

Doc. No.: 30-QCL-004  
 Revision: 006  
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**TITLE: BUILDING 3 BMG AREA ENVIRONMENTAL MONITORING**

**ATTACHMENT I**

**ROOM CLASSIFICATIONS/MONITORING FREQUENCY**

Room Number	Room Classification	Room Description	Monitoring Type	Monitoring Frequency	Room Condition *
406	ISO 8	Raw Materials Sampling Suite	Total Particulates / Air Viable / Surface Viable	Not less than once per week	D or S
608/609	ISO 7	Ante Room 2 / Manufacturing 2	Total Particulates / Air Viable / Surface Viable	When in use and not less than twice per week	D or S
610/613	ISO 8	Ante Room / BMG Glasswash	Total Particulates / Air Viable / Surface Viable	Not less than once per week	D or S
611/612	ISO 8	Media Prep / Exit Ante Room	Total Particulates / Air Viable / Surface Viable	Not less than once per week	D or S
614	ISO 8	Hallway	Total Particulates / Air Viable / Surface Viable	Not less than once per week	D or S
615	ISO 8	Ante Room	Total Particulates / Air Viable / Surface Viable	Not less than once per week	D or S
616	ISO 7	Manufacturing I	Total Particulates / Air Viable / Surface Viable	When in use and not less than twice per week	D or S
617	ISO 8	Fermentation II	Total Particulates / Air Viable / Surface Viable	Not less than once per week	D or S
618/619	ISO 8	Ante Room / Large Scale Buffer Prep	Total Particulates / Air Viable / Surface Viable	Not less than once per week	D or S
620/621	ISO 8	Ante Room / Fermentation III	Total Particulates / Air Viable / Surface Viable	Not less than once per week	D or S
609/616/617 621/406 BCS	ISO 6	Biological Safety Cabinets	Total Particulates / Air Viable / Surface Viable	Not less than once per week	D or S

ISO 6 is equivalent to USP, Class 1,000

ISO 7 is equivalent to USP, Class 10,000

ISO 8 is equivalent to USP, Class 100,000

\*Condition that each room must be in during environmental sampling. 'D' means dynamic condition, 'S' means static condition. See section 3.0 for definitions of dynamic and static.

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**TITLE: BUILDING 3 BMG AREA ENVIRONMENTAL MONITORING****ATTACHMENT 2****ALERT AND ACTION LEVELS****Alert and Action Levels (Static or Dynamic)**

Sampling Method		ISO 6 Hoods (Class 1,000)		ISO 7 (Class 10,000)		ISO 8 (Class 100,000)	
		Alert	Action	Alert	Action	Alert	Action
Air Viables (CFU/m <sup>3</sup> )		2	5	5	10	10	15
Surface Viables (CFU/25 cm <sup>2</sup> )	Surface	2	3	3	5	12	25
	Floor	NA	NA	7	10	12	25
Total Particle Count at 0.5 µm		1000 particles/m <sup>3</sup>	3000 particles/m <sup>3</sup>	500 particles/ft <sup>3</sup>	1500 particles/ft <sup>3</sup>	1000 particles/ft <sup>3</sup>	1500 particles/ft <sup>3</sup>
Total Particle Count at 5.0 µm		500 particles/m <sup>3</sup>	1000 particles/m <sup>3</sup>	30 particles/ft <sup>3</sup>	60 particles/ft <sup>3</sup>	50 particles/ft <sup>3</sup>	100 particles/ft <sup>3</sup>

Note: Alert and action levels are met when results exceed the above listed levels.

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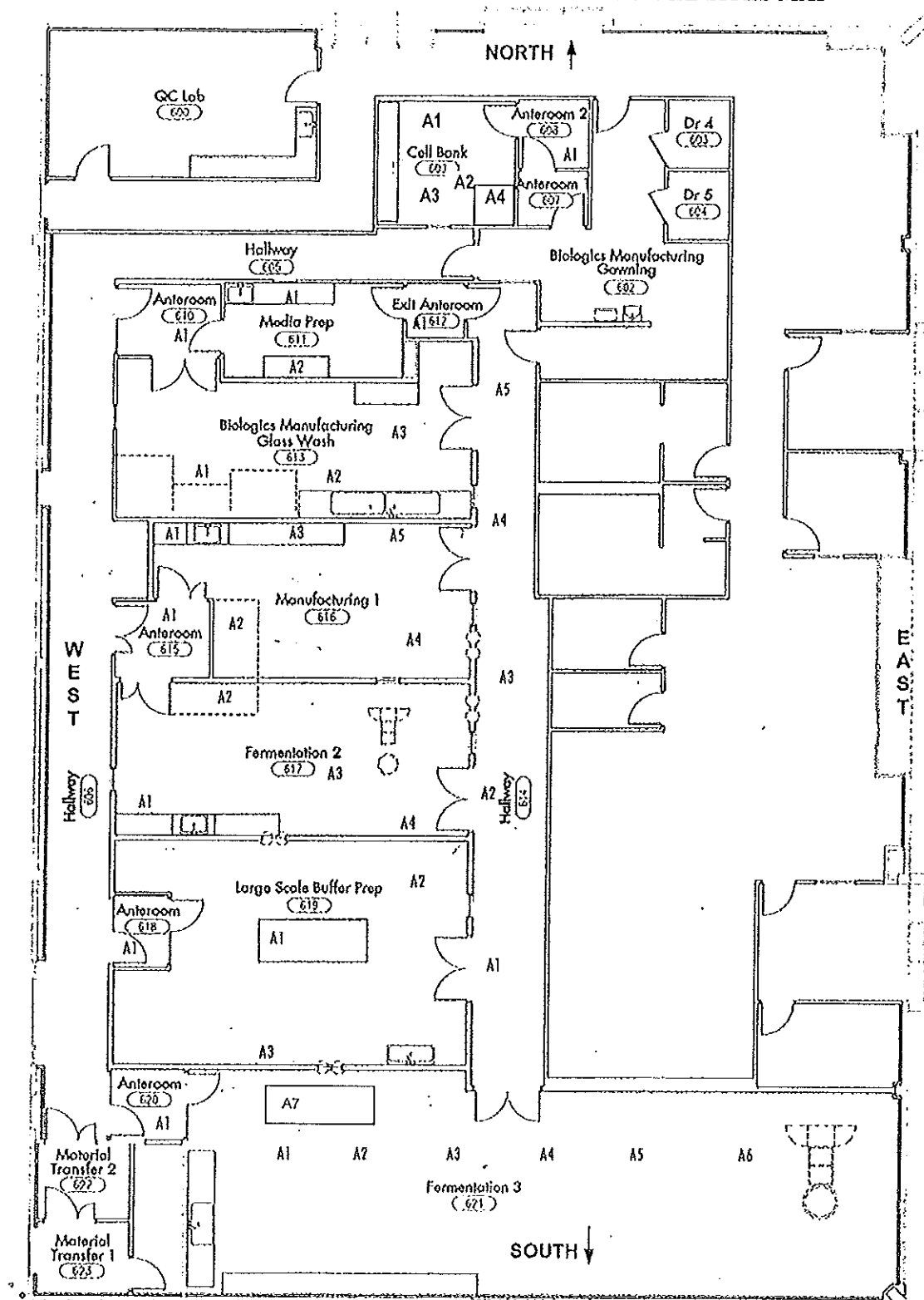
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ATTACHMENT 3 (Page 1 of 3)

**TOTAL PARTICULATE AND AIR VIABLE SAMPLE SITES MAP**



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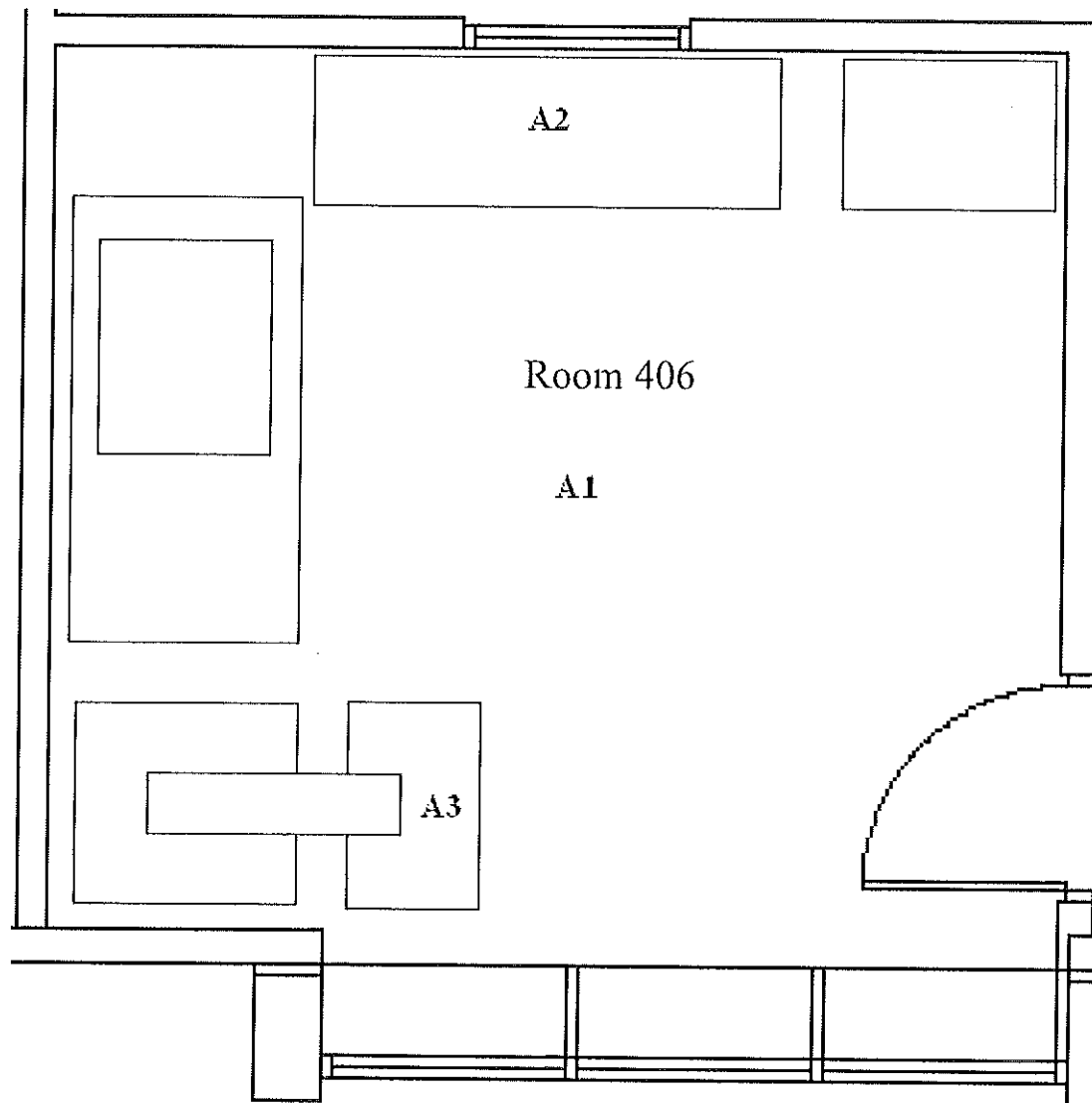
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**ATTACHMENT 3 (Page 2 of 3)**

**TOTAL PARTICULATE AND AIR VIABLE SAMPLE SITES MAP**



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**TITLE: BUILDING 3 BMG AREA ENVIRONMENTAL MONITORING****ATTACHMENT 3 (Page 3 of 3)****TOTAL PARTICULATE AND AIR VIABLE SAMPLE SITES  
DESCRIPTION OF SITES**

Room	Site ID	Description
406	A1	Center Room
406	A2	By Table
406	A3	Clean Station
608	A1	Center Room
609	A1	North Side Center of Room
609	A2	Center Room
609	A3	South Side of Room
609	A4	In Hood
610	A1	Center Room
611	A1	Counter North
611	A2	Counter South
612	A1	Center Room
613	A1	By Depyrogenation Oven
613	A2	By Glasswasher
613	A3	By Counter
614	A1	By Room 619
614	A2	By Room 617
614	A3	By Trash Chute (Room 624)
614	A4	By Room 616
614	A5	North End of Hallway
615	A1	Center Room
616	A1	Left of Sink
616	A2	In Hood
616	A3	Center North Side of Room
616	A4	East Side of Room
616	A5	By Door to 614
617	A1	By Sink
617	A2	In Hood
617	A3	Center Room
617	A4	By Door to 614
618	A1	Center Room
619	A1	Counter West Side
619	A2	Northeast Corner of Room
619	A3	LAP
620	A1	Center Room
621	A1	West Side of Room
621	A2	Center Room West
621	A3	Center Room
621	A4	Center Room By Door to 614
621	A5	Center Room East
621	A6	East Side of Room
621	A7	In Hood

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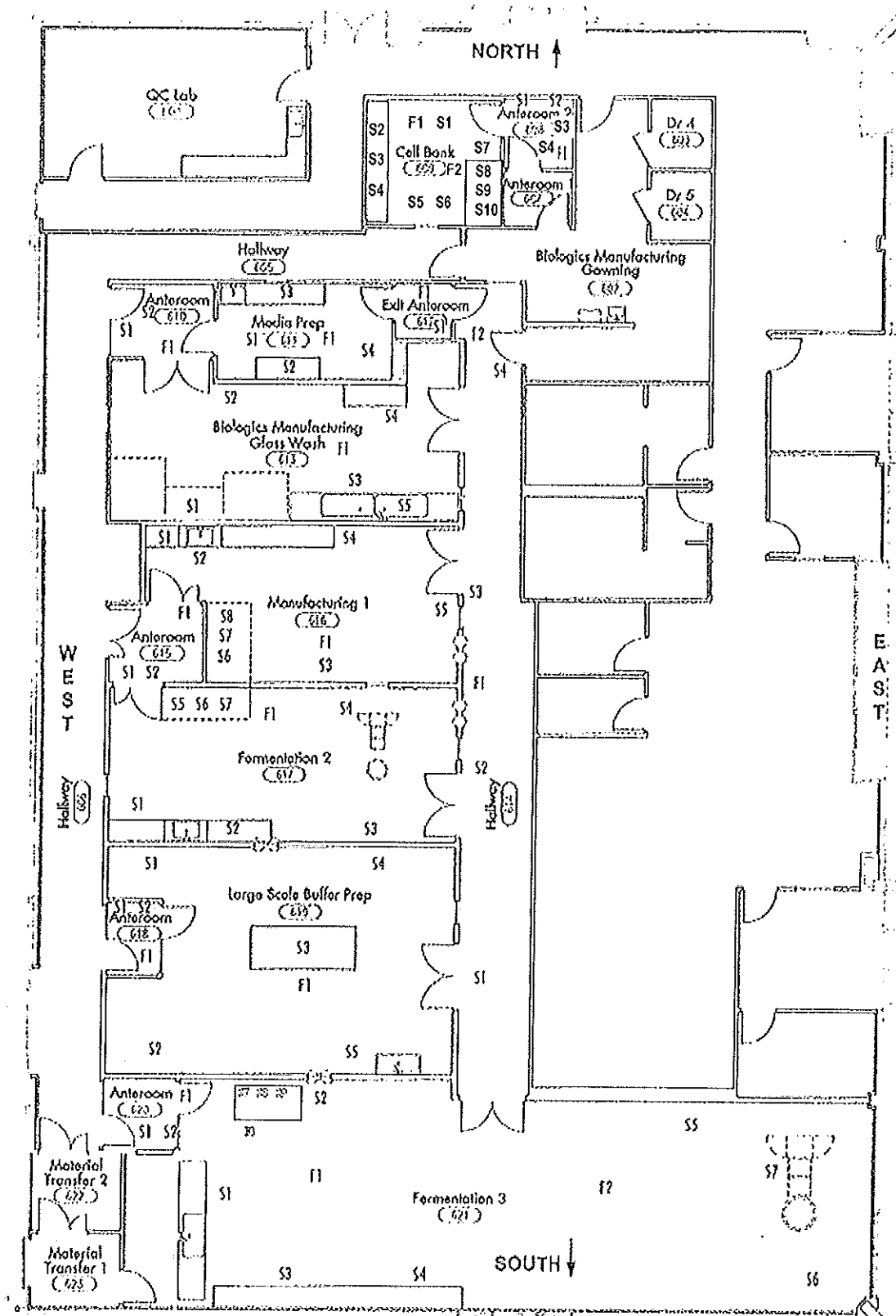
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**TITLE: BUILDING 3 BMG AREA ENVIRONMENTAL MONITORING**

**ATTACHMENT 4 (Page 1 of 3)  
SURFACE VIABLE SAMPLE SITES MAP**



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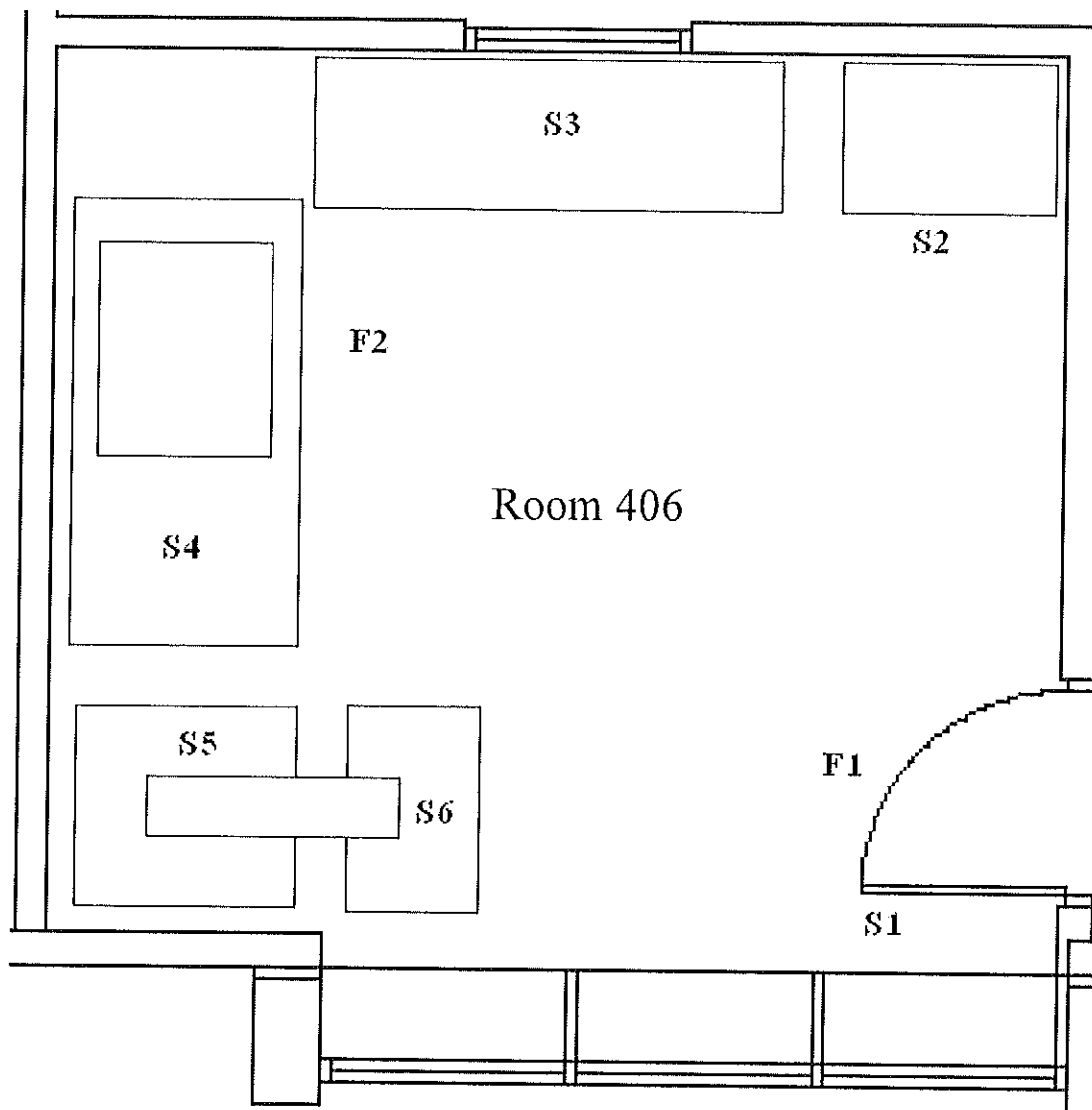
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**SURFACE VIABLE SAMPLE SITES MAP**



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**TITLE: BUILDING 3 BMG AREA ENVIRONMENTAL MONITORING****ATTACHMENT 4 (Page 3 of 3)****SURFACE VIABLE SAMPLE SITES****DESCRIPTION OF SITES**

Room	Site ID	Description	Room	Site ID	Description
406	S1	Door to 405	615	S1	Wall
406	S2	Storage Cabinet	615	S2	Cart/Rack/Container/Stool
406	S3	Table	615	F1	Floor by Door to 616
406	S4	Table with Hood	616	S1	Wall by Sink
406	S5	Control Panel	616	S2	Cabinet
406	S6	Curtain Inside Clean Station	616	S3	South Counter
406	F1	Floor by Door to 405	616	S4	North Counter
406	F2	Floor by Hood	616	S5	Door to 614
608	S1	Door to 609	616	S6	In Hood Left
608	S2	Wall	616	S7	In Hood Center
608	S3	Cart/Rack	616	S8	In Hood Right
608	S4	Door to 608	616	F1	Floor by Door to 615
608	F1	Floor Center	617	S1	Counter by Sink Right
609	S1	Door Handle to 608	617	S2	Counter by Sink Left
609	S2	Flammable Cabinet	617	S3	South Wall
609	S3	Counter	617	S4	Fermentor Control Panel
609	S4	Multimeter	617	S5	In Hood Left
609	S5	Refrigerator	617	S6	In Hood Center
609	S6	Window	617	S7	In Hood Right
609	S7	Wall	617	F1	Floor by Hood
609	S8	In Hood Left	618	S1	North Wall
609	S9	In Hood Center	618	S2	Stool
609	S10	In Hood Right	618	F1	Floor by Door to 619
609	F1	Floor by Door to 608	619	S1	Rack/Cabinet
609	F2	Floor by Hood	619	S2	Wall by PW Drop
610	S1	Door to 606	619	S3	Counter Center
610	S2	Cart/Rack/Container	619	S4	Wall Above Sink
610	F1	Floor by Door to 611	619	S5	Door to 614
611	S1	Wall Above Sink	619	S6	Curtain inside LAP
611	S2	Counter South Side	619	F1	Floor Center
611	S3	Counter North Side	619	F2	Floor LAP
611	S4	Hood Arm	620	S1	Stool/Rack/Cart
611	F1	Floor Center	620	S2	Door to 621
612	S1	Wall	620	F1	Floor by Door to 621
612	F1	Floor Center	621	S1	Wall by Sink
613	S1	Front of Autoclave/oven/washer	621	S2	Window
613	S2	Wall	621	S3	Counter Right Side
613	S3	Cabinet	621	S4	Counter Left Side
613	S4	Countertop	621	S5	CIP Tank
613	S5	Wall by Sink	621	S6	Wall by PW Drop
613	F1	Floor by Door to 610	621	S7	Fermentor Control Panel
614	S1	Door to 619	621	S8	In Hood Left
614	S2	Door to 617	621	S9	In Hood Center
614	S3	Door to 616	621	S10	In Hood Right
614	S4	Door to 602	621	F1	Floor West
614	F1	Floor by 617/616	621	F2	Floor East
614	F2	Floor by 602	621	F3	Floor by Hood