

MDI CLEANROOM TRAINING GUIDE AND USERS MANUAL

Introduction

The cleanroom provides an environment that minimizes contaminants, which may adversely affect the manufacture of a product. It is a facility in which the concentration of airborne particulates and other contaminants are controlled to remain below specific threshold limits. Once the environment has been thoroughly cleaned to eliminate contaminants, maintenance of the facility to keep it in compliance with the threshold limit of contamination becomes a matter of process control. People, processes, equipment, and the enclosures of the facility continually generate contaminants. These contaminants must be continually removed from the air as well as prevented entry into the facility. The level to which particles must be held to a minimum depends upon the standards required by the facility and the processes undertaken within the facility. The most frequently used standards are the Federal Standard 209E and the International Standard ISO 14644-1. Although Federal Standard 209E establishes commonly referenced standard classes, it is considered rather outdated and has been replaced by ANSI (American National Standards Institute) and IEST (Institute for Environmental Sciences and Technology) in favor of the International Standard ISO 14644 series of standards due to the simplification of the certification process and the greater suitability ISO 14644 has for sterile environment processes. Table 1 presents the upper limit of allowable contamination for various classes of cleanrooms. The Molecular Design Institute (MDI) cleanroom attempts to maintain a contamination level of ISO 5 according to the ISO 14644 standard and is equivalent to Class 100 by Federal Standard 209E regarding allowable particle contamination. Measurement of contamination in the MDI cleanroom is done by frequent tracking of the number of contaminants $\geq 0.3 \mu\text{m}$, $\geq 0.5 \mu\text{m}$, and $\geq 5.0 \mu\text{m}$ per cubic meter of air (highlighted in gray).

Table 1.

Class	Maximum particles / m ³						FED STD 209E equivalent
	$\geq 0.1 \mu\text{m}$	$\geq 0.2 \mu\text{m}$	$\geq 0.3 \mu\text{m}$	$\geq 0.5 \mu\text{m}$	$\geq 1.0 \mu\text{m}$	$\geq 5.0 \mu\text{m}$	
ISO 1	10	2	-	-	-	-	
ISO 2	100	24	10	4	-	-	
ISO 3	1000	237	102	35	8	-	Class 1
ISO 4	10000	2370	1020	352	83	-	Class 10
ISO 5	100000	23700	10200	3520	832	29	Class 100
ISO 6	1000000	237000	102000	35200	8320	293	Class 1000
ISO 7	-	-	-	352000	83200	2930	Class 10000
ISO 8	-	-	-	3520000	832000	29300	Class 100000
ISO 9	-	-	-	35200000	8320000	293000	Room Air

Control of the total environment including all processes and activity within the environment is necessary to control contamination. Air flow rates and direction, pressurization, temperature, humidity, and filtration all need to be tightly controlled. Introduction of material, motion within the environment, and the logistics for operating procedures are just as important if not more so than simply the filtration of the air coming into the cleanroom. Cleanrooms are planned and manufactured using strict design principles and operating protocols. They are frequently found in electronics, pharmaceutical, biopharmaceutical medical device industries, and other critical manufacturing environments.

Details of Contamination

Contamination is a process or act that causes materials or surfaces to be polluted by foreign matter that is detrimental to the state of the material or to a process involving the material. There are two primary categories of surface contamination: films and particulates. Both types of

contamination can produce detrimental effects to or completely ruin an end product. Although films of only a few nm thickness can drastically reduce coating adhesion on a surface or completely change the nature of the surface chemistry, it is particles $\geq 0.5 \mu\text{m}$ in diameter that are widely accepted as the primary culprit for most contamination in industrial processes. A partial list of sources of contamination is found below to assist users of the MDI cleanroom to have an adequate appreciation for the attention to detail every user must have in order to keep the cleanroom within specification. Users should review this list to understand where contamination originates.

(1) Fluids

- Particulates floating in air due to partial vapor pressures
- Floor finishes or coatings
- Cleaning chemicals
- Outgassing plasticizers
- Air-borne bacteria
- Moisture

(2) Research Samples

- Silicon chips / dust
- Quartz or Mica flakes
- Cleanroom debris
- Aluminum particles

(3) Tools

- Friction and wear particles
- Lubricants and emissions
- Vibrations
- Brooms, mops, dusters

(4) People

- Skin flakes and skin oil
- Cosmetics and perfume
- Saliva
- Clothing debris
- Hair

(5) Facilities

- Walls, floors, ceilings
- Paint and coatings
- Construction material (drywall, saw dust, etc.)
- Air conditioning or HVAC debris
- Room air and vapors
- Spills and leaks

Contamination Control

The MDI cleanroom employs a High Efficiency Particulate Air Filter (HEPA Filter) to prevent entry of particles into the inner-cleanroom. HEPA Filters typically filter particles as small $0.3 \mu\text{m}$ with a 99.97% minimum particle collection efficiency. Cleanroom architecture is also important.

Most cleanrooms are designed to promote laminar flow from the ceiling to the floor where the air is removed *via* positive pressure through a diffuser to the outside environment. The MDI inner-cleanroom has mild positive pressure through the HEPA Filter in the ceiling near the door and allows the air to exit *via* the fume-hood in the back of the inner-cleanroom. Maintenance of a low particle count relies largely on preventing the introduction of particles to the cleanroom and by regular cleaning (see *Housekeeping*).

To illustrate exactly the impact contamination can have on a process it is noteworthy to point out the size of a human hair. A human hair is approximately 75-100 μm in diameter. A particle 200 times smaller than the width of a human hair was responsible for damage of the Hubble space telescope prior to its launch in 1990 due to contamination from the cologne of an operator working inside the cleanroom of Hubble's manufacture. Contamination can lead to expensive downtime and increased production costs in industrial environments or may lead to a simple inability to produce high quality research samples in the case of the MDI laboratory cleanroom. It is for this reason that the MDI cleanroom must be maintained and cleaned to the same high standards as when it was initially cleaned. This operational guideline manual has been prepared to ensure the MDI cleanroom remains within specification when used by authorized personnel.

Pre-Gowning

The following items and activities are required to begin the process of entering/using the cleanroom. These activities are known to affect the level of particulate contamination created in the cleanroom environment and adhering to these pre-gowning requirements is tantamount to maintaining proper cleanroom cleanliness.

- (1) A daily bath/shower is required for all users as well as the wearing of clean, freshly laundered clothing.
- (2) The use of make-up, hair gel, body lotions, and other personal skin care products should be kept to a minimum as these products have the potential to affect the rate at which the human body sloughs particulates or contaminate re-usable cleanroom attire and equipment.
- (3) Users must not smoke within 45 minutes of use of the cleanroom. This is strictly prohibited because it is well documented that personnel who smoke, shed sub-micron sized particles for well over one half-hour after smoking a cigarette. This can be a severe source of contamination within the cleanroom.
- (4) Users should plan out their work prior to entry of the cleanroom so that traffic going in and out of the facility is minimized. This includes making a list of all materials, solvents, tools, etc. that a user will need to successfully complete their cleanroom session as well as preparing these items for entry into the cleanroom according to the material entry procedure (see *Material Entry Procedure*).
- (5) Do not enter the antechamber if a cleanroom user already occupies it. Only one person is admitted to this area at a time.
- (6) Prior to entering the antechamber, remove extraneous street clothing that is not easily covered by the cleanroom jumpsuit and attire, *i.e.* hats, jackets, or sunglasses, and leave these elsewhere outside of the antechamber.

Gowning

(1) Before entering the antechamber, check to make sure you are wearing safety glasses. Reach through the curtain and pull the pneumatic line out of the antechamber. Use the air pressure from the pneumatic line to blow off as many contaminants on your clothing as possible. This helps prevent extra particulates from entering the cleanroom antechamber.

(2) Immediately following entry into the antechamber of the cleanroom facility, take three to four light baby steps on the sticky mat located farthest from the sliding door into the inner cleanroom and sign-in using the log book. **Do not touch anything but the log book, disposable shoe covers, disposable hair covers, or gloves with your bare hands.** Select a pair of disposable shoe covers from the shelving located in the antechamber and pull these over your shoes being careful to minimize contact between the disposable shoe-cover and the outer parts of the shoe.

(3) For long hair, select a hair cover and don the hair cover ensuring that all hair remains inside the cover.

(4) Select a face mask and pinch the metal wire to match the curvature across the bridge of your nose. Don the face mask and adjust it so that it is snug to the face with a minimum of gaps between the skin and the face mask. The upper ties should be tied such that they fit comfortably over your ears and tie behind your head. The lower ties should be tied such that they fit comfortably behind your neck and tie behind your head.

(5) Select a pair of gloves from the shelving in the antechamber and put them on while trying to minimize contact between your hands and the exterior of the gloves.

(6) Once the disposable shoe covers, hair cover, face mask, and gloves are being worn, select and don a hooded jumpsuit from the rack of hooks in the antechamber. The recommended practice is to carefully gather the arm and leg cuffs of the jumpsuit at the base of the zipper while being careful to not allow any part of the jumpsuit to touch the floor. Place one of your legs into the leg of the jumpsuit while releasing it from the base of the zipper and pull the jumpsuit on that leg such that the disposable shoe cover completely clears the cuff of the jumpsuit and never contacts the outside of the jumpsuit. Repeat this procedure for the second leg. While continuing to hold the sleeves of the jumpsuit at the base of the zipper, pull the waist of the jumpsuit up to your waist. Place one arm into the correct sleeve of the jumpsuit while releasing this sleeve from the base of the zipper and ensure that the gloved hand completely clears the cuff of the jumpsuit while minimizing any contact between the glove and the exterior of the jumpsuit. Repeat this procedure for the other arm. Close the zipper of the jumpsuit and adjust the hood such that the elastic is snug against the head and minimizes any exposed skin. Ensure that if a hair cover is also worn, it is completely inside the hood.

(7) Select a pair of re-usable shoe covers hanging from the lowest shelf in the antechamber. Carefully step into the re-usable shoe covers, minimizing any contact between the disposable shoe cover and the exterior of the re-usable shoe cover.

(8) Check yourself in the mirror to ensure that all cleanroom attire is being properly worn and is adjusted correctly.

(9) Take three to four light baby steps on the sticky mat placed closest to the sliding door and enter the cleanroom ensuring that the sliding door is completely closed behind you.

(10) Upon entering the inner-cleanroom, don an additional pair of gloves. Users must wear two pair of gloves at all times inside the inner-cleanroom.

Degowning

- (1) Before exiting the cleanroom be sure to run a particle count measurement using the Kanomax laser particle counter (see *Operating the Kanomax Laser Particle Counter*).
- (2) When the antechamber is vacant, open the sliding door and exit the cleanroom making sure to carefully close the sliding door behind you.
- (3) Carefully remove the re-usable shoe covers, trying to minimize the contact between the disposable shoe and the exterior of the re-usable shoe covers. Return the re-usable shoe covers to their correct storage location hanging from the lowest shelf.
- (4) Carefully remove the jumpsuit while not allowing any part of the jumpsuit to contact the floor. Return the jumpsuit to its correct location on the hooks of the wall in the antechamber.
- (5) Remove the disposable hair cover (if worn), the face mask, and gloves, and place those items in the trash receptacle under the shelving units in the antechamber. **Do not remove the disposable shoe covers.**
- (6) End the cleanroom session by signing out on the clipboard near the entrance to the cleanroom. Failure to sign out may result in revocation of cleanroom privileges.
- (7) Exit the antechamber. The disposable shoe covers should be worn out of the cleanroom and disposed of elsewhere. Tracking the dirt on the disposable shoe covers out of the antechamber will help to keep the antechamber and the cleanroom clean.

Cleanroom Guidelines

- (1) **No eating or drinking in the cleanroom.** The policy for any laboratory involving the use of chemicals or other potentially hazardous materials is that there shall not be any eating, drinking, or chewing of gum within the laboratory at any time. The policy for the cleanroom is no different and this area should be treated the same as any other laboratory.
- (2) **Acceptable materials allowed in the cleanroom.** The following is a general list outlining criteria for cleanroom-compatible materials and cleanroom-incompatible materials. The distinction between the two lists is the tendency for material to shed particles or contaminate other surfaces. Anything that sheds particles or emits vapors that could result in contamination of other surfaces through the development of a coating is generally not allowed. If you have any questions regarding whether or not a material is acceptable in the cleanroom please ask Brian Olmsted (brian.olmsted@nyu.edu) or Trey Piñón (trey.pinon@nyu.edu).

The following are generally considered incompatible in a cleanroom environment:

- (a) Wood pulp-based paper products, including regular paper, tissues, Kimwipes®, cardboard, books, magazines, and lab notebooks.
- (b) Styrofoam products, including packing material, disposable coolers, and sample dividers.
- (c) Any powders, powdered chemical samples, or materials that shed particles including food, gum, drinks, tobacco, cosmetics, foam, or research samples.
- (d) Erasers, pencils, clickable pens, felt-tipped pens other than Sharpie® markers.
- (e) Anything that can easily tear, shred, or efflux particles or plasticizers.

The following are generally considered compatible in a cleanroom environment.

- (a) Cleanroom notebooks and cleanroom paper (available for purchase from many cleanroom equipment supply distributors).
- (b) Wafers, tweezers, and other material handling equipment as long as they are stored in labeled boxes when not used.
- (c) Non-clickable ballpoint pens.
- (d) Materials with smooth, non-soluble surfaces that can be cleaned with isopropanol soaked cleanroom wipes.

(3) **Human activity in cleanrooms.** The primary source of particulate contamination in the cleanroom is users and the rates at which users shed particles correlate to the level of physical activity or motion by the individual. Studies have found that the amount of particles shed per minute by people can increase by an order of magnitude between being motionless and engaging in horseplay. Therefore, it is best to keep movements to a minimum and avoid activities like pacing, extraneous walking, or horseplay.

(4) **Maximum number of personnel.** Because the MDI cleanroom is not very large, it is a good idea to keep the number of personnel working in the cleanroom to a maximum of three at any given time. Exceeding this number is not practical for efficient work practices and will most likely result in wasted motions, a large increase in particle generation, and ruined samples.

(5) **Material Entry.** All tools, containers, implements, and fixtures should be cleaned to the same degree as the cleanroom surfaces before the item is allowed to enter the cleanroom (See *Material Entry Procedure*).

General Practices and Policies

All safe lab practices that are required elsewhere in the MDI laboratory are also required within the cleanroom. In addition to safe general laboratory practices, operations within the cleanroom must adhere to a much more stringent set of guidelines and operating procedures.

MDI laboratories mandate that the buddy system be used in order to prevent accidents and injuries from going unnoticed. The cleanroom is not exempt from this policy although your buddy need not be with you inside the cleanroom. It is important that at least one other person is in the lab and is aware of your activities and location in the event you need assistance.

Communication between personnel inside the inner-cleanroom and the other laboratory areas is facilitated by the use of the phone located in room 558 (MDI Shared Instrumentation Facility). The phone number to contact cleanroom personnel inside the cleanroom is 212.998.3622. Initiating an intercom call to personnel from the phone in room 558 is done by pressing the 'intercom' button (bottom right corner of the button array of the handset), using the up/down arrow keys to scroll down until 'extension #2' is displayed, and selecting the top-right button labeled 'select'. This will cause the handset inside the cleanroom to ring, alerting personnel that someone is trying to contact them.

The logbook must be used each and every time a user enters or exits the cleanroom. Failure to do so will result in revocation of cleanroom privileges.

Keep hair and ears covered by the jumpsuit hood (and hair net when applicable) at all times.

Never touch your skin with your gloves. If your glove comes into contact with any part of your skin, immediately discard the contaminated gloves and replace them with a clean pair (this is why two pair of gloves are required inside the inner-cleanroom).

There is to be NO sanding, filing, drilling, cutting, or breaking of materials inside any part of the

cleanroom. This includes cleaving glass samples or silicon wafers.

Samples, tools, and other materials owned by cleanroom personnel may be stored inside the inner-cleanroom provided that these materials are properly labeled and contained within a labeled storage tote. Excessive personal storage is not permitted. Be reasonable.

Tools in the cleanroom must be introduced according to the material entry procedure (see *Material Entry Procedure*) and must never be placed directly on a horizontal surface inside the cleanroom. Tools must be placed on a cleanroom wipe when not in use.

Items stored in pockets or elsewhere on the body must remain inside the jumpsuit while the user is in the cleanroom.

Do not write on equipment or garments.

Do not sit or lean on equipment or surfaces.

Do not wear torn garments. If any portion of a garment becomes torn while inside the cleanroom, immediately leave the cleanroom and correct the problem.

Do not wear cleanroom garments outside the cleanroom.

Only ballpoint pens (non-clickable) are allowed inside the inner-cleanroom area and paper or notebooks must be specifically approved for cleanroom use.

Open-toed shoes are prohibited.

When using the fume-hood, make sure it is cleaner at the end of your procedure than when you found it.

If you make a mess, immediately clean it up. A spill kit is located under the sink in the case of a chemical spill.

Be aware of supplies. If quantities of stock appear to be low, report it to either Brian Olmsted (brian.olmsted@nyu.edu) or Trey Piñón (trey.pinon@nyu.edu).

Operating the Kanomax Laser Particle Counter (LPC)

Performing a particle count is part of the exiting and degowning process. This is done every time a user leaves the inner-cleanroom so that it is feasible to keep track of potential sources of contamination. If a user neglects to perform a particle count upon leaving the facility, it may result in revocation of cleanroom privileges or other such penalties.

The laser particle counter operates by flowing a controlled stream of air through an inlet tube. The volume of air is measured as it flows through the tube to the device. The mechanics of the device include a series of focusing optics, a laser, and a detector. The laser is focused across the stream of air flowing through the tube and is focused onto a detector through a series of optics such that interruptions between the laser and the detector are counted and correlated to a specific size of particle. The ratio of particles of a given size range to the current volume of air allows a particle count measurement to be reported as particles per volume of air over three different size categories. The size categories recorded by the Kanomax LPC are $\geq 0.3 \mu\text{m}$, $\geq 0.5 \mu\text{m}$, and $\geq 5.0 \mu\text{m}$. The MDI laboratory uses these measurements to correlate the level of contamination to the ISO 14644 guidelines for cleanroom specifications. Performing a particle is done as follows:

(1) Make sure the LPC power is on. If there is no menu presented on the display press the 'POWER' key. If it is turned on, the display will present the following menu:

1. MEASURE MODE
2. DATA PROCESSING
3. OPTIONS

Use the 'UP/DOWN' keys to highlight '1' on the display. Press the 'ENTER' key.

(2) The following menu will be presented on the display:

1. REPEAT
2. SINGLE
3. CONT
4. CALC
5. REMOTE
6. ISO>4

Use the 'UP/DOWN' keys to highlight '2' on the display. Press the 'ENTER' key.

(3) Wait 10 seconds until the display presents a *READY* status on the display and press the 'START/STOP' key. The LPC will now perform a particle count measurement and will record the data in its memory module.

Housekeeping

General housekeeping is important to maintain a low particle count and prevent further contaminants from entering the cleanroom. Please remove the trash when you notice a receptacle is full and remove soiled sticky mats to expose a fresh layer. A particle count is done each and every time a user of the cleanroom facility is ready to exit the facility. Performing particle counts in such a manner allows particle contamination to be correlated to amount of use, type of work done, and by source of potential contamination. Good housekeeping practices warrant regular trash removal, replacement of tacky mats, and the occasional cleaning of all surfaces in the cleanroom. However, when the particle count begins to approach the upper limit of acceptable contamination (above ISO 5 specifications), the cleanroom should be completely re-cleaned such that conditions return below ISO 5 specifications. A thorough cleaning of the cleanroom consists of the following:

- (1) Trash removal.
- (2) Mopping of the floor with water.
- (3) Wipe down of vertical surfaces, nooks & crannies of doors and windows, all visible and hidden surfaces on pull-out drawers, and thorough cleaning of horizontal work surfaces with isopropanol.
- (4) Replacement of tacky mats.
- (5) Sticky roll cleaning of walls, work surfaces, and floor.

Material Entry Procedure

Items known to shed particles are prohibited from being brought into the cleanroom. All other items such as research samples, gas cylinders, tools, etc. must be thoroughly wiped down with a cleanroom wipe soaked in isopropanol. This means that items such as razor blades, aluminum foil, pens, tweezers, and sample vials must have the cardboard or other prohibited wrapping or container removed and the actual items are to be cleaned and placed in an allowed

tote before they are admitted into the cleanroom. Typically, 1 gallon Ziploc® freezer-bags are suitable and preferred as allowed totes to be brought into the inner-cleanroom but other Tupperware® variety totes are also acceptable.

Evacuation Policy

If an incident occurs inside the cleanroom that warrants a dangerous situation not correctable by personnel, unplug any equipment that is currently turned on or running, close all gas cylinder valves, and exit the cleanroom as quickly as possible. It is not necessary to remove any cleanroom specific attire in such a situation. In the event that a fire alarm is sounded, cleanroom personnel are to leave equipment and gas cylinders as they are, but are to immediately vacate the cleanroom facility and should disregard the usual de-gowning procedure.

CLEANROOM USER ORIENTATION FORM

Certification of Completion:

User Name:	
P.I. Name:	
Institute/Department/Organization:	
Phone	Email:

By signing this document, the User certifies that they have fully completed all of the steps required to become a New York University Department of Chemistry User of the MDI Cleanroom and will abide by all of the rules, policies, protocols, and procedures, contained therein. User also agrees to follow the policies that are part of the general user information and policies section of New York University's Lab Safety Training and Hazardous Waste Training courses. The MDI laboratory reserves the rights to change, add, delete, alter, or amend the protocols regarding use of the MDI Cleanroom at any time with or without written notice. User, by signing this form, agrees to follow the direction of the MDI Cleanroom Manager at all times regarding use of the facility.

User Signature:

User name (please print):	
Signature:	Date:

MDI Cleanroom Manager Signature:

Manager name (please print):	
Signature:	Date: