ISO 9001 certified for its Quality Management System by TÜV America, Inc. This certification applies to Prudential's corporate headquarters and its national network of cleanroom and industrial processing facilities. The scope of the Quality Management System ISO certification includes providing industrial and cleanroom apparel along with other contamination control products and services for use in controlled environments.

The certification is based upon a registration audit. Prudential undertook the quality certification process as part of its long-term commitment to our customers to provide 'best-in-class' contamination control products and services.



To view current certificate please visit our website:  
<https://www.prudentialuniforms.com/cleanroom-laundry-services/iso-certification/>

## STERILE & PARTICULATE CERTIFICATIONS

For customers manufacturing aseptically, PCS provides labeling with lot traceability with the expiration date and the dosimeter dot that indicates exposure to irradiation. Sterile items are released by Quality Assurance after a review of all gamma processing records.

**Prudential Cleanroom Services**  
Certificate of Sterilization (Gamma Irradiation)

Issue Date: <u>XX/XX/XX</u>	Irradiation Run Number: <u>1479533</u>
Customer: <u>ABC Bio</u>	Irradiation Run: <u>XX/XX/XX</u>
PCS Lot Number: <u>032020-15</u>	Number of Containers: <u>25</u>
Gamma Irradiator: <u>Sterigenics</u>	Expiration Date: <u>XX/XX/XX</u>
Gamma Processing Location: <u>Corona, CA</u>	Minimum Dose Received (kGy): <u>29.1</u>
Sterilization Dose Range* (kGy): <u>25-50 kGy</u>	Maximum Dose Received (kGy): <u>36.5</u>

\*Per PCS Sterilization Validation Manual, Revision Date: XX/XX/XX

Based on the minimum sterilization dose, this shipment is certified to meet a Sterility Assurance Level (SAL) of 10<sup>-6</sup>. Sterility validation was conducted per ANSI/AAMI/ISO 11137.


**Prudential Cleanroom Services**

*Jane Doe*  
 Quality Assurance Technicians Signature / Date:  
 Jane Doe  
 Quality Assurance Technicians Name (printed):  
 PCS PROCESSING FACILITY  
 Plant Location (City and State):  
*John Doe*  
 Reviewed by / Date:


Form 10302, Rev. 07/17/19

Certificate of Sterilization

**PRUDENTIAL CR SERVICES**  
**Lot Date**  
Exp Date



**PRUDENTIAL CR SERVICES**  
**Lot Date**  
Exp Date



## STERILE LABELING

Gold: Pre-exposure  
Red: Post-exposed

Issued To: ABC Bio  
Account: 51579000 Day: 5 Route: 79

**Prudential Cleanroom Services**

**HELMKE Particle Test Certification**  
Date: XX/XX/XX

Product Code	Description	Size Code	ID Code	Batch No.	Characteristic Description	Value
CR0679COG	COG COVERALLS	MED	1599900000670806	032320-10	Reading of Particles @ ≥ 0.5µm	155
					Reading of Particles @ ≥ 0.3µm	200

Certification Performed by: *Jane Doe*  
PCS Quality Assurance Technician

Reviewed by: *John Doe* Date: XX/XX/XX

The garments processed by Prudential Cleanroom Services, on the date indicated above, have been processed and tested in accordance with IEST-PP-CC003 using Helmke Drum method and garments are certified to meet standards for Category 1 garments.

Industry Practices Specifications for Category 1 garment: Coverall <math>\leq 2000</math> particles @ 30.3µm & <math>\leq 1200</math> particles @ 30.5µm  
 Hood <math>\leq 1700</math> particles @ 30.3µm & <math>\leq 1000</math> particles @ 30.5µm  
 3 Hoods <math>\leq 780</math> particles @ 30.3µm & <math>\leq 450</math> particles @ 30.5µm

List Customer Specification if different than above:

Plant Address: Phone: Fax: Main Office:

Form 10357, Rev. 06/14/19

Helmke Drum Certification

Issued To: ABC Bio  
Account: 51579000 Day: 5 Route: 79

**Prudential Cleanroom Services**

**ASTM F-51 Particle Test Certification**  
Date: XX/XX/XX

Product Code	Description	Size Code	ID No.	Batch No.	Characteristic Description	Value
CR5979	COVERALL-ABS800-WHITE	MED	1599900000670806	032420-23	Number of Particles @ ≥ 0.5µm	105
					Number of Fibers	0

Certification Performed by: *Jane Doe*  
PCS Quality Assurance Technician

Reviewed by: *John Doe* Date: XX/XX/XX

The garments processed by Prudential Cleanroom Services, on the date indicated above, have been processed and tested in accordance with IEST-PP-CC003 using industry particle specification for Class A garment: 0 to 999 particles @ ≥ 5.0µm and 0-30 fibers.

List Customer Specification if different:

Plant Address: Phone: Fax: Main Office:

Form 10356, Rev. 12/08/16

ASTM F51-F51M Certification

# CLEANROOM FABRIC STUDY

## AVAILABLE

### CLEANROOM FABRIC STUDY

Prudential Cleanroom Services offers the contamination control industry an independent third party cleanroom fabric study that credibly tests and rates the industry's most widely recognized fabrics. Prudential Cleanroom Services has invested heavily into the release of this study. The study tests and rates unique fabrics on core criteria points. The study was conducted by CPC Laboratories, Inc. of Mission Viejo, CA.

As expressed by John Clark, CEO of Prudential Overall Supply, "Prudential invested in this study to compliment the Cleanroom division's goal for being the industry leader at transferring knowledge into customer solutions. The marketplace didn't have anything like this, so we felt it was the right thing to do for our customers."

The Prudential sponsored CPC study tests fabrics that have specific applications across the contamination control industry's primary market segments. These market segments include industries that manufacture and operate in critically controlled environments like Pharmaceutical, Bioscience, Medical Device, Semiconductor, Electronics, Aerospace, Paint-Spray, Laser and Agriculture/Food.

Mr. Clark continues, "The CPC cleanroom fabric study is designed to be a resource for critical environmental control decision makers. The intent is to assist them with the knowledge that helps to determine the proper fabric solution for their specific application."

## METHODOLOGY

### FABRIC STUDY

CPC Laboratories, Inc. was contracted by Prudential Cleanroom Services (PCS) to perform the specified testing on fabric swatches and assembled cleanroom coveralls. Test items were laundered at Prudential Cleanroom Services at specified processing intervals prior to testing.

When possible, tests were performed per published methods (ASTM, IEST, Federal Standards) used in the cleanroom industry. When no published method existed for a particular test, internal CPC Laboratories test procedures were employed. The test results apply to only the samples tested, within the limits of the test procedures, and are not necessarily representative of the characteristics of other samples from the same or other lots.

Test conditions were controlled to the greatest degree possible to ensure that all samples were tested in a similar fashion and that comparisons based on the data are fair and meaningful. Samples were tested using equipment that was operating properly and was in calibration (when applicable).

CPC Laboratories, Inc. considers Prudential Cleanroom Services the sole client in this study and will, therefore, provide test results only to Prudential Cleanroom Services. No exceptions will be made. The results of the Fabric Study should not be interpreted as an endorsement of any particular product(s). Company trademarks have been authorized to be printed in this study.

Data is supplied for comparison only. Testing for consistency between lots, repeatability and reproducibility was not performed. Therefore, this data is not intended for determining specification limits.

No warranty for product performance, expressed or implied, is intended by this report.

**INDUSTRY  
BENCHMARK**

**Prudential  
Cleanroom  
Services®**

## INDUSTRY APPLICATION



WHAT IS APPROPRIATE FOR YOUR CLEANROOM?

### Application to Product Group List

<p><b>Pharmaceutical / Biotechnology</b></p> <ul style="list-style-type: none"> <li>• Biologicals</li> <li>• Biomedical</li> <li>• USP 797</li> <li>• Nano Technology</li> </ul>	<p><b>Aerospace</b></p> <ul style="list-style-type: none"> <li>• Defense Contractor</li> </ul>
<p><b>Medical Device</b></p> <ul style="list-style-type: none"> <li>• Implantables</li> <li>• Catheters</li> <li>• Surgical Disposables</li> </ul>	<p><b>Automotive</b></p> <ul style="list-style-type: none"> <li>• EV / Automotive</li> <li>• Plastics</li> <li>• Rubber</li> <li>• Metal Parts</li> <li>• Components</li> <li>• Precision Tooling</li> </ul>
<p><b>Semiconductors</b></p> <ul style="list-style-type: none"> <li>• Integrated Circuits</li> <li>• Hybrids</li> <li>• Flat Panel Displays</li> <li>• Process</li> <li>• Cleaning Equipment</li> <li>• Nano Technology</li> </ul>	<p><b>Laser</b></p> <ul style="list-style-type: none"> <li>• Optics</li> <li>• Solar Devices</li> <li>• Photography</li> <li>• Printing</li> <li>• Holography</li> <li>• Photo-Duplication</li> </ul>
<p><b>Electronics</b></p> <ul style="list-style-type: none"> <li>• Printed Circuits</li> <li>• Sensors</li> <li>• Relays</li> <li>• Switches</li> </ul>	<p><b>Chemicals</b></p>
<p><b>Disk Drive</b></p> <ul style="list-style-type: none"> <li>• Compact Disks</li> <li>• Other Magnetic Media</li> <li>• Computers</li> <li>• Computer Peripherals</li> </ul>	<p><b>Hospital / Healthcare</b></p> <ul style="list-style-type: none"> <li>• USP 797</li> </ul>
	<p><b>Agriculture / Food</b></p> <ul style="list-style-type: none"> <li>• Cannabis</li> <li>• P</li> <li>• Hood</li> <li>• VAP</li> </ul>

**LEGEND:**

- Reusable Stripe Pattern
- Reusable Grid Pattern
- Disposable Solid Non-ECF (Non Electro Conductive Fiber)

## INDUSTRY GRADING

### Cleanroom Fabric Study Grading

This study contains the results of the PCS Cleanroom Fabric Study. Three data points for analysis have been issued for each fabric tested.



- Data Summary Analysis**  
This analysis contains the actual results of the tests performed (numerical values).
- Grade Summary Analysis**  
This analysis contains grades (exceptional through unsatisfactory) translated from the numerical values. This analysis can be used to quickly compare specific tests for two or more fabrics.
- Category Summary Analysis**  
This analysis is a summary of the testing, and it also anticipates fabric lifetime, as well as grouping specific tests into categories, such as comfort and barrier properties.

	Pharmaceutical / Biotechnology <small>Test Data: Particle Emission</small>	Medical Device	Semiconductors <small>Test Data: Particle Emission / Static</small>	Electronics <small>Test Data: Surface Contamination</small>	Disk Drive <small>Test Data: Surface Contamination</small>	Aerospace <small>Test Data: Particle Emission / Static</small>	EV Automotive <small>Test Data: Particle Emission / Static / Ion Gens / Static</small>	Laser <small>Test Data: Surface Contamination</small>	Chemicals	Hospital / Healthcare <small>Test Data: Particle Emission</small>	Agriculture/Food <small>Test Data: Microbial / Static / Particle Emission</small>
Reusable Stripe	HDESD PFG Integrity 705	Exceptional	Exceptional				Exceptional (Particle)		Commendable	Exceptional	Exceptional
	HDESD PFG Integrity 1800	Exceptional	Exceptional						Exceptional	Exceptional	Exceptional
	HDESD Maxima ESD	Exceptional	Exceptional						Commendable	Exceptional	Satisfactory
Reusable Grid	AB4800		Commendable	Satisfactory	Exceptional	Exceptional	Satisfactory	Commendable	Exceptional		
	AB5800		Commendable	Satisfactory	Commendable	Commendable	Satisfactory	Commendable	Commendable		Commendable
	Ground Zero Extreme ESD		Exceptional	Exceptional	Exceptional	Exceptional	Exceptional	Exceptional	Exceptional		
	PFG Integrity 1750		Exceptional	Satisfactory	Exceptional	Exceptional	Satisfactory	Commendable	Exceptional		Satisfactory
	PFG Integrity 2000	Exceptional	Exceptional	Exceptional	Exceptional	Exceptional	Exceptional	Exceptional	Exceptional	Exceptional	
	C3 ESD	Exceptional	Exceptional	Satisfactory	Commendable	Commendable	Satisfactory	Exceptional	Commendable		
Disposable Solid	C3 Nano ESD	Exceptional	Satisfactory	Exceptional	Exceptional	Satisfactory	Exceptional	Exceptional			
	Chemstat 909A		Satisfactory	Commendable	Commendable	Satisfactory	Exceptional	Commendable			
	GORE™	Exceptional	Exceptional	Exceptional	Exceptional	Satisfactory			Exceptional		
	Tyvek	Satisfactory	Satisfactory						Satisfactory	Satisfactory	Exceptional

Ratings Key: **Exceptional** **Commendable** **Satisfactory** **Fair** **Unsatisfactory**

# CLEANROOM REUSABLE PRODUCTS



# CLEANROOM GARMENT SYSTEM FEATURES

## HOOD

Snaps to adjust sizing.

Available with attached tricot eye only facemask or an open faced hood with snap in tricot facemask.

## GOGGLES

## COVERALL

Provides maximum contamination control, comfort and mobility.

PCS requires the over locking/surging of cut or raw edges. This helps to minimize the potential of a cut panel fraying and protruding through the seam. Since cleanroom polyester fabric is made from long continuous filament yarn, there can be an "angel hair" type fraying that is a result of fiber separation at the edge of a cut panel. If over locked/surged, the cut panel is encapsulated by the thread.

The typical size (STOCK garment sizing) for the PCS coverall is generous. It is at the high or generous end of the industry standards for coverall sizing. This should insure a more comfortable fit for the wearer.

These same statements can be made for all of our garments.

## BOOTS

Available in many sizes with molded soles or soft hypalon soles.

PCS continues to be an innovator in boot design. While most of our competition uses a single ankle strap design, we provide a better fitting boot by adding extra webbing. The extra webbing (refer to styles TW, D3, D3C) makes the outer boot more comfortable to wear since it holds to the shoe more efficiently. In addition, we invest in the longevity of the boot by using a corona fender material on most hard sole designs. Many of our competitors choose to not add a corona fender which will lead to a shorter boot life span and a faster replacement charge.

## RFID/BARCODES

Garment Tracking System



## LABELS

Label format can easily be read by user.



# HD ESD - STERILE & NON-STERILE



## APPLICATION GRADE

Pharmaceutical .....Exceptional  
 Biotechnology .....Exceptional  
 Medical Device .....Exceptional  
 Hospital / Healthcare .....Exceptional  
 Agriculture / Food .....Satisfactory

**\*The ESD fabric is a non-linting, high density fabric with durable resistance to fluids, and microbes with anti-static carbon fibers in vertical stripes.**

## FABRIC DESIGN

Non-Linting yarns reduce the risk of fiber generated infection. High density construction resists fluids and bacterial penetration.

## ESD PERFORMANCE

Anti-static carbon fibers enhance safety in high O2 Environments and protect sensitive electronic equipment.

## TOTAL VALUE

Calendered with 90 tons of heated pressure, maintains long-term resistance to fluid and microbe penetration. High longevity construction for severe washing environments. Long-term durability reduces per use disposal costs.

HDES is woven with 99% polyester / 1% carbon fibers. The ESD fiber is carbon and woven in a vertical pattern.

\*Fabric description is supplied by fabric manufacturer.

Test	Units	Aver. 3-75
Filtration Efficiency	% captured, >0.5um	56%
Filtration Efficiency	% captured, >5um	90%
Particle Generation (All types)	# >5um/sq.ft.	65
Fiber Generation (All types)	# >100um/sq.ft.	1
Particle Generation (Sloughed)	# >5um/sq.ft.	17
Fiber Generation (Polyester)	# >100um/sq.ft.	0
Surface Resistivity	10 volts Ohms/square	10 <sup>^7</sup>
Surface Resistivity	100 volts Ohms/square	10 <sup>^7</sup>
Static Decay Time	5K->50v Seconds	0.03
Abrasion Resistance, 1000 cy.	% weight loss	9.24
Abrasion Resistance, 1000 cy.	# of tears	*
Air Permeability	cu.ft./minute/sq.ft.	0.47
Water Vapor Transmission	grams/sq.m/24 hours	111
Extractable Matter	Hot DIW grams/sq.ft.	0.000
Bacterial Migration Resistance	% captured	100%
Antibacterial Effectiveness	% inhibition	93%
nt = not to be tested at this interval x = will be tested at this interval * = Minor to moderate break-through at 1000 cycles Prudential Cleanroom Services, Cleanroom Fabric Study, Test data provided by CPC Laboratories, Inc.		



# HD ESD - STERILE & NON-STERILE

## HOOD

### HE1179LZ

White  
Unisize

### HE1144LZ

Navy Blue  
Unisize

- Eyes only hood
- Built in face mask
- Flared skirt for over the shoulder coverage
- Elastic encased back
- Horizontal snap back adjustment
- One male snap, three female snaps

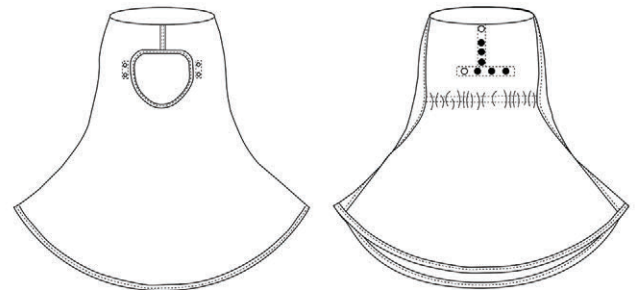


## HOOD

### HF1179LZ

White  
Unisize

- Open face hood
- Two snaps on each side of face opening for snap in face mask
- Flared skirt for over the shoulder coverage
- Horizontal and vertical snap back adjustment
- One female snap, three male snaps, in each direction
- Elastic encased back

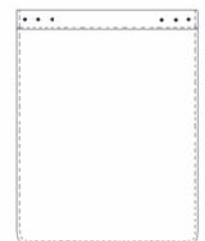


## FACEMASK

### FM7179RT

White  
Unisize

- Polyester shiny knit tricot
- Bias taped edge
- Adjustable snaps at top



# HD ESD - STERILE & NON-STERILE

## COVERALLS

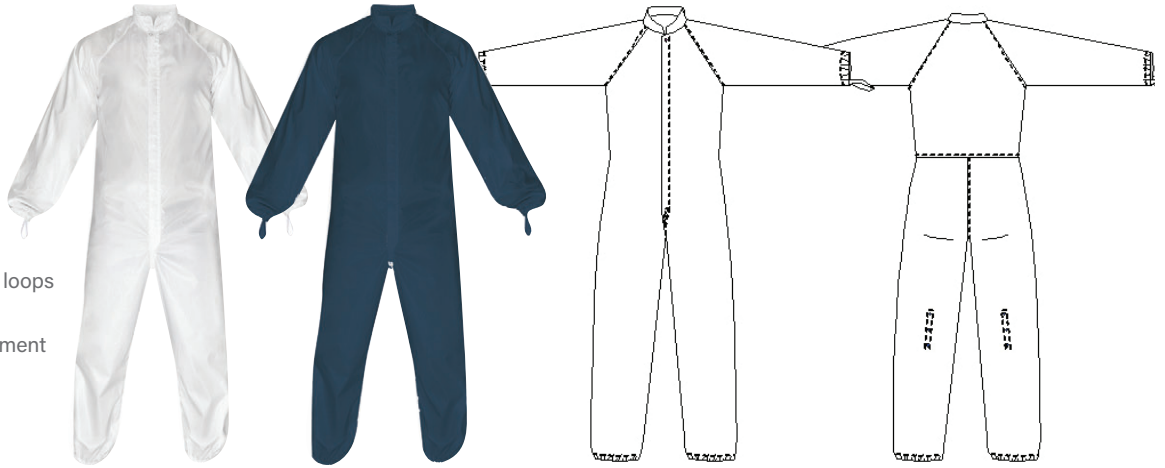
### CR1179A8

White  
SM - 4XLG

### CR1144A8

Navy Blue  
SM - 4XLG

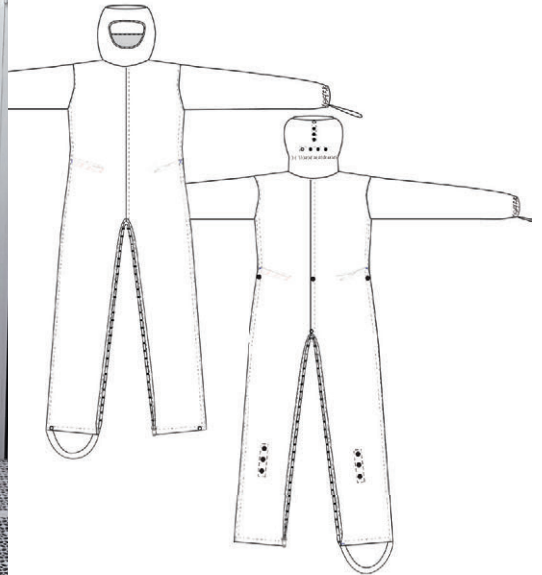
- Mandarin collar
- Raglan sleeves
- Tunneled elastic wrist with thumb loops
- Zipper front
- Three snap knee high boot attachment
- Tunneled elastic leg opening



### CR1179HE

Eyes Only - High Density ESD  
White  
XSM - 5XLG

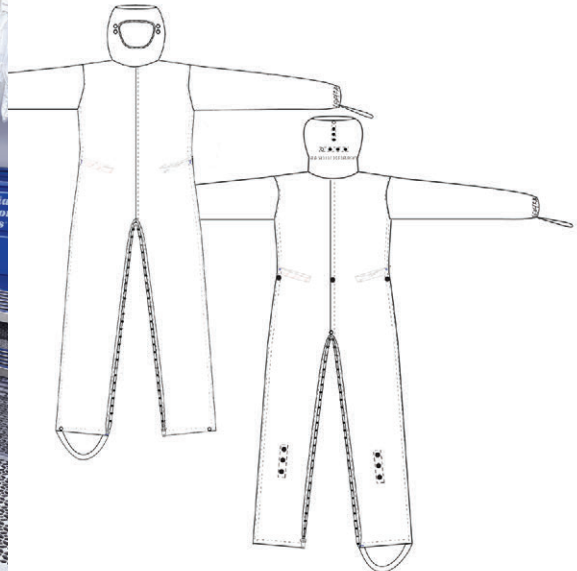
- Attached hood with eyes only tricot facemask
- Permanently closed zipper on right leg
- Reinforcement inside and around hem
- Tunneled elastic
- In-set sleeves
- Vertical and horizontal snaps on back of hood
- Matching thumb loops



### CR1179HF

Open Face - High Density ESD  
White  
XSM - 5XLG

- Attached hood with open face
- Permanently closed zipper on right leg
- Reinforcement inside and around hem
- In-set sleeves
- Tunneled elastic
- Vertical horizontal snaps on back of hood
- Matching thumb loops
- Stainless steel snaps
- Constructed with silicone free thread



## FROCK

### FR1179JX

White  
SM - 4XLG

### FR1144JX

Navy Blue  
SM - 4XLG

- Mandarin collar
- Raglan sleeves
- Extended sleeve length
- Tunnelled elastic wrist with thumb loops
- Zipper front

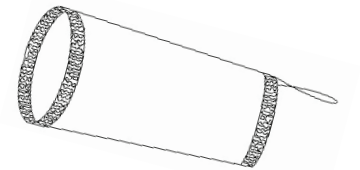


## SLEEVE COVER

### SL1179TG

White  
Unisize

- Tunnelled 3/8" elastic closure at top and wrist end
- Thumb loop at wrist



# HD ESD - STERILE & NON-STERILE

## BOOTS

### BK1179D3C

White  
SM - 3XLG

- High gray molded sole
- "X" style webbing with side release buckle
- Corona fender
- Elastic and snap adjustable tab top



## BOOTS

### BK1179PR

White  
SM - 4XLG

### BK1144PR

Navy Blue  
SM - 4XLG

- Large top opening
- Hypalon tan soft sole
- Ankle strap with side release buckle
- Extended toe straps with snaps
- Elastic and snap adjustable tab top
- Corona fender

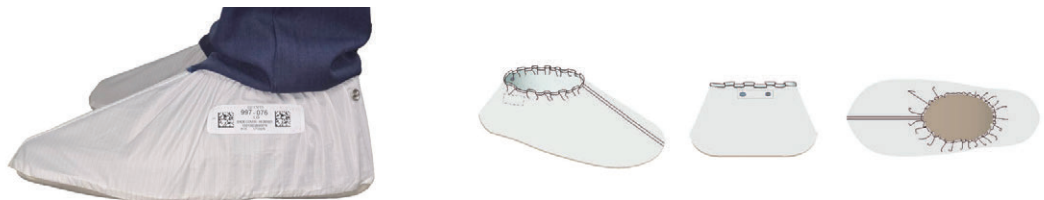


## SHOE COVER

### SC1179TS

White  
XSM-3XLG

- HD-ESD fabric
- Tan Hypalon soft sole
- Back adjustable snap



# PCS VALIDATED REUSABLE GOGGLE PROGRAM



## VALIDATED STERILE REUSABLE GOGGLE PROGRAM

ALL REUSABLE GOGGLES  
VALIDATED AT SAL  $10^{-6}$

**"A game changer for reusable sterile goggle programs"**

PCS has developed a sustainable reusable validated (SAL  $10^{-6}$ ) rental goggle program with zero visual degradation, creating exponential increase in the life of your sterile goggles!

Contact your PCS professional for more information.

## IS YOUR PROCESS FDA COMPLIANT?

### A STUDY OF STERILE VS. SANITIZED GOGGLES GUIDANCE

The proper operation of an aseptic cleanroom has always required the greatest attention to every detail. The highest standard of operation and control must be maintained. One of these controls has long been the use of a sterile cleanroom garment gowning system.

The standard aseptic gowning configuration calls for the use of goggles to contain contamination from the operator's eyes and face. Historically, goggles have been sanitized at the point of use which may not meet the traditional definition of sterile.

The current "Guidance for Industry Sterile Drug Products produced by Aseptic Processing-Current Good Manufacturing Practice" has attempted to extend this control. This issue for industry comment is being followed by many companies who wish to achieve compliance prior to the document becoming a regulation. The Agency recommends "gowns that are sterilized and non shedding, and cover the skin and hair (face-masks, hoods, beard/moustache

covers, protective goggles, and elastic gloves are examples of common elements of gowns)." This document if left unchanged will require all garment elements including eye wear to be sterile if used in the aseptic cleanroom. The historical methods for sanitizing goggles, solvent wipe, UV cabinets etc. are not likely to be able to meet these enhanced requirements.

In order to help address this concern, Prudential Cleanroom Services provides a validated reusable sterilized goggle. PCS sterile goggles will ensure that every operator will comply with the most recent industry guidelines.

Prudential Cleanroom Services' sterile goggles are tested to insure that their composition and properties remain intact after repeated sterilization.

A Prudential Cleanroom Services Validated Sterile Goggle Program delivers sterile goggles in accordance with the guideline!

**Prudential  
Cleanroom  
Services®**

\*U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER) Office of Regulatory affairs (ORA) September 2004 Pharmaceutical CGMPs

The FDA does not specifically endorse Prudential's goggle program.

# STERILE GOGGLES

## REUSABLE DIRECT VENT GOGGLE

### **GG008011S**

Unisize

- Sterile
- Direct Vent
- Gamma Irradiated SAL 10<sup>-6</sup>
- Light Blue Frame
- Clear Byoxene Lens



## REUSABLE INDIRECT VENT GOGGLE

### **GG008011S1**

Unisize

- Sterile
- Indirect Vent
- Gamma Irradiated SAL 10<sup>-6</sup>
- Light Blue Frame
- Clear Byoxene Lens
- Protects against chemical splash & particles



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## REUSABLE DIRECT VENT GOGGLE

### **GG00801905**

Unisize

- Sterile
- Direct Vent
- Gamma Irradiated SAL 10<sup>-6</sup>
- Light blue frame
- Polycarbonate Lens



## REUSABLE INDIRECT VENT GOGGLE

### **GG008019**

Unisize

- Sterile
- Indirect Vent
- Gamma Irradiated SAL 10<sup>-6</sup>
- Light blue frame
- Polycarbonate Lens
- Protects against chemical splash & particles



## REUSABLE DIRECT VENT GOGGLE

### **GG0080SVAF**

Unisize

- Sterile
- Gamma Irradiated SAL  $10^{-6}$
- Special anti-fog coating and ventilation design prevent fogging
- Panoramic lens and soft frame material offer maximum wearer comfort and all-round vision



## REUSABLE CREW GOGGLE

### **GG008051**

Unisize

- Sterile
- Gamma Irradiated SAL  $10^{-6}$
- Goggle PVC
- Soft sides
- Clear light clear body
- Clear lens
- Indirect ventilation
- Blocks 100% UV
- Rubber head band



## REUSABLE CONTEMPO GOGGLE

### **GG008056**

Unisize

- Sterile
- Gamma Irradiated SAL  $10^{-6}$
- PVC
- Clear light blue body
- Clear lens
- Indirect ventilation
- Blocks 100% UV



## REUSABLE CENTURION IMPACT GOGGLE

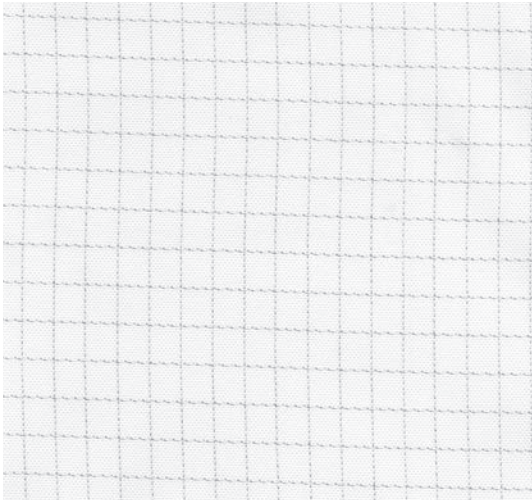
### **GG008036**

Unisize

- Sterile
- Gamma Irradiated SAL  $10^{-6}$
- Without black ventilation caps
- With uncoated lens
- Elastic strap



# AB4800 ESD



Test	Units	3-75x AVG
Filtration Efficiency	% captured, >0.5um	11.1
Filtration Efficiency	% captured, >5um	62.9
Particles Helmke Drum	# >0.5um/minute	256
Particle Generation (All types)	# >5um/sq.ft.	993
Fiber Generation (All types)	# >100um/sq.ft.	9
Particle Generation (Sloughed)	# >5um/sq.ft.	69
Fiber Generation (Polyester)	# >100um/sq.ft.	7
Abrasion Resistance, 1000 cy.	% weight loss	3.8
Abrasion Resistance, 1000 cy.	# of tears	0
Air Permeability	cu.ft./minute/sq.ft.	>2.0
Water Vapor Transmission	grams/sq.m/24 hours	97.8
Surface Resistivity 100 volts	Ohms/square	10E6 - 10E7

nt = not to be tested at this interval

\* = test run for 24 hours

Prudential Cleanroom Services, Cleanroom Fabric Study,  
Test data provided by CPC Laboratories, Inc.

## APPLICATION GRADE

Medical Device	Commendable
Semiconductors	Satisfactory
Electronics	Exceptional
Disk Drive	Exceptional
Aerospace	Satisfactory
Automotive	Commendable
Laser	Exceptional

## PERFORMANCE CHARACTERISTICS

Excellent Durability / Economical / Electrostatic Discharge /  
Dissipative & Comfortable to Wear

AB4800 fabric offers the greatest value and dependability and is designed for use in cleanroom applications where ESD characteristics are paramount. Fabric is light weight, proven to be durable and comfortable to wear.

AB4800 is woven with 98% polyester / 2% carbon fibers. The ESD fiber is carbon and woven in a grid pattern.



## COVERALL

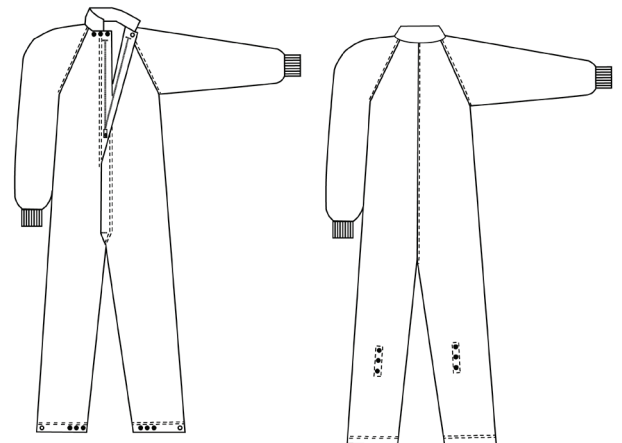
### CR4879

White  
XS - 6XLG

### CR4844

Navy Blue  
XS - 6XLG

- Mandarin collar
- Raglan sleeve
- Zipper front
- Knit cuff
- Snap leg closure
- Three snap knee high boot attachment



## HOODS

### HF4879CL

White

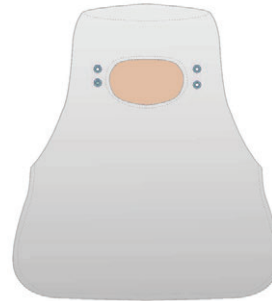
fits sizes SM - XLG

### HF4879CLX

White

fits sizes 2XLG - 4XLG

- Open face
- Two snaps on side of face
- Elastic back
- Snap adjustments

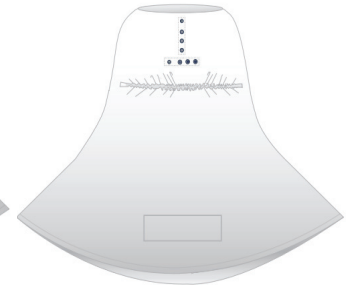
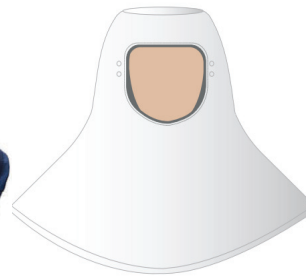


### HF4844LZ

Navy Blue

Unisize

- Two snaps on each side of face
- Over the shoulder bib
- Horizontal and vertical snap adjustment back
- Elastic encased back
- Side snaps for facemask installation



## FROCKS

### FR4879KF

White

XSM - 4XLG

### FR4844KF

Navy Blue

XSM - 4XLG

- Snap front
- Mandarin collar
- Raglan sleeve
- Knit cuff



FR4879KF



FZ4879KF



### FZ4879KF

White

XSM - 4XLG

### FZ4844KF

Navy Blue

XSM - 4XLG

- Zipper front
- Mandarin collar
- Raglan sleeve
- Knit cuff

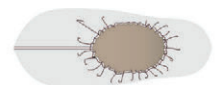
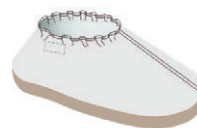
## SHOE COVER

### SC4879SW

White

XSM - 5XLG

- Tan Hypalon soft sole
- Sidewall same Hypalon fabric as sole
- Back adjustable snap



## BOOTS



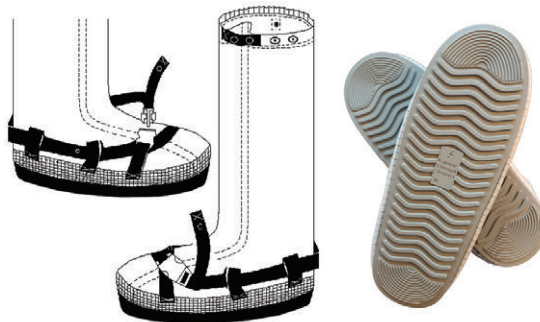
### BK4879AD

White  
XSM - 2XLG

- ESD Specific Boot
- Gray ESD Molded Sole Boot
- "X" style webbing with side release buckle
- Corona fender
- Elastic and snap adjustable tab top



BK4879AD



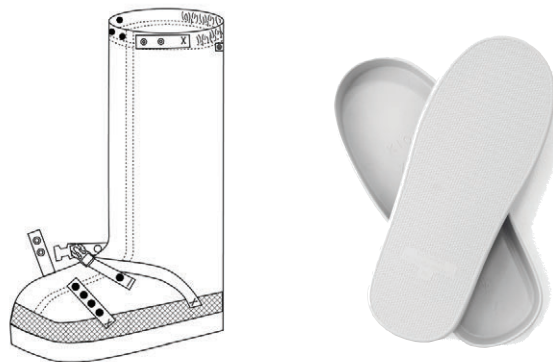
### BK4879D3CX

White  
SM-2XLG

- Hard sole
- Ankle strap
- Side release buckle
- Extended toe straps
- Elastic and snap adjustable top



BK4879D3CX



### BK4879PR

White  
XSM - 5XLG

- Hypalon tan soft sole
- Ankle strap
- Size release buckle
- Extended toe straps
- Elastic and snap adjustable top



BK4879PR



### BK4844TW

Navy Blue  
XSM - 2XLG

- Hypalon tan soft sole
- Ankle strap
- Size release buckle
- Toe straps and snaps
- Elastic and snap adjustable top



BK4844TW



# EV CLEANROOM BATTERY COVERALLS

offered by

**Prudential  
Cleanroom  
Services®**

- ✓ Reduce Cost
- ✓ Cooler Comfort
- ✓ Contamination Control,  
Particle & ESD

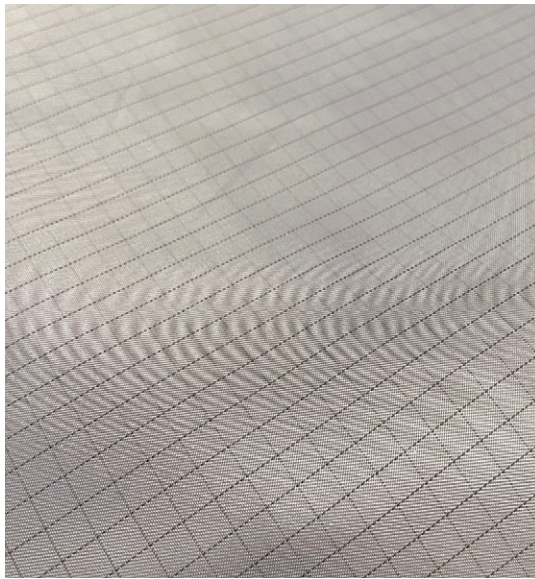


## EV SPECIFIC REUSABLE CLEANROOM GARMENT LAUNDRY SERVICE

Prudential offers:

- ✓ Hats
- ✓ Tool pouches
- ✓ Fanny Packs
- ✓ Vented Barrier Garments
- ✓ Building Suits - Improved Comfort
- ✓ ARC Flash FR garments (NFPA 70E)
- ✓ Webbing Tabs for radios & lock-out tags

# EV CLEANROOM BATTERY COVERALLS



Test	Units	3-75x AVG
Filtration Efficiency	% captured, >0.5um	11.1
Filtration Efficiency	% captured, >5um	62.9
Particles Helmke Drum	# >0.5um/minute	256
Particle Generation (All types)	# >5um/sq.ft.	993
Fiber Generation (All types)	# >100um/sq.ft.	9
Particle Generation (Sloughed)	# >5um/sq.ft.	69
Fiber Generation (Polyester)	# >100um/sq.ft.	7
Abrasion Resistance, 1000 cy.	% weight loss	3.8
Abrasion Resistance, 1000 cy.	# of tears	0
Air Permeability	cu.ft./minute/sq.ft.	>2.0
Water Vapor Transmission	grams/sq.m/24 hours	97.8
Surface Resistivity 100 volts	Ohms/square	10E6 - 10E7

nt = not to be tested at this interval

\* = test run for 24 hours

Prudential Cleanroom Services, Cleanroom Fabric Study,  
Test data provided by CPC Laboratories, Inc.

## APPLICATION GRADE

EV Automotive. . . . . Exceptional



## PERFORMANCE CHARACTERISTICS

Excellent Durability / Outstanding Breathability / Economical / Electrostatic Discharge (ESD) / Dissipative & Comfortable to Wear

Our EV Cleanroom Coverall fabric combination offers superior contamination control, comfort, value, and dependability. Specifically designed for the unique needs of EV Cleanroom manufacturing environments, these coveralls feature proven ESD characteristics that ensure durability and safety. The fabrics used in our EV Cleanroom Garments provide exceptional ESD performance, ensuring wearer comfort while meeting all necessary features and benefits. This results in strong, all-around performance for your Cleanroom EV gowning requirements.

EV Cleanroom Coverall is woven with 98% polyester / 2% carbon fibers. The ESD fiber is carbon and woven in a grid pattern.

**NOTE:**

For those with critical EV Cleanroom Battery Gowning concerns, please contact your PCS Account Executive for a more precise EV gowning solution.

# EV CLEANROOM BATTERY COVERALLS

## COVERALL AB4800

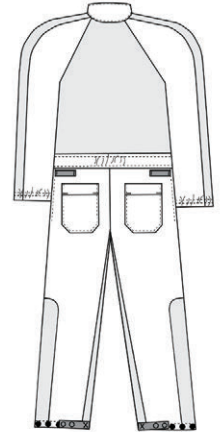
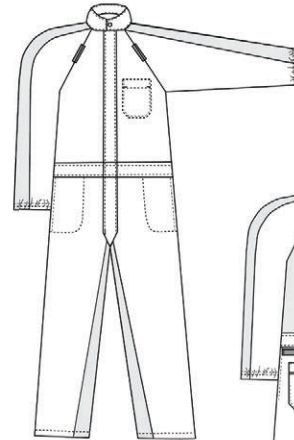
### CR4817EV

Grey / Black  
SM - 4XLG

### CR4844EV

Navy / Black  
SM - 4XLG

- Military collar
- Raglan sleeves
- Full tunneled elastic
- Closed coil zipper
- Pre-serged/felled
- Snaps on top of zipper at neck and back of leg opening with web tab for adjustment at waist
- Front chest left inside pocket (1)
- Shoulder radio tabs (L/R) (2)
- Side pockets (L/R) (2) with pass through behind front pocket to reach inner garment pant pocket (2)
- Rear hip (2) tabs
- Rear pockets (L/R)(2) rear hip tag-out tabs (L/R) (2)



## COVERALL - C-01

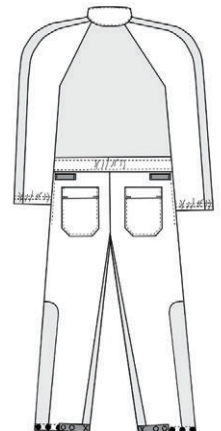
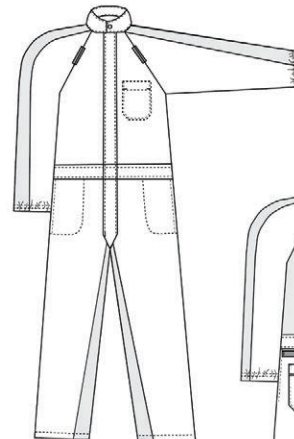
### CR0517EV

Grey / Black  
SM - 4XLG

### CR0544EV

Navy / Black  
SM - 4XLG

- Military collar
- raglan sleeves
- full tunneled elastic
- closed coil zipper
- pre-serged/felled
- snaps on top of zipper at neck and back of leg opening with web tab for adjustment at waist
- front chest left inside pocket (1)
- shoulder radio tabs (L/R) (2)
- side pockets (L/R) (2) with pass through behind front pocket to reach inner garment pant pocket (2)
- rear hip (2) tabs
- rear pockets (L/R)(2) rear hip tag-out tabs (L/R) (2)



## Arc Flash Protection

OSHA regulation 1910.269 requires that "employees shall wear clothing resistant to flash flame wherever there is possible exposure to an electric arc flash." The National Fire Protection Association (NFPA) has issued NFPA 70E advising that apparel made of polyester, nylon, acetate, or rayon be prohibited from the workplace where a risk of arc flash exists. The American Society for Testing of Materials (ASTM) has issued specification ASTM 1506, "Standard Performance Specification for Textile Materials for Wearing Apparel for Use by Electrical Workers Exposed to Momentary Electric Arc and Related Thermal Hazards."

Cleanrooms present a unique situation for electrical arc protection because of the additional prohibition on self-linting materials. Few materials exist in filament forms that satisfy both OSHA requirements for safety and cleanroom requirements for non-linting. Composed of 100% filament Nomex(r) and meeting the requirements of ASTM F1506, ChemStat 919, ChemStat 487, and ChemStat 541 are not only inherently flame resistant and static dissipative; compatible with most cleanroom protocols. They exhibit Arc Thermal Performance ATPv ratings of 6.3, 5.0, and 12.0 cal/cm<sup>2</sup>, respectively, in accordance with ASTM F1959-99.

The rating of the fabric in itself is not an indicator of protection; ultimately the protective garment must be rated for total arc flash protection. Moreover, the use of flame resistant Nomex(r) clothing does not necessarily preclude the possibility of burn injury; the thickness of a fabric layer or the number of layers must increase with increased hazard levels.

ChemStat 919, ChemStat 487, and ChemStat 541 may be used as the outer layer of a protective garment. ChemStat 16 SG is a lightweight Nomex(r) fabric without static protection that can be used as part of multi-layer garment system to provide additional layering and protection.

ChemStat 919, ChemStat 487, ChemStat 541, and ChemStat 16 SG exhibit high resistance to beta and gamma radiation.

Designed for outer garments, ChemStat 919, ChemStat 487, and ChemStat 541 employ a patented grid of conductive carbon-polyester yarn (US Patent 4,606,968). The grid rises slightly above the plane of the fabric, acting as a wick to draw static electricity out of the fabric and then to dissipate it innocuously into the surrounding humidified air.

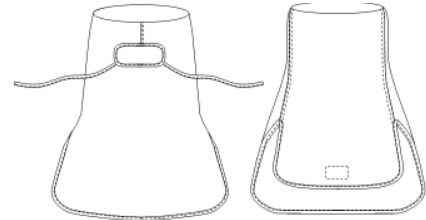
Source: <http://www.sternandstern.com/category/26/arc-flash.html>

### HOOD

#### HE6606IN

Natural  
Unisize

- Nomex
- Eyes only
- Ties affixed to both sides of face
- Opening to cinch hood to user
- Arc Flash Compliance Category 1

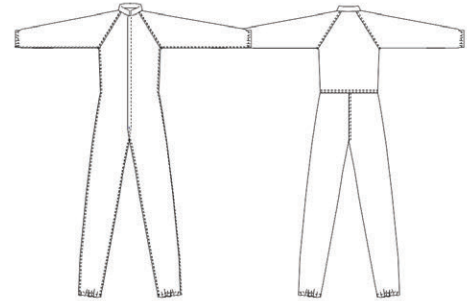


### COVERALL

#### CR6606IN

Natural  
SM-XLG

- Nomex
- Mandarin collar
- Raglan sleeves
- Elastic sleeves & pant cuffs
- Arc Flash Compliance Category 1

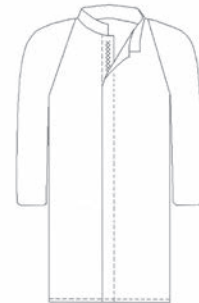


### FROCK

#### FR6606IN

Natural  
XSM-6XLG

- Nomex
- Mandarin collar
- Raglan sleeves
- Tunneled elastic wrist
- Zippered front
- Arc Flash Compliance Category 1

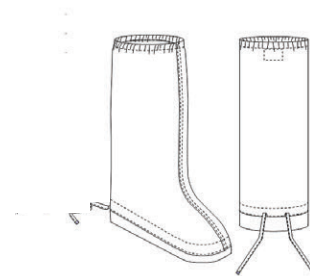


### KNEE HIGH BOOT

#### BK6606IN

Natural  
SM-XLG

- Nomex
- 3/8" full elastic top
- 939 sole
- 20" long
- 1/4" heel straps
- Arc Flash Compliance Category 1



# INNER WEAR - ESD MICRO DENIER



## CONTAMINATION CONTROL FABRICS FEATURES & BENEFITS

**MAXIMUM COMFORT:** Microfiber fabric with moisture management absorbs and moves moisture away from the body for a more comfortable wearer experience.

**EXCELLENT ESD:** Performs through 100 launderings.

**LOW PARTICULATION:** Maintains performance at all wash levels.

**EXCELLENT VALUE:** Reusable textiles save money and are environmentally friendly.

ESD Micro Denier is woven with 99% polyester / 1% carbon fibers.

## MICRO DENIER TECHNICAL INFO

Physical Properties	Values English Units	Values SI Units	Test Method
Width	63.5 in	161em	ASTM-D-3774
Weight	3 oz/yd2	99 g/m2	ASTM-D-3776
Construction			ASTM-D-3735
Warp	125 per inch	49 per em	
Weft	84 per inch	33 per em	
Tensile Strength- Warp (Grab Method) -Fill	109 lbs	24 n	ASTM-5034
Air Porosity@ 125 Pa	18 W/ft2*min	46 n	ASTM-D-737
Mean Pore Size	N10 microns		Parameter method
MVTR	1350 g/m2/24 hours		ASTM 96 Method B
Surface Resistivity			
Weft (66499 only)	1x 108 9 ohms/sq		AATCC-76
Crock	wet 4.5 dry 4.5		AATCC-8
Wash Shrinkage			AATCC-135
Warp	-3%		
Weft	+1%		
Colorfastness Stain	3.5		AATCC-61
Water Absorbency	4 sec		AATCC-79

All values are nominal. Data represents actual test results and is not to serve as specification. Fabrics in dyed shades may change color after extended gamma sterilization cycles. Customer should verify whether such color changes are objectionable. Because gamma sterilizations vary widely, PFG cannot be responsible for color changes that occur.

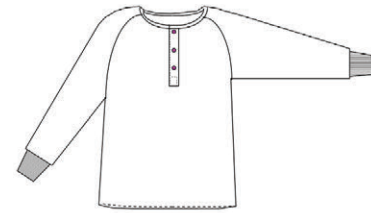
\*Fabric description is supplied by fabric manufacturer and test results are actual lab test data and are not to be used as specifications.

### SHIRT

#### US2044EXA

Navy Blue  
SM-4XLG

- ESD Micro Denier
- Three snap front
- Henley collar
- Long sleeves
- Color matched knit cuffs

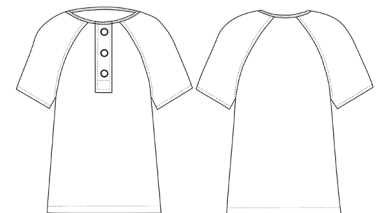


### SHIRT

#### US2044EXASS

Navy Blue  
SM-4XLG

- ESD Micro Denier
- Three snap front
- Henley collar
- Short sleeves

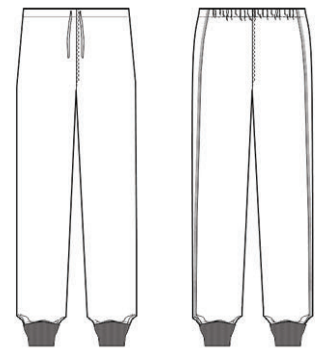


### PANT

#### UP2044MK

Navy Blue  
SM-4XLG

- ESD Micro Denier
- Elastic back
- Drawcord front
- Color matched knit cuffs



# SHOE COVERS - HD ESD & SOCKS

## SUSTAINABLE GOWNING PROTOCOL

### POLYAMIDE CLEANROOM TUBE SOCK SK0379

White  
One size fits all

- ANNEX 1 compliant
- Seamless
- High quality
- Comfortable
- ISO Class 3 cleanroom process and packaged
- Product may vary based on availability
- Available in other styles and colors



**CLEANROOM GOWNING COMPLIANT  
WITH EU GMP ANNEX 1**

Meets the recommendation for wearing socks  
in cleanroom environments

### PERFORMANCE CHARACTERISTICS

LIGHTWEIGHT AND BREATHABLE  
User comfort during long procedures

ECONOMICALLY PRICED



**REDUCE WASTE.**

**REPLACE THOSE  
BLUE DISPOSABLE  
SHOE COVERS AND  
BOOTIES!**

### SHOE COVERS

#### SC1179TS

White  
XSM-3XLG

- HD-ESD fabric
- Tan Hypalon soft sole
- Back adjustable snap



#### SC1179SW

White  
SM-2XLG

- Tan Hypalon soft sole
- Same fabric side walls
- Back adjustable snap



#### SC4879SW

White  
XSM - 5XLG

- Tan Hypalon soft sole
- Sidewall same Hypalon fabric as sole
- Back adjustable snap



# GARMENT BAGS - AB4800 ESD

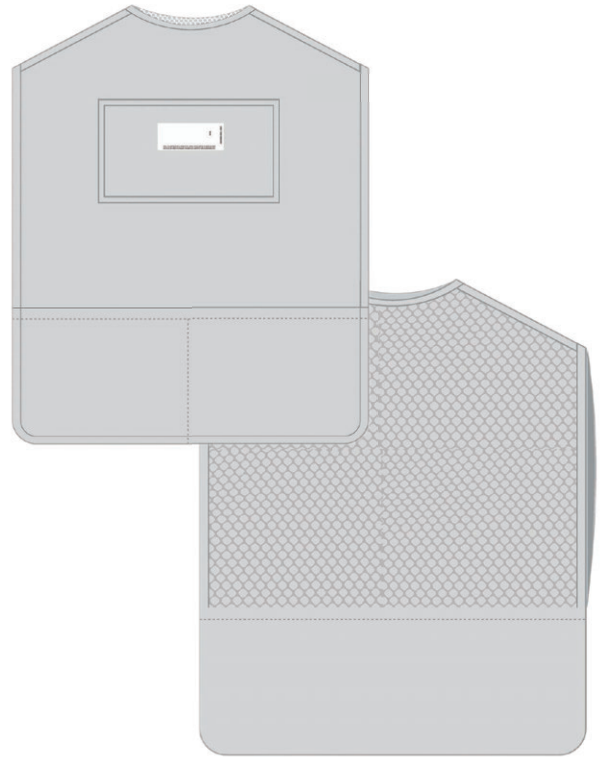
## 23" SMALL GARMENT BAG

### GB4879Q23

White

20" x 23"

- AB4800 front with mesh backing
- One 12" left side opening
- One front top pocket 9.5" x 6"
- Two front bottom pockets 10" x 8"



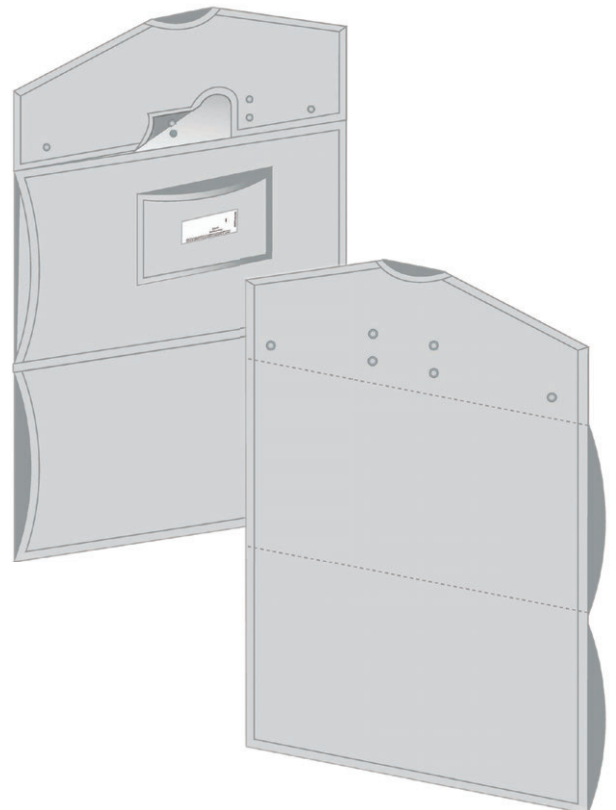
## 32" LARGE GARMENT BAG

### GB4879Q32

White

20" x 32"

- AB4800
- Two 11.5" left side openings
- One front top pocket 7.5" x 6"



# STERILE REUSABLE MOP PROGRAM

**PURMOP®** 

## CLEANROOM REUSABLE MOP PROGRAM - GAMMA IRRADIATED

### VALIDATED CLEANROOM MOP HEAD

#### PURMOP® PMML40

- Available as Sterile or Non-Sterile
- For use with PurMop® hands free system
- Gamma irradiated
- 100% polyester microfiber looped pile
- Water absorbable backing
- White
- 15.75"



### FOLDABLE MOP FRAME

#### PURMOP® PMKEK40

- For use with PurMop® PMML40 mop head
- Quick-connect Ergo Touch Free operation
- Stainless Steel frame
- 15.75"



### MOP HANDLES

#### PURMOP® PMSET2100

- For use with PurMop® system
- Extendable Stainless Steel handle
- Quick-Connect system
- Stainless Steel
- 44" - 83"



PMSET2100

#### PURMOP® PMSAT2150

- For use with PurMop ML40 system
- Extendable Aluminum handle
- Quick-Connect system
- Anodized Aluminum
- 62" - 121"



PMSAT2150



# STERILE REUSABLE MOP PROGRAM

**PURMOP®** 

## REUSABLE CLEANROOM HOOD MOP PAD - GAMMA IRRADIATED POLYESTER AND MICROFIBER

### CLEANROOM HOOD MOP PAD

#### PURMOP® P MEC20S

- Available as Sterile or Non-Sterile
- For Isolator Cleaning Tool
- 100% Polyester
- White
- 7.87"



P MEC20S



P MEF20S

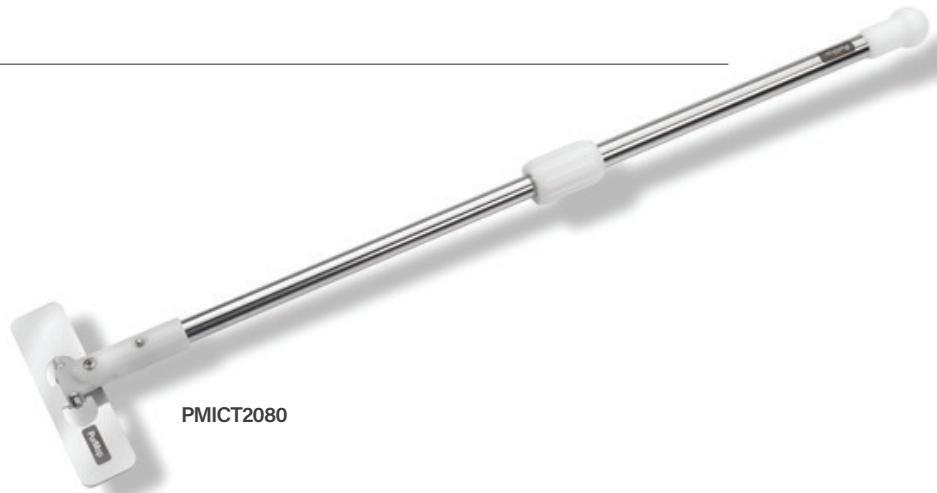
#### PURMOP® P MEF20S

- Available as Sterile or Non-Sterile
- For Isolator Cleaning Tool
- 100% Microfiber - Hydroflex 80/20 Micro/Poly
- White
- 7.87"

### HANDLE AND FRAME

#### PURMOP® P MICT2080

- For Purmop P MEC20S and EPMF20S Hood Mops
- Adjustable
- Stainless Steel
- 24.5" - 36.5"



P MICT2080

#### PURMOP® P MICTA2080

- For Hood Mop
- Adjustable Handle and Frame
- Anodized Aluminum
- 21.65" - 34.25"



P MICTA2080

# REUSABLE MOP PROGRAM

## PURMOP® Hydroflex

### CLEANROOM CLEANING SYSTEM FOR HOOD/ISOLATOR

Easy and safe cleaning of isolators, workbenches and hard to access areas

The PCS Reusable PurMop® ICT is a compact cleaning tool for isolators, workbenches and hard to access areas in GMP and sterile cleanrooms

The set consists of three parts:

1. Stainless steel or aluminium handle
2. Stainless steel mop frame
3. Reusable environmental friendly Hood Mop PurMop® EC20 and EF20

The EC20 and EF20 are Gamma Irradiated at SAL 10<sup>-6</sup>, high-purity reusable hood mop pad made of 100% polyester or 100% Microfiber, suitable for effective disinfection of critical surfaces such as glass and stainless steel. Reduce environmental waste.

#### FACTS

- Ergonomic, lightweight maneuverable tool made of stainless steel or aluminum
- Reusable Gamma Irradiated 10<sup>-6</sup>, abrasion resistant and GMP compliant
- Guarantees maximum user safety for the disinfection of health-hazardous areas such as safety workbenches, hood, etc.
- For improved ergonomics and easy accessibility of hard-to-reach areas
- High-quality Reusable hood mop EC20 with good absorbency
- EF20 Microfiber great absorbency, high-quality reusable hood mop

#### CLEANROOM HOOD MOP PAD

##### PURMOP® PMEF20S

- Available as Sterile or Non-Sterile
- For Isolator Cleaning Tool
- 100% Microfiber
- White
- 7.87"



PMEF20S

#### HANDLE AND FRAME

##### PURMOP® PMICT2080

- For Hood Mop Pad
- Adjustable
- Stainless Steel
- 24.5" – 36.5"



PMICT2080

## CLEANROOM T-MOP

#### REUSABLE DOUBLE FACED T-MOP PAD

##### TMOPL

- Available as Sterile or Non-Sterile
- 100% polyester microfiber terry cloth
- Gamma Irradiated
- Grey
- 15"

#### CLEANROOM WALL & CEILING MOP T-FRAME

##### PMTE40

- Quick-connect system for T-Mop Pad
- Works with the PurMop quick-connect mop handles
- Polished Stainless Steel
- 15 3/4"



TMOPL



PMTE40

## PURMOP® CLEANROOM MOP CLEANING SYSTEMS

### PURMOP® CLEANROOM MOP PRE-SATURATION SYSTEM BUCKETS

#### PURMOP® PMPSS

- Two bucket system
- SUS sieve and mop carrier
- For up to 10 mop heads
- Stainless Steel
- 13" x 21" x 13"



### PURMOP® TOUCHLESS CLEANROOM CLEANING SYSTEM BUCKETS & TROLLEY

#### PURMOP® PMP311SS

- Prepare bucket system in front
- Extra buckets at rear
- For up to 20 mop heads with trolley
- Stainless Steel
- 22" x 23" x 35"



### PURMOP® CLEANROOM CLEANING SYSTEM BUCKETS, TROLLEY & WRINGER

#### PURMOP® PMPD311SS

- Three bucket system
- Extra mop bucket, wringer and trolley
- Stainless Steel
- 34.5" x 23" X 37.75"



### ERGONOMIC CLEANROOM CLEANING SYSTEM

#### PME230

- Wetting unit
- Touchless operation
- 3-step workflow (mop pick-up / fluid dosing / discarding)
- Plastic Grey / Stainless Steel Frame
- 30.75" x 27.5" X 41.25"

#### PME230S

- Wetting unit
- Touchless operation
- 3-step workflow (mop pick-up / fluid dosing / discarding)
- Stainless Steel
- 30.75" x 27.5" X 41.25"



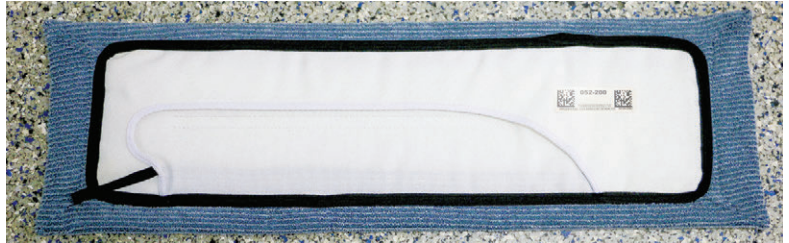
# VALIDATED REUSABLE MOP PROGRAM

## STERILE & NON-STERILE REUSABLE MOP PROGRAM

### VALIDATED REUSABLE MICROFIBER FLAT MOP HEAD

#### HYDROLE

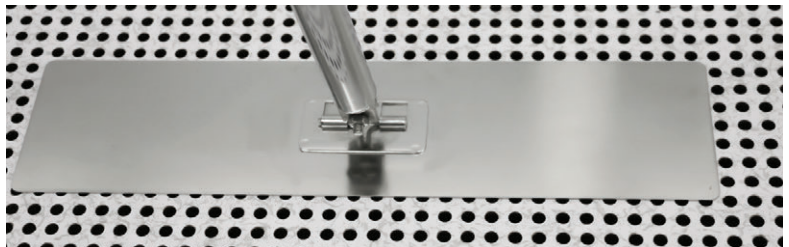
- Available as Sterile or Non-Sterile
- Gamma Irradiated (10 processes)
- Grey
- 22"



### FLAT MOP FRAME

#### HF16SS

- For HYDROLE flat mop head
- Stainless Steel frame and hardware
- Lighter than aluminum frame
- Bolts onto Stainless Steel poles
- Universal 16"



### STAINLESS STEEL MOP HANDLES

#### H30TSS

- Size: 30"
- Telescoping pole
- Wall wash
- Stainless Steel

#### H60NTSS

- Size: 60"
- Non-telescoping pole
- Stainless Steel

#### H92TSS

- Size: 92"
- Telescoping pole
- Stainless Steel



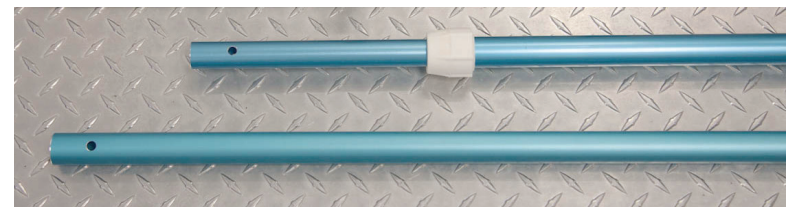
### ANODIZED ALUMINUM MOP HANDLES

#### H57NT

- Non-telescoping pole
- Hand grip
- Blue
- 57"

#### H92T

- Two piece telescoping pole
- Hand grip
- Blue
- 92"



*PLEASE VISIT OUR  
WEBSITE TO VIEW OUR  
MICROFIBER MOP VIDEO!*



# VALIDATED REUSABLE MOP PROGRAM

## STERILE & NON-STERILE REUSABLE MOP PROGRAM

WHY PURCHASE MOP HEADS AND DISPOSE OF THEM WHEN YOU CAN REUSE THEM?

- ✓ Reduce carbon footprint
- ✓ Enhance compliance
- ✓ Reduce waste
- ✓ Reduced costs by > 47%
- ✓ Sustainable

### PRUDENTIAL CR SERVICES

**Lot Date**

*Exp Date*



### PRUDENTIAL CR SERVICES

**Lot Date**

*Exp Date*



### STERILE LABELING

Gold: Pre-exposure

Red: Post-exposed

#### VALIDATED REUSABLE MOP HEAD

##### MPOEM12NL

- Validated Sterile to SAL 10<sup>-6</sup>
- Gamma Irradiated
- 100% continuous monofilament polyester string mop
- White
- Standard size



#### VALIDATED REUSABLE POLYGEN MOP HEAD

##### 9328

- Validated Sterile to SAL 10<sup>-6</sup>
- Gamma Irradiated
- White
- 12"



#### VALIDATED REUSABLE MICROLOOP MOP HEAD

##### 9329

- Validated Sterile to SAL 10<sup>-6</sup>
- Gamma Irradiated
- White
- 5-12"



## FIFO

Offered by **Prudential  
Cleanroom  
Services®**

### BIG ADVANTAGES

- ✓ Item rotation
- ✓ Portable (on casters)
- ✓ Loss prevention
- ✓ Prevent expired inventory
- ✓ Easy restocking visibility
- ✓ Powder coat finish
- ✓ Eco-friendly
- ✓ Large front lip for easy access

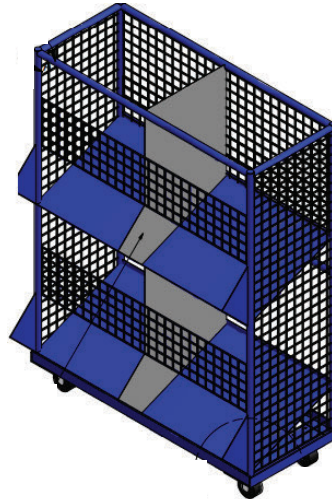


### FIFO BIN CARTS - MADE TO ORDER

#### 4 SECTION UTILITY BIN CART

##### FIFOBINS-04

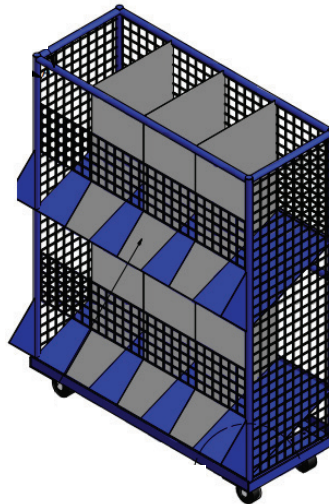
- 2 Shelves - 2 Sections On Each Shelf & Large Front Lip
- Plastic edge protector
- Casters: 4" - All Swivel Total Lock Front & 4" Swivels Rear
- Weight: 257 lbs
- Colors: Blue Powder Coated or Gray Powder Coated
- 22"D x 53 3/4"W x 66 1/4"H without casters
- 72" overall height with casters



#### 8 SECTION UTILITY BIN CART

##### FIFOBINS-08

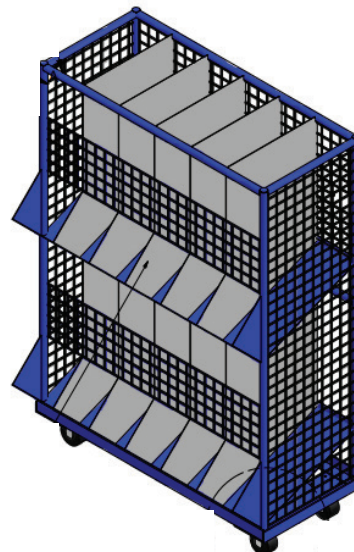
- 2 Shelves - 4 Sections On Each Shelf & Large Front Lip
- Plastic edge protector
- Casters: 4" - All Swivel Total Lock Front & 4" Swivels Rear
- Weight: 341 lbs
- Colors: Blue Powder Coated or Gray Powder Coated
- 22"D x 53 3/4"W x 66 1/4"H without casters
- 72" overall height with casters



#### 12 SECTION UTILITY BIN CART

##### FIFOBINS-12

- 2 Shelves - 6 Sections On Each Shelf & Large Front Lip
- Plastic edge protector
- Casters: 4" - All Swivel Total Lock Front & 4" Swivels Rear
- Weight: 431 lbs
- Colors: Blue Powder Coated or Gray Powder Coated
- 22"D x 53 3/4"W x 66 1/4"H without casters
- 72" overall height with casters



# NON-STERILE GOWNING PROCEDURE

## NON-STERILE GOWNING PROCEDURE BEGINS >



1. GLOVES

Don two pairs of cleanroom gloves, placing the second pair over the first pair.



5. HOOD

Remove hood from packaging making sure that the I.D. label is on the inside. Don hood. Adjust the hood for a comfortable, yet snug fit using the adjusting snaps.



6. COVERALL

Remove coverall from package. Grasp coverall by the neck area to unfold, yet not to touch the ground. Unzip coverall.



9. GLOVES

Roll down donning gloves slightly to expose cuff. Snap cuffs of coverall (if applicable). Place cleanroom working gloves over or under the cuff depending on your requirement.



10. BOOTS

Remove boots from package and don the first boot. Snap upper leg and buckle straps as needed. Swivel that leg to the clean zone without making contact with the top of the bench (if applicable). Don the second boot. Swivel that leg to the clean zone without making contact with the top of the bench (if applicable).

# NON-STERILE GOWNING PROCEDURE



Don bouffant hair cover and a pair of shoe covers prior to entering the controlled environment gowning area outer corridor.

## 2. HAIR & SHOE COVERS



Enter the change room across tacky mat or other debris control mat taking at least three steps with each foot.

## 3. CHANGE ROOM



Select proper size garments (hood, boots, coverall & goggles)

## 4. SELECT SIZE



Grasp right cuff to bottom right of zipper and left cuff to bottom left of zipper. Gather coverall upper torso and step into the coverall.

## 7. COVERALL



Tuck in the hood. Completely zip up all zippers. Snap the collar and anklets of coverall (if applicable).

## 8. HOOD



Don goggles. Place goggles so they cover the exposed skin and eye area.

## 11. GOGGLES



Use a mirror to check proper gowning. Discard donning gloves and enter the cleanroom.

## 12. OVERALL CHECK

# NON-STERILE DE-GOWNING PROCEDURE

## NON-STERILE DE-GOWNING PROCEDURE BEGINS >



1. SIT ON BENCH

Sit on the bench. Swivel both legs over to the entry zone without making contact with the top of the bench.



5. REPROCESSING

If you do not intend to re-don the same garment, place the garment in the appropriate receptacle for reprocessing.



6. HANG GARMENTS

If garments are to be re-donned, garments must be hung or stored in a controlled environment.



9. HANG GOGGLES

Hang goggles on hanger or on front snap of coverall. Garment bags may also be used for storage.



10. DISPOSE & EXIT

Exit the change room then dispose of bouffant hair cover, shoe covers appropriately.

# NON-STERILE DE-GOWNING PROCEDURE



Remove goggles. Remove boots one at a time without letting the tops touch the step or floor areas.

## 2. REMOVE GOGGLES



Continue to use a bench to avoid accidental contact with the floor and remove your coverall.

## 3. COVERALL



Grasp cuffs to waist and remove the coverall.

## 4. COVERALL



If coverall is hung snap both boots to the back of your coverall legs so the boot tops do not come in contact with the floor.

## 7. SNAP BOOTS



Remove hood and snap it to the sleeve or neck opening.

## 8. HOOD



End Result. Proper storage configuration for reuse.

## 11. STORE & REUSE

**PLEASE VISIT OUR WEBSITE TO VIEW THE GOWNING AND DE-GOWNING PROCEDURE VIDEO!**



**Table 1 - Selected airborne particulate cleanliness classes for cleanrooms and clean zones**

ISO classification number (N) calculated	Maximum concentration limits (particles/m <sup>3</sup> of air) for particles equal to and larger than the considered sizes shown below (concentration limits are in accordance with equation (1) in 3.2)					
	0.1 micron	0.2 micron	0.3 micron	0.5 micron	1 micron	5 micron
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1 000	237	102	35	8	
ISO Class 4	10 000	2 370	1 020	352	83	
ISO Class 5	100 000	23 700	10 200	3 520	832	29
ISO Class 6	1 000 000	237 000	102 000	35 200	8 320	293
ISO Class 7				352 000	83 200	2 930
ISO Class 8				3 520 000	832 000	29 300
ISO Class 9				35 200 000	8 320 000	293 000

Note: Uncertainties related to the measurement process require that concentration data with no more than three significant figures be used in determining the classification level.

Source:ISO 14644-1:1999(E)

By Richard A. Matthews

## ISO 14644-1

**TITLE:** Cleanrooms and Associated Controlled Environments Part 1: Classification of Air Cleanliness.

**SCOPE:** Defines the classification of air cleanliness in cleanrooms and associated controlled environments exclusively in terms of airborne particles in sizes from 0.1 micrometer to 5.0 micrometer.

**STATUS:** Published as an official ISO Standard, this document contains some of the only mandatory criteria called for in these new ISO Cleanroom Standards. All other information provided is for guidance only.

This document defines the new international classes of air cleanliness measured in number of particles per cubic meter in six different particle sizes (see Table 1).

There are nine major classes of air cleanliness, which can be further divided into 1/10th increments from ISO Class 1 to ISO Class 9, thereby providing 81 separate classes for fine tolerance clean space design. ISO Class 7 would be comparable to a Class 50,000 under US Federal Standard 209E). Under ISO 14644-1, air cleanliness can be determined in three different occupancy states-"as built," "at rest" and "operational."

ISO 14644-1 requires that air cleanliness be reported by ISO class number, by occupancy status and by specific particle size or sizes. Reported data must read as follows:

ISO Class 5 "as built" at 0.2 micron and 0.5 micron, for example.

There are further provisions for defining air cleanliness based upon particles larger than 5.0 micrometers. These are called macroparticles or M descriptors. Macroparticles are necessary for defining relatively dirty clean environments where powders or heavy dusts are present as part of a controlled manufacturing process.

There are also provisions for particles smaller than 0.1 micrometer. These are called ultrafine particles or U descriptors. As certain research and manufacturing processes tend toward nanometer dimensions, U descriptors can be utilized to qualify and quantify clean space.

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M descriptors and U descriptors cannot be used to define airborne particle cleanliness classes. However, they may be used independently or in conjunction with specific airborne particle cleanliness classes in Table 1.

ISO Standards by design have normative (mandatory) sections and informative (non-mandatory) sections. It is important to know the difference.

### Mandatory criteria

Normative sections specify required or directive information. For example, the classes of air cleanliness are normative. How classes are determined is specifically spelled out by a clearly defined mathematical formula. This is also normative.

The basic document, which includes scope, definitions, classification of air cleanliness and demonstration for compliance, is all normative.

In addition, two of the six annexes in this document are normative. They are:

Annex B: Determination of particle cleanliness classification using a discrete-particle-counting, light scattering instrument. Annex C: Statistical treatment of particle concentration data.

## WHERE IT ALL BEGAN

The new family of ISO Global Cleanroom Standards was written by experienced operations personnel whose practical experience had great influence in the development of these new standards.

ISO/TC209, the ISO Technical Committee on "Cleanrooms and associated controlled environments," draws from over 1,000 volunteers from 37 countries to create realistic standards for practical use in the global cleanroom community.

ISO14644-1 is the keystone for the full series of ISO global cleanroom standards. The use of this document became mandatory in the European Union on November 1, 1999. Other parts of the world have also adopted 14644-1 as their baseline cleanroom (clean space) classification document. ISO 9000-certified organizations are required to utilize ISO 14644-1 in defining their clean space. -RAM

**Table 1 - Schedule of testing to demonstrate compliance with particle concentration limits**

Classification	Maximum time interval	Test method
≤ ISO Class 5	6 months	Annex B in ISO 14644-1:1999
> ISO Class 5	12 months	Annex B in ISO 14644-1:1999

NOTE: Particle count tests will normally be performed in the operational state, but may also be performed in the at-rest state in accordance with the designated ISO classification.

**Table 2 - Schedule of additional tests for all classes<sup>1</sup>**

Test parameter	Maximum time interval	Test procedure
Airflow velocity or airflow volume <sup>2</sup>	12 months	ISO 14644-3: --, clause B4
Air pressure difference <sup>3</sup>	12 months	ISO 14644-3: --, clause B5

<sup>1</sup> These tests may normally be performed in either the operation or at-rest state in accordance with the designated ISO classification.

<sup>2</sup> Airflow volume may be determined by either air flow velocity or airflow volume measurement techniques.

<sup>3</sup> This test will not apply to clean zones that are not totally enclosed.

**Table A.1**

Test parameter	Class	Suggested maximum time interval	Test procedure
Installed filter leakage	All classes	24 months	ISO 14644-3: --, clause B.6
Airflow visualization	All classes	24 months	ISO 14644-3: --, clause B.7
Recovery	All classes	24 months	ISO 14644-3: --, clause B.13
Contamination leakage	All classes	24 months	ISO 14644-3: --, clause B.14

Source ISO 14644-2:2000(E)

## Non-mandatory criteria

The other four annexes are informative and are provided for user guidance. They provide a relative graphical illustration of the air cleanliness classes, examples of classification calculations, consideration for counting and sizing both macroparticles and ultrafine particles as well as a procedure for sequential sampling.

### ISO 14644-2

**TITLE:** Cleanrooms and Associated Controlled Environments-Part 2: Specifications for Testing and Monitoring to Prove Continued Compliance with ISO 14644-1.

**SCOPE:** Specifies the requirements for periodic testing of a cleanroom or clean zone to prove -continued compliance with ISO 14644-1 classification of airborne particle cleanliness.

**STATUS:** Published as an official ISO standard September 15, 2000.

ISO 14644-2 draws its strength from ISO 14644-1. ISO 14644-2 spells out the mandatory and non-mandatory tests that must be performed to prove compliance with ISO 14644-1. This short document, only 8 pages long, holds lots of clout.

The three mandatory tests that must be performed to prove compliance with ISO 14644-1 are:

- classification of air cleanliness
- pressure difference
- airflow (either volume or velocity)

Tables 1 and 2 from ISO 14644-2 spell out the mandatory time interval between tests and also reference the proper test methods from ISO-14644-3 "Metrology and Test Methods."

ISO 14644-2 also spells out four owner optional tests that are non-mandatory. However, use of some or all of these tests may be appropriate for evaluating clean space performance. These additional four tests are:

- installed filter leakage
- airflow visualization
- recovery time
- containment leakage

Table A.1 from ISO 14644-2 spells out the time intervals between these owner optional tests and references the proper test methods from ISO 14644-3.

It is significant to note that if an installation has a continuous or frequent monitoring of airborne particle concentration and air pressure difference, the maximum time intervals expressed in Tables 1 and 2 may be extended, provided that the results of this continuous or frequent monitoring remain within the specified limits. The time intervals between tests have a new flexibility with US Federal Standard 209E. The monitoring plan option based upon risk assessment allows for user-friendly flexibility, but such a plan must be carefully and thoroughly thought out.

Generally, ISO 14644-1 and ISO 14644-2 require fewer sample locations for air cleanliness classification than is the case with US Federal Standard 209E, thereby providing cost savings at no sacrifice to air cleanliness quality.

Note: ISO 14644-1 and ISO 14644-2 effectively replaced US Federal Standard 209 E which was withdrawn as a US Standard in November 2001.

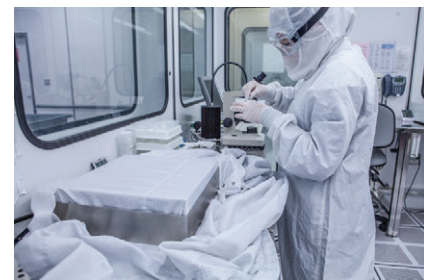
### ISO 14644-3

**TITLE:** Cleanrooms and Associated Controlled Environments-Part 3: Test Methods.

**SCOPE:** Specifies the metrology and testing methods for characterizing the performance of cleanrooms and clean zones.

**STATUS:** Published as an ISO Standard December 2005 places emphasis on the 14 recommended tests used to characterize cleanrooms and clean zones. These tests are:

- 1) airborne particle count for classification
- 2) airborne particle count for ultrafine particles
- 3) airborne particle count for macroparticles
- 4) airflow
- 5) air pressure difference
- 6) installed filter system leakage
- 7) flow visualization
- 8) air flow direction
- 9) temperature
- 10) humidity
- 11) electrostatic and ion generator
- 12) particle deposition
- 13) recovery
- 14) containment leak



Overview of a PCS (ISO Class 3) (FedSTD 209 Class 1) Quality Assurance Test Lab.

Continuous air monitoring data collected within the lab is entered into a statistical process control (SPC) data base. Monthly SPC charts are maintained on all critical parameters of plant processes.



ISO 14644-5 addresses the cleanliness of both stationary and portable equipment used in a ISO Class 3 cleanroom environment.

# ISO GLOBAL CLEANROOM STANDARDS

## CLEANROOM STANDARDS

### *Continued*

As identified in ISO 14644-1 and ISO 14644-2, some of these tests are mandatory and most are voluntary. The key controlling factor is the quality level the cleanroom owner desires and what measurements are necessary to help achieve that level.

The overall emphasis of all these tests and their metrology is performance. We build and operate clean space to specific performance criteria in order to achieve a quality standard determined by end-user needs.

ISO 14644-3 does not specifically address measurements on products or processes in cleanrooms. Rather it covers the cleanroom performance characteristics that lead to the ability to measure product and process quality levels desired by the cleanroom owner.

Of the 14 recommended cleanroom qualification tests, choice of which tests will apply to a particular cleanroom is per agreement between buyer and seller, that is, customer and supplier.

There are three major annexes in ISO 14644-3. Annex A lists all the recommended tests and provides a means of defining the sequence in which these tests are to be utilized in classifying and qualifying a cleanroom or clean zone.

Annex B details the individual test methods so there can be no misunderstanding between customer and supplier. How the test is conducted, any test limitations, and how the test data is reported are given here.

Annex C of ISO 14644-3 lists all the test instrumentation used by the 14 recommended tests. The performance parameters for each instrument are given. What are the sensitivity limits, measuring range, acceptable error, response time, calibration interval, counting efficiency, data display, etc.

#### ISO 14644-4

**TITLE:** Cleanrooms and Associated Controlled Environments-Part 4: Design, Construction and Start-up

**SCOPE:** Specifies the requirements for the design and construction of cleanroom facilities

**STATUS:** Published as an ISO Standard on April 1, 2001.

ISO 14644-4 covers all aspects of the design and construction of cleanrooms.

ISO 14644-4 is a primer to intelligent cleanroom design and construction. It starts with requiring a clear definition of the roles of the primary parties involved in a cleanroom project, i.e. the customer and the supplier as well as ancillary parties such as consultants, regulatory authorities and service organizations.

The Scope of Requirements section necessitates that the purpose of the cleanroom and the operations to be carried out within it are clearly defined. Parameters such as utility needs, process support, dimensions, overall layout, entry and exit of materials and personnel must be defined. Measurement control and monitoring parameters and the influence of external environmental factors are all part of this specification process. The Scope of Requirements section details the assignment of tasks for the preparation, approval, execution, supervision, documentation, statement of

criteria, basis of design, detailed design, construction, testing, commissioning, qualification and the performance and witnessing of tests. More concisely, it states who is responsible for what.

Second is the Planning and Design section, which provides an overview of the details necessary for proper cleanroom design. How does the design address the specification of requirements described above? For example, a contamination control concept should be developed for each zone of a cleanroom installation. Cost factors, time scale factors, design options, constructability of design and project flexibility are all covered in this section.

Third is the section on Construction and Start-up. Specific contamination control requirements apply to construction activities whether performed on the job site or in a remote location. A cleanroom construction protocol and clean-up procedure should be established for all locations as part of an overall quality program. Security and access control should be part of a continuous clean-up plan. Thorough cleaning is required before start-up.

After completion of construction comes the critical phase of Testing and Approval of the cleanroom. This section requires that all personnel in charge of the new cleanroom be properly trained in its operation. Such training is to include cleanroom operations, maintenance and in-process control.

Testing and Approval comes in three distinct stages-construction approval (does the cleanroom comply with the design requirements?), functional approval (do all parts of the cleanroom operate together to achieve the required "as-built" or "at rest" state?) and operational approval (does the cleanroom operate properly under the "operational" state?).

It is important that proper documentation be created and maintained. There is an entire section of ISO 14644-4 devoted to suggestions for appropriate documentation. Included are "as built" drawings, test and certification data, operational and maintenance manuals, spare parts lists and training records.

There are eight comprehensive Annex sections to ISO 14644-4, which are helpful in detailing suggested design criteria, materials of construction, approval stages, installation layout, construction procedures, environmental control requirements and air cleanliness control.

#### ISO 14644-5

**TITLE:** Cleanrooms and associated controlled environments-Part 5: Operations

**SCOPE:** Specifies the basic requirements for operating a cleanroom.

**STATUS:** Published as an ISO Standard August 2004 and this document covers all aspects of operating a cleanroom no matter what class of cleanliness or type of product produced therein. It is a referee document for smart cleanroom operation.

There are six major areas of concern. This first is "Operational Systems" where attention is focused on establishing a framework for providing quality products and processes in a cleanroom environment. Covered are such factors as contamination risk assessment, training procedures, mechanical equipment operation and maintenance, safety, and proper documentation to prove that appropriate procedures are in place and being followed.

The second major area is "Cleanroom Clothing." Who wears what? How is it put on? When should it be replaced or laundered? What type of fabric is appropriate to your situation? We all recognize that the primary function of cleanroom clothing is to act as a barrier that protects products and processes from human contamination. The degree of enclosing an individual is process and product dependent. It could be done by a simple lab coat or a totally enclosed body suit with self-supporting breathing device.



Cleanroom design (including components such as "touch-less" doors and electro-polished stainless steel) as well as proper gowning and operational protocol all play a role in establishing and maintaining an ISO Class 3 (FED-STD-209 Class 1) environment. Pictured is a PCS gowning room.

## CLEANROOM STANDARDS

### *Continued*

The third major area is "Personnel." Only properly trained personnel should be allowed to enter a cleanroom. To do otherwise is to create additional risk. Personal hygiene, cosmetics and jewelry can cause contamination problems. What is your policy in these areas? How should people enter and leave clean space? What is your personnel emergency response procedure?

Fourth is the concern for the impact of "Stationary Equipment." How clean should this equipment be before it is placed in a cleanroom? How should it be moved into this space and set in place? What kind of maintenance will be required? What types of ongoing support services will be needed? What will be the impact of these factors on control of contamination?

The fifth major area of concern covers "Portable Equipment and Materials" that is, items easily transported in and out of the cleanroom. What procedures are needed for control of these items in a cleanroom? Do some materials require protective storage and isolation? How is this done? How are waste materials collected, identified and removed from a cleanroom? Should there be a separate set of tools kept in the cleanroom? What items require sterilization? What items in the cleanroom have out-gassing properties? What items cause static? Because all consumable items in a cleanroom are potential contamination sources, what do you do to control them from entry through use to disposal?

The last area of concern is "Cleanroom Cleaning," otherwise known as "Housekeeping." Outlined are detailed cleaning methods and procedures along with personnel responsibilities. Here again, personnel training is important. How do you clean properly, how frequently and what contamination checks are required? Do you have an assessment system in place for evaluating your housekeeping? What special requirements are required, particularly in areas of risk due to hazardous material, hazardous equipment, equipment location, etc.? How aggressive are your cleaning compounds? How do you avoid adding contamination by your own cleaning procedures?

#### **ISO 14644-6**

**TITLE:** Cleanrooms and associated controlled environments-Part 6: Vocabulary

**SCOPE:** Defines those terms that require more specific description than is found in normal dictionary sources.

**STATUS:** Published as an ISO Standard July 2007.

ISO 14644-6 is the repository of all the common terms, definitions and units used in all the other ISO 14644 and ISO 14698 documents pertaining to cleanrooms and associated controlled environments. It is a database of terms that is applicable to the new family of ISO cleanroom standards. It has been important to harmonize these definitions so they have uniformity of meaning across these new cleanroom standards.

This standard is divided into two main sections. Annex A alphabetically lists all terms and definitions for ease of reference. Annex B lists these same terms and definitions by major category affinity group. For example, there are 23 specific terms listed under Biological Measurement. There are another 29 terms listed under Particle Measurement.

#### **ISO 14644-7**

**TITLE:** Cleanrooms and associated controlled environments-Part 7: Separative devices (clean air hoods, glove boxes, isolators, mini-environments).

**SCOPE:** Published as an ISO Standard October 2004. Specifies the minimum requirements for the design, construction, installation, testing and approval of separative devices in those respects where they differ from cleanrooms.

**STATUS:** A "separative device" is a cleanroom without any people inside. It is usually relatively small in size, but not necessarily so. Examples are clean air hoods, glove boxes, isolators and mini environments-terms that, in many cases, are industry specific. For example, what the healthcare industry refers to as an isolator, the microelectronics industry refers to as a mini environment. However, the healthcare user quite often has to sterilize these enclosures, whereas the microelectronic user does not. This leads to significant design and construction differences. By way of clarification, prior to May 2000, ISO 14644-7 was referred to as "Enhanced clean devices." The writers of this ISO document were not satisfied with its title, and it was changed to the term "Separative Enclosures" and later to "Separative Devices" because that term is more descriptive and definitive of these types of clean environments. The term "Separative Devices" is generic as is the subject matter covered in ISO 14644-7. Separative devices encompass a wide range of configurations from open unrestricted air over-spill to totally contained hard wall containers. They provide the appropriate level of protection from unwanted particle, microbiological, gaseous and liquid contamination, as well as worker safety and comfort. They provide for special atmospheres and bio-decontamination, as well as remote manipulation of enclosed manufacturing processes. In writing this ISO-14644-7 standard, all factors of a clean environment had to be considered in miniature. Such issues of material ingress and egress, personnel interface, installation and maintenance, support services, testing and certification had to be considered for a very different style of clean enclosure than what is required for a typical cleanroom.

ISO 14644-7 is recommended for those who manufacture or use clean-air hoods, glove boxes, isolators, mini environments or similar devices. Such devices may be no-wall, soft-wall or hard-wall, but they share a unifying concept-that a continuum of separation exists between the operator and the operation.

The standard covers such issues as design and construction, risk analysis, contamination control concept, assessment of external influences, access devices, transfer devices, installation, and testing and approval procedures, including glove breach test, leak test, pressure differential test and routine alarm requirements.

There are many other aspects of these separative devices for which guidance is provided in the etailed annexes.

Probably the most valuable is Annex A, which spells out the newly created "Separation continuum concept." This is the key basis for defining a particular separative device. It weighs the separation means (from aerodynamic to physical) against the assurance of maintaining separation (from low to high). In simple terms, anything from an airflow curtain to a stainless steel wall can be used, recognizing that the more physical the barrier, the higher the assurance of separation. Additional annexes address such issues as air handling and gas systems, access device options in detail, transfer device options in detail, leak detection and testing methods, pressure integrity of enclosures and support devices, as well as design and construction parameters.

## CLEANROOM STANDARDS

### Continued

#### ISO 14644-8

**TITLE:** Cleanrooms and associated controlled environments-Part 8: Classification of airborne molecular contamination.

**SCOPE:** Covers the classification of molecular contamination in terms of airborne concentrations of specific compounds or chemicals and provides a protocol that includes test methods and analysis for concentrations between  $10^0$  and  $10^{-12}$  grams/cubic meter.

**STATUS:** Published as an ISO Standard August 2006.

ISO-14644-8 is the base document for controlling molecular contamination in cleanrooms and associated controlled environments. It includes the special requirements of Separative Devices (see ISO 14644-7) such as mini environments, isolators, glove boxes and clean hoods. Airborne molecular contamination (AMC) is the presence in a cleanroom atmosphere of chemicals (non-particle) in the gaseous, vapor or liquid state which may have a deleterious effect on a product, process or analytical instrument.

Surface molecular contamination (SMC) in a cleanroom is the presence on the surface of a product or analytical instrument of chemicals (non-particle) in the gaseous, vapor or liquid state which may have a deleterious effect.

Outgassing is gaseous products released from a material under specified conditions of temperature and pressure.

ISO 14644-8 provides a formal classification system of AMC. This system has an ISO descriptors which is as follows:

ISO-AMC Class N(x)

N = the logarithmic index of concentration expressed in grams/cubic meter

x = a chemical category (acid, base, organic, inorganic) or a contaminant category (biotoxic, condensable, corrosive dopant, oxidant)

Let's review a few examples:

1) "ISO-AMC Class -6:( $\Sigma$ Base)

Translated this is an airborne concentration of Bases of  $10^{-6}$  grams/cubic meter.

2) ISO-AMC Class  $^{-6}$  ( $\text{NH}_3$ ) This expresses an airborne concentration of ammonia of  $6^{-6}$  grams per cubic meter.

There is also a provision for measuring surface molecular contamination and this is expressed in concentration per unit area.

Passive diffusive sampling (DIFF) analyzed using gas chromatography mass spectroscopy (GC-MS).

ISO 14644-8 is well organized to give guidance for developing a sound procedure assessing the parameters affecting airborne and surface molecular contamination in a cleanroom or other controlled environment. The AMC and SMC classifications for molecular contamination are entirely separate from the classification of air cleanliness found in ISO 14644-1 for particulate air cleanliness.

Sources of molecular contamination can be from outdoor air, construction materials cross-contamination within a facility, and from daily cleanroom operation and maintenance, including garments, cleaning fluids, packaging materials and portable equipment.

ISO 14644-8 provides a detailed checklist of potential cleanroom-related molecular contamination sources. In addition, it lists typical contaminating chemicals and substances. There is also a listing of typical methods for the measurement and analysis of molecular contamination both passive and dynamic. The instruments and methods must be measurable, verifiable and repeatable.

The idiosyncrasies of barrier technology, as found in isolators, mini environments, glove boxes, clean hoods and the impact of molecular contamination therein, is addressed in ISO 14644-8.

The control of molecular contamination is a field still in its infancy but growing and changing rapidly. It is important to our future. ISO 14644-8 does not recommend any specific control program or device. Rather it provides the means for identifying and assessing the amount of molecular contamination present. How it is best controlled must be determined by the facility involved through determining the source, the carrier, and the resultant interactions on product, process and yield, etc. Elimination at the source is the best place to start. Establishing levels of acceptance is another key parameter.

Molecular contamination can also be controlled by chemical filtration systems, dilute chemistry, alternate chemistries, event control, that is, spills or product handling and common sense when sources are identified and quantified.

#### ISO14698-1

**TITLE:** Cleanrooms and Associated Controlled Environments-Biocontamination Control-Part 1: General Principles and Methods.

**SCOPE:** Describes the principles and basic methodology for a formal system to assess and control biocontamination in cleanrooms.

**STATUS:** Revised as an ISO Standard in 2003.

Good hygiene practices have become increasingly important in modern society. As we increase international trade in hygiene-sensitive products, there is a strong requirement for stable and safe products, particularly in the healthcare field.

To achieve this stability and safety requires good control of biocontamination in the design, specification, operation and control of cleanrooms and associated controlled environments.

ISO 14698-1 provides guideline principles for establishing and maintaining a formal system to assess and control biocontamination in these special environments. It is not a general standard covering all aspects of biocontamination control. It is specific to cleanrooms and associated controlled environments.

A formal system of biocontamination control will assess and control factors that can affect the microbiological quality of a process or product. There are a number of formalized systems to achieve this, such as Hazardous Analysis Critical Control Point (HACCP), Fault Tree Analysis (FTA), Failure Mode and Effect Analysis (FMEA) and others.

ISO 14698-1 is concerned only with a formal system to address microbiological hazards in cleanrooms. Such a system must have the means to identify potential hazards, determine the resultant likelihood of occurrence, designate risk zones, establish measures of prevention or control, establish control limits, establish monitoring and observation schedules, establish corrective actions, establish training procedures, and provide proper documentation.

A formal system requires a sampling procedure for the detection and monitoring of biocontamination in risk zones. Biocontamination can be airborne, on surfaces, on clothing, in liquids, even in the laundering of cleanroom textiles such as garments and wipers.

## CLEANROOM STANDARDS

### *Continued*

Target, alert and action levels must be determined for a given risk zone. Such levels will determine the required remediation effort. All of these impact product quality. A biocontamination sampling program must be established for cleanroom air, walls, floors, ceilings, process equipment, raw materials, process liquids and gases, furniture, storage containers, personal attire and protective clothing. Sampling frequency, site location, sample identification, culturing methods and evaluation criteria must be part of this formal system for biocontamination control. ISO-14698-1 provides a foundation for developing a formal system for biocontamination control in cleanrooms. It provides detailed guidance on how to measure airborne biocontamination, how to validate air samples and how to measure biocontamination of surfaces, liquids and textiles used in cleanrooms; it also provides guidance for validating laundering processes and how to provide proper personnel training.

### **ISO 14698-2**

**TITLE:** Cleanrooms and associated controlled environments-Biocontamination control-Part 2: Evaluation and interpretation of biocontamination data.

**SCOPE:** Gives guidance on basic principles and methodology requirements for all microbiological data evaluation obtained from sampling for viable particles in specified risk zones in cleanrooms.

**STATUS:** Published as an ISO Standard in 2003.

ISO 14698-2 is designed to be used in conjunction with ISO-14698-1. It provides guidelines for how to estimate and evaluate biocontamination data from microbial monitoring of risk zones. To determine the presence and significance of biocontamination is a multi-step task. Sampling techniques, time factors, culturing techniques, analysis method (qualitative or quantitative estimates) all have to be carefully planned. Target, alert and action levels have to be determined for each risk zone based upon an initial biocontamination data collection and evaluation plan.

Each enumeration technique must be validated considering the viable particles involved. Good data collection and evaluation documentation is necessary to determine trend analysis and the quality of risk zones. Out-of-specification results require verification. "Did we have a true result or is it a laboratory error?" ISO 14698-2 provides the guidance for answering this question accurately.



*Housekeeping, as discussed in ISO 14644-5, keeps this ISO Class 8 (FED-STD-209 Class 100,000) immaculate on both a visual and microscopic level. Pictured is a PCS soil sort room.*

*Editor's Note: These documents may be purchased from the Institute of Environmental Sciences and Technology (IEST), Arlington Place - 2340 South Arlington Heights Road, Suite 100, Arlington Heights, IL 60005-4516. Phone: (847) 981-0100; Fax: (847) 981-4130 or [www.iest.org](http://www.iest.org).*

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# GLOSSARY OF TERMS

## EXCERPTS FROM "A Glossary of Terms and Definitions Relating to Contamination Control" IEST-RD-CC011

*The terms and definitions included in this document generally have distinctive meanings within the context of contamination control. Terms having a more generic nature are not included in this document; their definitions as found in the American Heritage Dictionary are considered acceptable.*

**ABRASION RESISTANCE**  
The ability of a surface of a material to resist abrasion while in use.

**ADHESION**  
The force exerted across a surface of contact between liquids and solids, or solids and solids, that resists their separation.

**ABSORBER CELL**  
A modular container for an adsorbent (with provision for sealing to a mounting frame) that can be used singly or in multiples to build a system of any airflow capacity.

**AEROSOL**  
A gaseous suspension of fine solid or liquid particles.

**AEROSOL, Air Generated**  
The aerosol that results when the pneumatic force of a high-velocity stream of air breaks up a specified room-temperature liquid into droplets.

**AEROSOL PHOTOMETER**  
An instrument that measures mass concentrations of aerosol by using the forward light-scattering principle. At a minimum, the instrument is capable of measuring aerosol concentrations of up to 100 mg/m<sup>3</sup>, and it has a threshold sensitivity capable of measuring 1 µg/m<sup>3</sup>.

**AIRBORNE PARTICLES**  
Particles suspended in moving or stationary air.

**AIRBORNE PARTICULATE CLEANLINESS CLASS**  
A numerical designation that signifies a maximum allowable concentration of airborne particles of a specified particle size.

**AS ESTABLISHED BY FED-STD-209**, the numerical value of a class is related to the concentration of particles in the size range of 0.5 µm and larger.

**AIRFLOW**  
Movement of air in a given direction with respect to a specified reference plane or other designated physical reference.  
The rate of airflow is expressed in terms of volume per unit time.

**AIRFLOW, PARALLEL** Unidirectional airflow, as demonstrated by a measured deviation of not more than 14 degrees from straight-line flow.

**AIRFLOW PARALLELISM**  
Unidirectionality of airflow, as determined in reference to measured dispersion that does not exceed 14 degrees from straight-line flow.

**AIRFLOW, Uniform**  
A unidirectional airflow pattern in which the point-to-point readings are within ±20% of the average airflow velocity for the total area of the

unidirectional flow work zone.

**AIR IONS**  
Molecular clusters of about ten molecules or more (water, impurities, etc.) that are bound by polarization forces to a singly charged oxygen or nitrogen molecule.

**AIR RESISTANCE**  
The loss of pressure caused by gas moving through the filter medium.

**ANENOMETER**  
An instrument for measuring airflow velocity.

**ANENOMETER, Hot-wire**  
See thermoanemometer.

**ANENOMETER, Vane**  
An instrument that measures the velocity of air by mechanically converting the momentum of the air into the rotation or deflection of a vane.

**ANION**  
A negatively charged atom or group of atoms.

**ANISOKINETIC SAMPLING**  
The condition of sampling in which the mean velocity of the flowing air stream differs from the mean velocity of the air entering the inlet of the sampling probe. Because of particle inertia, anisokinetic sampling can cause the concentration of particles in the sample to differ from the concentration of particles in the air being sampled.

**ANTISTATIC COMPOUND**  
A chemical substance that is capable of neutralizing a surface charge.

**ASEPTIC PROCESSING**  
Production activities that exclude all extraneous living matter, especially microscopic forms such as bacteria and fungi, from the production units being assembled, filled, packaged, or built.

**AS-FOUND DATA**  
Data showing the response of an instrument to known standards before adjusting or calibrating the instrument.  
The term may also be applied to measured data indicating status or condition of a process or environment before any remedial or other required actions are taken.

**BACTERIAL SPORE**  
A resistant body produced by a vegetative bacterial cell. These spores may be resistant to heat, ultraviolet light, and desiccation, and may remain dormant for extended periods of time.

**BACTERICIDE**  
A substance or formulation capable of destroying bacteria.

**BACTERIOSTAT**  
A compound or formulation that retards or prevents the growth of bacteria. Bacteriostats act reversibly; when they are removed, cells resume their normal growth patterns.

**BIOBURDEN**  
A measure of the number of microorganisms resident on or within products and inanimate objects. A common synonym is micro count.

**BYPASS**  
The deliberate or non deliberate diversion of air around a unit whose purpose is to filter that air.

**CALIBRATED EQUIPMENT**  
Test equipment that has been calibrated in accordance with the equipment manufacturer's recommendations or accepted industry practices.

**CERTIFICATE OF COMPLIANCE (conformance)**  
A written statement, signed by a qualified person and accompanied by substantiating information, attesting that the items or services are in accordance with specified requirements.

**CERTIFICATION (see also validation and verification)**  
The culmination of procedures leading to validation, expressed in the form of written evidence (certificate of compliance) that verification has been accomplished in accordance with specified testing procedures, such as FED-STD-209 or IEST-CC006.

**CFU (colony-forming unit)**  
An individual or an aggregate of many microbial cells which, when cultivated on solid media, will develop into a single visual colony.

**CHALLENGE AEROSOL**  
An aerosol derived from the selected aerosol source material and used as the test challenge for filter medium testing. Challenge aerosols may be produced by a variety of methods, the choice determining the aerosol type and particle size characteristics. Air-generated aerosols have a polydisperse nature, while thermally generated aerosols are monodisperse.

**DIOCTYL PHTHALATE (DOP), air-generated aerosol:** An aerosol produced by forcing compressed air through DOP at room temperature.  
The choice of the nozzle determines the mean diameter of the distribution of DOP droplets in the aerosol.

**DIOCTYL PHTHALATE (DOP), gas-thermally generated aerosol:** An aerosol produced by injecting a regulated quantity of liquid DOP into a heated zone by pressure supplied by an inert gas.

**DIOCTYL PHTHALATE (DOP), thermally generated aerosol:** An aerosol produced by condensing DOP vapor which has been evaporated from the liquid phase by the application of heat. Aerosols so produced have a light-scattering mean diameter of approximately 0.3 micrometer and a geometric standard deviation of 1.4. See also thermally generated aerosol.

**CHALLENGE CONCENTRATION**  
The concentration (e.g., mg/m<sup>3</sup>) of an aerosol (number of particles per unit volume) or gas used to challenge a filter, adsorber, or other air cleaning device under conditions specified for testing such devices.

**CHEMICAL COMPATIBILITY**  
The ability of a material to withstand chemical contact with minimal interaction.

**CHEMICAL DEGRADATION**  
Changes in materials that occur when they come into contact with chemicals. Degradation may take such forms as swelling, loss of tensile

strength, deformation, or loss of abrasion resistance.

**CLASS (Airborne Particulate)**  
The cleanliness class, as defined by ISO 14644-1.

**CLEANABILITY**  
The level of cleanliness attainable when a material or a surface is subjected to a specified cleaning process.

**CLEAN-AIR DEVICE**  
A clean bench, clean work station, down flow module, or other equipment designed to control particulate air cleanliness in a localized working area and incorporating, as a minimum, a HEPA filter and a blower.

**CLEAN-AIR DEVICE, Laminar Flow**  
This term is no longer in use. See Clean-air device, unidirectional flow.

**CLEAN-AIR DEVICE, unidirectional flow**  
A clean work station or other device (other than a cleanroom or clean zone) that incorporates one or more HEPA or ULPA filters and one or more motor-blowers for the purpose of supplying unidirectional-flow clean air to a controlled work space.

**CLEAN AIR SYSTEM** A system designed to maintain the cleanliness of air in a cleanroom or clean zone at or below a specified airborne particulate cleanliness class.

**CLEANING AGENT**  
A liquid that enhances the removal of contaminants from surfaces, by such mechanisms as dissolution, reducing surface tension, and neutralizing electrostatic charge.  
Cleaning agents can also be disinfectants. To be acceptable for use in cleanrooms and other environmentally controlled areas, cleaning agents should be chemically and physically compatible with the process or product, or both, and should not themselves contribute measurably to the overall burden of contamination.

**CLEANLINESS LEVEL**  
The established maximum allowable amount of contamination in a given area or volume or on a component.

**CLEANROOM**  
A room in which the concentration of airborne particles is controlled and which contains one or more clean zones.

**CLEANROOM (Facility), As-built**  
A cleanroom (facility) that is complete and ready for operation, with all services connected and functional, but without production equipment or personnel within the facility.

**CLEANROOM (Facility), At-rest**  
A cleanroom (facility) that is complete and has the production equipment installed and operating, but is without personnel within the facility.

**CLEANROOM (Facility), Operational**  
A cleanroom (facility) in normal operation with all services functioning and with production equipment and personnel, if applicable, present and performing their normal work functions in the facility.

**CLEANROOM, Laminar Airflow**  
This term is no longer in use. See cleanroom, unidirectional.

## **CLEANROOM, Mixed Airflow**

A hybrid cleanroom consisting of a combination of a unidirectional-airflow cleanroom and a non unidirectional-flow cleanroom.

## **CLEANROOM, Non unidirectional Airflow:**

A cleanroom in which airflows exist with a multiplicity of flow directions or multiple-pass circulation (eddies) or both.

## **CLEANROOM, Turbulent Airflow**

This term is no longer in use. See cleanroom, non unidirectional airflow.

## **CLEANROOM, Unidirectional-Airflow**

A cleanroom in which airflows have generally parallel streamlines operating in a single direction and with uniform velocity over the cross section.

## **CLEAN WORK STATION**

A clean-air device such as a bench or similar enclosure, characterized by having its own supply of filtered air.

## **CONDENSATION NUCLEI**

Small particles, normally within the size range from 0.001 to 0.1  $\mu\text{m}$  radius, upon which water vapor condenses in the atmosphere.

## **CONDENSATION NUCLEUS COUNTER (sometimes referred to as a condensation particle counter)**

An instrument for counting airborne particles, in the nanometer size range and larger, by optically detecting droplets formed by condensation of a vapor upon the particles.

## **CONDUCTIVE MATERIALS**

For the purpose of controlling static charge, conductive materials are generally considered to be those that have a surface resistivity less than 105 ohms/square or a volume resistivity of less than 103 ohm-cm.

A conductive material is not necessarily static dissipative. For example, a non isotropic (e.g., laminated) material can be surface conductive, but not necessarily volume conductive.

## **CONTAMINANT**

Any unwanted substance present in or on a material or any surface within a clean zone.

## **CONTAMINATE**

To reduce the level of quality by the addition of contaminants.

## **CONTAMINATION**

The result of the addition of contaminants to a material or to any surface within a clean zone.

## **CONTAMINATION CONTROL**

Any organized effort taken to reduce the level of contamination.

## **CONTROLLED ENVIRONMENT**

An environment in which parameters such as temperature, pressure, humidity, contaminant level, and so forth are controlled within specified limits.

## **DECAY TIME**

The time interval between two specified values of a variable that decreases with time.

## **DECONTAMINATION**

The removal of contaminants present in or on a material.

## **DECONTAMINATION FACTOR**

The ratio of the concentrations of contaminants before and after decontamination, cleaning, or treating.

## **DEGRADATION**

Undesirable changes, physical or chemical or both, which take place when a material is exposed to certain solids, liquids, or gases or to harmful environmental conditions. These may include swelling, dissolution, loss of physical strength, etc.

## **DISINFECTANT**

An agent, chemical or physical, designed to reduce the population of microorganisms.

## **DISPERSE SYSTEM**

A two-phase system consisting of a dispersion medium and a disperse phase.

## **DISPERSION**

A general term for a system consisting of solid particles or liquid droplets suspended in a fluid.

## **ELECTRET FILTER MEDIA**

Media made of fibers that carry electrical charge on their surfaces.

## **ELECTROMAGNETIC INTERFERENCE (EMI)**

Conducted or radiated electrical disturbances that can interfere with equipment operation; these disturbances occur anywhere in the electromagnetic spectrum, from less than 10 Hz to cosmic rays, including radio, light, and x-rays.

## **ELECTROSTATIC DAMAGE**

Damage to a product caused by static electricity resulting from either 1) discharge from a charged conductor, 2) field induction, or 3) self discharge.

## **ELECTROSTATIC DISCHARGE CONTROL (ESDC):**

The limitation or elimination of the transfer of electrostatic charge.

## **ELECTROSTATIC FIELD**

a) The space surrounding a charged object within which another charged object will be attracted or repelled. b) A voltage gradient between one electrostatically charged surface and another surface at a different electrostatic potential.

## **ENTRANCE PLANE**

A plane perpendicular to the unidirectional airflow located immediately upstream of a specified region (typically the work area unless otherwise specified) and having the same dimensions of the cross section of the clean zone perpendicular to the direction of the airflow.

## **ESD-PROTECTIVE MATERIAL**

Material generally classified by resistivity as either conductive or static-dissipative; materials capable of dissipating, avoiding, or shielding electrostatic occurrences.

## **FILTER**

A device used to remove particulate matter or impurities from a fluid (gas or liquid) flowing through it.

## **FILTER, Controlled-Pore**

A filter of various plastics or metals having a structure of controlled range of pore size; sometimes referred to as a membrane or molecular filter.

## **FILTER, Extended-Medium**

A filter having a medium in a form that employs pleats, bags, socks, or other shapes to increase the effective surface area available for filtration within a defined filter cross section.

## **FILTER, High-Efficiency particulate air (HEPA)**

A throwaway, extended-medium, dry-type filter in a rigid frame, having a minimum particle-collection efficiency of 99.97% (that is, a maximum particle penetration of 0.03%) for 0.3- $\mu\text{m}$  particles of thermally generated DOP or specified alternative aerosol.

## **FILTER, Mechanical**

Any device that removes particles from a fluid by the mechanisms of impaction, settling, screening, inertia, diffusion, or any combination thereof.

## **FILTER, Membrane**

A filter, generally thin and manufactured from polymeric plastics or from metal, the open structure of which is comprised of pores or capillaries in a controlled range of sizes.

## **FILTER, Ultralow-penetration Air (ULPA)**

A throwaway, extended-medium, dry-type filter in a rigid frame, having a minimum particle-collection efficiency of 99.999% (that is, a maximum particle penetration of 0.001%) for particles in the size range of 0.1 to 0.2  $\mu\text{m}$ , when tested in accordance with the methods of IEST-RP-CC007 (see pp. 36-38).

## **FILTER FLOW RESISTANCE**

Resistance to fluid flow offered by a filter medium, the pressure difference required to give unit flow of a fluid of unit viscosity through a unit cube of filter medium. See also resistance.

## **FILTER MEDIUM**

A permeable material that separates solid particles or liquid droplets from a fluid passing through it.

## **FINGER COT**

A covering or sheath for a finger.

## **FLORA**

The types of microbiological organisms found in an environment.

## **FUMIGATION**

A process of decontamination in which the decontaminant is administered in gaseous, smoke, or aerosol form at ambient pressure.

## **FUNGI**

Non photosynthetic microorganisms possessing cell walls and usually growing as a mass of branching, interlacing filaments known as mycelia. The mycelial forms are called molds, and the non mycelial forms are called yeasts. Fungi are usually larger than 0.4  $\mu\text{m}$  in size.

## **FUNGICIDE**

A substance that is capable of destroying fungi.

## **FUNGISTAT**

A substance that retards or prevents the growth of fungi. The effects of fungi stats are reversible; when the fungi stats are removed, the fungi resume their normal growth patterns.

## **GARMENTS, Cleanroom**

Specially designed items of clothing that are worn to prevent or reduce the dispersion of contaminants that may be shed or released.

## **GENERATED PARTICLES**

Particles that were not previously present on the surface of a substrate, e.g. wipers, but are generated and released in response to mechanical energy imparted to that surface.

## **GOWNING SYSTEM**

A set of specified articles of apparel and accessories, together with specifications governing their donning, use, removal, reprocessing or replacement, and storage, as well as specifications related to the way in which they interface with equipment, fixtures, and facilities.

## **GRAM-NEGATIVE BACTERIA**

Bacteria that do not retain the purple color of the crystal violet dye when treated with Gram's staining technique.

## **GRAM-POSITIVE BACTERIA**

Bacteria that retain the purple color of the crystal violet dye when treated with Gram's staining technique.

Gram's staining technique A method for staining and classifying bacteria, developed by Dr. Hans C.J. Gram.

## **GRAVIMETRIC ANALYSIS**

A standard analytical technique used to determine the mass of a specified material, and commonly used to quantify the amount of nonvolatile residue in a solvent. In this application, the contaminated surface is rinsed with a solvent, the solvent is evaporated, and the mass of the substance remaining is determined. This residue, the NVR, is expressed as mass per unit area of surface.

## **GROUND**

An electrically conducting connection to the earth or to another conducting body that serves in place of the earth.

## **GROUND LEAD**

Conductive cabling or a similar device used as a wrist strap or other form of grounding system. In a wrist strap system, the lead connects the cuff with a ground. In a foot strap system, the lead may connect the body-contacting portion to the ground-contacting portion.

## **GROUND STRAPS**

A skin-contacting wrist, leg, or ankle strap that rapidly and safely dissipates personnel electrostatic charges to the ground and equalizes electrostatic levels of personnel with that of the work surface. The strap may contain a current-limiting resistor for safety.

## **HEPA (High Efficiency Particulate Air Filter)**

See filter, HEPA.

## **IMPACTION**

Physical contact of particles with other surfaces in response to the application of an external force. The term is occasionally used synonymously with impingement.

## **IMPACTOR**

A sampling device capable of removing particles from a gaseous suspension using the principle of impaction (impingement).

A "cascade impactor" refers to a specific instrument that employs several impactions in series to collect particles of successively smaller sizes.

## **IMPINGEMENT**

A sampling procedure whereby particles are removed from a gaseous suspension by forcibly directing the flowing gas against a collection surface.

## **IMPINGEMENT, Dry**

Impingement in which the particle-collecting surface is a solid or a solid coated with an adhesive.

# GLOSSARY OF TERMS

## **IMPINGEMENT, Wet**

Impingement in which the particle-collecting surface is a liquid or is located beneath the surface of a liquid bath.

## **IMPREGNATED CARBON**

Activated carbon to which one or more ingredients have been added to enhance the adsorption of selected molecular species from air or other gases.

## **INSULATIVE MATERIAL**

A material having a surface resistivity of at least 10<sup>12</sup> ohms/square, or 10<sup>10</sup> ohm-cm volume resistivity.

## **IONIC CONTAMINATION**

Contamination in the form of atoms having electrical charge. Common examples include singly charged atoms (ions) from Group IA (such as sodium and potassium) and Group VIIA (such as fluorine and chlorine) of the periodic table.

## **ISOAXIAL**

A condition of sampling in which the direction of the airflow into the sampling probe inlet is the same as that of the unidirectional airflow being sampled.

## **ISOKINETIC SAMPLING**

The condition of isoaxial sampling in which the mean velocity of the air entering the sampling probe inlet is the same as the mean velocity of the unidirectional airflow at that location.

## **ISOKINETIC TEST AEROSOL GENERATOR (Formerly Isokinetic Smoke Generator)**

An air-generated source of a visible aerosol connected to a length of tubing and fitted with a valve capable of metering the flow of the aerosol to match the flow direction and velocity of the surrounding air within  $\pm 1.5$  m/min (5 ft/min). The outlet of the tubing should not exceed 6.4 mm (0.25 in.) in diameter.

## **LAMINAR AIRFLOW**

This term is no longer in use. See unidirectional airflow.

## **LAMINAR FLOW**

Streamline flow within a fluid (such as air) near a solid boundary (such as a duct wall), characterized by an upper-limit Reynolds number.

## **LAMINAR FLOW CLEAN-AIR DEVICE**

This term is no longer in use. See clean-air device, unidirectional flow.

## **LAMINATE**

A material formed by bonding together two or more layers in order to achieve an effect not otherwise attainable from each of the component layers separately.

## **LAUNDERABILITY**

The ability of an article such as a glove or garment to be laundered to a specified level of cleanliness.

## **LEAK, Absorber**

A gap or void in the adsorbent, gaskets, or metal framework that allows unfiltered air to bypass the adsorbent and enter the cleanroom or clean zone.

## **LEAK, Air-Filter**

A gap or void in the medium, gaskets, or framework of a filter that allows unfiltered air to bypass the filter and enter the cleanroom or clean zone.

## **LEAK TEST, Induction**

A procedure for evaluating the potential for particle intrusion into a clean zone or clean-air device by induction through unsealed construction joints, through structural

## **LEAK TEST, Induction CONT.**

penetrations for piping or utilities, or by back streaming from openings in the work space boundaries.

## **LEAK TEST, In-place**

A leak test performed on installed components, either individually or in banks. Two basic types of in-place testing are: 1) gross testing, which is designed to challenge all parts of the installation, including possible bypass of the bank; and 2) shrouded testing, in which selected portions of the bank are isolated so that only a limited area is subjected to the challenge aerosol or gas at any one time, thereby limiting the total quantity of challenge aerosol or gas presented to the bank.

## **LEAK-TIGHTEDNESS**

The condition of a component, unit, or system where leakage through the pressure boundary is less than a specified value at a specified differential pressure.

## **LIQUID-BORNE PARTICLE CLEANLINESS**

The level of cleanliness specified by the maximum allowable number of particles in a specified size range per unit volume of liquid.

## **MECHANICAL LEAK**

The measure of the direct leakage through metal parts of the cell or its gasket due to manufacturing defects, bypassing of the sorbent because of settling of the sorbent in the bed, or inadequate cell design. The results are reported as percent refrigerant penetration.

## **MICROBIOLOGICAL CLEAN AREA**

A defined space with a filtered air supply that is designed to accommodate the performance of activities for which the control of viable particles is essential.

## **MINIENVIRONMENT**

An environment that provides localized control of airborne contaminants by means of an enclosure designed to isolate product-handling areas from personnel and the surrounding room environment. Four basic types of mini environments are: microenvironment, tool-in-a-box, tunnel, and ducted flow.

## **MOLECULAR DIFFUSION**

The mixing of different substances when subjected to a concentration gradient. The phenomenon originates with molecular motion and tends to produce a uniform concentration.

## **MONITORING**

The routine determination of airborne particle concentrations, as well as other relevant parameters, in cleanrooms and clean zones.

## **MOST-PENETRATING PARTICLE SIZE (MPPS)**

The size of the particles that achieve maximum penetration of the filter medium. Particles that are smaller or larger than the most penetrating size exhibit a lower rate of penetration; the reduced penetration of the smaller particles is due to diffusion mechanisms, while for the large particles it is due to interception and inertial effects. The most penetrating particle size is a function of the structure of the filter medium, the velocity of the airflow through the filter, and the physical and chemical nature of the particles.

## **NONCORROSIVE, Nonstaining**

Terms applied to substances that have a minimal effect on the integrity or appearance of surfaces with which they come in contact.

## **NONIONIC**

A term used to describe materials that do not possess a net electrical charge.

## **NON UNIDIRECTIONAL AIRFLOW**

Airflow that does not qualify as unidirectional because it has a multiplicity of flow directions or multiple-pass circulation (eddies), or both.

## **NON UNIDIRECTIONAL AIRFLOW CLEANROOM (or clean zone)**

A cleanroom or clean zone that is characterized by random, turbulent airflow vectors throughout the work zones.

## **NUMERICAL APERTURE**

A measure of the light-gathering and resolving power of a microscope objective.

## **OPERATIONAL CLEANROOM (Facility)**

See cleanroom, operational.

## **OUTGASSING**

The liberation of a gas from any material other than by change of state.

## **PARTICLE**

An object that is solid, liquid, or both, usually between 1 nanometer and 1 millimeter in size.

## **PARTICLE BURDEN**

The number of particles in the relevant size range per unit area of surface.

## **PARTICLE CONCENTRATION**

The number of particles per unit volume of fluid.

## **PARTICLE COUNT**

The number of particles detected (or reported) in a given volume of fluid.

## **PARTICLE COUNTER, Airborne**

An instrument for continuous counting of airborne particles larger than a given threshold size. The sensing means may be optical, electrical, aerodynamic, etc.

## **PARTICLE COUNTER, Optical**

An instrument that measures particle scattering or extinction of light to report the count and size of discrete particles suspended in a fluid stream passing through the light.

## **PARTICLE DEPOSITION**

The portion of the transient particle population that does not remain airborne, typically with respect to a specified period of time, under the influence of ambient airflow conditions, air and surface temperatures, and localized electrostatic charges.

## **PARTICLE DIAMETER, Mass Median**

A measure of median particle diameter based on the particle mass. For the mass median, one-half of the particle mass is contributed by particles with a size smaller than the mass median size, and one-half by particles larger than the mass median size.

## **PARTICLE SIZE**

The apparent maximum linear dimension of a particle in the plane of observation, as observed with an optical microscope, or the equivalent diameter of a particle detected by automatic instrumentation. The equivalent diameter is the diameter of a reference sphere having known properties and producing the same response in the sensing instrument as the particle being measured.

## **PARTICLE SIZE DISTRIBUTION**

The relative mass or number of particles present in a series of discrete subdivisions of the overall range of designated particle sizes.

## **PARTICULATE**

An adjective referring to particles, e.g., particulate matter.

## **PARTICULATE CLEANLINESS LEVEL, Fluid**

A cleanliness ranking system based on the number of particles, equal to or larger than specified sizes, that are present in a unit volume of fluid (gas or liquid).

## **PARTICULATE PERCENT AREA COVERAGE**

The fraction of the surface that is covered by particles, reported as total particle projected area divided by total surface area.

## **PATHOGEN**

A microorganism capable of causing disease.

## **PENETRATION**

The ratio of the number of particles in fluid exiting a filter to the number of particles in a given volume of the fluid entering the filter, normally expressed as a percentage for a specified particle size range.

## **OBSERVED PENETRATION**

Penetration as calculated from observed counts for limited testing.

## **PENETROMETER**

An instrument for determining penetration characteristics of very high-efficiency filtration media and filter units, using thermally generated challenge aerosol in accordance with MIL-STD-282.

## **PERCENT ELONGATION**

The percent increase in the dimension of the material in the direction of stress at the point of failure.

## **PERMEABILITY**

A quantitative measure of the ability of a material to transfer mass (solid, liquid or gaseous) through its pores and/or capillaries under the influence of a pressure gradient.

## **PHOTOMETER**

See aerosol photometer

## **PLENUM CHAMBER**

An enclosed, positive-pressure section of a gas supply system, designed to ensure even distribution of flow. Examples include: a) the point of origin for air distribution in air-conditioning and ventilation, and b) the supply source for a filtration system to create even distribution of the gas to each filter unit.

## **POD**

A type of box designed to interface with an I/O device so that the outside of the pod is never introduced into the mini environment.

## **PRECISION**

The closeness of agreement between values obtained by repeated measurements of the same quantity under the identical conditions; also known as repeatability or reproducibility.

## **PREFILTER**

A cleaning unit installed upstream of another unit to protect the latter from high concentrations of contaminants. Pre filters are usually less efficient and less expensive than the units they protect.

## **PREP AREA (Decontamination Area)**

A cleanroom or clean zone in which preliminary cleaning or other preparatory procedures are performed before entry into the operational cleanroom. The prep area typically is less clean than the operational cleanroom.

## **PRESSURE, Differential**

The difference in pressure between two points of a system, which may be separated by a solid or fluid barrier.

## **PRESSURE, Gauge**

The amount by which the total absolute pressure exceeds the ambient atmospheric pressure.

## **PRESSURE, Static**

The pressure exerted by a fluid at rest or, if the fluid is in motion, the pressure it exerts perpendicular to its direction of flow.

## **PRESSURE, Total**

The sum of static pressure and velocity pressure at the point of measurement.

## **PRESSURE, Velocity**

The impact pressure associated with the velocity of a flowing fluid. It is related to the kinetic energy per unit volume of the flow.

## **PROCESSING, Garment**

Procedures performed to meet cleanliness and usability specifications for apparel and accessories.

## **RADIO FREQUENCY INTERFERENCE (RFI)**

Noise that disrupts desired instrument signals. As a general rule, interference is restricted to the radio frequency spectrum of 10 kHz to 10 GHz.

## **RECIRCULATED AIR**

The portion of the cleanroom air supply that has been recirculated by the air-handling equipment.

## **RECOMMENDED PRACTICE**

A published document that provides technical guidance, philosophy, or preferred procedures regarding a given topic.

## **RELEASABLE PARTICLES**

Particles present on the surface of a substrate that are readily releasable therefrom by wetting it with a liquid, but without imparting mechanical energy to the substrate.

## **RESIDENCE TIME**

The finite period of time during which a material is contained within a handling or processing system, wherein components of the material may be subjected to change. Calculation of the time of contact is based on the time required for the volume of fluid to completely traverse the medium. The time required for the fluid to traverse the medium is a function of the flow rate of the fluid and the physical parameters of the system.

## **RESIDUAL ACTIVITY**

Residue, which may or may not be active, that remains on surfaces after treatment with an antimicrobial substance.

## **RESISTANCE, Filter**

The pressure drop across a filter under known conditions of flow, temperature, etc., commonly expressed in units of: Pascals (N/m<sup>2</sup>), mm water gauge, inches w.g., or psi (lb/in.<sup>2</sup>).

## **RESOLUTION, Particle Size**

The capability of a particle sizing device to discriminate between particles that are similar in size. The resolution is expressed as the ratio of the minimum size differential required to indicate a size change to the size of the particle being measured.

## **REYNOLDS NUMBER**

A nondimensional value indicating the transition from laminar to turbulent flow in contained fluid systems. It is based upon fluid density, viscosity, and velocity, and the cross-sectional dimensions of the fluid flow system.

## **REUSABILITY**

The capability of a product to be used more than once and to be cleaned to a definable level of cleanliness.

## **ROUGHING FILTER**

A prefilter with high efficiency for large particles and fibers and low efficiency for smaller particles.

## **SAMPLING**

A process consisting of the withdrawal or isolation of a fractional part of a whole. In air or gas analysis, the separation of a portion of an ambient atmosphere with or without the simultaneous isolation of selected components.

## **SAMPLING, Continuous**

Sampling without interruptions throughout an operation or for a predetermined time.

## **SAMPLING, Instantaneous**

Sampling for a period of time that is negligible in comparison to the duration of the operation or to the total period of time being studied.

## **SAMPLING, Intermittent**

Sampling successively for a limited period of time throughout an operation or for a predetermined period of time. The duration of sampling periods and of the intervals between are not necessarily regular and are not specified.

## **SCALE DIVISION**

On a photometer with numbered major scale divisions (0, 1, 2, 3, 4, 5), the term one scale division indicates the interval between consecutive numbered divisions.

## **SENSIBLE HEAT**

The heat absorbed or emitted by a body when its temperature is changed; in contrast with latent heat, the heat interchange associated with a change of state but without change in temperature.

## **SENSOR**

A device designed to respond to a physical stimulus (as temperature, illumination, and pressure, etc.) and transmit a resulting signal for interpretation, or measurement, or for operating a control.

## **SERGE**

A technique of sealing a raw edge of fabric by sewing the edge over onto itself to produce a smooth face to the fabric prior to use in a garment.

## **SETTLING VELOCITY**

The terminal rate of fall of a particle through a fluid as induced by gravity or other external forces.

## **SIMULTANEOUS COUNTING SYSTEM**

A system that uses a pair of detectors to simultaneously determine the concentrations of the test aerosol both upstream and downstream of the filter medium.

## **SORBENCY**

A collective term describing the tendency of a swab or wiper to hold liquids, whether by absorption (within its capillaries or pores) or by adsorption (a surface phenomenon).

## **SORBER BED**

A layer of sorbent contained between two perforated sheets spaced at a specified distance. Also, the assembly of perforated and nonperforated members that comprises the volume into which the sorbent is packed.

## **SORBER CELL**

A modular container for a sorbent (with provision for sealing to a mounting frame) that can be used singly or in multiples to build a system of any airflow capacity.

## **SORPTION**

A general term-applicable to wipers, swabs, and other sorbent materials—which comprises both absorption (within capillaries and pores) and adsorption (a surface phenomenon) without differentiating between them.

## **SPORICIDE**

A substance or formulation capable of destroying bacterial spores.

## **STANDARD AIR**

Air at 50% relative humidity, with a temperature of 21°C (69.8°F), and pressure of 760 mm Hg (29.92 in. Hg).

## **STANDARD AIR DENSITY**

Air having a density of approximately 1.201 kg/m<sup>3</sup> (0.075 lb/ft<sup>3</sup>; that is, standard air with a specific volume of 0.832 m<sup>3</sup>/kg (13.33 ft<sup>3</sup>/lb).

## **STANDARD LEAK PENETRATION**

The leak penetration that would be detected by a discrete-particle counter with a standard sample flow rate of 28.3 L/min (1.0 ft<sup>3</sup>/min) when the sampling probe is stationary over the leak.

## **STANDARD MECHANICAL INTERFACE (SMIF)**

The connecting plate that mates with the bottom of a pod or carrier.

## **STATIC-DISSIPATIVE GARMENTS**

All body coverings specifically designed or treated to prevent buildup of electrostatic charge.

## **STATIC-DISSIPATIVE MATERIALS**

Materials having a surface resistivity between 105 and 1012 ohms/square, or between 103 and 1010 ohm-cm volume resistivity.

## **STERILIZATION**

A physical or chemical process that completely destroys or eliminates all forms of microbial life.

## **STRENGTH**

The combined properties of tensile strength, elongation, and modulus of materials that relate to the ability to resist stress.

## **SURFACE FINISH**

Characteristic properties of the surface of a material; e.g., features such as adhesiveness, abrasiveness, hardness, coefficient of friction, and the propensity to contribute particles.

## **SURFACE RESISTIVITY**

An inverse measure of the conductivity of a material, equal to the ratio of the potential gradient to the current per unit width of the surface, with the potential gradient measured in the direction of current flow in the material. Surface resistivity is numerically equal to the surface resistance between two electrodes forming opposite sides of a square of the material. The size of the square is irrelevant over a wide range of sizes. Surface resistivity is expressed in units of ohms per square (Ω/sq).

## **TENSILE STRENGTH**

The maximum stress a material can withstand when subjected to stretching.

## **THERMOANEMOMETER (Hot-wire Anemometer)**

An instrument that measures the velocity of air by sensing the change in the electrical resistance of a heated element cooled by the airflow.

## **THICKNESS, Filter Medium**

The dimension perpendicular to the plane of the filter medium.

## **TOTAL MASS LOSS**

The mass that outgasses from a material, expressed as a percentage of the initial mass of the specimen. (See ASTM E595.)

## **TRIBOELECTRIC CHARGING**

The generation of electrostatic charges that results when two objects in intimate contact are separated. Substantial charge can be caused by contact and separation of two materials or by rubbing two objects together.

## **TUNNEL**

A mini environment in which an enclosure separates the tools and wafer-handling robot aisle from the general cleanroom; or, an enclosed single-wafer track for transport into and between tools.

## **ULTRAFINE PARTICLES**

Particles in the size range from approximately 0.02 μm to the upper limit of detectability of the discrete-particle counter.

## **UNIDIRECTIONAL AIRFLOW**

Air that flows in a single pass in a single direction through a cleanroom or clean zone with generally parallel streamlines. Formerly referred to as laminar airflow.

## **VALIDATION (See Also Certification and Verification)**

Establishment, by means of a specified testing program, that a system or facility under test is capable of performing as intended.

## **VERIFICATION (See Also Certification and Validation)**

The procedure for determining compliance of air in a cleanroom or clean zone to a specified airborne particulate cleanliness class limit or U descriptors; also, the result of determining such compliance.

## **VIABLE PARTICLE**

A particle capable of reproduction; a living organism.

## **VIRUS**

An obligate intracellular parasite, typically in the size range of 0.01 to 0.1 μm, that can infect and cause disease in man, animals, plants, and insects.

## **VOLUME RESISTIVITY**





















An inverse measure of the conductivity of a material, equal to the ratio of the potential gradient to the current density, where the potential gradient is measured in the direction of current flow in the material. Units are expressed in ohm-centimeters (W-cm).





















## **WIPER**

A piece of fabric or cloth designed for cleaning and removing liquids from critical surfaces.

# WE ARE DIFFERENT

*and our differences **BENEFIT YOUR TEAM!***

Features	Prudential	Domestic Competitor
What is the Sterility Assurance Level (SAL)?	 (SAL) 10 <sup>6</sup>	 TBD: Mostly 10 <sup>3</sup> , sometimes 10 <sup>6</sup>
Do you receive account RFID / bar coding and accurate usage reports?	 Yes	 TBD
What is the true validated ISO classification of the Folding and Packaging Cleanrooms?	 ISO Class 3	 TBD: ISO 4 / 5 or No ISO
What is the Federal Standard Classification of your Cleanroom?	 ISO 14644-1 ISO Class 3	 TBD: ISO14644-1 / Not truly classified
How many ISO 9001 Certified Cleanroom processing facilities?	 We have 8 and Corporate Services and Central Distribution Center (1 more facility under construction)	 TBD
Are irradiation indicators used for sterile products?	 Yes, absolutely!	 TBD
Is a dosimeter indicator sticker applied to your sterile garments?	 Yes	 TBD
Is LOT # traceability & Lot Expiration Date labeling provided on sterile product bags?	 Yes	 TBD
Do you currently have an all inclusive program to manage your budget cost?	 Yes	 No
Does your current or prospective cleanroom laundry supplier guarantee the established rental pricing on all items for the whole term?	 Yes, we guarantee it!	 TBD: Off Cycle Price Increases

Features	Prudential	Domestic Competitor
Does your current or prospective cleanroom laundry supplier launder garments for customers who produce Penicillin?	 No	 TBD
Additional back-up processing facilities?	 We have 6 back-up facilities!	 TBD
How many Service Managers / Supervisors cover your Plant Service Area for customers needs?	 More than three!	 Less than two
Are your garments supplied using a "first in first out" system?	 Yes	 TBD
Are Service Managers evaluated, compensated(\$ ) and measured on billed and collected loss and ruin garment charges(\$)?	 No	 Yes
Do Service Managers have set goals on billing and collecting loss and ruin garment charges at 25% > per customer?	 No	 Yes
What is the estimated loss and ruin cost exposure based on percentage of rental revenue?	 Lowest in the industry!	 TBD: Greater than 25%
Service Charge?	 You can depend on our <i>fixed</i> service charge	 TBD
Total estimated annual cost in addition to standard rental program?	 Less than 6%!	 TBD: More than 25%
Are Test Certifications issued based specifically on your garments?	 Yes	 Garments randomly sampled and tested — only one garment each day from the aggregate total.

\*Comparisons reflect market averages and may not represent specific customer outcomes.

# PRICING COMMITMENT & COST GUARANTEE



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Family owned and operated since 1932, Prudential Overall Supply is dedicated to enhancing our customers' image at the best dollar value. By providing premium quality work wear uniforms, career apparel and casual wear, Prudential is able to outfit your entire organization. This on-time weekly service also addresses your facility's image and safety requirements by offering logo floor mats, wiping towels and paper products.

### A MESSAGE FROM OUR FOUNDER

*"Tell the customer exactly what we can and cannot do. Then, do everything we have promised and expect a fair price for our services.*

*If we all do this, we will grow, retain our customers and prosper."*

# PRICING COMMITMENT & COST GUARANTEE



## BUDGET PROTECTION PROGRAM

- ✓ Never pay an unexpected charge again for loss, damage or prep! Allows you to correctly budget your program costs.



## PRICE GUARANTEE



### ✓ Prudential's Promise

We Guarantee the established pricing on all rental items for a **1 year period**. That means you never have to worry about random price increases and it allows you to budget costs for your business precisely.



## CUSTOMER EXCEPTION REPORT

- ✓ Exception report alerts will occur for any items that are not listed on the account template: Merchandise, Pricing, etc.



## ISO 9001 CERTIFIED

- ✓ Each location is independently certified



# PRUDENTIAL OVERALL SUPPLY

## PRUDENTIAL'S POSITIVE IMAGE PROGRAM



Prudential Overall Supply offers a variety of uniform and related services. Businesses of all types use our services for needs in career, casual and executive apparel.

Prudential Overall Supply can accommodate any business with rental, lease and purchase programs. Also available are custom embroidery and name tags.

As a supplier of industrial products, Prudential Overall Supply offers facility products such as wiping towels, mats, mops, restroom supplies and paper products.



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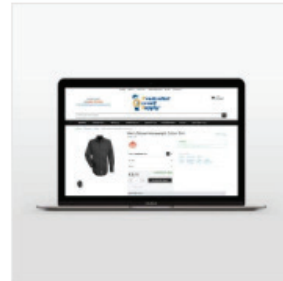
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FACILITY SERVICES



CLEANROOM SERVICES



ONLINE STORE



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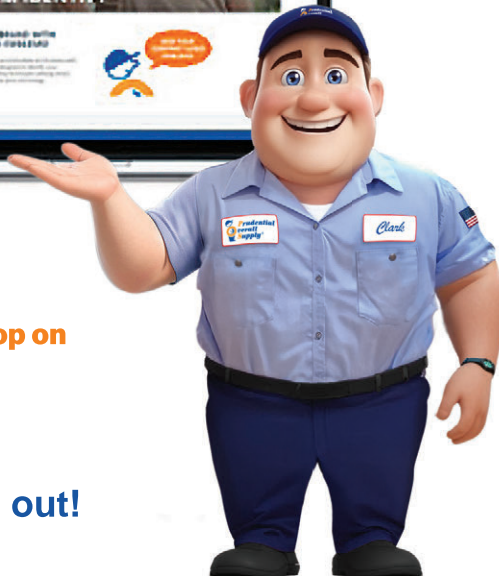


HOSPITALITY



*Our online store offers thousands of image apparel choices for all shoppers.*

- All online customers can browse and pay via credit card at checkout.
- Current Prudential customers can establish credit accounts to make online store purchases.
- Larger volume customers can setup Preferred Customer sites for repeat orders.



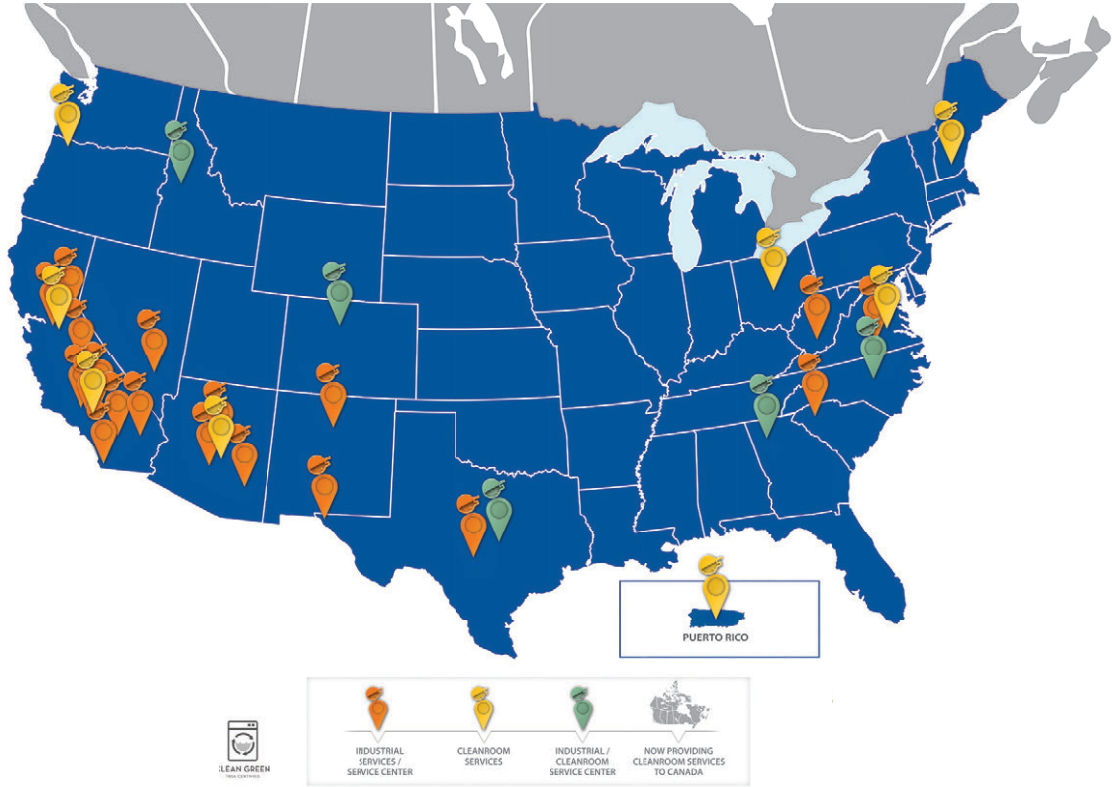
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**DISASTER OR EMERGENCY CAPABILITIES:**

*Prudential's national network of cleanroom garment processing facilities are strategically located, so they support each other in the event of an emergency. Emergency procedures have been designed to ensure uninterrupted service for Prudential customers even during times of calamity or catastrophe.*

*MERCHANDISE IS SUBJECT TO CHANGE OR WITHDRAW WITHOUT NOTICE.*

