



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Entry & Exit of male and female staff in the Production area	Effective Date:
Supersedes: Nil	Review Date:
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Vernacular SOP: Yes

1.0 OBJECTIVE:

1.1 To lay down a procedure for entry and exit of male and female staff in the Production /Store area

2.0 SCOPE:

2.1 This procedure is applicable to entry and exit procedure of both male & female staff in the Production / Store area.

3.0 RESPONSIBILITY:

3.1 All Personnel: Follow the change room procedure.

3.2 Head Production / Quality Control / Quality Assurance / Utility / Stores / Personnel and Administration: SOP compliance.

3.3 Personnel and Administration: Cleaning of Change Room & provide resources.

4.0 DEFINITION (S):

4.1 Soiled Factory Garments: Those garments which can be use after washing.

4.2 Factory Garments: Those garments which are used to wear during entering it to the processing area.

5.0 PROCEDURE:

5.1 Entry procedure through primary change room

5.1.1 Open the main door for entry in primary change room and (If required) proceed to wash room or open the main door for entry in primary change room, remove the street shoes in street shoes locker room and keep them in assigned shoe rack/locker. Take slippers from the racks/locker to proceed for washroom.

5.1.2 Wet your hands with running water.

5.1.3 Dispense sufficient quantity of soap into the palm and lather on your hand for at least 10 to 15 seconds and rub hands vigorously as per the given procedure in Annexure-I (Procedure for Hand Washing, Format)

5.1.4 Wash the hands with sufficient quantity water and dry your hands with hand dryer as per given procedure in Annexure-II (Procedure for hand dryer, Format)

5.1.5 After usage move out from the washroom and keep the slippers or street shoes in the rack / Locker provided at street shoe room.



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- 5.1.6 Open the primary change room door for entry in to the primary change room.
- 5.1.7 Disinfect the hands with 70% v/v IPA solution. Remove street clothes and personal belongings (like wrist watch, wallet, jewelry and Bindi, etc.) and put them in the individual locker at primary change room. If nose piercing / pin not removable then cover it by wearing nose mask.
- 5.1.8 Cross the cross over bench (cross over the bench by sitting on the bench and swinging the legs over the bench one by one). Collect the dedicated primary factory garments from dedicated locker or linen room. Primary factory garments consist of cap, shirt, and trouser (pant) and factory shoes. Put on the factory garment in following sequence cap, shirt, trouser and shoes.
- 5.1.9 Check the attire in the mirror for proper gowning. Disinfect hands with 70% v/v IPA solution provided before entering into the production area. Open the door enters into core area.
- Note:** Persons who working in core area (Like- primary packing, Granulation, compression, coating and inspection area etc.) collect secondary gown from linen room window in primary change room or collect from designated locker at secondary change room.
- 5.1.10 For both male and female those who are meant to work on packing line or store, shall go directly to the packing hall/ stores from the primary change room.
- 5.1.11 Staff/ workmen shall ensure their movement in their assigned section only.
- 5.2 **Entry procedure into manufacturing area through secondary change room**
- 5.2.1 Enter in to the secondary change room by push button of door interlock. (Ensure that only one door of secondary change room will open at one time, wait to open the door till other door is closed completely).
- 5.2.2 Wear snood followed by boiler suit. Ensure that the thrills of snood are packed into the neck of the boiler suit.
- 5.2.3 Cross the cross over bench by sitting on the bench and swinging the legs over the bench one by one after wearing booties over the factory shoes.
- 5.2.4 Check the attire in the mirror for proper gowning.
- 5.2.5 Disinfect the hands with 70% v/v IPA solution provided before entering into the manufacturing area. Enter into the manufacturing area by pressing the push button of door interlock (Ensure that only one door of secondary change room will open at one time, wait to open the door till other door is closed completely).
- 5.2.6 The persons who shall enter into the main passage of manufacturing area. Ensure wearing the gowning as described in points 5.2.2 to 5.2.4.



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Note- Use lift/stairs (Lift where provided for man movement only) case for man movement for entering into Granulation, compression, coating, and inspection area as per the facility provided.

- 5.2.7 For persons working in the granulation area, compression areas, and inspection area boiler suits shall be area name coded as defined in Annexure-IV (Boiler suits and apron over the boiler suit area name code, Format)
- 5.2.8 Collect and wear fresh yellow color shoes cover to enter into all process area over the booties. Fresh yellow color shoes cover will be available at secondary change room / lift air lock / designated area change room.
- 5.2.9 Enter into granulation area, as assigned. Wear apron provided over the boiler suits, next wear full-length hand gloves at designated area of respective cubical. Each apron shall be area name coded as describe in Annexure-IV (Boiler suits and apron over the boiler suit area name code, Format)
- 5.2.10 To enter one cubicle to another with different product under manufacturing fresh gowning shall be used for each entry.
- 5.2.11 In case of liquid department no need to wear additional shoe covers at secondary change room during entry.
- 5.2.12 Collect and wear water protective gown (rain coat), high neck boot (gum boot) over complete gown as per specific area when type B cleaning performed if required. After use dry the rain coat and gum boot in same cubical and put it in Polly bag, Affix cleaned label on it and transfer to the designated spare room.
- 5.3 Exit Procedure from manufacturing area.**
- 5.3.1 **From Granulation area:** Remove the hand gloves and discard into the waste bin. Then remove aprons which will wear for entry into granulation area (with area coding), yellow shoes cover and discard into the bin/container for “SOILED FACTORY GARMENTS” at designated area of respective cubical. At the end of day label the bag as “SOILED FACTORY GARMENTS” and send them to the linen area for the cleaning as per SOP “Washing of Linen”.
- 5.3.2 **From Compression area:** Remove the hand gloves and discard into the waste bin. Then remove the yellow shoes cover into compression area and discard into the “SOILED FACTORY GARMENTS” at designated area of respective compression cubical and exit from the area. At the end of day label the bag as “SOILED FACTORY GARMENTS” and send them to the linen area for the cleaning as per SOP “Washing of Linen”.



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5.3.3 **From areas other than granulation and compression area:** Remove the hand gloves and discard into the waste bin. Next, remove the yellow shoes cover and discard into the bin/container for “SOILED FACTORY GARMENTS” provided in to the area. At the end of day label the bag as “SOILED FACTORY GARMENTS” and send them to the linen area for the cleaning as per SOP “Washing of Linen”.

5.3.4 Enter directly into the secondary change room, without entering any other area.

Note: Use designated secondary change (as per the facility provided) room for gowning and entry one cubical to another cubical.

5.3.5 Remove the booties and discard at the designated place in secondary change room.

5.3.6 Cross the cross over bench by sitting on the bench and swinging the legs one by one.

5.3.7 Remove boiler suit followed by snood one by one and discard them at designated place in secondary change room.

5.3.8 Disinfect hands with 70 % v/v IPA and exit from the secondary change room.

Note: In case of liquid department booties shall be removed at secondary change room during exit at waste bin.

5.4 Procedure to enter one cubicle to another with different product under manufacturing.

5.4.1 For entering of other cubicle follow the entry exit procedure as mentioned point no 5.2.1 to 5.2.4 and 5.3.1 to 5.3.3 respectively where designated secondary change room is not available at floor.

5.4.2 For entering the other cubical where designated secondary change room is available at floor follow the procedure mention below.

5.4.2.1 Follow the exit procedure as describe in the point no 5.3.1 to 5.3.3

5.4.2.2 Enter directly into designated secondary change room without entering any other area.

5.4.2.3 Cross over the bench by sitting on the bench and swinging the legs over the bench one by one after removing booties over the factory shoes. Booties to be discard at the designated place.

5.4.2.4 Remove boiler suit and snood one by one and discard them at designated place.

5.4.2.5 Disinfect hands with 70 % v/v IPA.

5.4.2.6 Take fresh area dedicated secondary gown from locker and follow the procedure 5.2.1 to 5.2.4.

5.5 Exit Procedure from primary change room.

5.5.1 Enter into the primary change room.



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- 5.5.2 Remove factory footwear, keep in the assigner locker and primary gowning cap, shirt and trouser/pant, beard mask, and keep it at designated place.
- 5.5.3 Cross over the bench by sitting on the bench and swinging the legs one by one.
- 5.5.4 Wear street clothes; collect the personal belongings from the lockers provided and exit from the primary change room.
- 5.5.5 Wear street shoes and exit from the shoe storage room.

6.0 ABBREVIATION (S):

- 6.1 IPA : Iso Propyl Alcohol
- 6.2 SOP : Standard Operating Procedure
- 6.3 No. : Number
- 6.4 V/V : Volume / Volume

7.0 REFERENCES (S):

- 7.1 SOP: Washing of Linen

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format No.	Mode of Execution
Annexure-I	Procedure for Hand Wash		Chart Poster
Annexure-II	Procedure for Hand Dryer		Chart Poster
Annexure-III	Process Flow Chart for Entry into Manufacturing Area (Staff)		Chart Poster
Annexure-IV	Boiler suits and apron over the boiler suit area name code		Template

9.0 DISTRIBUTION:

- 9.1 Master Copy : Quality Assurance
- 9.2 Controlled copy (s) : Production (3), Personal & Administration (1), Quality Assurance (1), Utility (1), Quality Control (1), Quality Control (Microbiology) (1), and Store department (1)
- 9.3 Reference copy (s): Production Gb1 (03), Store GB3 (1), Personal & Administration (3).



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10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) For Revision	Details of Revision	Effective Date
01	00	NA	New SOP	NA	NA



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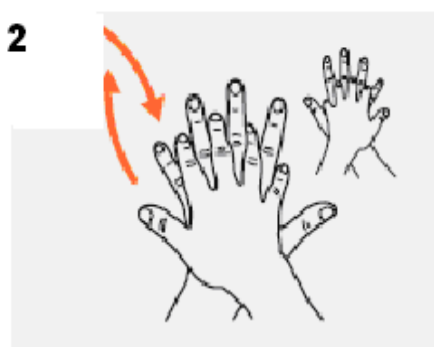
ANNEXURE I

Procedure for Hand Washing

1. Wet your hands under running water. Avoid contact with the urinals after this point.
2. Take the soap from the soap dispenser & lather on your hands for at least 10 to 15 seconds and then rub your hands together vigorously as per the given procedure –
3. Rinse your hands thoroughly under the running water.
4. Dry your hands with hand dryer or by paper towels.



1 Rub hands palm to palm;



2 Right palm over left dorsum with interlaced fingers and vice versa;



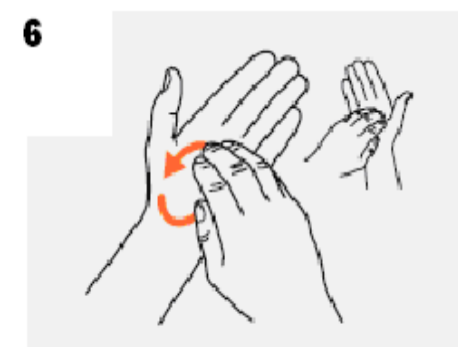
3 Palm to palm with fingers interlaced;



4 Backs of fingers to opposing palms with fingers interlocked;



5 Rotational rubbing of left thumb clasped in right palm and vice versa;



6 Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa;



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ANNEXURE II

Procedure for Hand Dryer

1. After washing of hands dry the hands using hand dryer as follows-

Figure. No.-1



Figure. No.-2



Figure. No.-3





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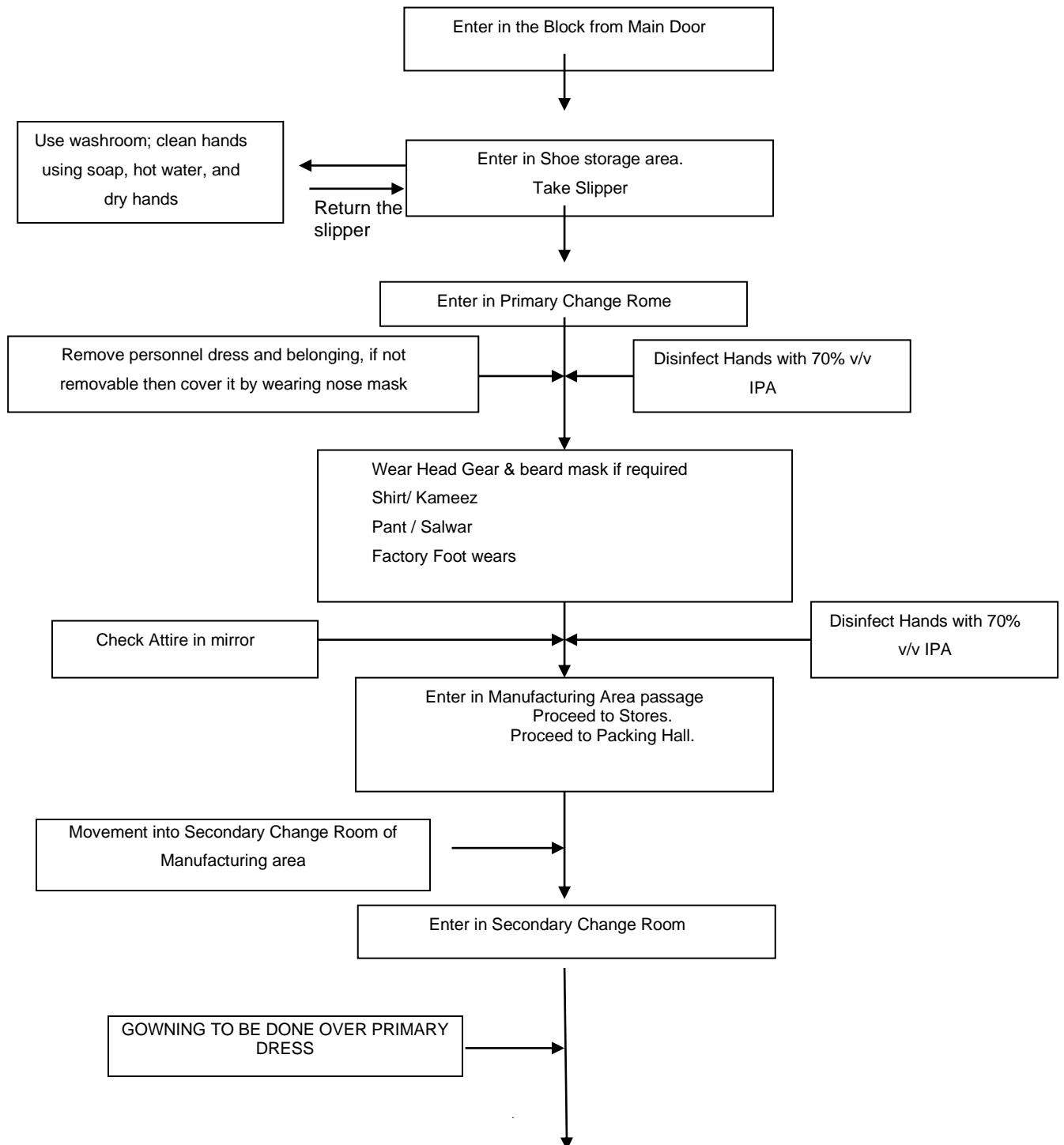
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ANNEXURE III

Process Flow Chart for Entry and Exit into Manufacturing Area

A. ENTRY



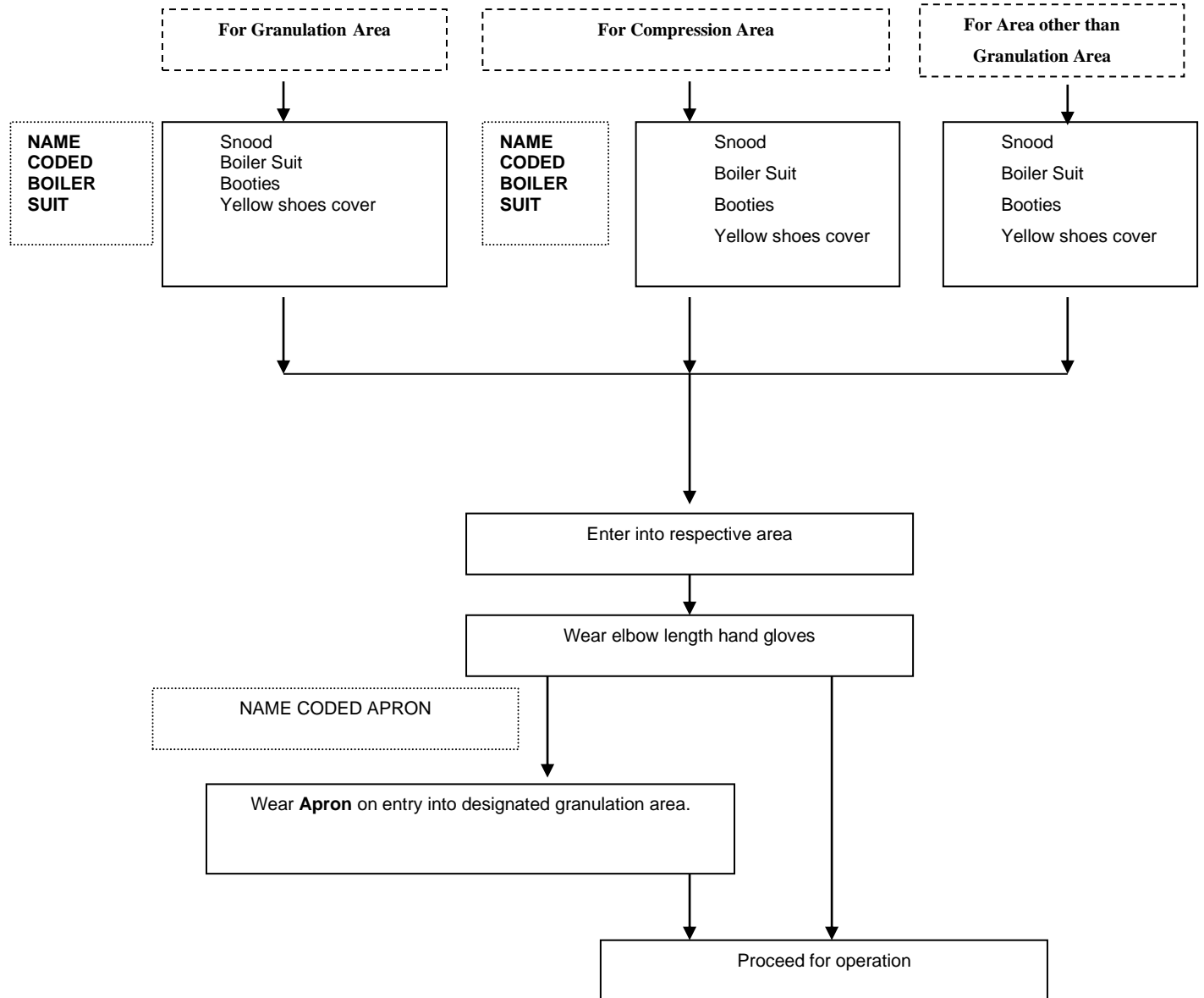


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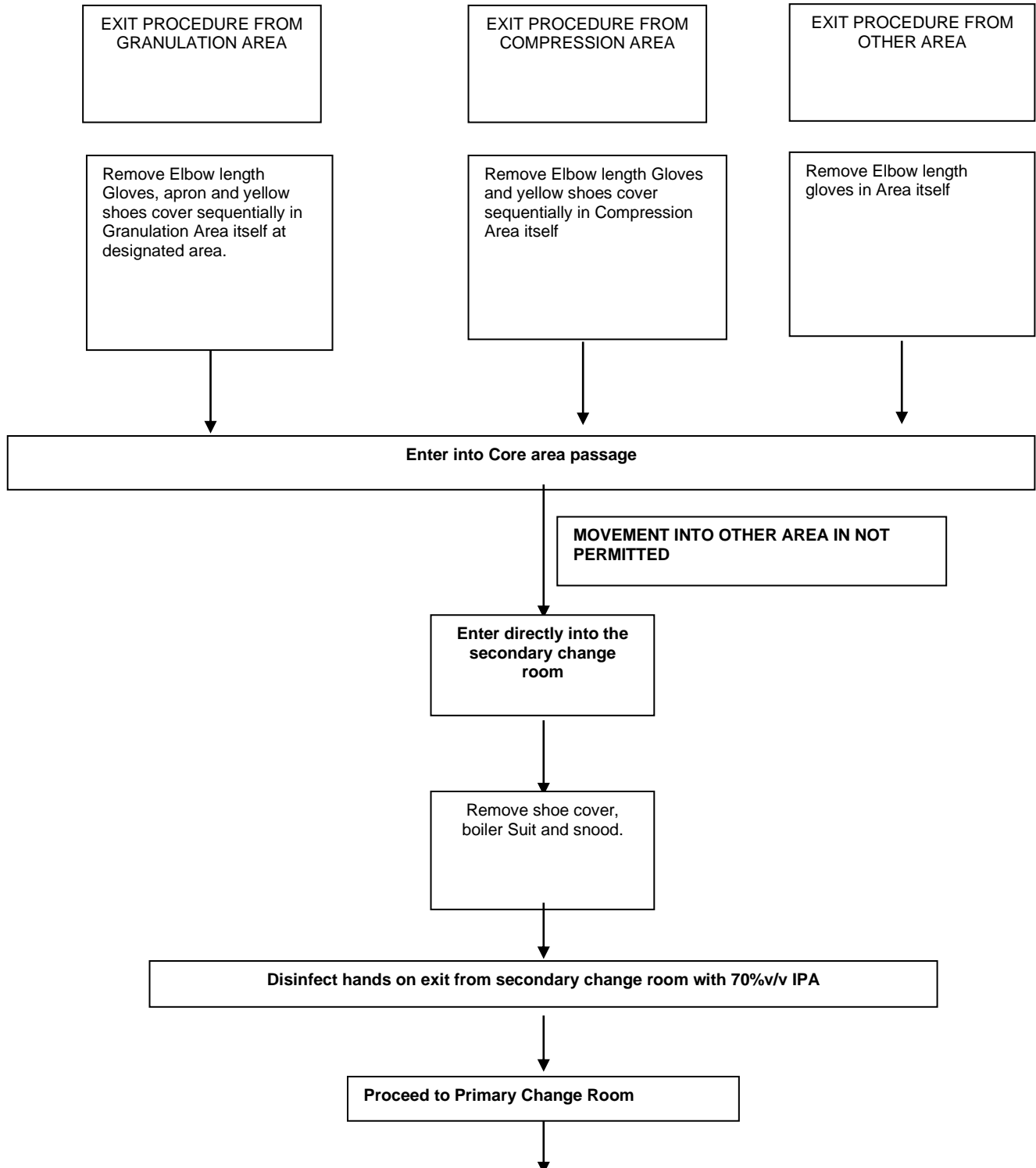
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B. EXIT





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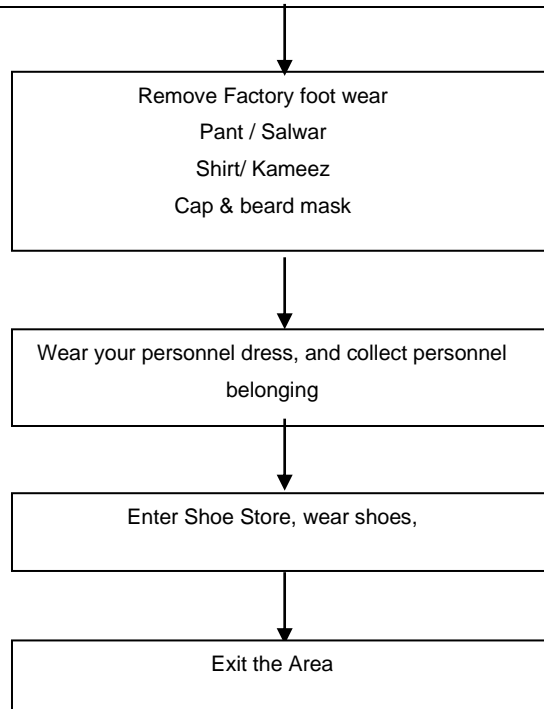
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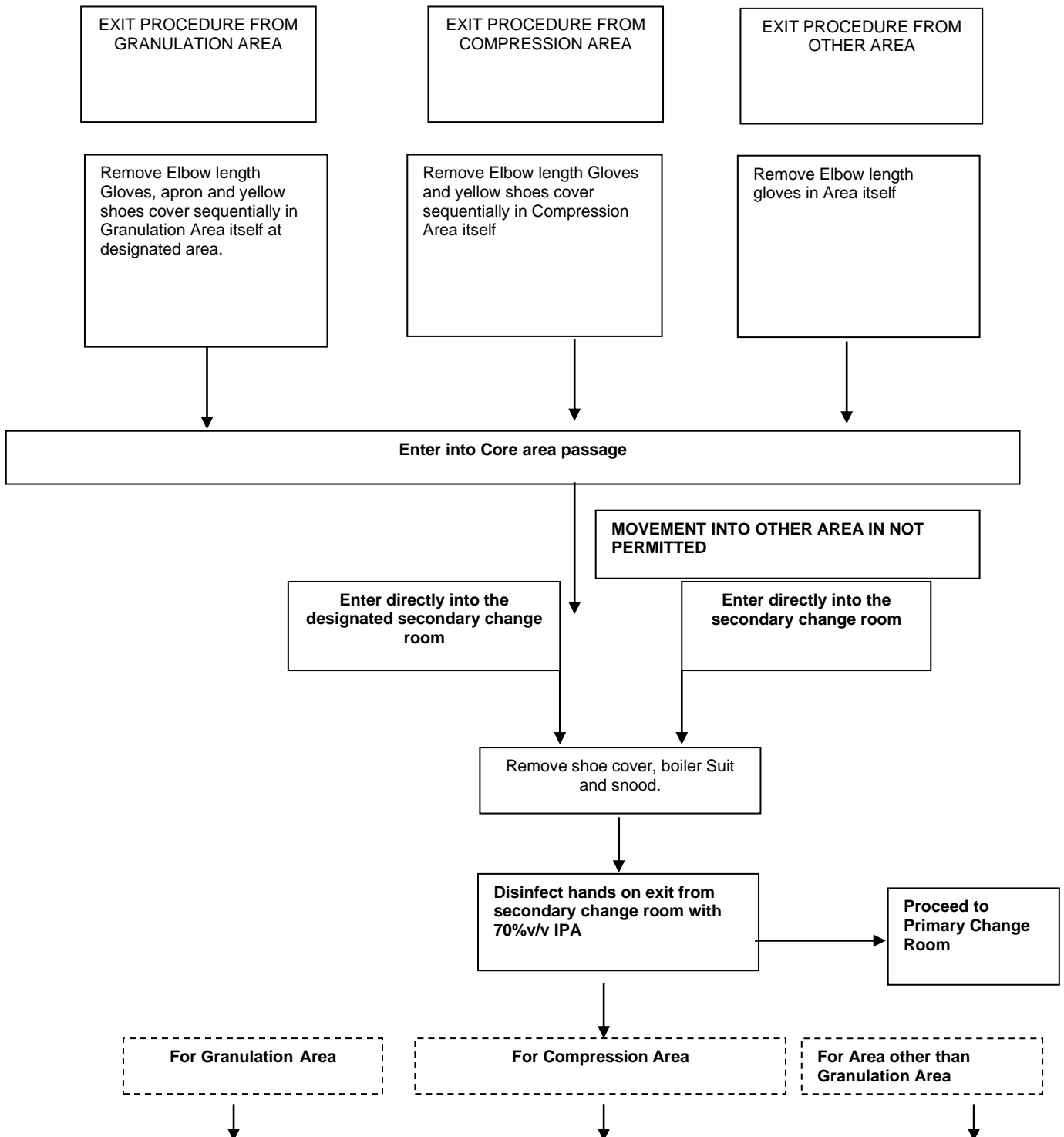
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C. Procedure to enter one cubicle to another with different product under manufacturing.



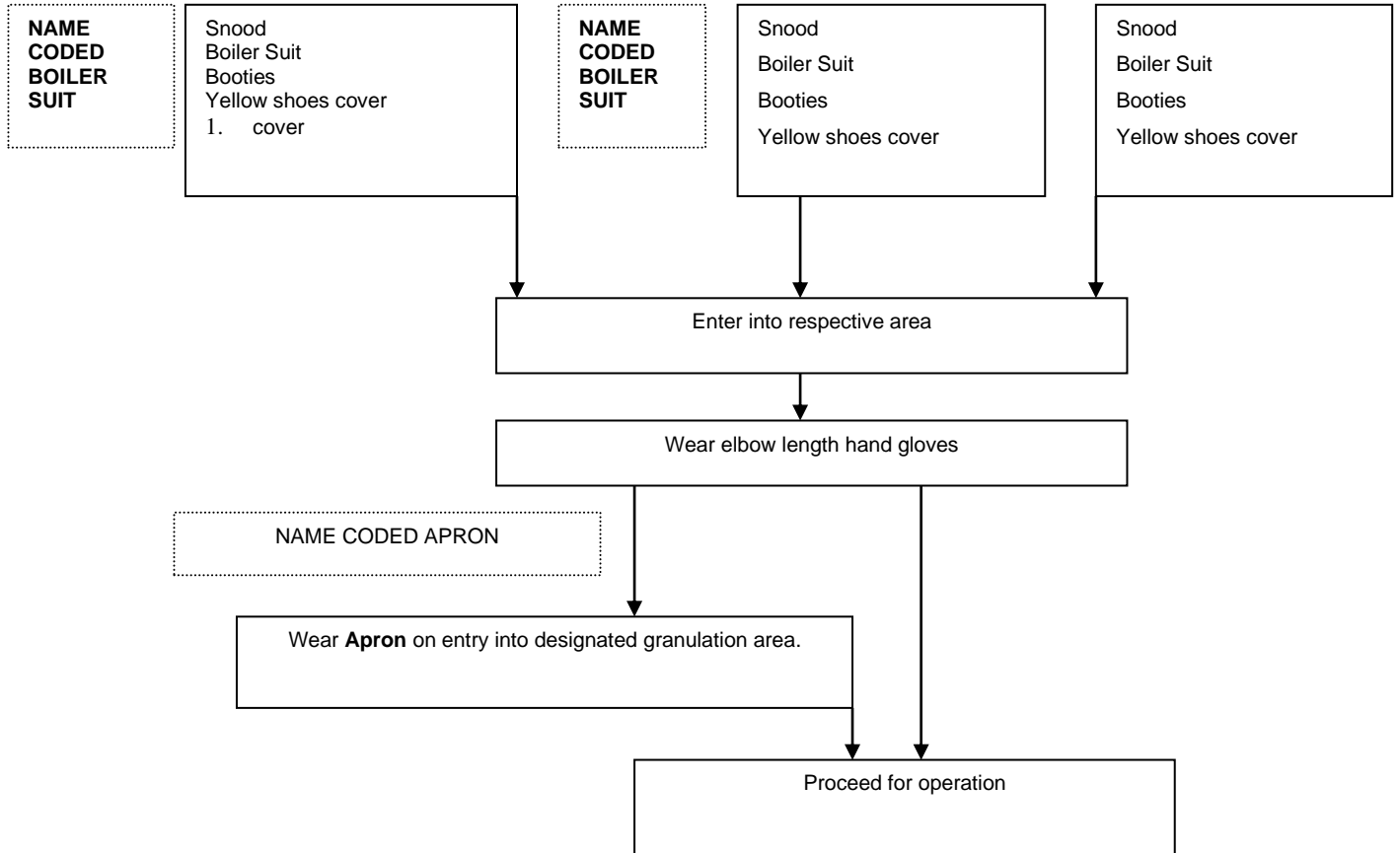


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ANNEXURE IV

Boiler suits and Apron over the Boiler suit area name code

S.No.	Area Name	Dress Code	S.No.	Area Name	Dress Code
1.	Granulation-I	GRL-I	34.	Compression-III	COM-III
2.	Granulation-II	GRL-II	35.	Compression-IV	COM-IV
3.	Granulation-III	GRL-III	36.	Compression-V	COM-V
4.	Granulation-IV	GRL-IV	37.	Compression-VI	COM-VI
5.	Granulation-V	GRL-V	38.	Compression-VII	COM-VII
6.	Granulation-VI	GRL-VI	39.	Compression-VIII	COM-VIII
7.	Granulation-VII	GRL-VII	40.	Compression-IX	COM-IX
8.	Granulation-VIII	GRL-VIII	41.	Compression-X	COM-X
9.	Granulation-IX	GRL-IX	42.	Compression-XI	COM-XI
10.	Granulation X	GRL-X	43.	Compression-XII	COM-XII
11.	Granulation XI	GRL-XI	44.	Compression-XIII	COM-XIII
12.	Granulation XII	GRL-XII	45.	Compression-XIV	COM-XIV
13.	Sifting & Milling-I	SFM-I	46.	Compression-XV	COM-XV
14.	Sifting & Milling-II	SFM-II	47.	Compression-XVI	COM-XVI
15.	Sifting & Milling-III	SFM-III	48.	Compression-XVII	COM-XVII
16.	Sifting & Milling-IV	SFM-IV	49.	Compression-XVIII	COM-XVIII
17.	Sifting & Milling-V	SFM-V	50.	Inspection-I	INS-I
18.	Sifting & Milling-VI	SFM-VI	51.	Inspection-II	INS-II
19.	Pilot Plant-I	PPL-I	52.	Inspection-III	INS-III
20.	Pilot Plant RMG	PPL-RMG	53.	Inspection-IV	INS-IV
21.	Pilot Plant FBD	PPL-FBD	54.	Inspection-V	INS-V



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S.No.	Area Name	Dress Code	S.No.	Area Name	Dress Code
22.	Pilot Plant-II	PPL-II	55.	Inspection-VI	INS-VI
23.	Roll Compactor-I	RCP-I	56.	Inspection-VIII	INS-VIII
24.	Roll Compactor-II	RCP-II	57.	Inspection-IX	INS-IX
25.	Roll Compactor-V	RCP-V	58.	Inspection-XI	INS-XI
26.	Roll compactor VI	RCP-VI	59.	Inspection-XIII	INS-XIII
27.	Roll compactor VII	RCP-VII	60.	Inspection-XV	INS-XV
28.	FBP-I	FBP-I	61.	Inspection XVI	INS-XVI
29.	FBP-III	FBP-III	62.	Inspection XVII	INS-XVII
30.	FBP-V	FBP-V	63.	Inspection XVIII	INS-XVIII
31.	FBP-VI	FBP-VI	64.	Capsules-II	CAP-II
32.	Compression-I	COM-I	65.	Capsules-IV	CAP-IV
33.	Compression-II	COM-II			