

**STANDARD OPERATING PROCEDURE
DYCEM HOUSEKEEPING - Aseptic Processes**

1/1/07

1.0 PURPOSE

The purpose of this document is to provide specifications for maintaining Dycem's High Performance Contamination Control Mats and Floor coverings in regulated/aseptic cleanrooms and controlled environments.

2.0 SCOPE and SIZING

2.1 This document specifies the proper techniques, methods and materials for performing cleaning and sanitization tasks at the prescribed level. Test methods are specified to assist in determining the appropriate level of surface cleanliness.

2.1.1.1 The size of the mat or flooring is critical to achieve the contamination control required based on the class of the cleanroom and the product sensitivity and specifications. For optimum contamination removal DYCEM needs to be unavoidable and sufficiently large enough to get at least six footsteps or wheel rotations on the surface.

2.1.1.2 The size is determined by the following factors: (see Appendix 3 intended as a guide only)

2.1.1.3 Number of people and/or carts per shift

2.1.1.4 Level of cleanliness required

2.1.1.5 Frequency of wet cleaning

3.0 SAFETY

- All personnel performing housekeeping maintenance shall follow guidelines of the Chemical and Safety Specification.
- Please note, as with all floors Dycem is slippery when wet so please follow reasonable health and safety precautions.

4.0 REFERENCES

The following documents (current issue) are referenced only in those areas, which directly influence this specification.

4.1 ISO 14644-1, "Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness."

4.2 American Society for Testing and Materials (ASTM) F24: "Measurement and Counting Particulate Contamination on Surfaces".

4.3 Institute of Environmental Sciences: IES-CC-018 "Cleanroom Housekeeping, Operating, and Monitoring Procedures".

4.4 ISO 14644-5, "Cleanrooms and associated controlled environments – Part 5: Operations"

5.0 MATERIALS

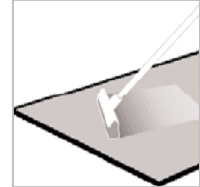
The following is a list of equipment and materials to be used for housekeeping. All cleaning materials must be approved for use in the cleanroom. Equipment designated for cleanroom

service must be restricted to use in the cleanroom(s). All equipment and material must be cleaned/sanitized to cleanroom standards prior to admittance to the cleanroom.

5.1 **Water** – WFI – (water for injection). Note warm water improves cleaning efficacy.

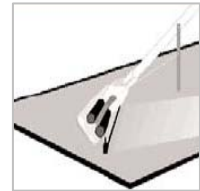
5.2 **Bucket:** Sterilized - stainless steel or non-porous material – double bucket clean system - 3 to 5 gallon capacity.

5.3 **Mop:** Sterilized foam or non-shedding head with a handle constructed of stainless steel or reinforced plastic. Handles and mop head supports must be sterilized.



5.4 **Disinfectant – per site SOP.** A sporicidal agent should be used per rotation of the site SOP.

5.5 **Squeegee:** Sterilized - Non-shedding rubber blade with support and handle constructed of stainless steel or reinforced plastic or equal. Handles and supports must be sterilized.



5.6 **Vacuum Cleaner Portable:** A portable vacuum with accessories and HEPA filtered exhausts. Unit must be certified.

5.6.1 This should only be used in cases where the Dycem has not been cleaned in accordance with the recommended practice or the size of Dycem is too small to cope with current traffic levels.

5.6.2 Soft bristles must only be used otherwise the Dycem surface can be scratched. Vacuum must be sanitized per site SOP.

6.0 FREQUENCY

6.1 Dycem has to be cleaned regularly to remain effective. If Dycem is not serviced there is a risk of the contamination control surface becoming saturated with contamination and allowing particles into the cleanroom or controlled environment by failing to remove the contamination from wheels or feet. A visible inspection will be the first indication that the flooring or mat needs cleaning.

Hence the importance of choosing the right size piece of Dycem in the first instance the chart below gives indicative sizing dependent upon the number of people, level of contamination and wet cleaning frequency. Please see Appendix 2 'What Size do I need.

6.2 Mat and floor cleaning will vary with the amount of traffic.

6.3 Test methods that will vary cleanliness are presented in Section 8.0.

7.0 PROCEDURES

7.1 General

- 7.1.1 Cleaning should always proceed from the most critical side and progress to the less critical side.
- 7.1.2 Circular or scrubbing motions must be avoided.
- 7.1.3 All cleaning strokes shall be top-to bottom with overlapping strokes.
- 7.1.4 The mopping solution must be changed after cleaning 500 square feet (at a minimum) (ISO class 7/8), 300 square feet at a minimum for ISO 5 or lower). Rinsing may be required depending upon the type of cleaning agent selected.
- 7.1.5 A two-bucket method will be used for all mop application.
 - 7.1.5.1 Both buckets contain the disinfectant based on the site SOP.
 - 7.1.5.2 The rinse bucket contains the disinfectant and is used to re-clean the mop. The mop is first placed into the rinse (bucket #2) bucket, wring out, and place in sanitizing (bucket #1) bucket, wring out and applied to the surface. After two passes (one on each side of the mop head), replace the mop into the rinse bucket, rinse and wring, and place mop into bucket #1-sanitizing bucket, wring. Repeat steps.

7.2 Installation

- 7.2.1 The ProtectaMat is generally placed adjacent to the entrance to the higher clean area on the lower clean floor.
- 7.2.2 The Clean Zone is generally installed on a high traffic floor and covers the entire room area. If this is used in a gownroom, a stripe or color difference should be considered to define the clean side from the less clean side of a gownroom.
- 7.2.3 The WorkZone is a installed fixed mat used in high traffic or heavy cart traffic areas.
- 7.2.4 To help the customer Dycem has created a 'What product do I need?' guide and can be found in Appendix 1.

7.3 Cleaning Methods

7.3.1 ProtectaMat

In the unlikely event that the Dycem contamination control surface has not been serviced and is totally saturated with contamination, as shown in the example adjacent, then vacuum the entire mat with a soft-brushed vacuum so the surface does not become scratched. Begin at one end of the mat and work to the other end. Begin by placing the vacuum tool on the mat and pull the tool toward the operator, lift and place at the



starting position, slightly overlapping the previous stroke path. This procedure is used until the entire mat is vacuumed.

The mat is damp mopped with a cleaning agent using the same technique as the vacuum – “pull-lift”. Squeegee the mop solution onto the dirty mat area. After two strokes (one on each side of the mop) remoisten the mop. A two-bucket clean system is recommended for this process so that dirty water is not put back onto the clean floor. Passes may not exceed 4 feet in width. Continue cleaning the entire mat. The last section of the mat should be mopped and squeegee onto the adjacent floor. Follow site SOP for the adjacent floor cleaning. (See section 7.15 – double bucket technique)

For the ProtectaMat you also need to lift the mat at least once a week to clean the underside and the floor it sits on. Replace the mat only when both the mat and floor are clean, dry and dust free.

Please ensure that no water gets underneath the mat as this is a potential slipping/safety hazard.

7.3.2 CleanZone & WorkZone are cleaned in the same way.

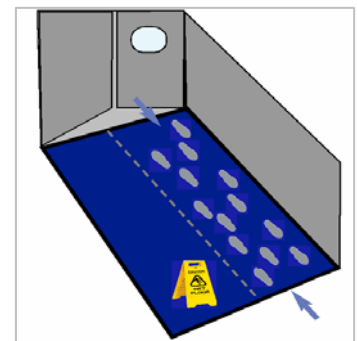
As with the ProtectaMat above it may or may not be necessary to vacuum. If it is, begin at the door or entrance on the clean side and progress to the less clean side. Begin by placing the vacuum tool on the mat and pull the tool toward the operator, lift and place at the starting position, slightly overlapping the previous stroke path. This procedure is used until the entire floor is vacuumed. If vacuuming is not needed please start with damp mopping. The mat is damp mopped with a cleaning agent using the same technique as the vacuum – “pull-lift”. Squeegee the mop solution onto the dirty floor area. After two strokes (one on each side of the mop) remoisten the mop. Passes may not exceed 4 feet in width. Continue cleaning the entire floor. The last section of the floor should be mopped and squeegee onto the floor outside the Dycem contamination control area”. Follow site SOP for the exterior floor cleaning.

7.3.3 Incorporating Dycem into your SOP

Once you are happy that Dycem is being cleaned effectively is recommended that the procedure is incorporated into your SOP for all floor cleaning.

7.3.4 Shift Changeovers

Cleaning during a "shift change" should be avoided whenever possible. As most clean environments are 24/7 operations, the suggested method for cleaning the Clean-Zone flooring surface is to damp mop and squeegee one side at a time, allowing traffic to flow on the opposite side -no room shut down required. As shown in the opposite image.



7.3.5 The Time and Cost of Cleaning Dycem

Dycem will become part of your existing wet floor cleaning regime so there is very little additional cost, you can in most cases use your own approved facilities cleaning agents so the only additional cost is the squeegee element and the collection of the contamination, this takes less than 1minute per 1 m² or 10 sq ft.

8.0 RESPONSIBILITIES

Visual inspection techniques are dependent upon the physical characteristics of the particles, the contrast with background surfaces, the wavelength and intensity of the light used, and the visual acuity and experience of the observer. (See table 1)

TABLE 1

Test Method	Particle Size
Visual	> 40 Micrometers
Wipe Test	> 40 Micrometers
UV Light	> 20 Micrometers
High-Intensity Oblique White Light	>10 Micrometers

- 8.1 Visual inspection using lighting - 120 foot candles equal to a bright sunny day.
- 8.2.1 Wipe Test - moistened wiper placed upon a surface. After cleaning to see if Dycem is really clean rub the wiper on the Dycem surface and check for visual residue and particles.
- 8.2.2 If you are concerned about microbial contamination a Hygiene Meter can be used to determine the level of ATP present before and after.
- 8.4 UV Light Inspection - UV light (365nm) light causes certain organic materials to fluoresce; however, not all-fluorescent material is contamination, nor does all contamination fluoresce. Metals and most glass will not fluoresce. WARNING: DO NOT shine unfiltered light into the eyes. Eye protection is recommended.
 - 8.4.1 Equipment - UV light (a light source with an UV lamp - 365nm).
 - 8.4.2 Procedure - allow the UV light to warm-up for a minimum of 5 minutes to reach operational output. Perform the inspection with facility light as low as practical in order to detect small particles. Inspect all surfaces. If more extensive particle analysis is required, remove the particles from the surface using proper sampling techniques. CAUTION: DO NOT use this technique in proximity to process equipment sensitive to UV light.
- 8.5 High-intensity Oblique White Light - this technique makes use of reflected light and contrast of color and shadow effects caused by particles on relatively smooth surfaces. The angle at which the light is held is critical to detecting very small particles. Angles between 15 and 45 degrees relative to the surface being inspected are most effective. In general, the smaller the particle, the smaller the angle needed to detect it. WARNING: This method of inspection may cause eyestrain with prolonged exposure and shining the light directly or indirectly into the eyes should be avoided.
 - 8.5.1 Equipment - variable-intensity white light source (0-600 foot candles at 1.17cm). A fiber-optic light pipe with a 150-watt halogen lamp will provide a cool light at the inspection point.

- 8.5.2 Procedure - to perform this test, lower the room light in the area to be inspected as low as possible (a minimum of 50% of normal). Inspect all surfaces by varying the distance and the angle of the light to detect the particles of various sizes.

9.0 ACCEPTANCE CRITERIA - NON-VIABLE PARTICLES

The following acceptance criteria shall be used by area:

- 9.1 Entrance corridors and Gown Rooms - free of visible dirt using 120-foot candles of light. Benches, racks, etc. must pass wipe test.
- 9.2 Cleanroom Class 100 and lower (ISO 5 – ISO 1) - inspection with UV or High-intensity Oblique White Light with acceptance level at 0 fiber and 10 particle per square foot.
- 9.3 Cleanroom Class 10,000/100,000 (ISO 7/8) inspection with UV or High Intensity Oblique White light with acceptance level of 20 fibers per square foot.





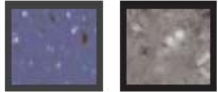

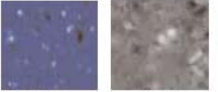

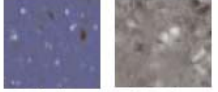

10.0 ACCEPTANCE CRITERIA - VIABLE PARTICLES

- 10.1 Acceptance criteria - refer to the following site SOPs:
RCS Monitoring
Monitoring Irregular Surfaces - Swabs
Monitoring Regular Surfaces – Contact plates
- 10.2 A daily log must be kept with the time and areas sanitized and the disinfectant applied.

11.0 Appendices

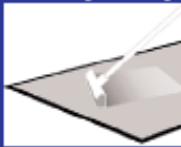
Appendix 1 – What product do I need?

What Product do I need?

Product	ProtectaZone	ProtectaMat	CleanZone	WorkZone
				
Type	Loose Laid	Loose Laid	Fixed	Fixed
Designed for	People (max 20)	People (max 50)	People & Light Carts	People & Heavier Carts (Straight line only)
Standard Size*	2.5mm thick, 1.1m (3.61ft) wide x 2m (6.56ft) or 2.75m (9ft) long*	7mm thick, 1.2m (4ft) wide 2m (6.5ft), 3m (10ft) or 4m (13ft) long*	2.1mm thick, 1.2 (3.94ft) or 2m (6.56ft) wide, 2m (6.56ft), 3m (9.84ft) 4m (13.12ft) or 6m (19.69ft) long*	2.1mm thick, 1.2 (3.94ft) or 2m (6.56ft) wide, 2m (6.56ft), 3m (9.84ft) 4m (13.12ft) or 6m (19.69ft) long*
Colours	 Cobalt or Granite (Decorative to mask the contamination) with black or red safety edges.	 Royal Blue with Red safety edges	 Cobalt or Titanium (Decorative to mask contamination)  Midnight or Slate (Solid to highlight contamination)	 Cobalt or Granite (Decorative to mask contamination)  Midnight or Charcoal (Solid to highlight contamination)

Dycem® Cleaning Procedure

Damp Mop



Installed Mats & Floor Coverings

Clean at least once a day. Use a damp mop or cleaning machine with soft brushes in combination with a Dycem detergent mix on the surface. This releases the contamination from the Dycem surface.

It is important that this is done regularly, otherwise the mat or floor covering will become less effective due to the build up of contaminants which may become difficult to remove.

Squeegee



The squeegee process is the most important step, as it physically removes the contamination and leaves the surface dry and ready for re-use. If this does not happen, two issues arise:

- The detergent mix evaporates, leaving the contamination on the surface.
- The floor remains wet, which is a potential safety hazard.

Wet pick-up

Collect the residue from the edge of the surface with a damp mop, wiper or wet pick-up vacuum.



Loose Laid Mats

Should be cleaned with a damp mop and squeegee. Please ensure that no water gets underneath the mat as this is a potential safety hazard. In addition you need to lift the mat at least once a week to clean the underside and the floor it sits on. Replace the mat only when both the mat & floor are clean, dry and dust free.

Tips & Advice

- Dycem recommends that you use its high performance cleaning detergents and equipment to optimize performance and life cycle.
- Warm water improves cleaning efficiency.
- After cleaning, wash out the equipment so it is ready for re-use.
- To remove built-up spots of contamination clean with a 70/30 Isopropyl alcohol/deionised water wiper.
- If you would like a rejuvenative clean, performance test or if you have any questions or concerns please contact Dycem.
- Where decontamination or sterilisation takes place using a phenolic or hydroxide please rinse off as per instructions above otherwise a film can develop which reduces the effectiveness of dycem
- Don't Use - Concentrated bleaching agents, scouring or abrasive powders, cleaning machines with stiff brushes, buffing or polishing machines will damage the surface, which shortens the active working life.

Active Working System

Dycem High Performance Contamination Control Zones are designed to collect dirt, particulates and bacteria. Between cleaning Dycem can look dirty. This is good news - otherwise all these particles and microbes would be in your critical areas with the risk of contaminating your products and processes.

For more information contact us today:

UK: Tel: +44 (0)117 955 9921 Email: uk@dycem.com
USA: Tel: 1-800 458 0060 Email: info@dycemusa.com

www.dycem.com



ISO 9001:2008
ISO 14001:2004

Appendix 3 – What Size do I need?

What Size do I need?

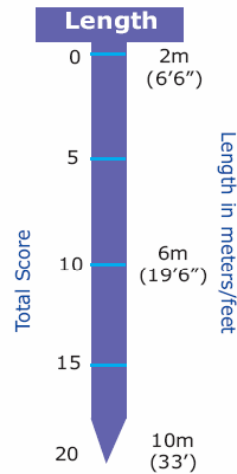
It is important to choose a large enough product for your facility, as size optimises performance, life cycle and satisfaction.

Your Dycem system needs to be unavoidable and sufficiently large to get at least six footsteps or wheel rotations on the contamination control surface.

Size is determined by the following inter-related factors:

- The physical size available.
- The number of operators & light carts per shift.
- The existing wet cleaning schedule.
- The level of cleanliness you need to achieve.

Questions?	Answer	Score
Number of people in/out per shift? <small>(Assuming 5 entry exits per person the average/shift)</small>	0 – 10	1
	10 – 25	2
	25 – 50	4
	50 – 100	6
	100+	10
Frequency of wet cleaning <small>(Involving a good quality detergent & squeegee dry process)?</small>	< Than once per day	10
	Once per day	5
	Once per shift	2
	Twice a shift	1
Total Score		



Cleaning

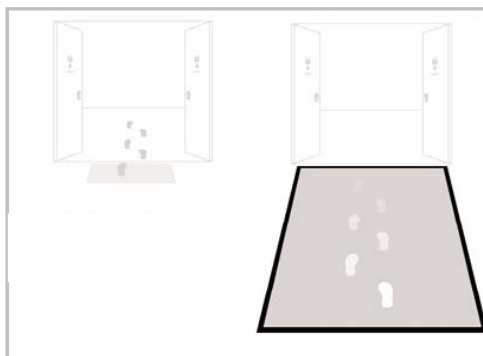
Dycem has to be cleaned regularly to remain effective. The 3 sketches below highlight the interrelationship between size and cleaning. The third diagram highlights that unless Dycem is cleaned shortly there is a risk of it becoming saturated with contamination and letting particles into your critical areas.



- Clean Dycem**
After 3 footsteps of both feet all contamination is removed.
- Between cleaning**
Now taking 4 footsteps of both feet to remove all the contamination.
- Needs Cleaning**
Now taking 6 footsteps of both feet to remove all the contamination.

Width

To ensure CleanZone & WorkZone is unavoidable and requires no overt action by personnel or carts it is best to cover the full width of the area.



Smaller areas can be used especially where footsteps follow a 'Z' traffic pattern such as in a gowning room but to maintain full effectiveness the cleaning frequency will need to be increased and life expectancy may be shortened.

