

sanofi pasteur

Etat d'un Etablissement Pharmaceutique Fabricant/Importateur - SITE MASTER FILE - Annexe 8/Appendix
8 - Val de Reuil - 2015



Matériel de laboratoire	Laboratory equipment
SYSTEME CO2	CO2 SYSTEM
SYSTEME DE CONTROLE ET DE SUIVI ENVIRONNEMENTAL	CONTROL AND ENVIRONMENTAL MONITORING SYSTEM
SECHEUR	DRYER
SPECTROPHOTOMETRE	SPECTROPHOTOMETER

Impression non contrôlée

Information Confidentielle
Page 16 de 18

ROXANA MONTEMILONE
DIRECTORA TECNICA
APODERADA
SANOFI PASTEUR S.A.

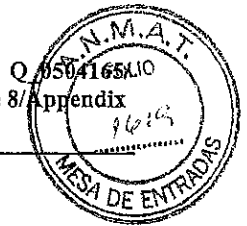
Par : NISHEVCI Vlora

Le : 19 oct. 2016 09:50:27

Catégorie : 1

Numéro : Q_0504165
Version : 4.0
Statut : Applicable





3 Principaux équipements des zones de stockage

Major Storage Equipment

Equipements de production	Production equipment
Bâtiment (Building) 11 – Stockage (Storage)	
CHAMBRE FROIDE	COLD ROOM

Equipements de production	Production equipment
Bâtiment (Building) 34 - Stockage de matières premières (Storage for raw materials)	
CENTRALE DE TRAITEMENT D'AIR CTA03	AIR HANDLING UNIT
2 CHAMBRES FROIDES +5°C	2 COLD CHAMBERS +5°C
2 CHAMBRES FROIDES -20°C	2 COLD CHAMBERS -20°C
SCSE SYSTEME CENTRALISE DE SUIVI ENVIRONNEMENTAL	CENTRAL MONITORING SYSTEM

Equipements de production	Production equipment
Bâtiment (Building) 23a - Transport and External Shipping (export sales) - Treatment of PFV, PFC, PRM and Samples	
CHAMBRE FROIDE AVEC SAS REFRIGERE	COLD CHAMBER WITH REFRIGERATED SAS
CONGÉLATEUR - 70°C	FREEZER - 70°C
CONGÉLATEUR - 20°C	FREEZER - 20°C
CAMION FRIGORIFIQUE	REFRIGERATED TRUCK

Equipements de production	Production equipment
Bâtiment (Building) 37 - Activité (Activity) Storage for flammable materials	
CENTRALE DE TRAITEMENT D'AIR	AIR HANDLING UNIT

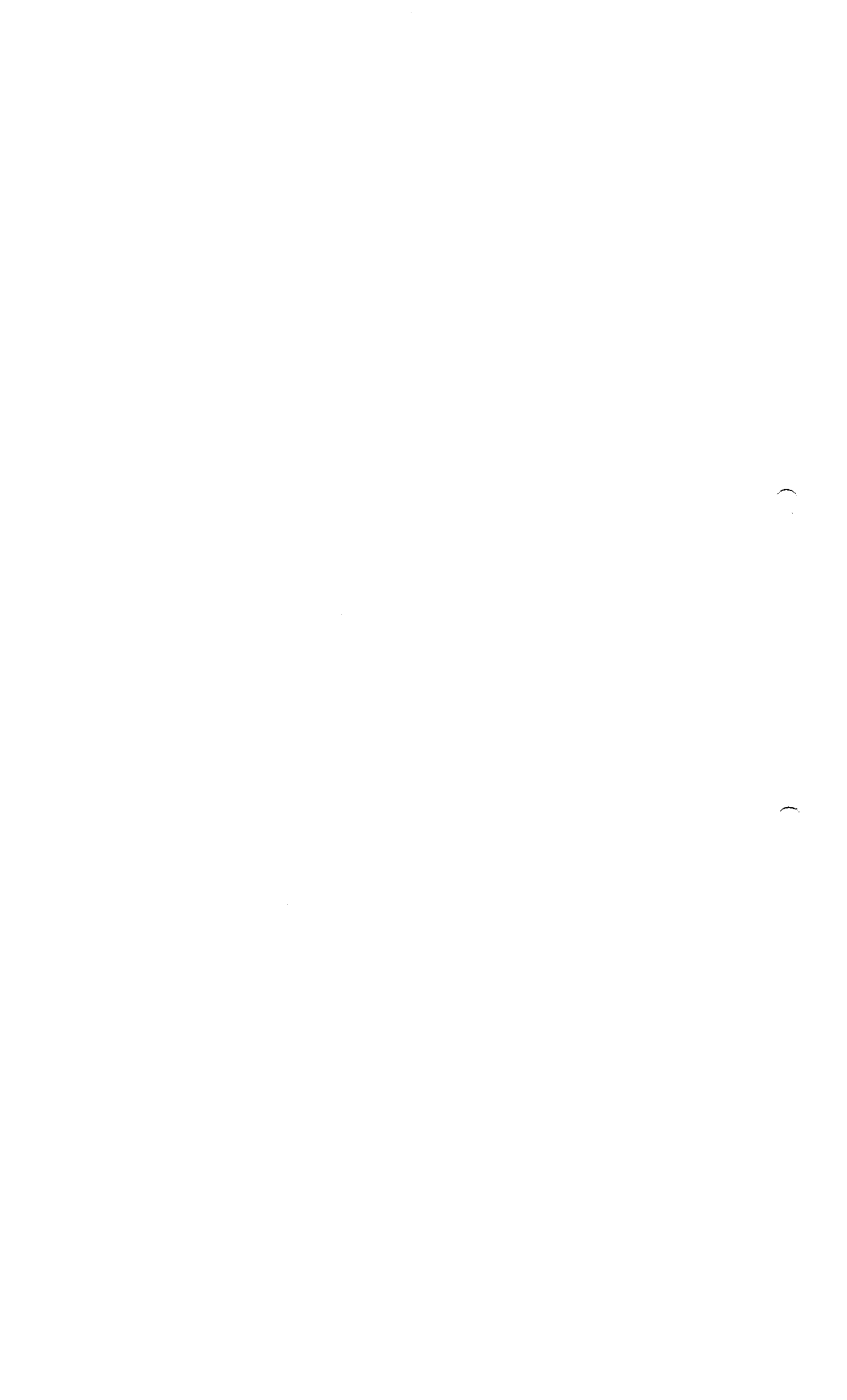
Impression non contrôlée

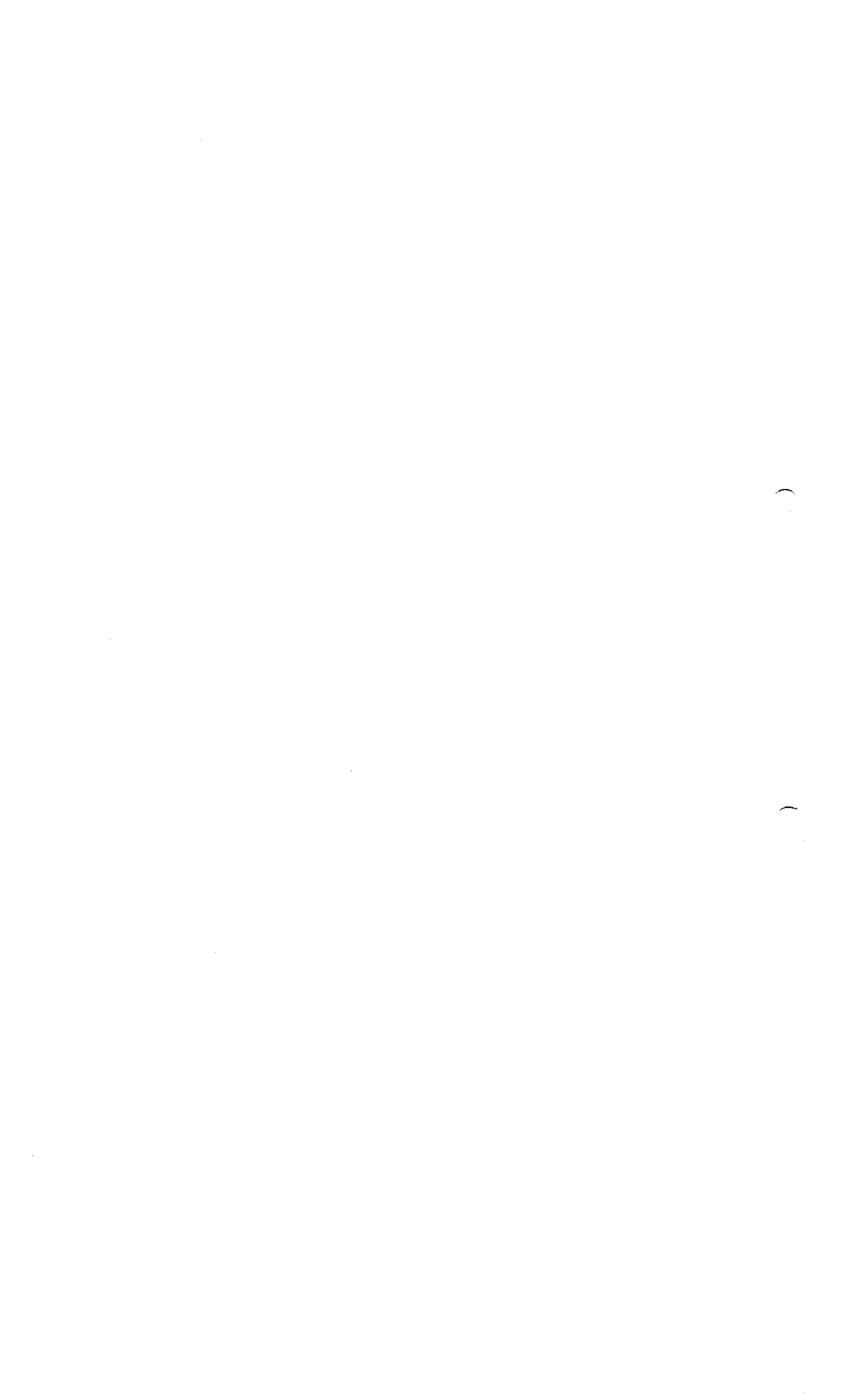




Equipements de production	Production equipment
Bâtiment (Building) 36 - Activité (Activity) Retour produits	
CHAMBRE FROIDE CF36-2 ≤ -20°C	COLD CHAMBER CF36-2 ≤ -20°C
CHAMBRE FROIDE CF36-3 +5°C ±3°C	COLD CHAMBER CF36-3 +5°C ±3°C
CHAMBRE FROIDE CF36-5 +5°C ±3°C	COLD CHAMBER CF36-5 +5°C ±3°C
Bâtiment (Building) 40 - Activité (Activity) Distribution	
CHAMBRE FROIDE +5°C±3°C – LOCAL 21	COLD CHAMBER +5°C±3°C – ROOM 21
CHAMBRE FROIDE +5°C±3°C – LOCAL 28	COLD CHAMBER +5°C±3°C – ROOM 28
PICK PUIS PACK +15°C/+25°C – LOCAL 20	PICK THEN PACK +15°C/+25°C – ROOM 20
CHAMBRE FROIDE +5°C ±3°C – LOCAL 30	COLD CHAMBER +5°C±3°C – ROOM 30
CHAMBRE FROIDE +5°C±3°C - LOCAL 31	COLD CHAMBER +5°C±3°C – ROOM 31
CHAMBRE FROIDE +5°C±3°C - LOCAL 60	COLD CHAMBER +5°C – ROOM 60
CHAMBRE FROIDE -25°C – LOCAL 29	COLD CHAMBER -25°C – ROOM 29
CONGELATEUR -80°C N°1 UF 606	FREEZER -80°C NUMBER 1 UF 606
CONGELATEUR -80°C N°2 UF 606	FREEZER -80°C NUMBER 2 UF 606
CONGELATEUR VERTICAL -80°C N°3	FREEZER VERTICAL -80°C NUMBER 3
CONGELATEUR VERTICAL -80°C N°4.	FREEZER VERTICAL -80°C NUMBER 4.
CONGELATEUR VERTICAL -80°C N°5.	FREEZER VERTICAL -80°C NUMBER 5
Bâtiment (Building) 06S183 - Activité (Activity) Stockage des lots de semences et banques cellulaires	
CONGÉLATEUR	FREEZER
ENREGISTREUR	RECORDER
RÉCIPIENT CRYOBIOLOGIQUE	BIO FREEZE VESSEL
Bâtiment (Building) 16S25 - Activité (Activity) Stockage des lots de semences	
CONGÉLATEUR	FREEZER
Bâtiment (Building) 05 - Activité (Activity) Stockage des banques cellulaires	
RÉCIPIENT CRYOBIOLOGIQUE	BIO FREEZE VESSEL
ENREGISTREUR	RECORDER
Bâtiment (Building) 51 - Activité (Activity) Stockage des lots de semences	
CONGÉLATEUR	FREEZER
SYSTÈME DE CONTRÔLE	CONTROL SYSTEM

Impression non contrôlée





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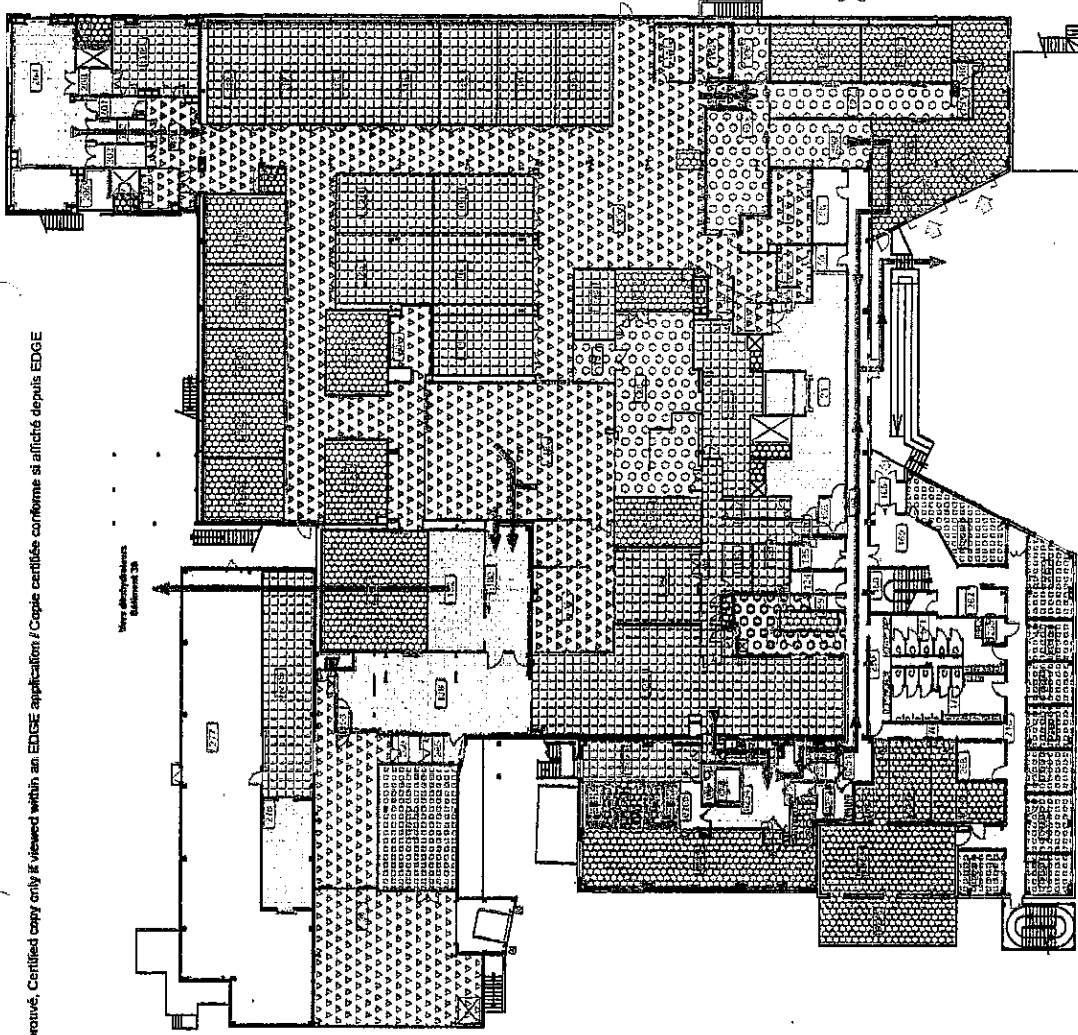
LEGEND

- ▨ Preparation area
- ▨ Inactivation area
- ▨ Incubation area
- ▨ Purification area
- ▨ Utilities
- ▨ Cold room
- ▨ Offices
- ▨ Washing area
- ▨ Locker room
- ▨ Delivery area
- ▨ Shipping area
- ▨ wastewater decontamination area
- ▨ Harvest inoculation area
- ▨ Buffer preparation area
- ▨ Storage area for clean equipment
- ▨ Storage area for eggs
- ▨ Reception area of eggs
- ▨ Not applicable
- ▨ Limit of BSL2 + area

Waste



ROXANA MONTEMILONE
DIRECTORA TÉCNICA
APODERADA
SANOFI PASTEUR S.A.



Modif.: MAJ LEGENDES FR, ET AN, Zone decont. ET (MANETTE, Netty) N° CCR: MA

Building: **B6** Floor: **0**

Sub-Building: **10 GRIPPE**

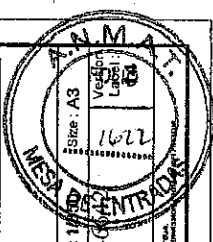
Discipline: Flux Sub-Discipline: Flux-Contrôle

Description: Waste flow for Influenza uncentrated monovalent bulk

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ENGINEERING
Parc industriel d'Incarville - BP 101 -
27101 Val de Reuil - France

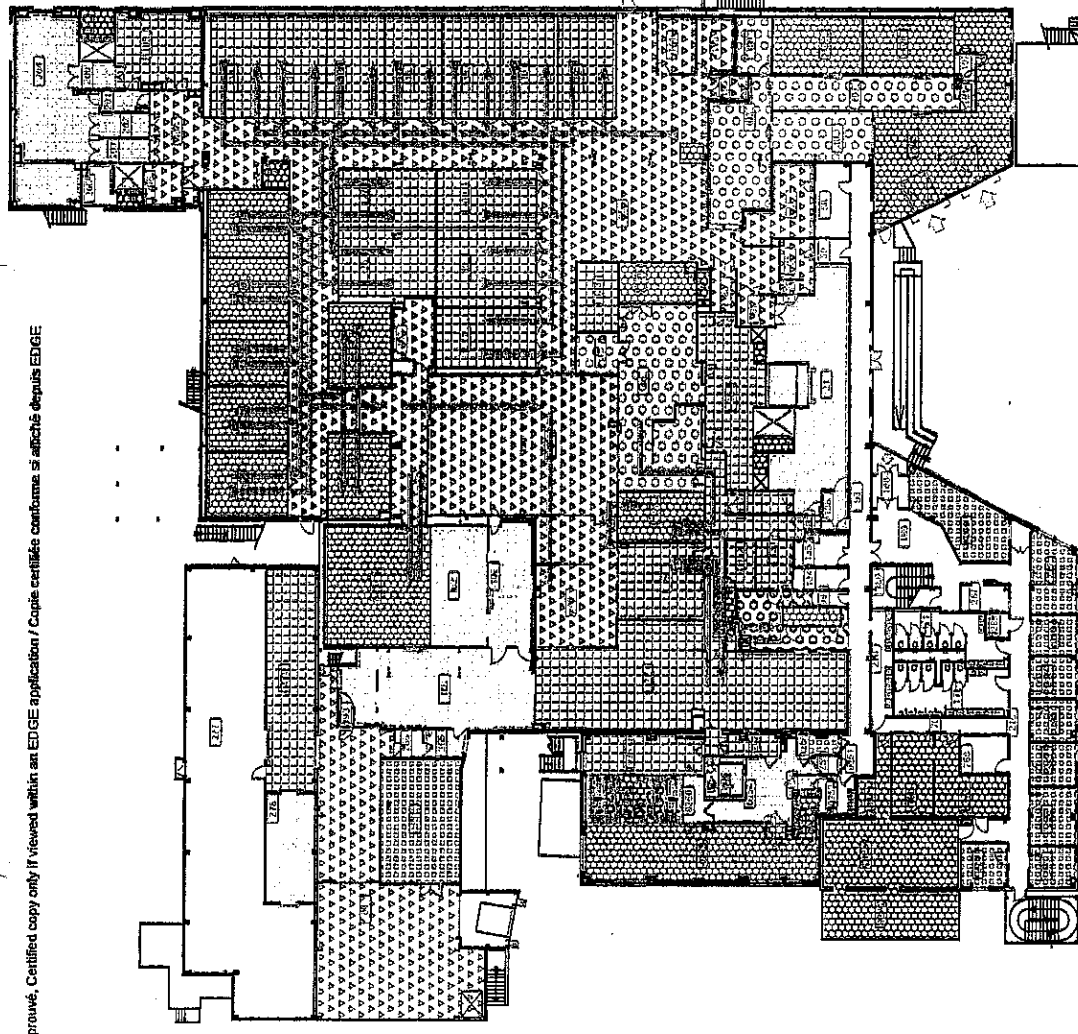
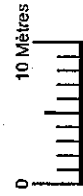
Layout Name: **12-DECH-A3-Anglais** Scale: 1/250
Document ID: RA_1040644
File Name: **B6_00115900_03_PIL_16**

Design Verifier:
Drawer: Christophe HARDY
Application Date: 24 Jul 2015



Accessed by: NISHEVCI.Mona
Approval withdrawn per internal decision on 15/07/2015 10:17:24 (44) - Approuvé et document

Access date: 28 oct. 2016 14:51:51



LEGEND

- Preparation area
- Inactivation area
- Incubation area
- Purification area
- Utilities
- Cold room
- Offices
- Washing area
- Locker room
- Delivery area
- Shipping area
- wastewater decontamination area
- Harvest preparation area
- Buffer preparation area
- Storage area for clean equipment
- Storage area for eggs
- Reception area of eggs
- Not applicable
- Limit of BSL2 + area

Flow of produces



ROXANA MONTEMLONE
DIRECTORA TÉCNICA
APODERADA
SANOFI PASTEUR S. A.

Approuvé
Accessed by: NISHEVGLI.MIYR
Approval: Approved for Richard Jordan, On: 28/07/2015 10:17:29 AM, Approved by: Richard Jordan

Access date: 28 oct. 2016 14:49:16

Modèle : MAJ LEGENDES FR. ET AN. "zone decont.EU"(MANETTE/Netty) N° CCR : NA

Design Verifier :
Dessiner : Christophe HARROY
Application Date : 24 Jul 2015

Floor : 0

Sub-Building : UO GRIPPE

Sub-Discipline : Flux+Contrôle

Car-Sub-Dis. : Product

Description : Product flow for influenza uncentrated monovalent bulk

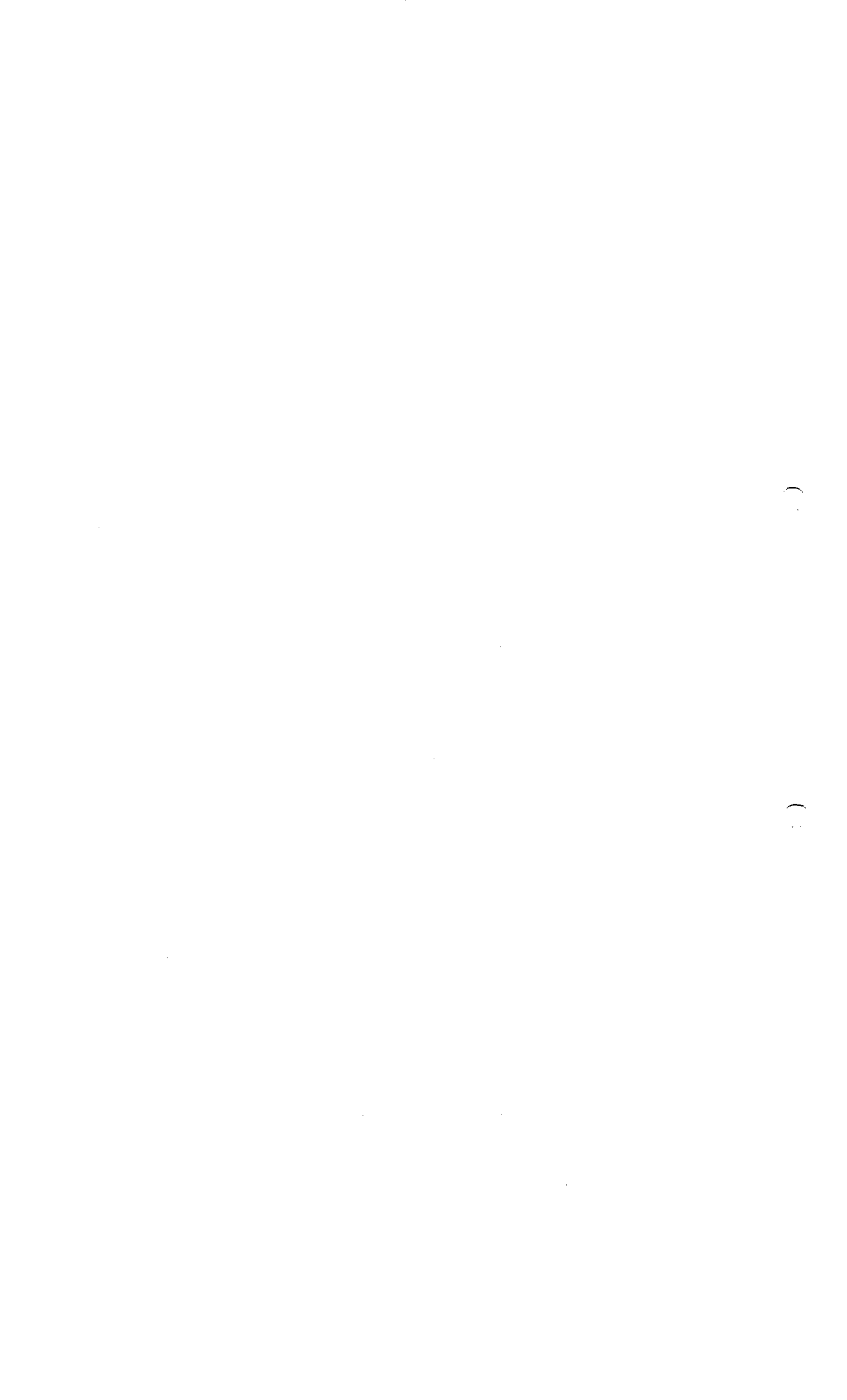
Layout Name : 06-PRO-A3-Anglais

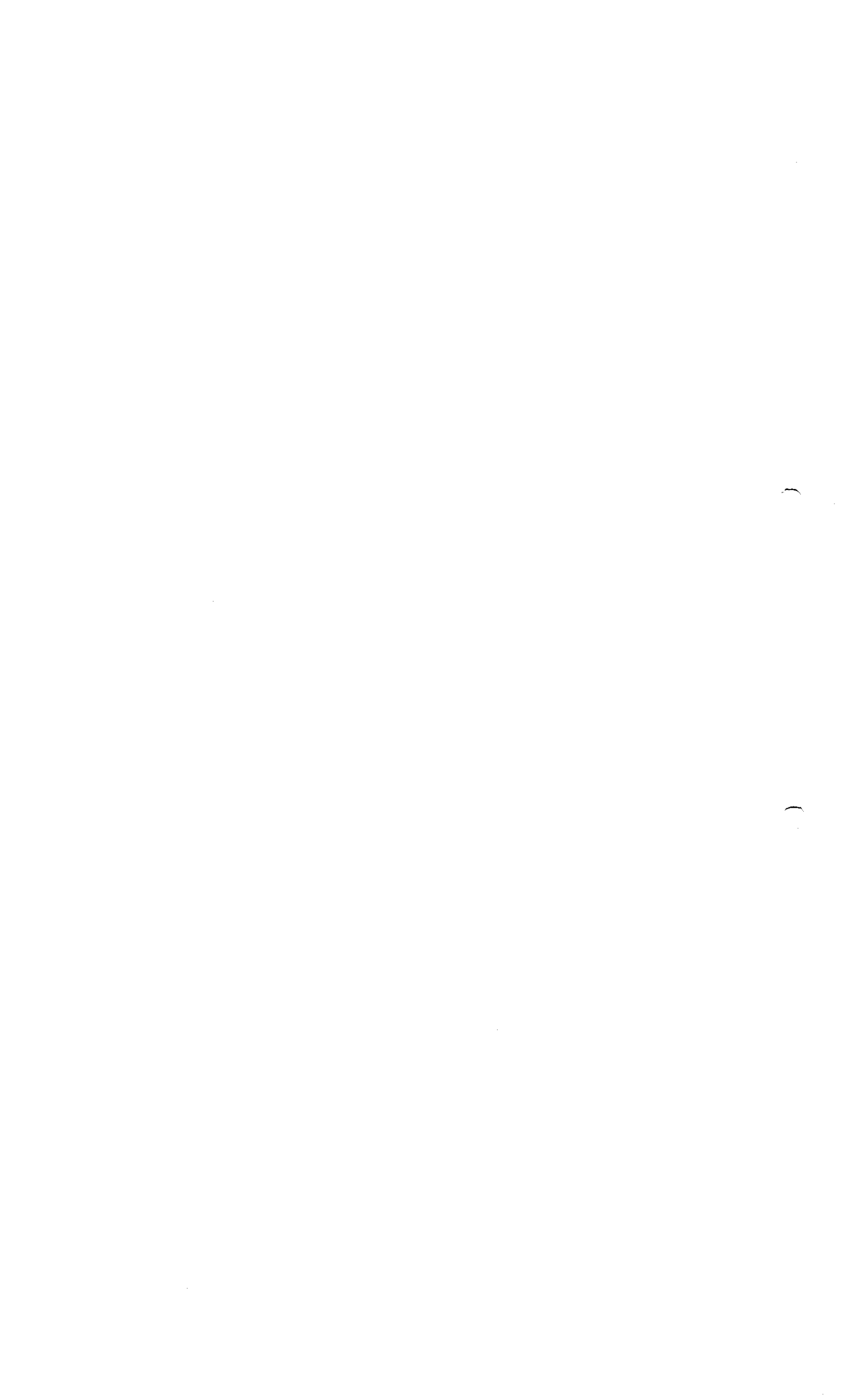
Scale : A3

Document ID: RA_1010140

File Name : B600015900_03_P16

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ENGINEERING
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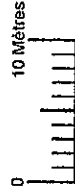
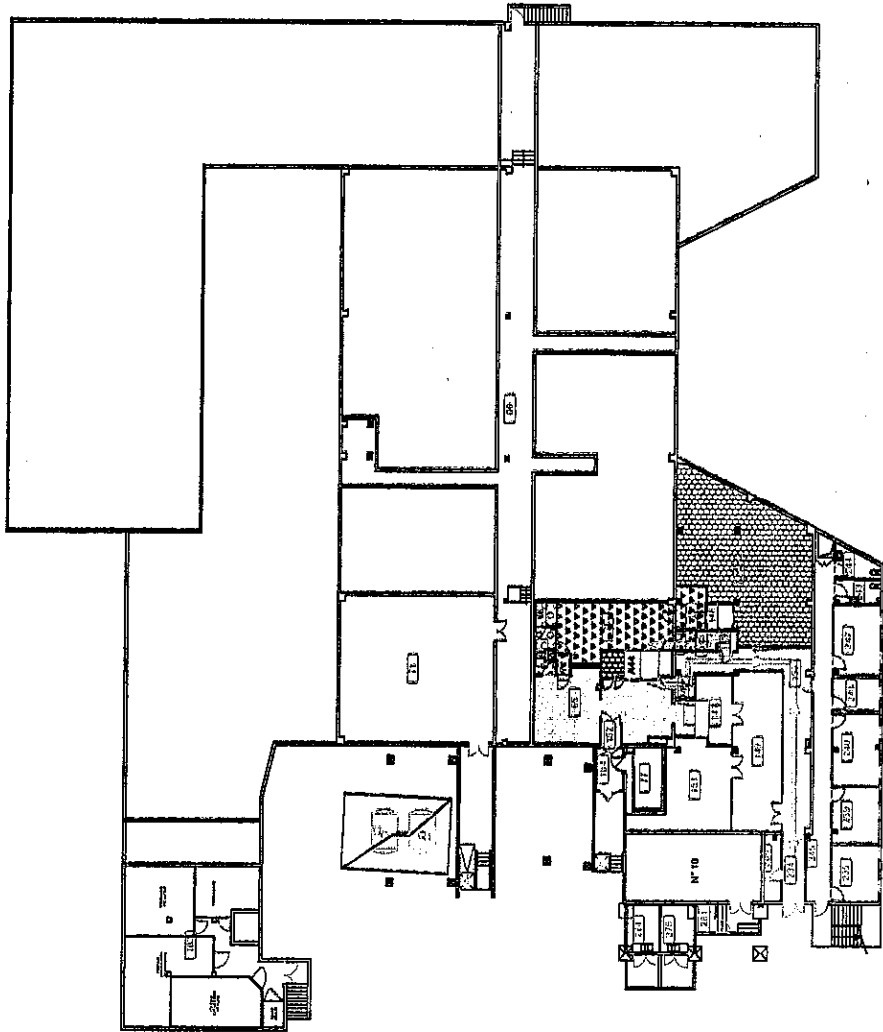


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LEGEND

- Washing area
- Utilities
- Buffer preparation area
- Cold room
- Filtration area
- Not applicable
- Flow of personnel



ROXANA MONTEMLONE
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 APODERADA
 SANOFI PASTEUR S. A.

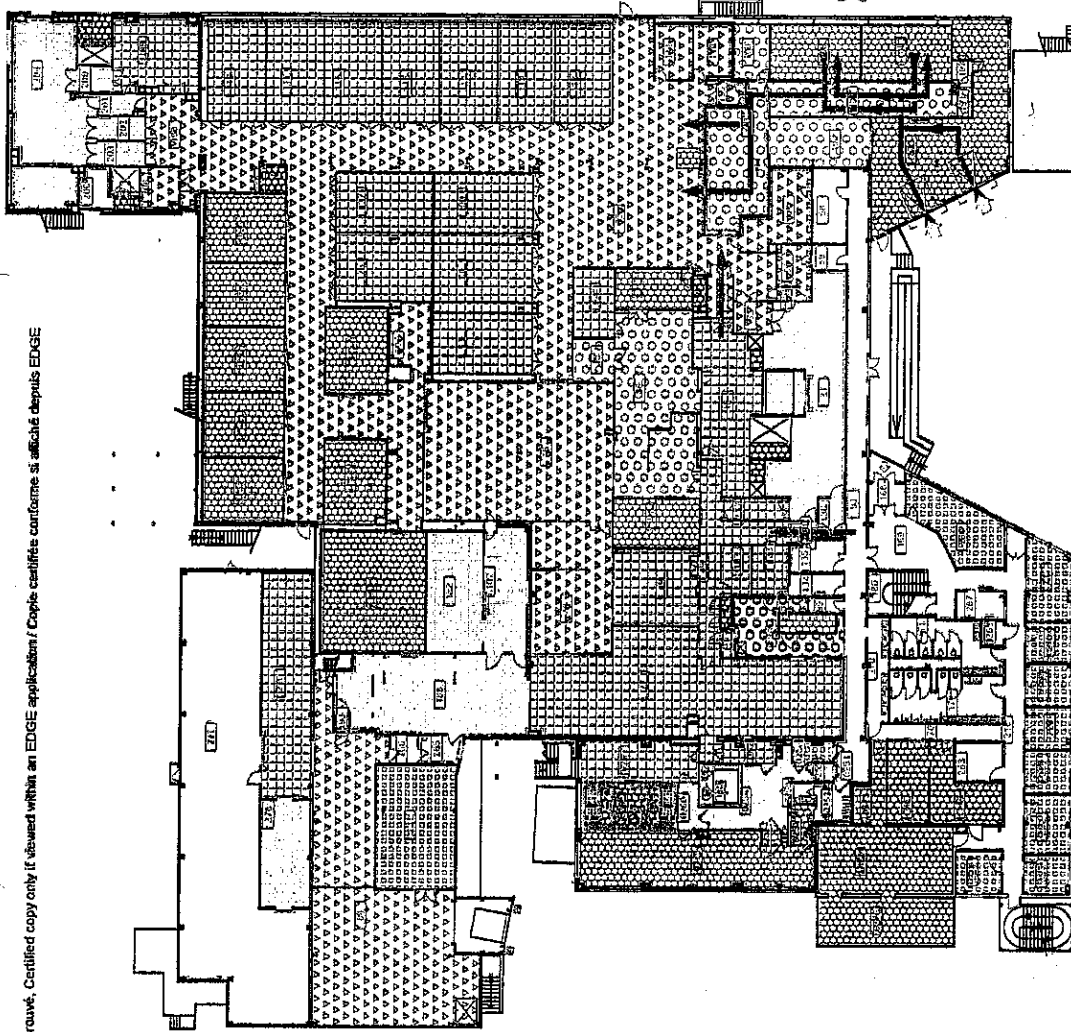
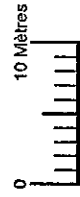
APPROUVÉ
 Roxana Montemilone
 Responsable technique
 Approuvé / approved par Roxana Montemilone Ch. N° 22520265 22237181 / approved document

Access date: 28 oct. 2016 14:51:22

Modif. : Mise à jour pour EDL 2014

N° CCR : NA	
Design Vanilier :	
Building : B6	Floor : -1
Sub-Building : UO GRIPPE	Drawer : Christophe HARDY
Discipline : Flux	Application Date : 25 Feb 2015
Sub-Discipline : Flux-Contrôle	Cal-Sub-Bis. : People
Description : Personnel flow for influenza un-concentrated monovalent bulk	
Layout Name : 04-PER-A3-Anglais	Scale : 1/500
File Name : B6000159004sRA-13	Document ID : RA_1047047
SANOFI PASTEUR ENGINEERING Parc Industriel d'Incarville - BP 101 - 27107 Val de Reuil - France	

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LEGEND

- ▨ Preparation area
- ▨ Incubation area
- ▨ Incubation area
- ▨ Purification area
- ▨ Utilities
- ▨ Cold room
- ▨ Offices
- ▨ Washing area
- ▨ Locker room
- ▨ Delivery area
- ▨ Shipping area
- ▨ wastewater decontamination area
- ▨ Harvest inoculation area
- ▨ Buffer preparation area
- ▨ Storage area for clean equipment
- ▨ Storage area for eggs
- ▨ Reception area of eggs
- ▨ Not applicable
- ▨ Limit of BSL2 + area
- ▨ Raw materials

ROXANA MONTEMILONE
DIRECTORA TÉCNICA
APODERADA
SANOFI PASTEUR S.A.

Approuvé
Roxana Montemilone
Approval - Approuvé par: Roxana Montemilone On: 15/07/2015 10:47:29 AM - Approuvé le: 15/07/2015 10:47:29 AM

Access date: 28 oct. 2016 14:47:55

Modif: MAJ LEGENDES FRET AN, zone decont. ELI (MANETTE NERY) N° CCR: NA

Design Verifier: Christophe HARDY
Application Date : 24 Jul 2015

Building: **B6** Floor: **0**

Sub-Building: **UO GRIPPE**

Discipline: **FLUX** Sub-Discipline: **Flux-Contrôle**

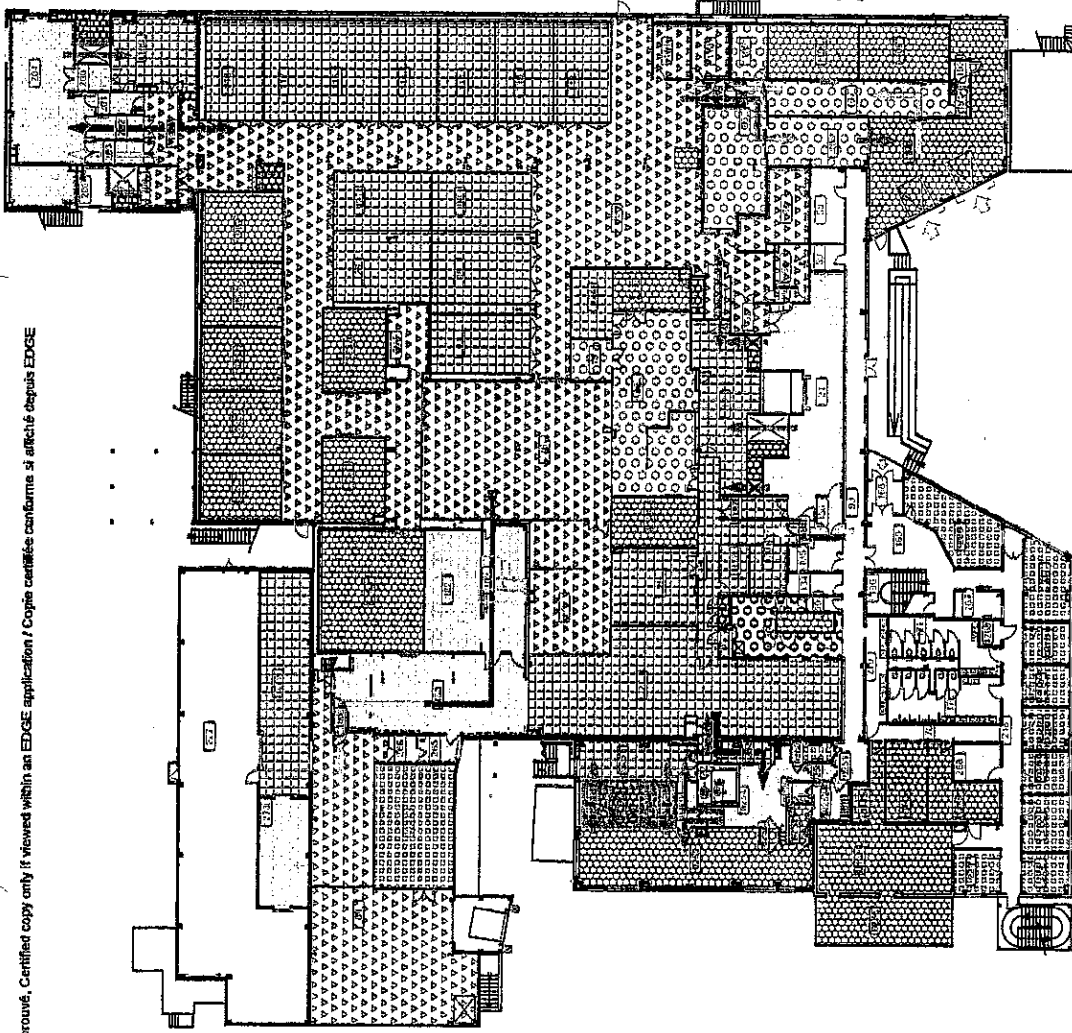
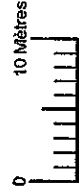
Description: **Raw materials flow for influenza un-concentrated monovalent bulk**

Layout Name: **08-MP-A3-Anglais** Scale: **1:500** Size: **A3**

File Name: **B6_001_F900_05_BL_16**

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Parc Industriel d'Incarville - BP 101 -
27101 Val de Reuil - France

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LEGEND

- Preparation area
- Inactivation area
- Incubation area
- Purification area
- Utilities
- Cold room
- Offices
- Washing area
- Locker room
- Delivery area
- Shipping area
- wastewater decontamination area
- Harvest inoculation area
- Buffer preparation area
- Storage area for clean equipment
- Storage area for eggs
- Reception area of eggs
- Not applicable
- Limit of BSL2 + area
- Soiled equipment
- Clean equipment
- Clean equipment not autoclavable

ROXANA MONTEMLONE
DIRECTORA TÉCNICA
APODERADA
SANOFI PASTEUR S. A.

APPROUVÉ NISHEVCI VLOZB
ACCESSÉD BY
Approved for: NISHEVCI VLOZB
Approved by: NISHEVCI VLOZB
Approved on: 28/07/2015 14:46:35

Access date: 28 oct. 2016 14:46:35

Modif: MAL LEGENDES FR. ET AN. Zone decontam. EU/MANETTE(Néby) N° CCR : NA

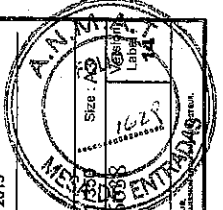
Building: **B6** Floor: **0**
Sub-Building: UO GRIPPE Design Verifier: Christophe HARDY
Application Date: 24 Jul 2015

Discipline: Flux Sub-Disciplines: Flux-Contrôle Cal-Sub-Disc.: Equipment
Description: Equipment flow for influenza uncentrated monovalent bulk

Layout Name: **10-MAT-A3-Anglais** Scale: **1/1000**
File Name: **B60016900_001PL10**

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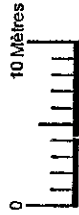
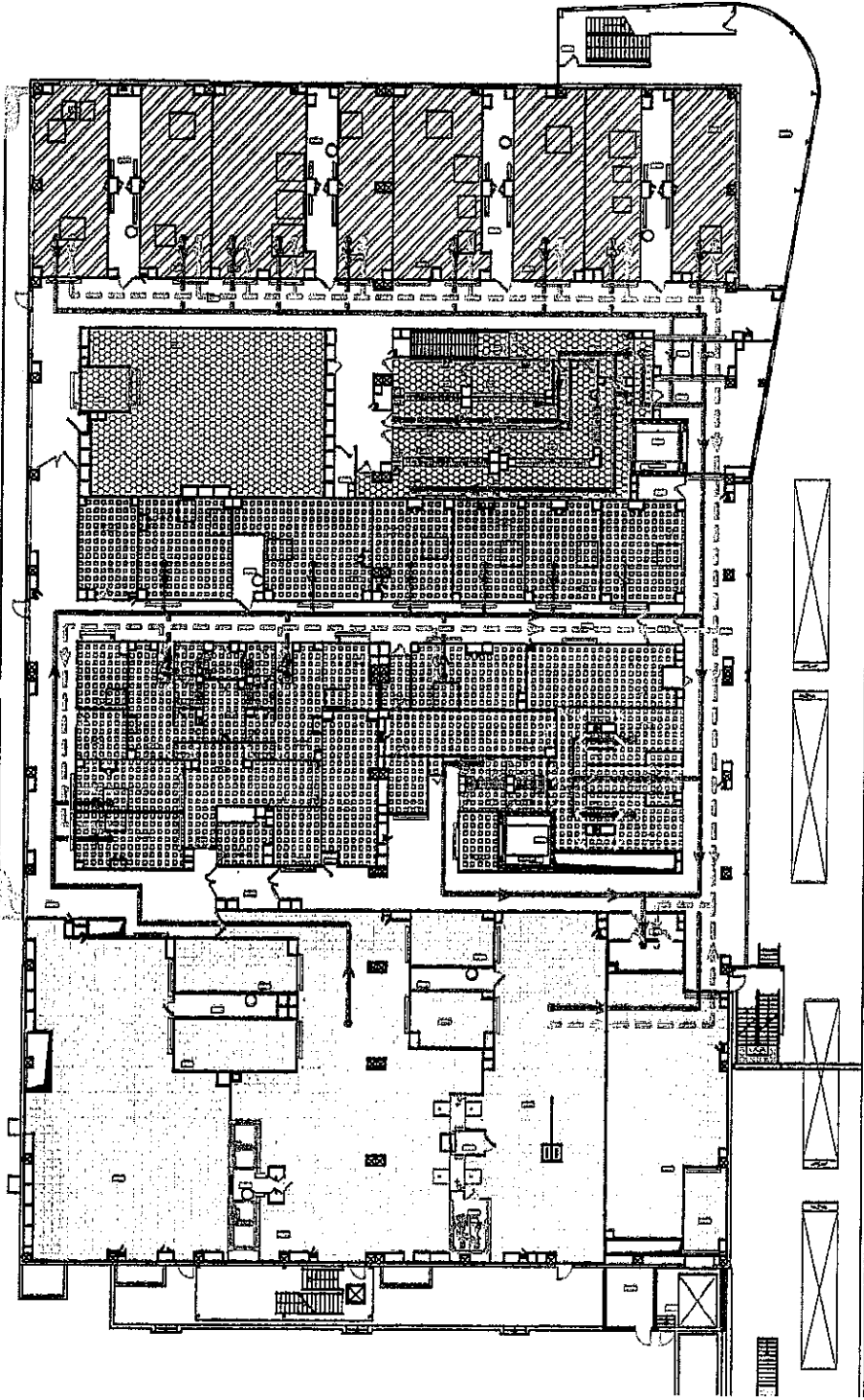
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27101 Val de Reuil - France



Manufacture of equipment for the production of influenza uncentrated monovalent bulk







LEGEND

- Preparation washing and sterilisation area
- Weighing area
- Intermediate solutions area
- Storage area
- Locker room
- Final bulk product area

- Waste flow
- Contact product waste flow

ROXANA MONTEMILO
DIRECTORA TÉCNICA
APODERADA
SANOFI PASTEUR, S. A.

ADRIANA NISHEVCI Viorica
Ingeniera de Documentación
Aprobado / Imprimado el 28/10/2016 14:55:10

Access date: 28 oct. 2016 14:55:10

Modif. : Préparation EDL 2013

Building : **B44**

Sub-Building : FORMULATION

Discipline : Flux

Description : Waste flow - Formulation B44 - Floor 1

N° CCR :

Floor : **1**

Design Verifier :
Drawer : Christophe HARDY

Application Date : 14 Feb 2014

Layout Name : **08-DECH-A3-Anglais**

Scale : 1/500

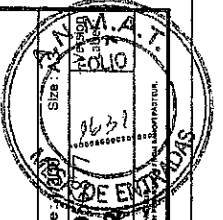
Document ID : RA_100887

File Name : **B44-F900-01-PL01**

Size : 1.1 MB

Project Name : **B44-F900-01-PL01**

Project Path : **08-DECH-A3-Anglais**



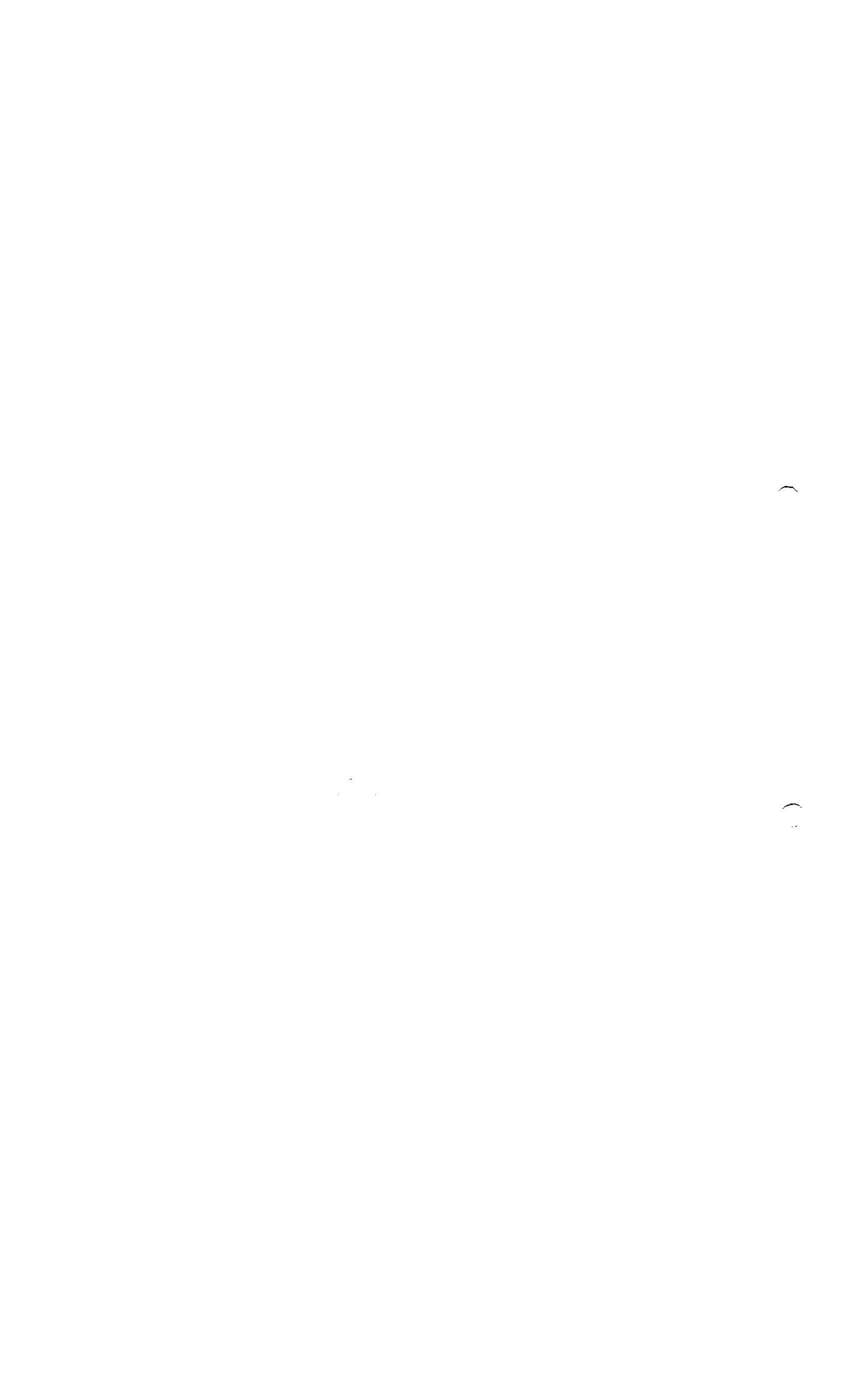
SANOFI PASTEUR

ENGINEERING

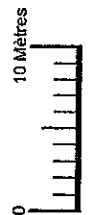
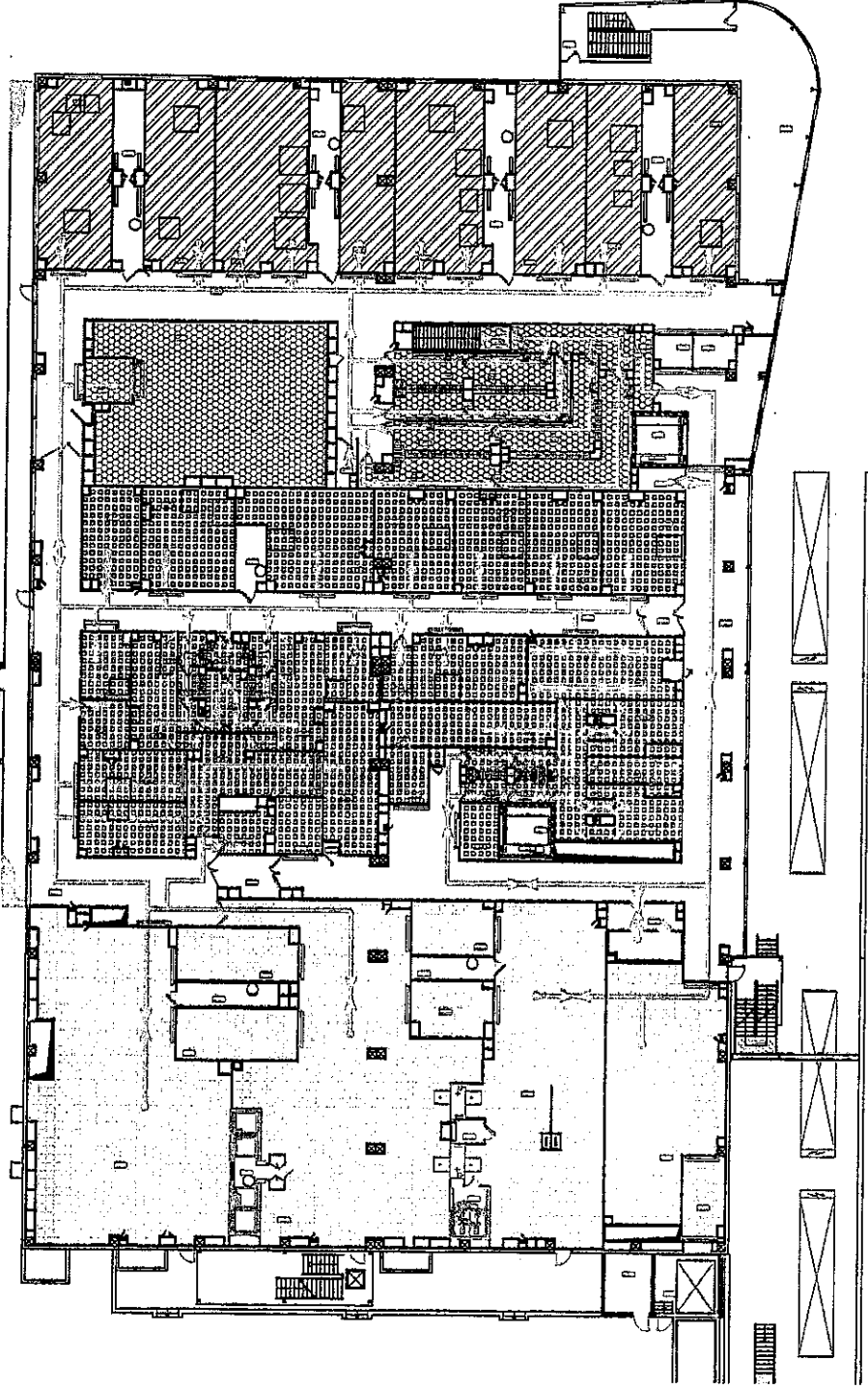
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LEGEND

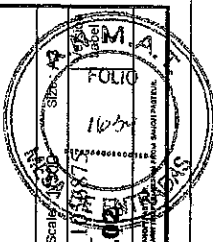
- Preparation washing and sterilisation area
- Weighing area
- Intermediate solutions area
- Storage area
- Locker room
- Final bulk product area
- Personnel flow

ROXANA MONTEMILO
DIRECTORA TECNICA
APODERADA
SANOPI PASTEUR S. A.

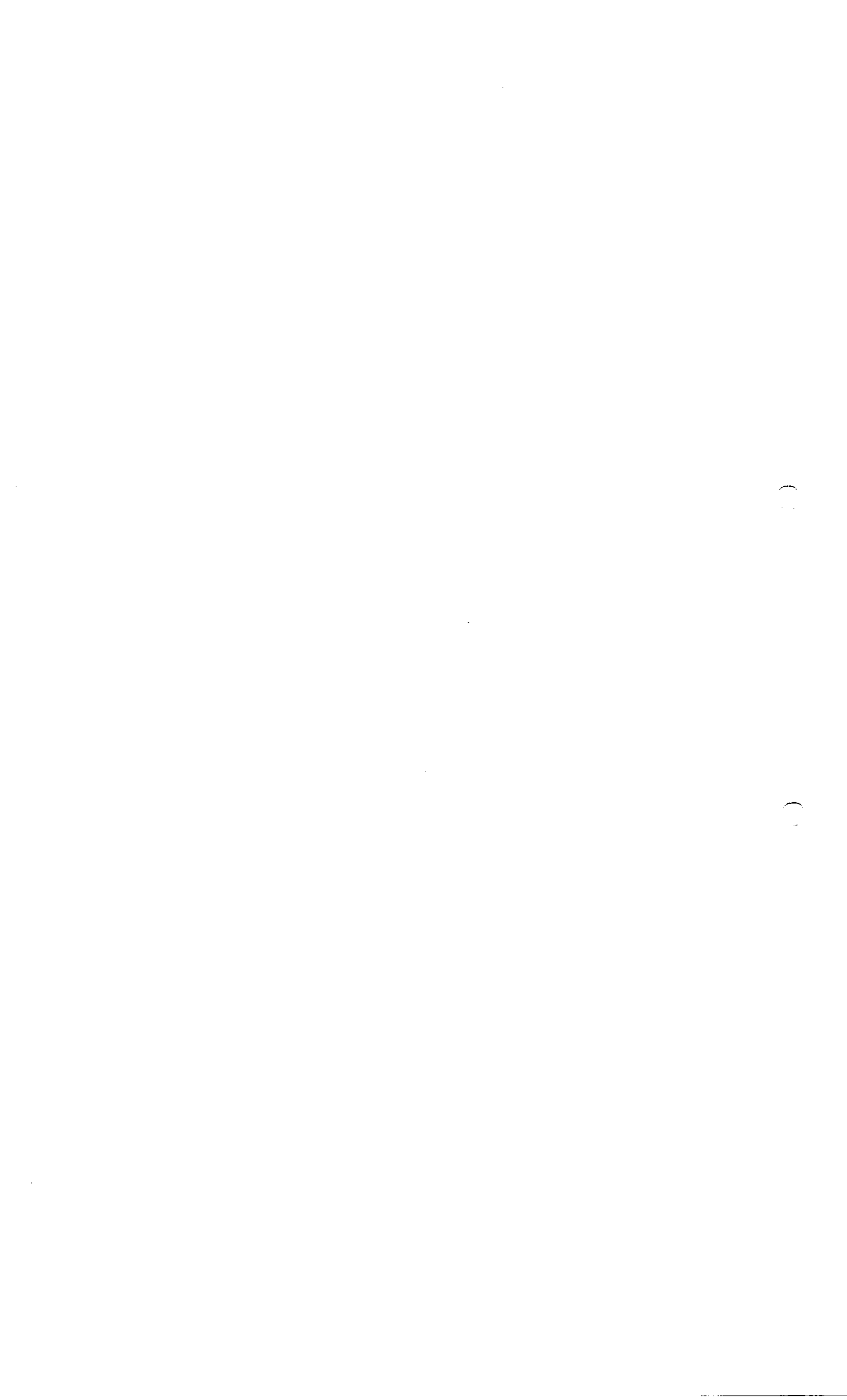
ADRIANA NISHEVICI Viorica
Aplicatia este aprobată de către Sanofi Pasteur S.A. în baza contractului nr. 1001/14 PK. Echipament de lucru aprobat pentru fabricarea de produse Sanofi Pasteur.

Access date: 28 oct. 2016 14:54:37

Modell: Préparation EDL 2013		N° CCR:	
Building: B44	Floor: 1	Design Verifier: Drawer: Christophe HARDY Application Date: 14 Feb 2014	
Sub-Building: FORMULATION		Ca-Sub-Dis.: Découpage de zones	
Description: Flux Personnel flow - Formulation B44 - Floor 1		Layout Name: 04-PER-A3-Anglais Scale: 1/500	
SANOFI PASTEUR ENGINEERING Parc Industriel d'Arcanville - BP 101 - 27101 Veit de Reuil - France		File Name: B44-EDL-F800-01-MLC	

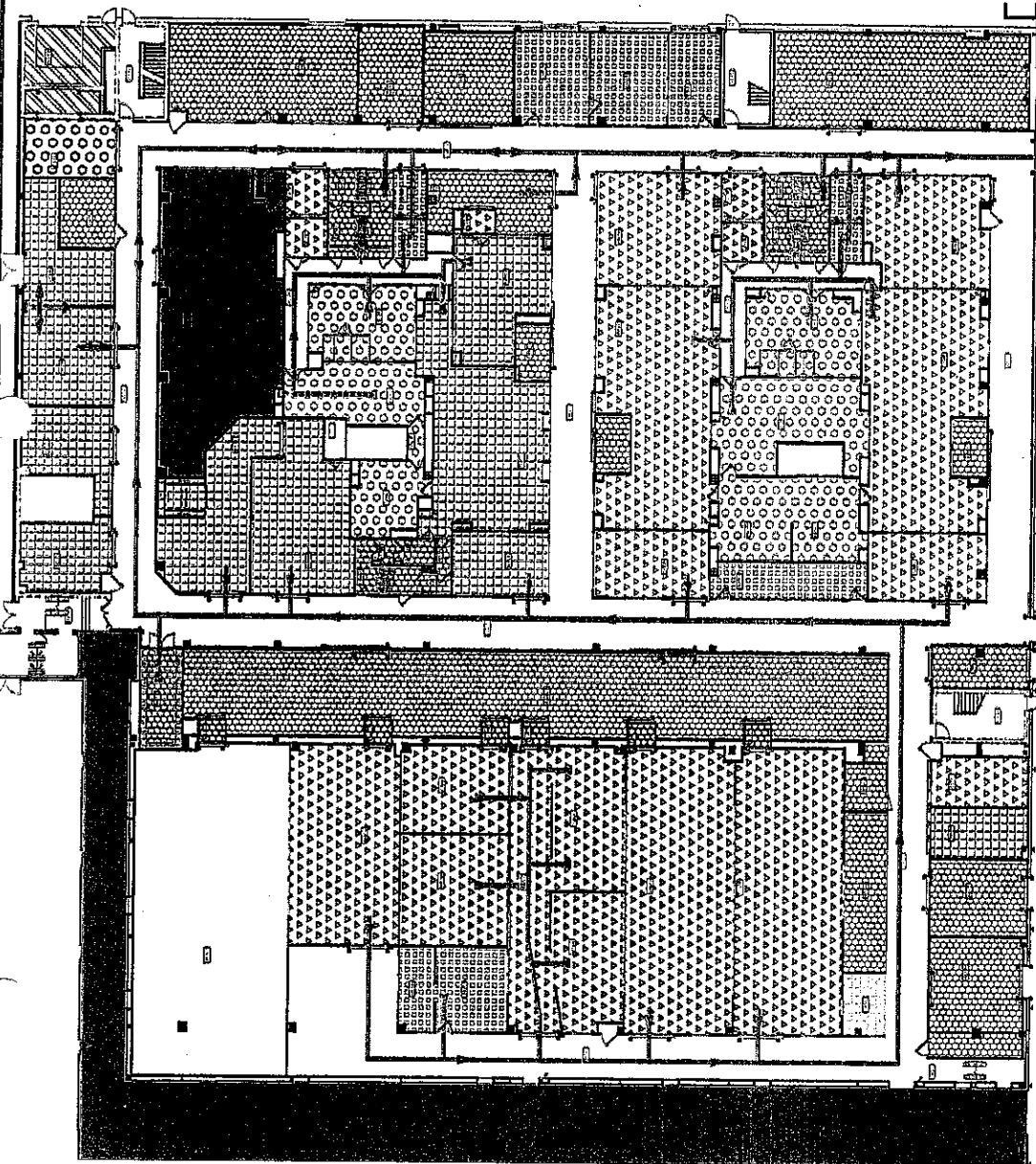








10 Mètres



LEGEND

- Final bulk product reception area
- Filled Product airlocks
- Autoclave
- Incubation area +32.5°C
- Incubation area +22.5°C
- Final Bulk Product airlock
- Pallet wrapping
- Solvent area
- Cold room +5°C
- Offices
- Personnel airlocks
- Filling area (syringe)
- Filling area (vial)
- Waste airlocks
- Equipment and primary packaging (Components airlocks)
- Preparation and Sterilization area (Equipment, primary packaging component)
- Storage area (except product)
- Waste area
- Inspection area
- Not allocated area
- Waste
- Waste temporary

ROXANA MONTEILONE
 DIRECTORA TÉCNICA
 APODERADA
 SANOFI PASTEUR S.A.

APPROUVÉ
 NISHIEVICI MORA
 Ingénieur en Chef
 Approuvé par: Roxana Montelone
 Directeur Technique
 Sanofi Pasteur S.A.
 Approuvé par: Jean-Michel Chaboussat
 Directeur Technique
 Sanofi Pasteur S.A.

Access date: 28 oct. 2016 15:00:27

Modif. : Mise à jour pour EDI 2014

Building : **B33**

Sub-Building : **REPARTITION**

Discipline : Flux

Description : Waste flow - Filling B33 - Ground floor

Floor : **0**

Call-Sub-Dis. : Waste

Design Verifier :
 Drawn : Christophe HARDY
 Application Date : 26 May 2015

N° CCR : 2160962

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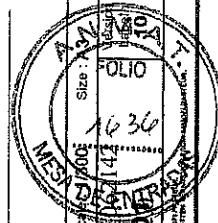
Parc Industriel d'Incarville - BP 101 -
 27101 Val de Reuil - France

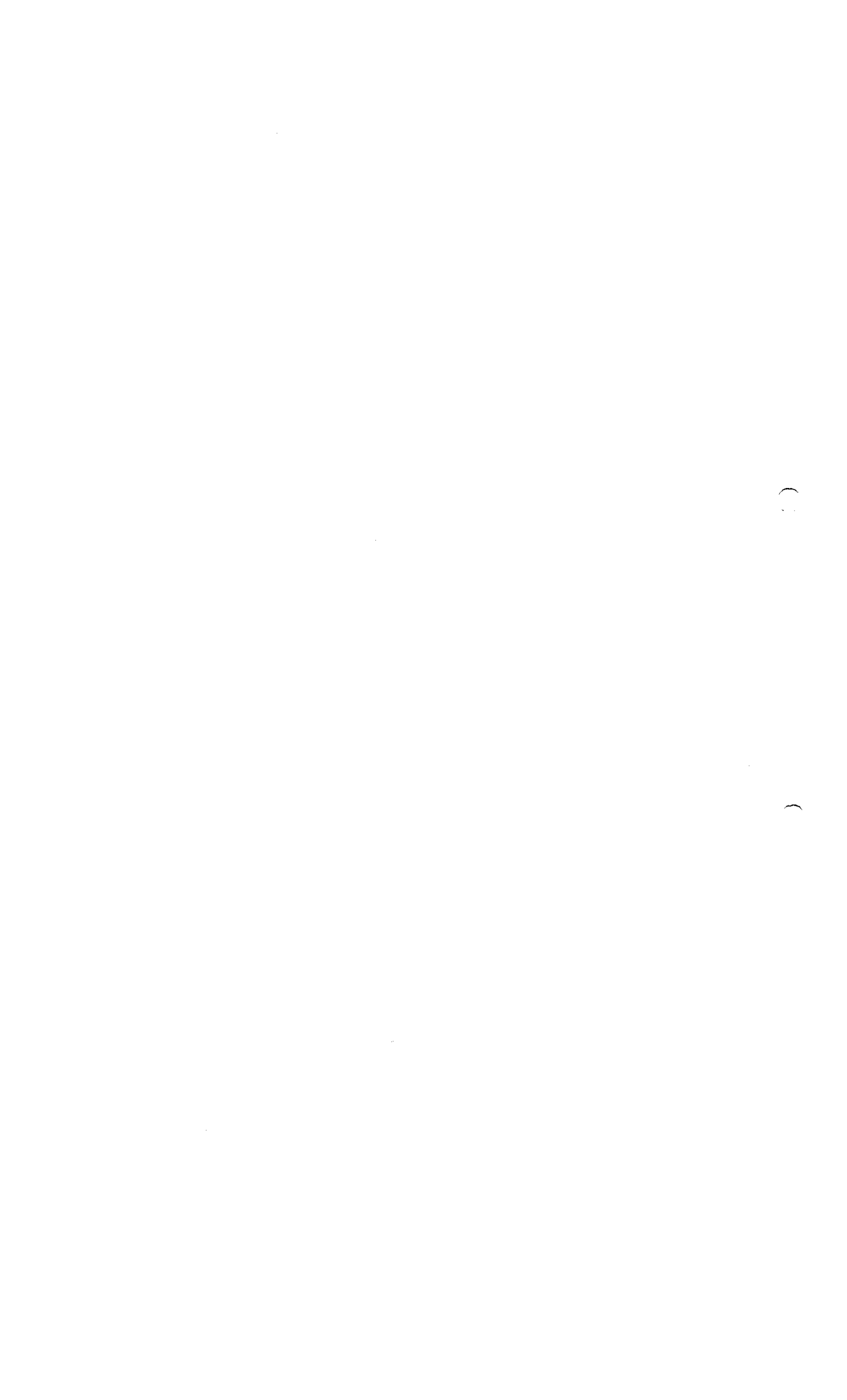
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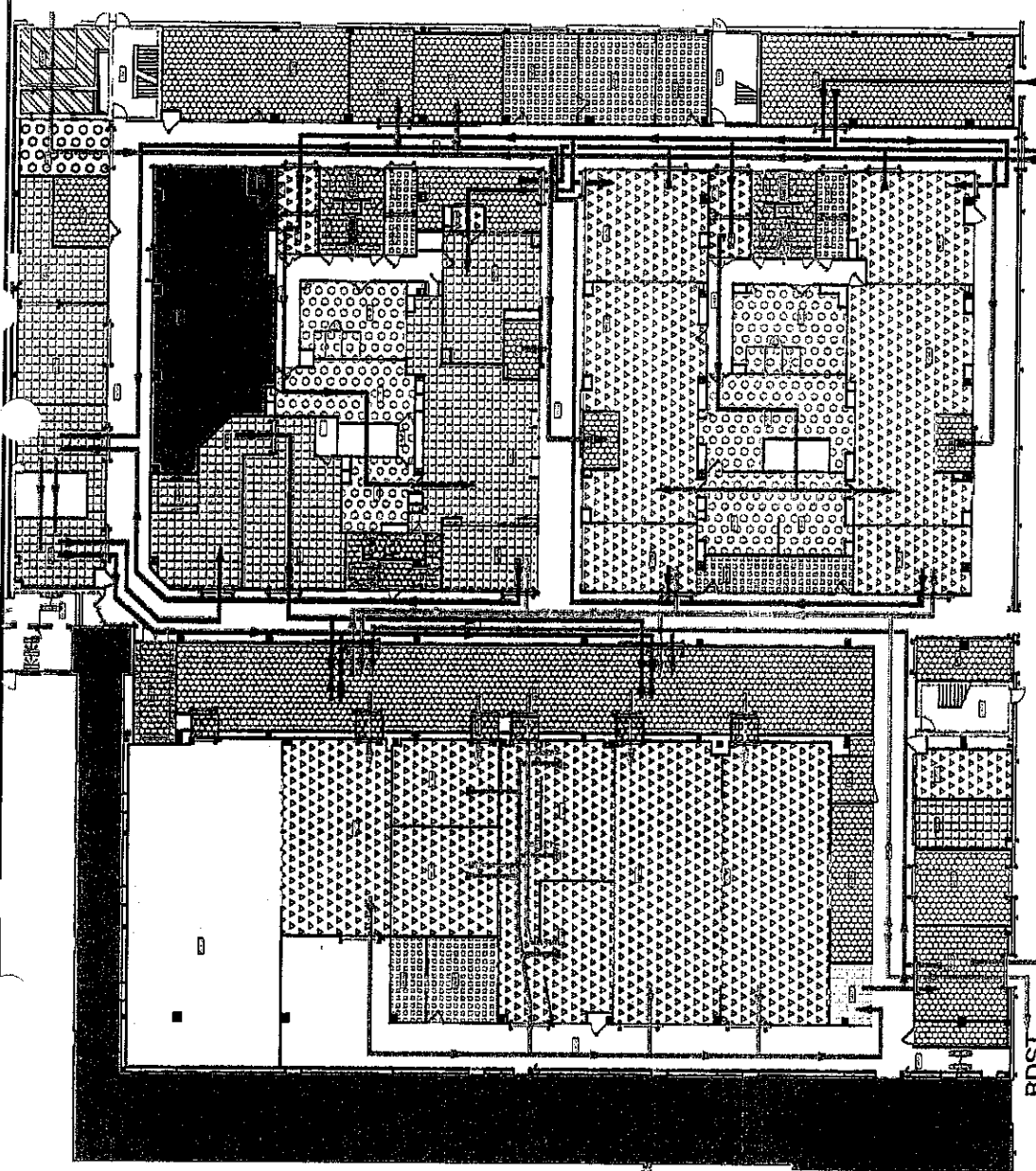
Document ID: RA_10144

File Name : **B33_wlf900_01_PLOI0**

Size : 1636







LEGEND

- Final bulk product reception area
 - Filled Product airlocks
 - Autoclave
 - Incubation area +32,5°C
 - Incubation area +22,5°C
 - Final Bulk Product airlock
 - Pallet wrapping
 - Solvent area
 - Cold room +5°C
 - Offices
 - Personnel airlocks
 - Filling area (syringe)
 - Filling area (Vial)
 - Waste airlocks
 - Equipment and primary packaging (Components airlocks)
 - Preparation and Sterilization area (Equipment, primary packaging components)
 - Storage area (except product)
 - Waste area
 - Inspection area
 - Not allocated area
-
- Filled product PR flow (solvent/vial)
 - Filled product PR flow (solvent/syring)
 - Final bulk product flow
 - Filled product flow
 - Inspected product flow
 - Primary packaging components flow

ROXANA MONTEMLONE
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 SANOFI PASTEUR S.A.

ADRIOLINA NISHEVICI Viora
 Inginer de proiectare
 Accesat la: 28 oct. 2016 14:58:16
 Aproposat de: Incastrarea de la Sanofi Pasteur S.A.

Access date: 28 oct. 2016 14:58:16

Modif. : Misc à jour pour EDL 2014

Building : **B33**

Sub-Building : **REPARTITION**

Discipline : **Flux**

Description : **Materials flow - Filling B33 - Ground floor**

Floor : **0**

Design Verifier :

Drawer : **CHRISTOPHE HARDY**

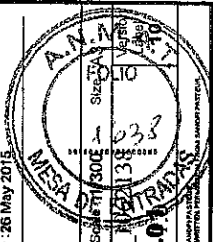
Application Date : **26 May 2015**

N° CCR : 2160682

Layout Name : **06-MP-A3-Anglais**

Document ID : **RA_00138_0338**

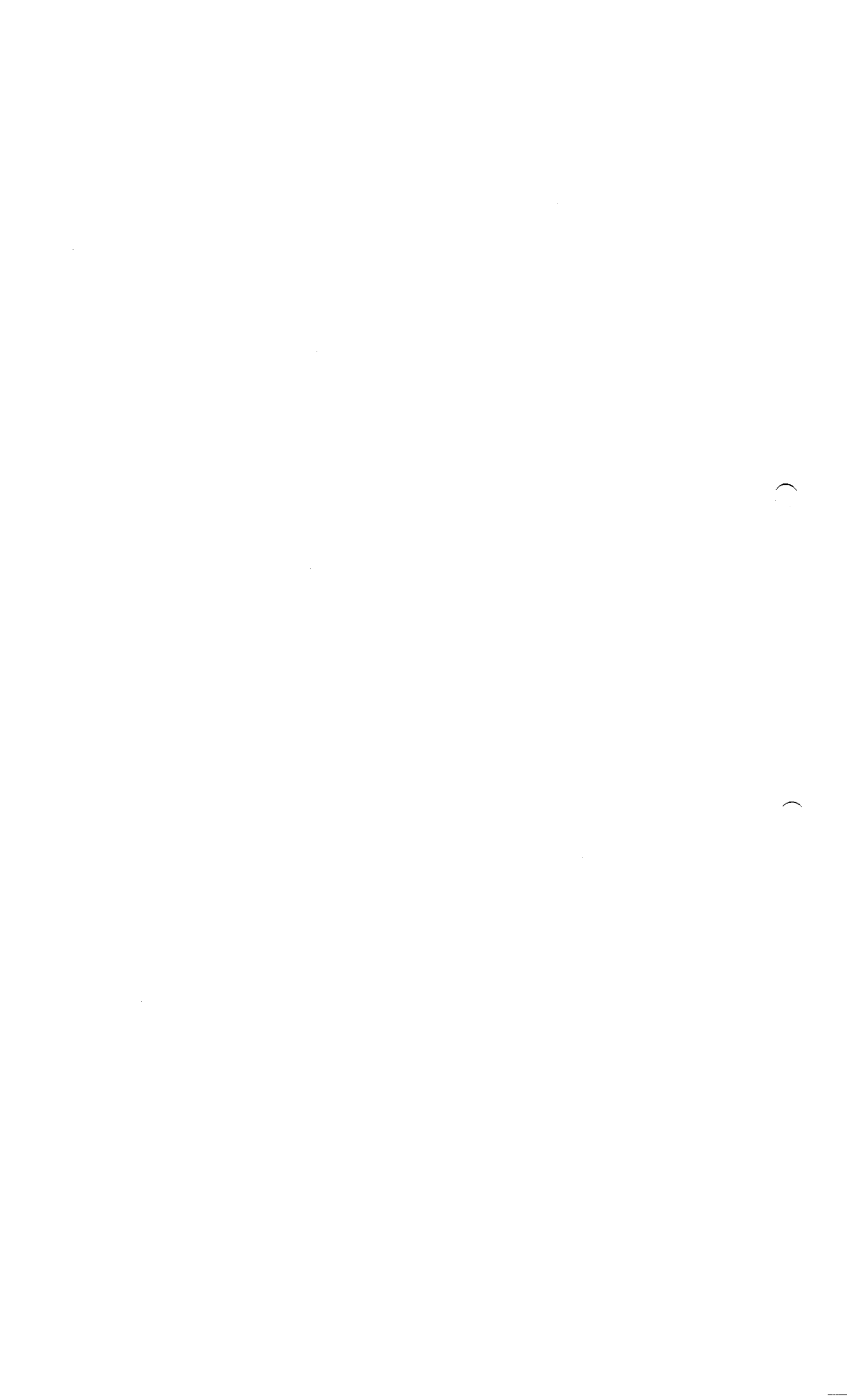
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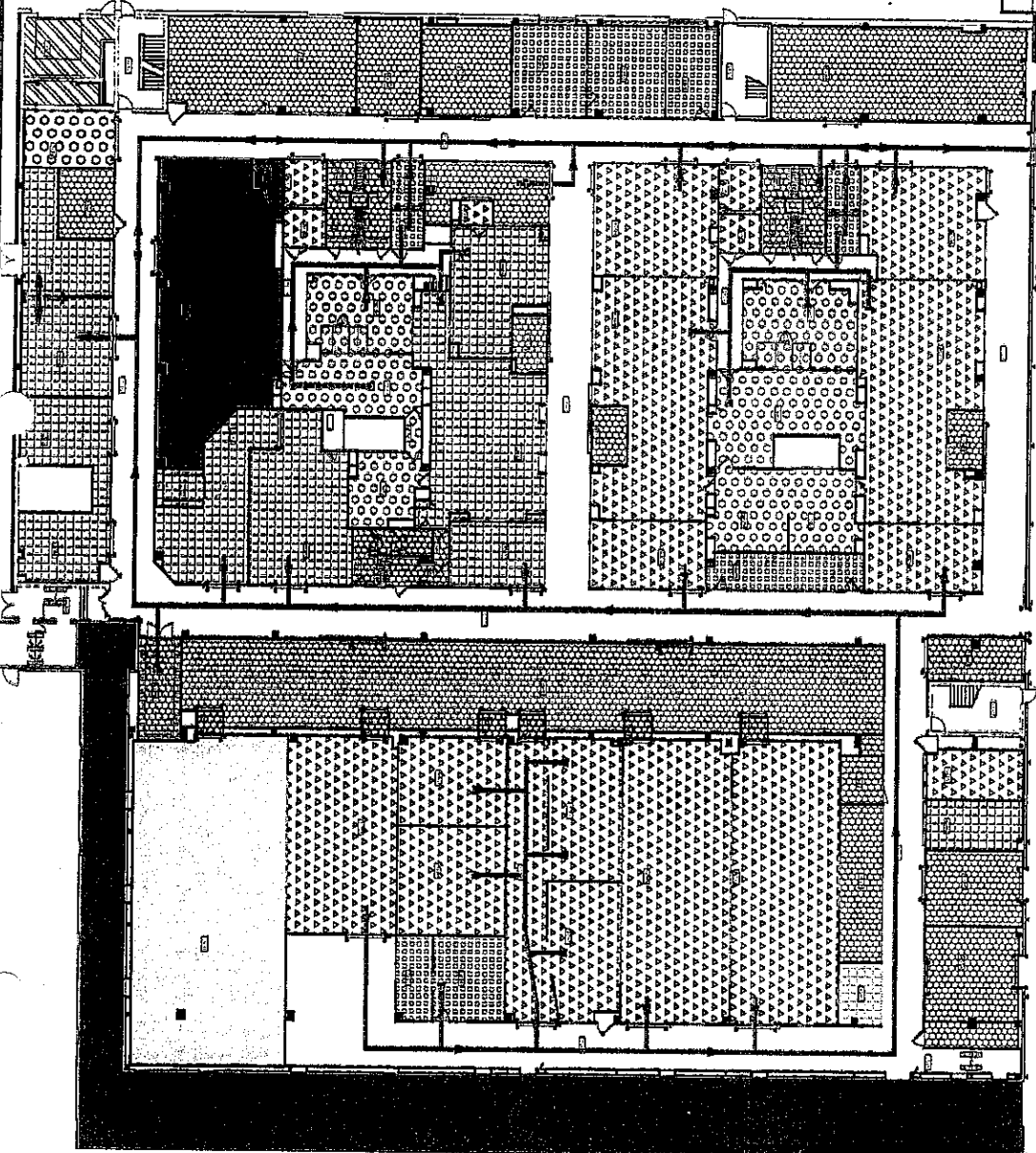


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LEGEND

- Final bulk product reception area
- Filled Product airlocks
- Autoclave
- Incubation area +32,5°C
- Incubation area +22,5°C
- Final Bulk Product airlock
- Pallet wrapping
- Solvent area
- Cold room +5°C
- Offices
- Personnel airlocks
- Filling area (syringe)
- Filling area (vial)
- Waste airlocks
- Equipment and primary packaging (Components airlocks)
- Preparation and Sterilization area (Equipment, primary packaging component)
- Storage area (except product)
- Waste area
- Inspection area
- Not allocated area
- Waste
- Waste temporary

ROXANA MONTEMLON
DIRECTORA TÉCNICA
APODERADA
SANOFI PASTEUR S. A.

ADOPCIÓN
Aprobado por: **NISHEVCI MIRON**
Aprobado por: **ROXANA MONTEMLON**
Aprobado por: **JENNIFER CHRISTOPHE**

Access date: 28 oct. 2016 15:00:27

Model: Mise à jour pour EDL 2014 N° CCR : 2150862

Design Vestier :
Drawer : Christophe HARDY
Application Date : 26 May 2015

Floor : **0**

Building : **B33**

Sub-Building : **REPARTITION**

Discipline : **Filtr**

Description : **Waste flow - Filling B33 - Ground floor**

Sub-Discipline : **Flux-Contrôle**

Cat-Sub-Dis. : **Waste**

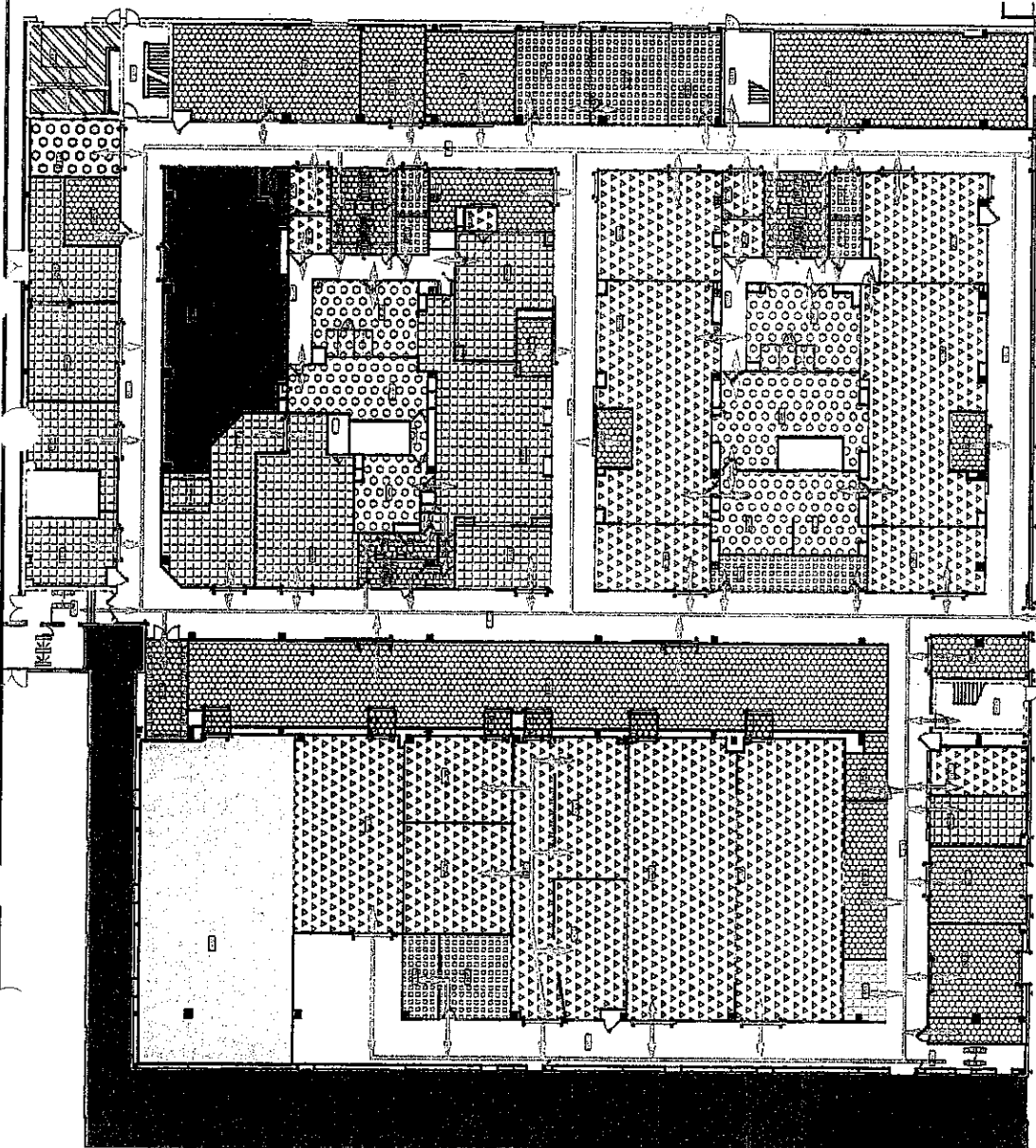
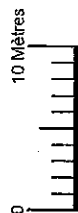
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Document ID : **RA-10-DECH-A3-Anglais**

File Name : **B33-10-DECH-A3-Anglais**

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MESA
1039
10



LEGEND

- Final bulk product reception area
- Filled Product airlocks
- Autoclave
- Incubation area +32,5°c
- Incubation area +22,5°c
- Final Bulk Product airlock
- Pallet wrapping
- Solvent area
- Cold room +5°c
- Offices
- Personnel airlocks
- Filling area (syringe)
- Filling area (vial)
- Waste airlocks
- Equipment and primary packaging (Components airlocks)
- Preparation and Sterilization area (Equipment, primary packaging component)
- Storage area (except product)
- Waste area
- Inspection area
- Not allocated area
- Flow of personnel

ROXANA MONTEMLONE
DIRECTORA TÉCNICA
APODERADA
SANOFI PASTEUR S.A.

APROBADO
NISHCHEVCIAN
Accessed by: NISHCHEVCIAN
Approved for: Jovanik Christofina On: 16/05/2015 15:25:15. All rights reserved. No document

Access date: 28 oct. 2016 15:00:01

Modif: Mise à jour pour EDL 2014

Building: **B33**

Sub-Building: REPARTITION

Discipline: Fibrix

Description: Personnel flow - Filling B33 - Ground floor

Floor: **0**

Design Verifier:

Drawer: Christophe HARDY

Application Date: 26 May 2015

Layout Name: **04-PER-A3-Anglais**

Document ID: RA-16214

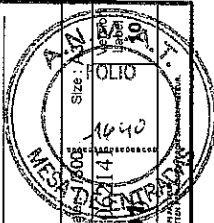
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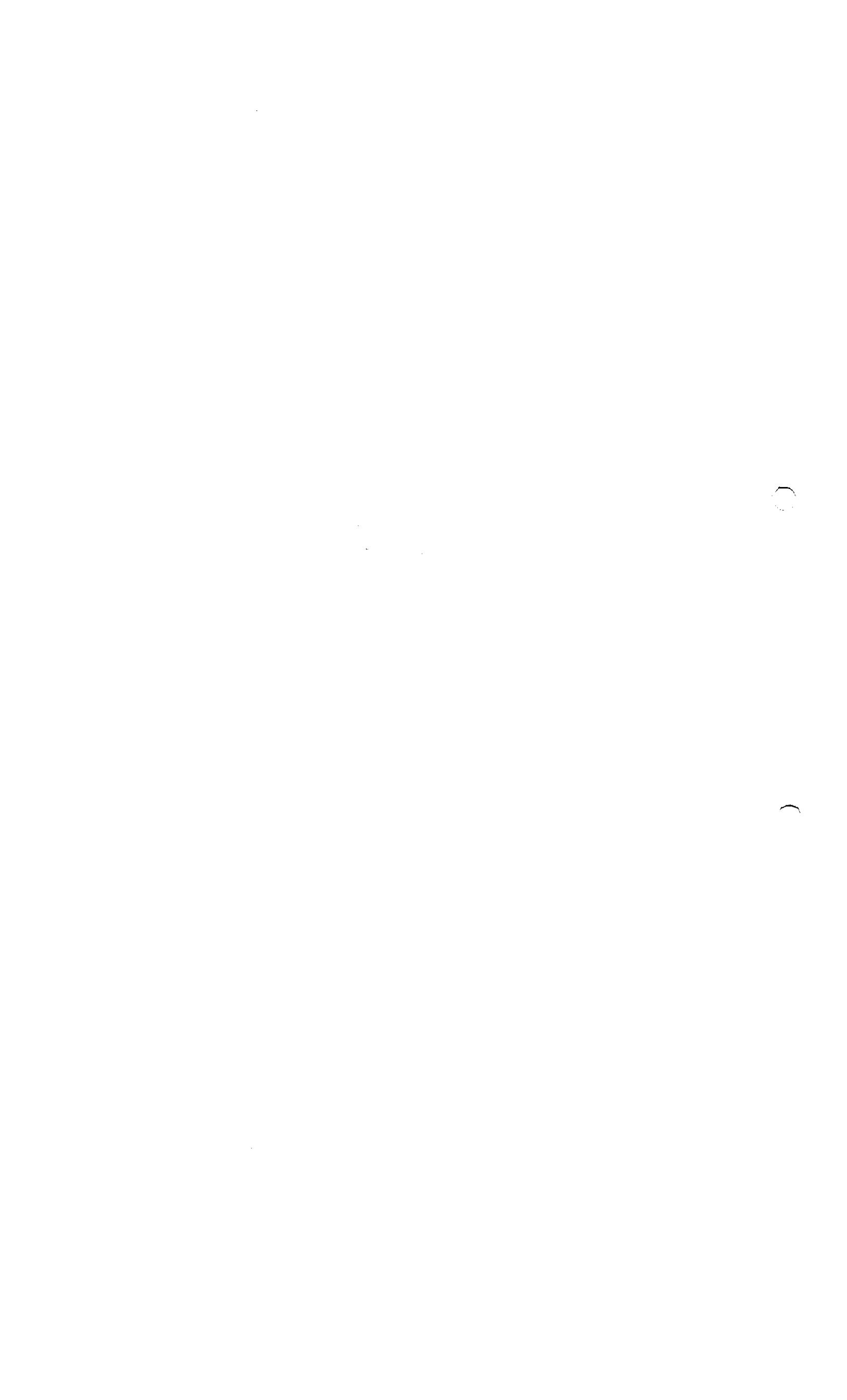
Parc Industriel d'Incarville - BP 101 -

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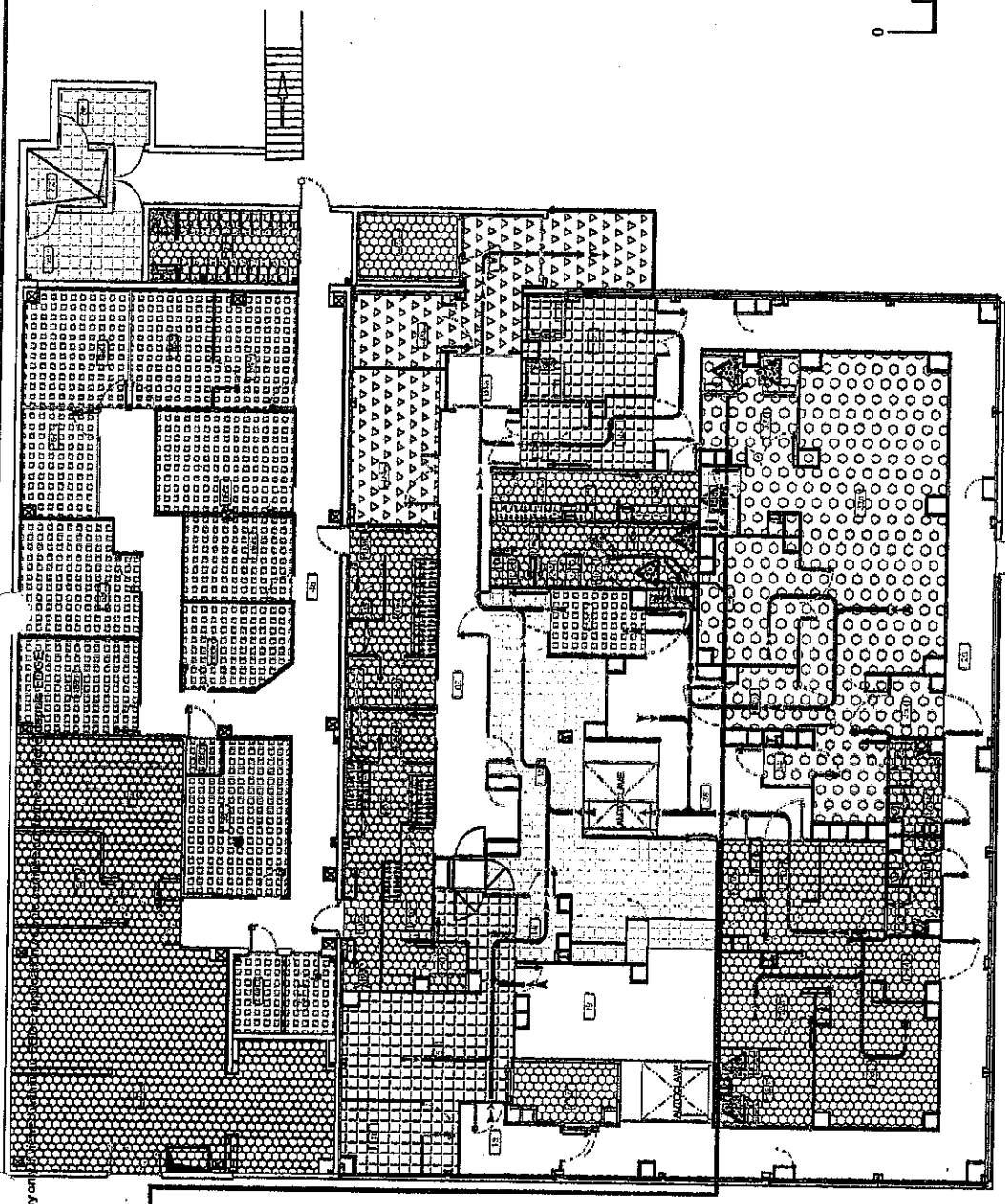
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LEGEND

- Washing area
- Utilities
- Offices
- Delivery area
- Medium preparation
- Locker room
- Preparation and storage area equipment
- Master and intermediate seed lots production area
- Working seed lots and scale down production area
- Primary incubation area
- Cold room of reception
- Decontamination area
- Virulent waste
- Non-virulent waste



Modif. : Ajout de la présentation N° : 21-DZ-A2

Building : **B26**

Sub-Building : **LABORATOIRE SEMENCE GRIPPE**

Discipline : Flux

Description : Waste flow for manufacture of influenza seed lots

Layout Name : **12-DECH-A3-Anglais**

File Name : **B26cauF90000818107**

Design Verifier : **Christophe HARDY**

Application Date : 21 Feb 2014

N° CCR :

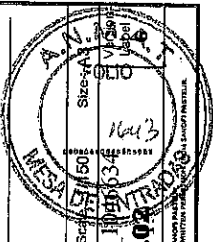
Floor : **0**

Ca-Sub-Dis. : Waste

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ROXANA MONTEILMON
DIRECTORA TÉCNICA
APODERADA
SANOFI PASTEUR S.A.

















Access date: 28 oct. 2016 14:39:08



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LEGEND

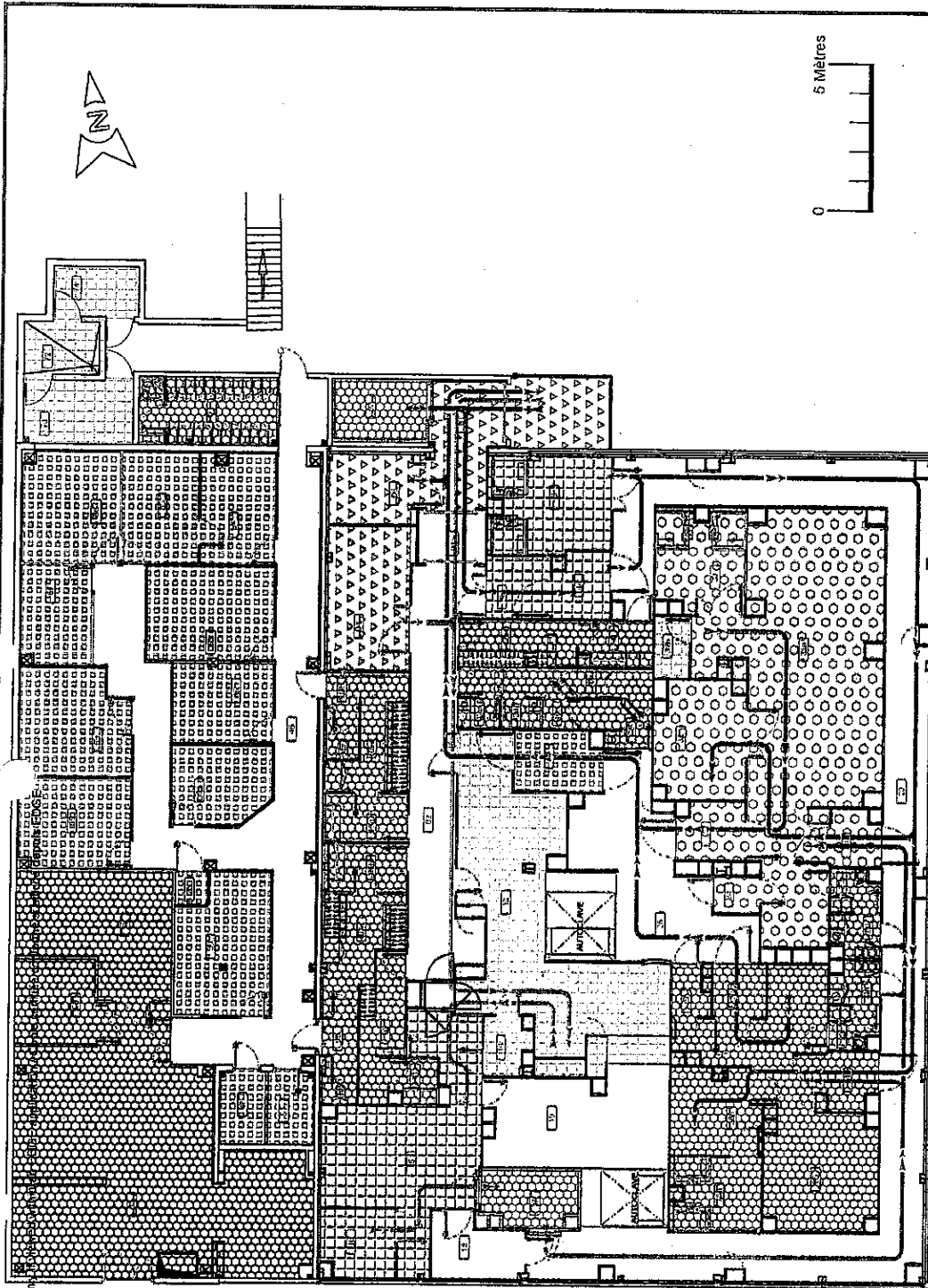
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-  Utilities
-  Offices
-  Delivery area
-  Medium preparation
-  Locker room
-  Preparation and storage area equipment
-  Master and intermediate seed lots production area
-  Working seed lots and scale down production area
-  Primary incubation area
-  Cold room of reception
-  Decontamination area
-  Solutions
-  Powders + liquids
-  Starting materials : eggs and strains
-  Seeds / samples




ROXANA MONTEILON
DIRECTORA TECNICA
APOKERADA
SANOFI PASTEUR S. A.

APPROUVE
APPROUVE PAR NISHENG/MOZ/28/04/2015 15:45:12
Approuvé par NISHENG/MOZ/28/04/2015 15:45:12

Access date: 28 oct. 2016 14:40:38



Modif. : Ajout de la présentation N° : 21-02-02

<p>N° CCR :</p> <p>Design Verifier : Drafter : Christophe HARDY Application Date : 21 Feb 2014</p>	<p>Floor : 0</p> <p>Cat-Sub-Dis. : Product</p>
<p>Building : B26</p> <p>Sub-Building : LABORATOIRE SEMENCE GRIPPE</p> <p>Discipline : Flux</p> <p>Description : Product flow for manufacture of influenza seed lots</p>	<p>Layout Name : 06-PRO-A3-Anglais</p> <p>Document ID : RA_1010030</p> <p>File Name : B26cu15900_06_PIL02</p>
 <p>SANOFI PASTEUR ENGINEERING</p> <p>Parc Industriel d'Incarville - BP 101 - 27101 Val de Reuil - France</p>	
<p>0 5 Metres</p>	



LEGEND

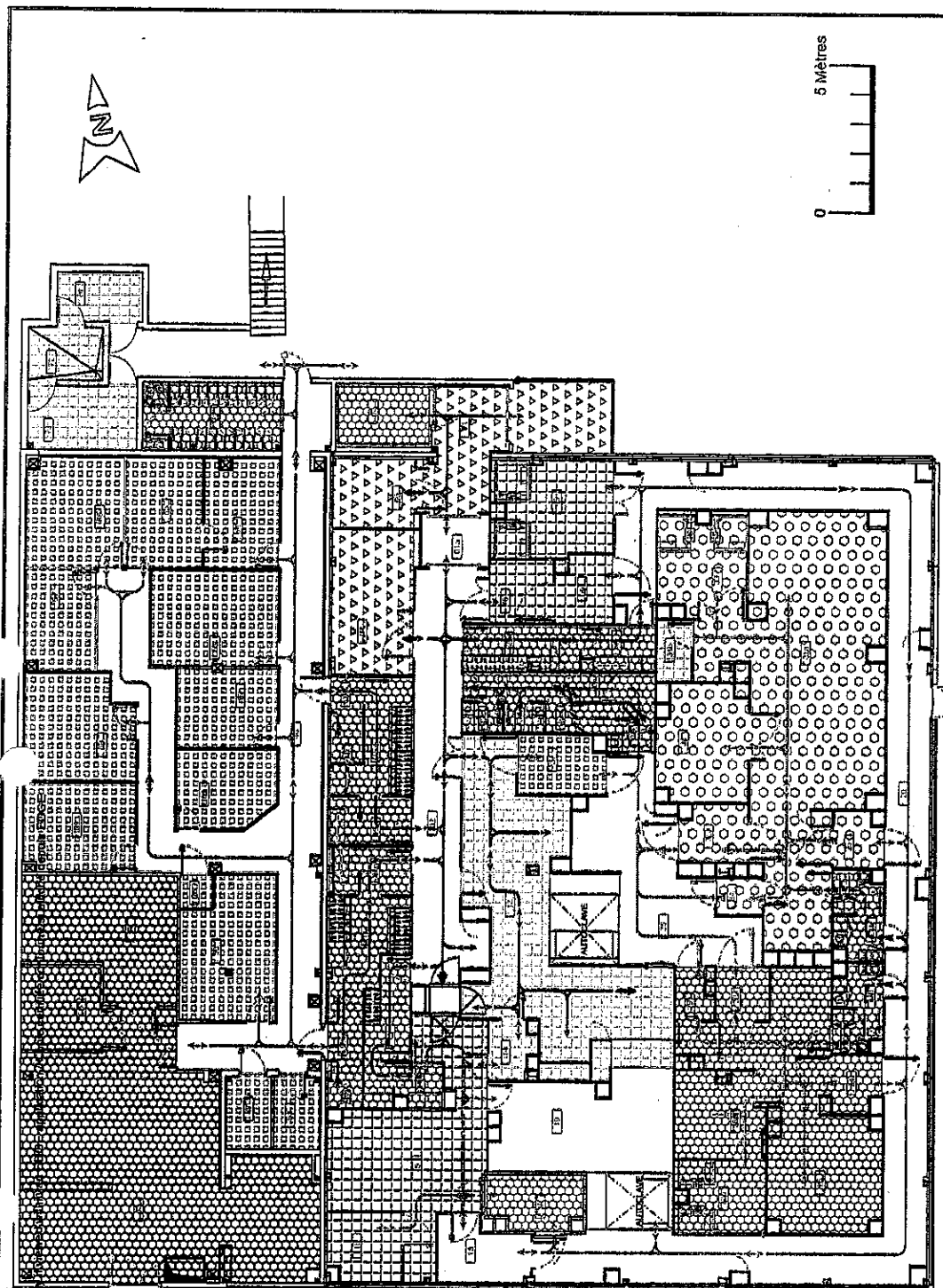
- Washing area
- Utilities
- Offices
- Delivery area
- Medium preparation
- Locker room
- Preparation and storage area equipment
- Master and intermediate seed lots production area
- Working seed lots and scale down production area
- Primary incubation area
- Cold room of reception
- Decontamination area

- Flow of personnel in the technical and administratives zones
- Flow of personnel to enter and exit the production zones
- Flow of personnel in non-virulent zone
- Flow of personnel in virulent zone

ROXANA MONTEILONE
DIRECTORA TECNICA
APODERADA
SANOFI PASTEUR S.A.

APPROUVÉ
Accessed by: NISHEVCIMLO72
Approved on: 28/04/2015 15:44:35
Approved by: [Signature]

Access date: 28 oct. 2016 14:37:19



Modif. / Ajout de la présentation N°: 21-02-A2

Building: **B26** Floor: **0**

Sub-Building: **LABORATOIRE SEMENCE GRIPPE**

Discipline: Flux

Description: Personnel flow for manufacture of influenza seed lots

Design Verifier: Christophe HARDY
Application Date: 21 Feb 2014

Cat-Sub-Dis.: People

Layout Name: **04-PER-A3-Anglais**

Document ID: RA_140631

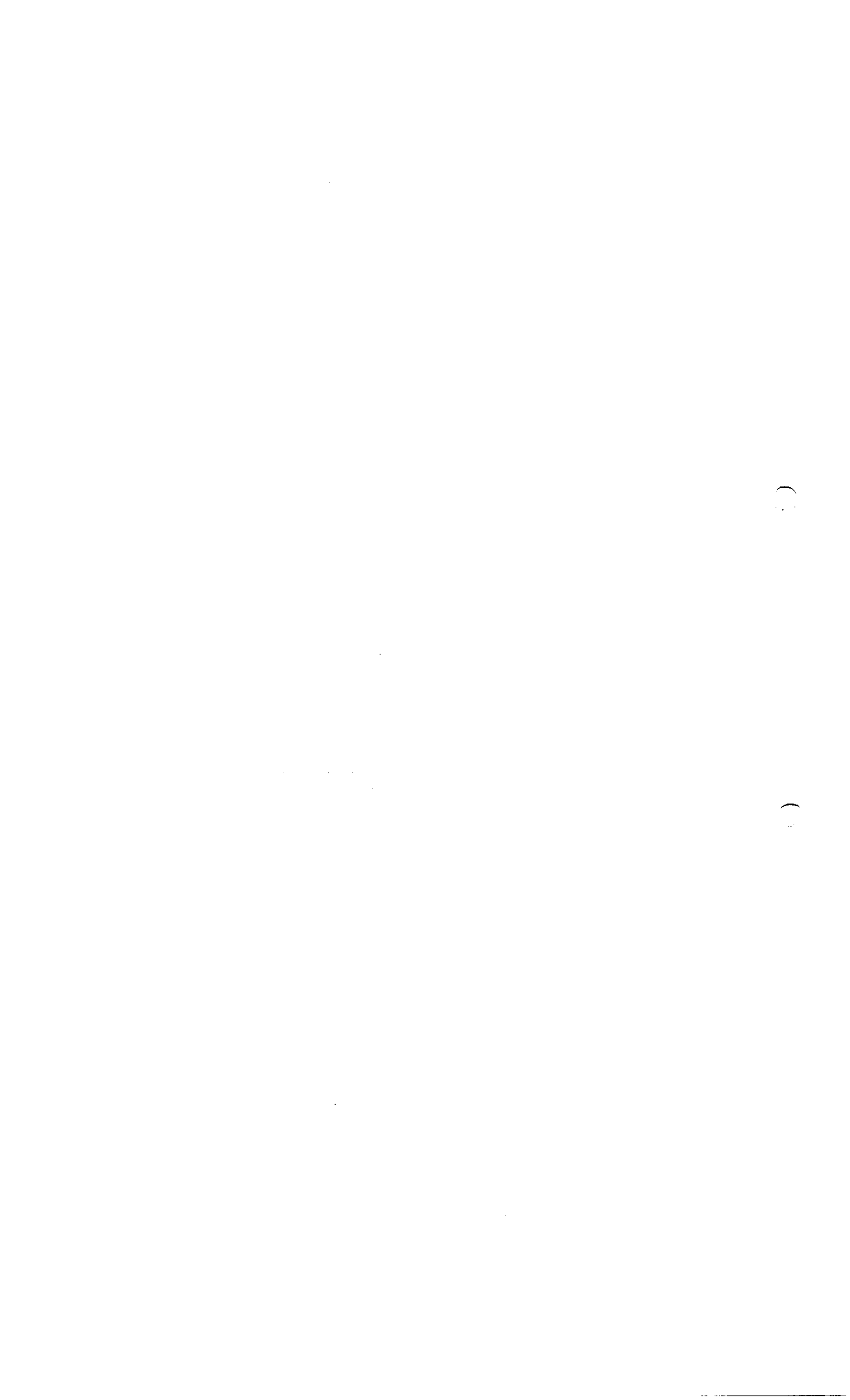
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Scale: 1/500

Size: 10x4

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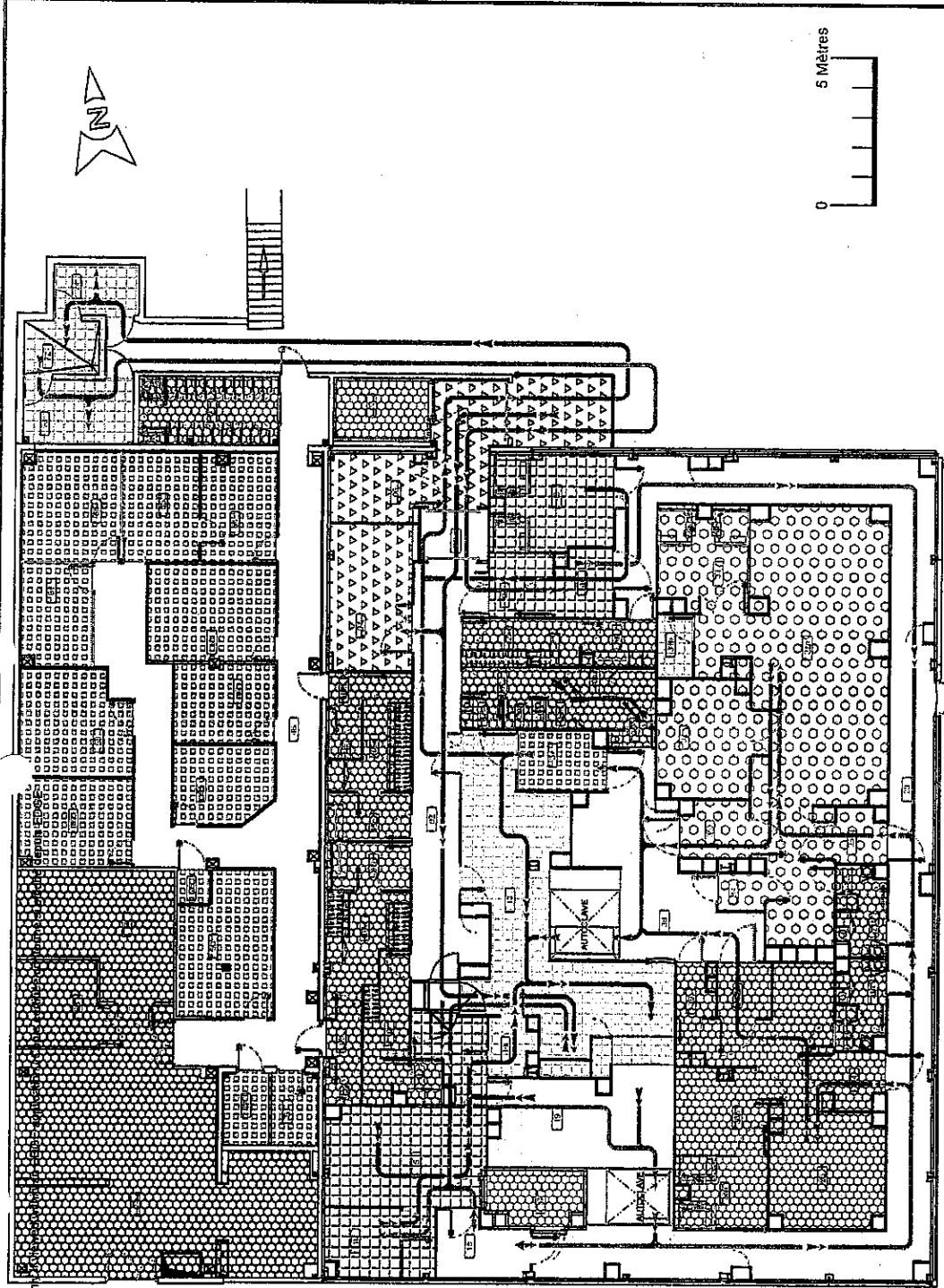
MINISTRE DE LA SANTE
DIRECTION GENERALE DE LA SANTE
BUREAU NATIONAL D'HYGIENE ALIMENTAIRE
ET NUTRITIONNELLE
N° 140631
FOLIO 10x4



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LEGEND

- Washing area
- Utilities
- Offices
- Delivery area
- Medium preparation
- Locker room
- Preparation and storage area equipment
- Master and intermediate seed lots production area
- Working seed lots and scale down production area
- Primary incubation area
- Cold room of reception
- Decontamination area
- Non-voluent soiled equipment
- Virulent soiled equipment
- Clean equipment
- Consumables equipment



Modif : Ajout de la présentation N° : 21-DZ-A2

Building : **B26** Floor : **0**

Sub-Building : **LABORATOIRE SEMENCE GRIPPE**

Discipline : Flux Sub-Discipline : Flux-Contrôle

Description : Equipment flow for manufacture of influenza seed lots

Design Verifier :
 Drawer : Christophe HARDY
 Application Date : 21 Feb 2014

Layout Name : **10-MAT-A3-Anglais** Scale : **1/200**

Document ID : RA_11_06_036

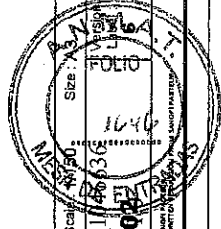
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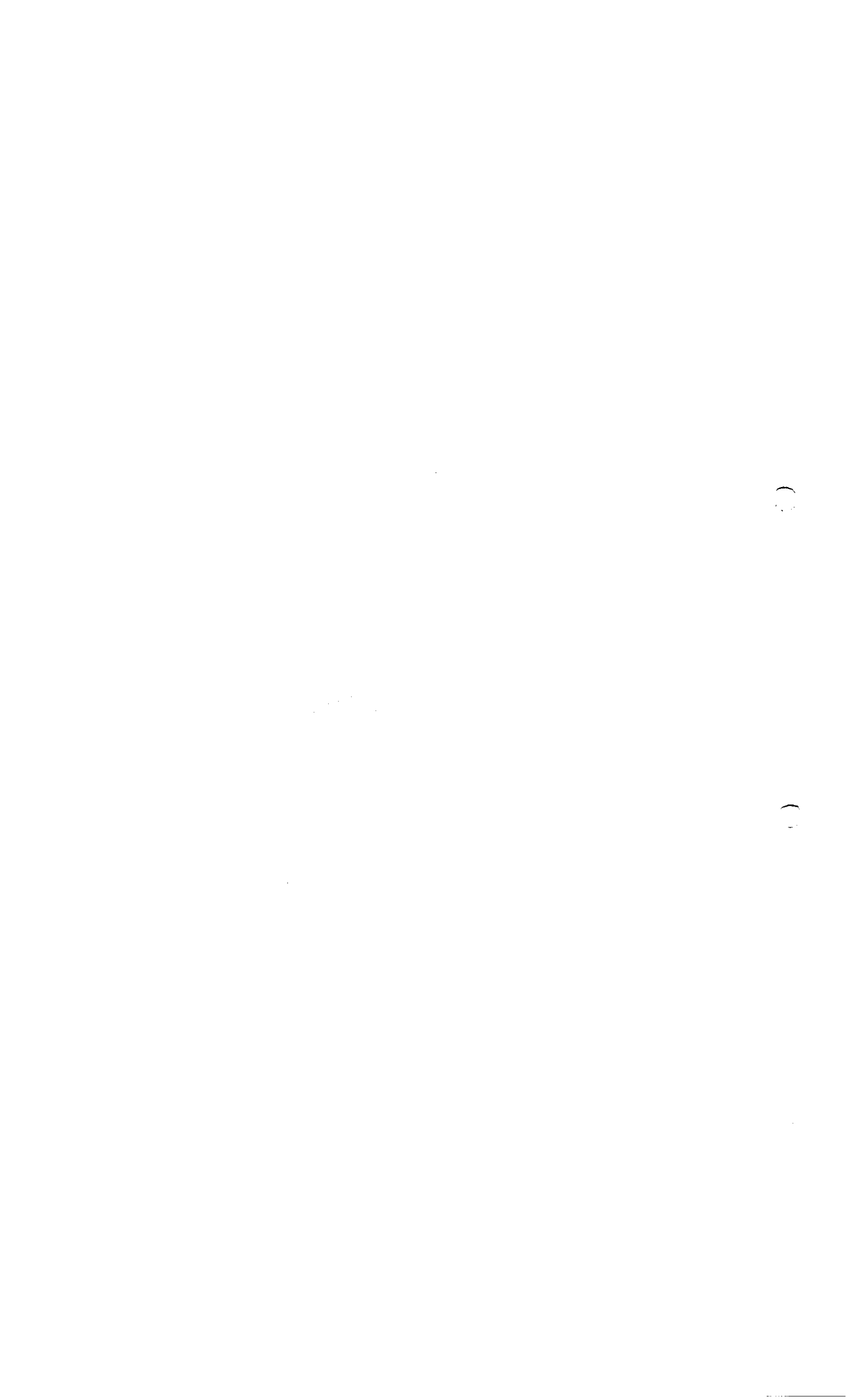
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 Parc Industriel d'Incarville - BP 101 -
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Access date: 28 oct. 2016 14:43:32

ROXANA MONTEMLONE
 DIRECTORA TÉCNICA
 APODERADA
 SANOFI PASTEUR S.A.

Approuvé
 NISHEVCI Miroslav
 Approved / Aprobado / Aprobado / Aprobado / Aprobado

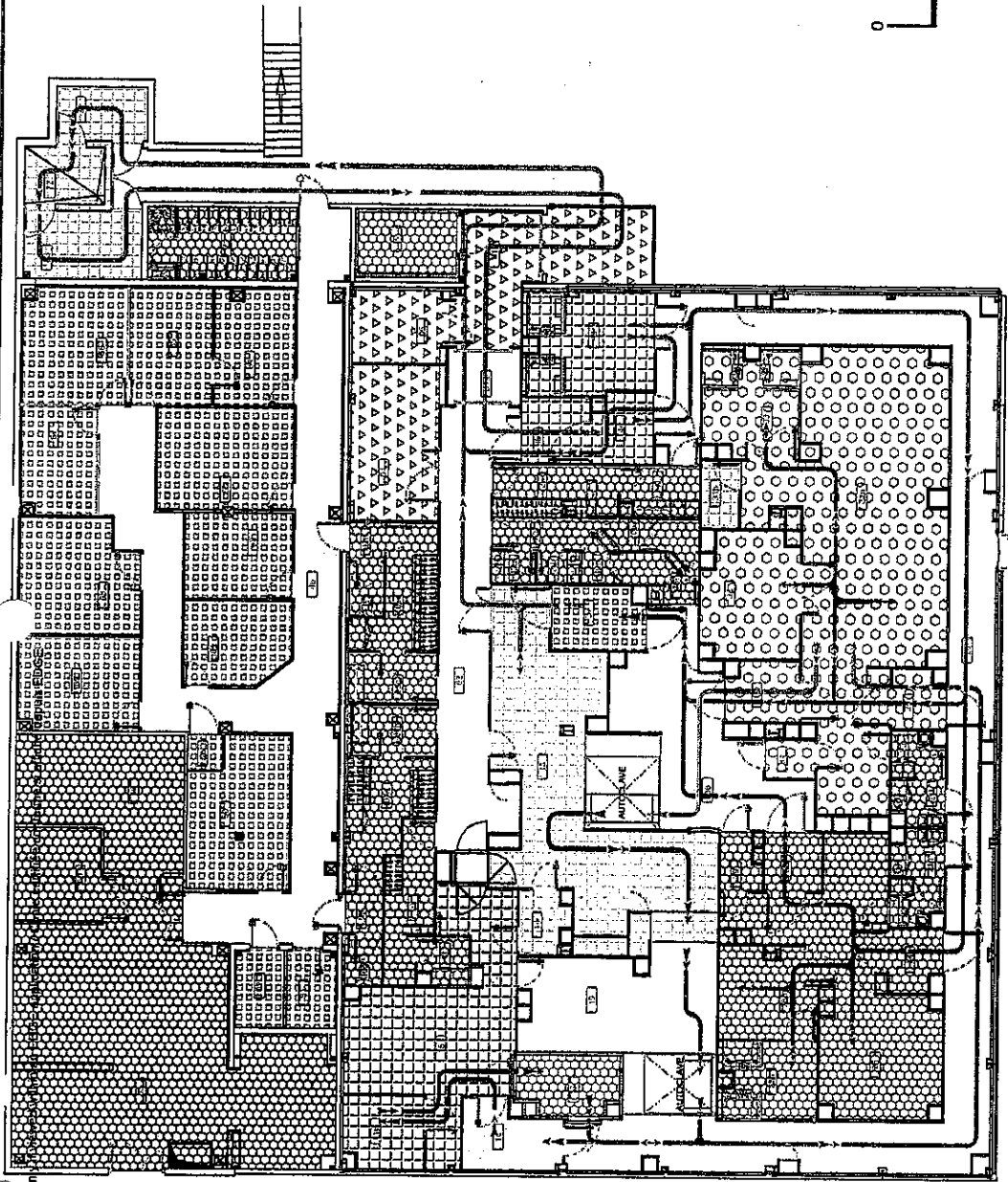




Printed On / Imprimé le 29/04/2015 15:45:42 Current Status: Approuvé, Certified copy on

LEGEND

- Washing area
- Utilities
- Offices
- Delivery area
- Medium preparation
- Locker room
- Preparation and storage area equipment
- Master and intermediate seed lots production area
- Working seed lots and scale down production area
- Primary incubation area
- Cofft room of reception
- Decontamination area
- Tub 50 L media (virulent)
- Tub 50 L media (non-virulent)
- Wagons eggs + portoirs (virulent)
- Wagons eggs + portoirs (non-virulent)



Modif: Ajout de la présentation N° : 21-DZ-A2

Building: **B26** Floor: **0**

Sub-Building: **LABORATOIRE SEMENCE GRIPPE**

Discipline: Flux Sub-Discipline: Flux-Contrôle

Description: Equipment flow for manufacture of influenza seed lots Cal-Sub-Dis.: Equipment

Design Verifier: **CHRISTOPHE HARDY**
 Application Date: 21 Feb 2014

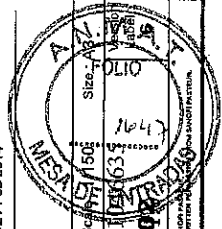
Layout Name: **08-MAT-A3-Anglais** Scale: 1/500
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 Parc Industriel d'Incarville - BP 101 -
 27101 Val de Reuil - France

APPROUVÉ NISHEXG/MofE...
 Approved / approuvé par: NISHEXG/MofE...
 Date: 28 oct. 2016 14:42:45

ROXANA MONTEMLONE
 DIRECTORA TÉCNICA
 APODERADA
 SANOFI PASTEUR S. A.

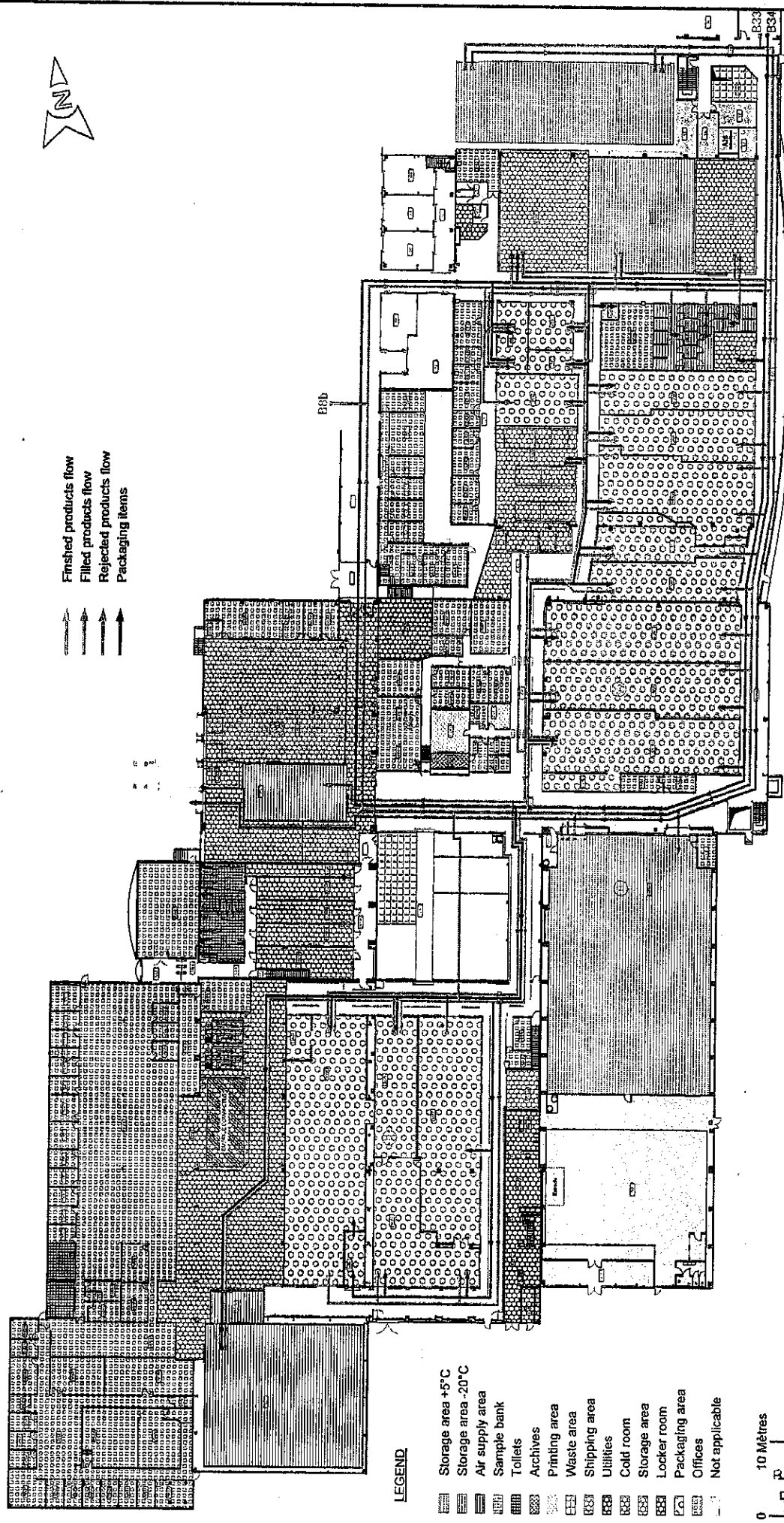
APPROUVÉ NISHEXG/MofE...
 Approved / approuvé par: NISHEXG/MofE...
 Date: 28 oct. 2016 14:42:45







Finished products flow
 Filled products flow
 Rejected products flow
 Packaging items



LEGEND

- Storage area +5°C
- Storage area -20°C
- Air supply area
- Sample bank
- Toilets
- Archives
- Printing area
- Waste area
- Shipping area
- Utilities
- Cold room
- Storage area
- Locker room
- Packaging area
- Offices
- Not applicable

0 10 Mètres

ROMANA MONTEMIRO
 DIRECTORA TECNICA
 APODERADA
 SANOFI PASTEUR S.A.

ROMANA MONTEMIRO
 DIRECTORA TECNICA
 APODERADA
 SANOFI PASTEUR S.A.

Access date: 28 oct. 2016 15:07:13

Modif. : Mise à jour des flux sur les présentations N° : 03-04-05-07-08
 N° CCR : NA
 Niveau : 0
 Resp. Affaire :
 Destinataire : HARDY Christophe
 Date Application : 17 Feb 2015

Discipline : Flux
 Sous-Discipline : Flux-Contrôle
 Cal-Sous-Dis. : Product
 Description : Products flow - Packaging - Ground floor

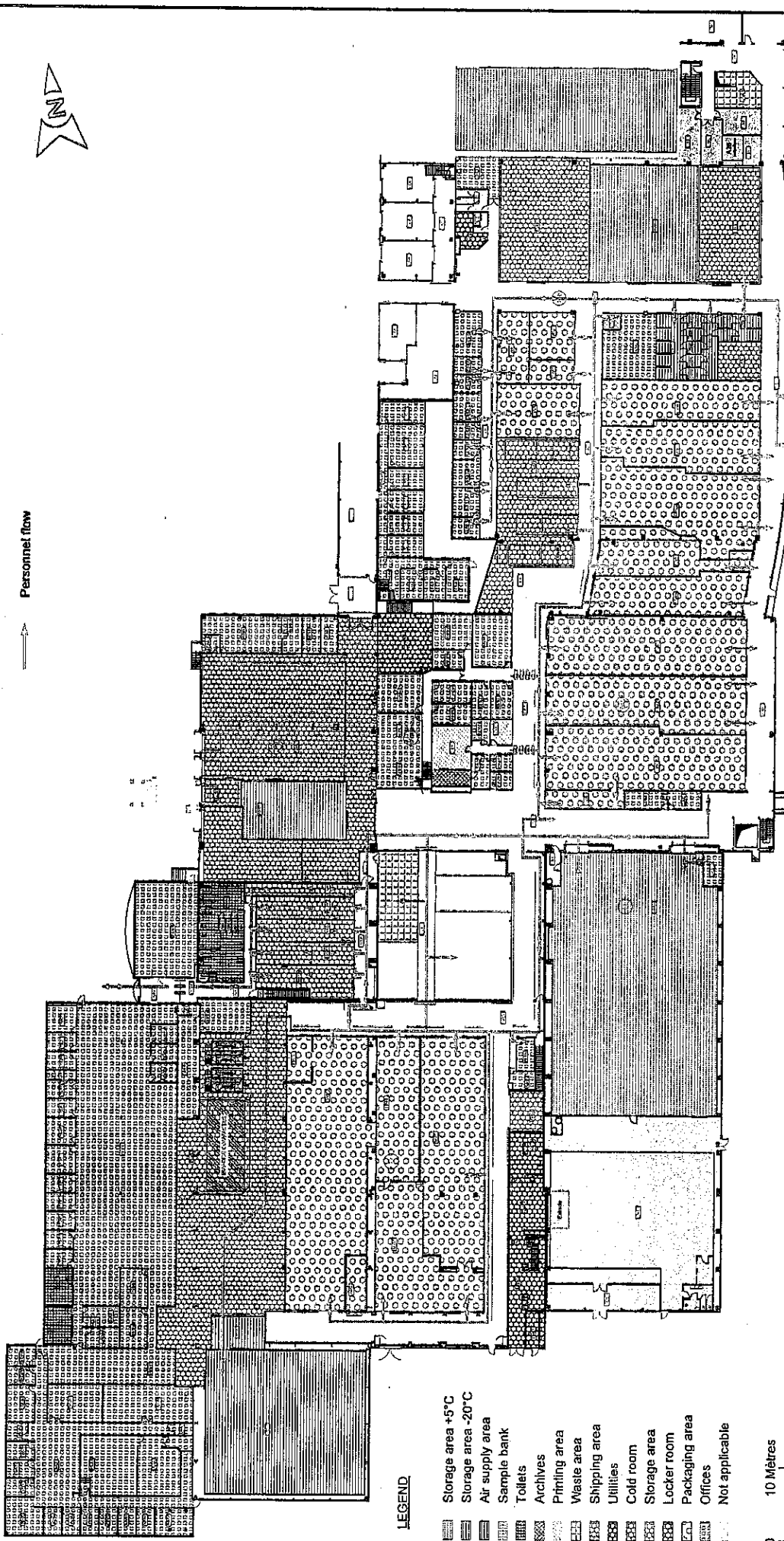
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 Nom Fichier : **BDSt_1990_00_P1_01**

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 Parc Industrielle d'Incaeville - BP 101 -
 27101 Vailles Reuil - France

MESA
 1648
 03-04-05-07-08



Personnel flow



LEGEND

- Storage area +5°C
- Storage area -20°C
- Air supply area
- Sample bank
- Toilets
- Archives
- Printing area
- Waste area
- Shipping area
- Utilities
- Cold room
- Storage area
- Locker room
- Packaging area
- Offices
- Not applicable

10 Mètres

SANOFI PASTEUR

 BUREAU D'ETUDE

NISHEVCI Viora

 Director

 Access date: 28 oct. 2016 15:07:31

Modif. : Mise à jour des flux sur les présentations N° : 03-04-05-06-07-08

Bâtiment : **BDST** Niveau : **0**

Sous-Bâtiment : **PACKAGING**

Discipline : Flux

Description : Personnel flow - Packaging - Ground floor

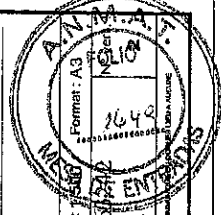
Resp. Affaire : **08-PER-AS-EDS-Anglais**

Dessinateur : **HARDY Christophe**

Date Application : **17 Feb 2015**

Document ID: **RA_106101**

Scale: **BDSU.F900.001P1.01**



Form: **A3**

 Echelle: **1/500**

 Nom Présent.: **08-PER-AS-EDS-Anglais**

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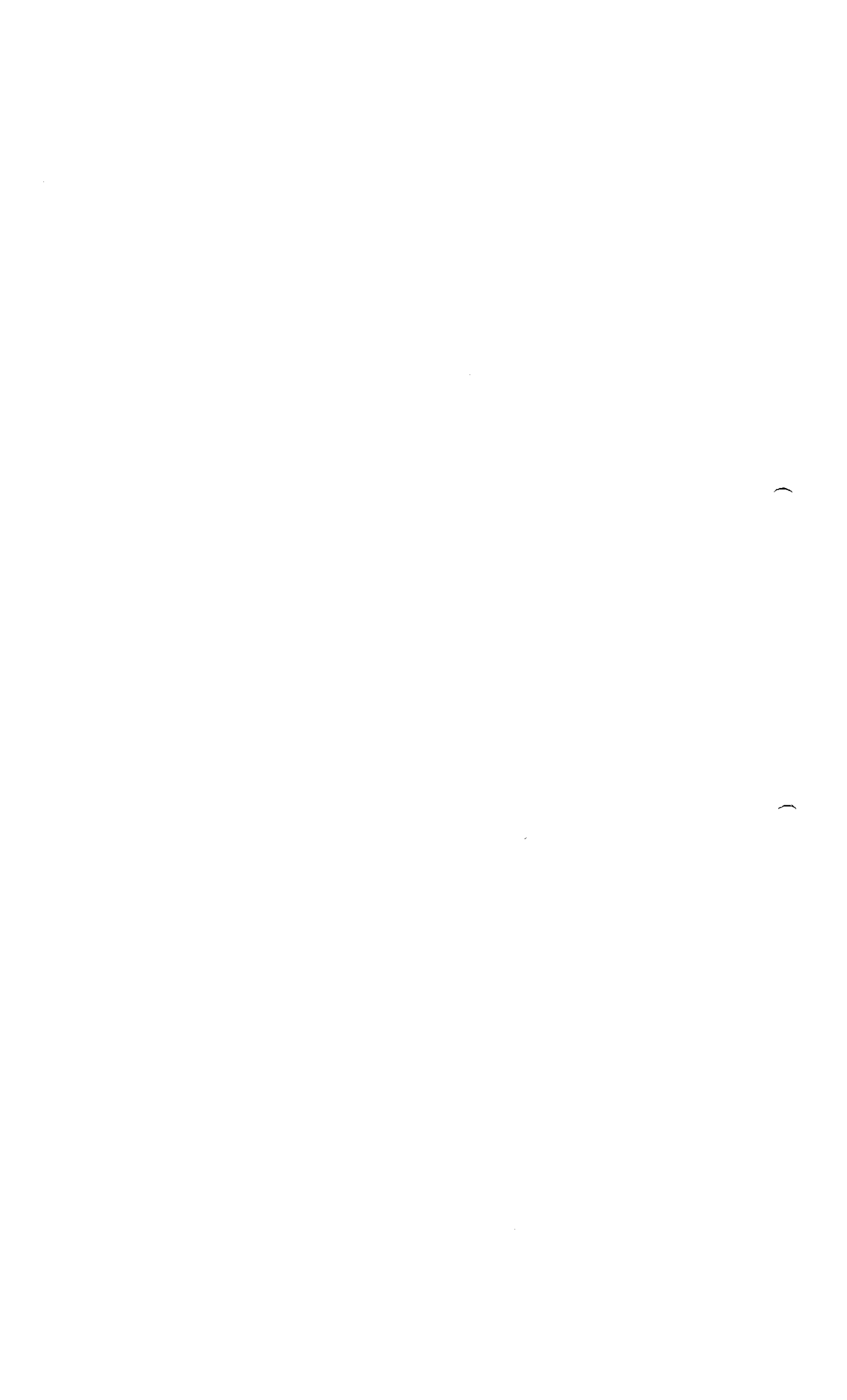
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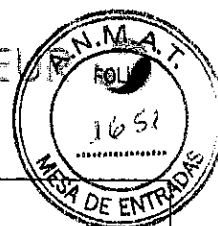
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Access date: 28 oct. 2016 15:07:31





Título		
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Número de documento Q_0505826	Nombre anterior del documento	Número de versión 4.0
Otros nombres anteriores		
Tipo Especificación		Subtipo Archivo maestro
Departamento emisor Opérations Qualité Marcy	Sección emisora Qualité Systèmes	Planta emisora Marcy

	Nombre del aprobador	Fecha (hora universal)	Motivo de la firma
Aprobación	JORDA Nathalie (sanofi pasteur)	16 Jun 2016 05:40:44	Apruebo este documento.
Aprobación	GEOFFROY Fabrice Directeur département (sanofi pasteur)	16 Jun 2016 09:18:40	Apruebo este documento.
	Fecha de vigencia:		


 ROXANA MONTEMLONE
 DIRECTORA TÉCNICA
 APODERADA
 SANOFI PASTEUR S.A.

