en-sure monitoring

IP 0001/14

STERLING CHEMICAL MALTA LTD, HAL FAR

APPLICATION FOR VARIATION OF IPPC PERMIT
VOLUME 2: IPPC APPLICATION DOCUMENT

Version 2: August 2018

Report Reference:

En-Sure Ltd, 2018. Sterling Chemical Malta Ltd, Hal Far. Application for Variation of IPPC Permit: Volume 2: IPPC Application Document (Version: 2). San Gwann, August 2018; vii + 71 pp. + 8 Annexes.

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Quality Assurance

Sterling Chemical Malta Ltd, Hal Far
Application for Variation of IPPC Permit: Volume 2
August 2018

Report for: Sterling Chemical Malta Ltd

Revision Schedule

Rev	Date	Details	Prepared by	Reviewed by	Approved by
00	Oct. 2017	Submission to client	**Rachel Decelis** Consultant	**Rachel Xuereb** Director	**Adrian Mallia** Managing Director
01	Aug. 2018	Re-submission to ERA	**Rachel Decelis** Senior Consultant	**Rachel Xuereb** Director	**Adrian Mallia** Managing Director

File ref: N:_Completed Projects\Environmental Permitting\ES_STG002 - Sterling IPPC variation\IPPC application\Feedback to ERA - July 2018\VOL 2 - IPPC variation application.docx

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CONTENTS

FIGURES

TABLES

ANNEXES

Annex 1: Micronisation unit

Annex 2: Glove boxes

Annex 3: New reactors

Annex 4: Engineer's report on new LPG tank

Annex 5: BAT assessment

Annex 6: Maintenance plan

Annex 7: HEPA filters test certificate

Annex 8: Carbon filter specification sheet

1. INTRODUCTION

1.1. This application for variation of the Integrated Pollution Prevention and Control (IPPC) permit was commissioned by Sterling Chemical Malta Ltd, herein referred to as 'the Operator'.

1.2. Sterling Chemical Malta Ltd operates a factory for the manufacture of Active Pharmaceutical Ingredients (APIs) at Ħal Far Industrial Estate.

1.3. The facility, herein referred to as the 'Scheme', is regulated by IPPC permit number IP 0001/14/A issued by the Malta Environment and Planning Authority (MEPA)[1]. The area currently authorised by the IPPC permit, at block HF 51, is shown in **Figure 1.1**.

1.4. In August 2017, the Operator applied for a minor variation to the IPPC permit, requesting an extension to the deadline for certification of the Scheme to the ISO 14001 Environmental Management System standard. That application is currently under review by ERA.

1.5. The current application includes additional requests for variations to the IPPC permit, comprising:

- A micronisation facility, with overlying laboratory and two offices;
- Three new reactors in the existing production lines, carrying out the same processes as those already authorised and operational;
- The addition of new cold rooms for storage of samples, raw materials, intermediates, and products;
- The addition of a new temporary waste storage area in part of the adjacent HF 50 block;
- Replacement of three existing LPG tanks with a single new tank in the adjacent HF 50 block; and
- New offices and meeting rooms in the second floor overlying the existing administration block.

1.6. **Figure 1.1** also shows the proposed extension to the currently permitted site boundary to cover the new temporary waste storage area and new LPG tank.

[1] In 2016, MEPA was split into two regulators, the Planning Authority (PA) and the Environment and Resources Authority (ERA). The IPPC permit is now regulated by the ERA.

Structure of the IPPC Application

1.7. The IPPC Application consists of three volumes:

- **Volume 1** comprises the IPPC application forms A and C;
- **Volume 2** (the current volume) consists of the IPPC application document; and
- **Volume 3** consists of an Addendum to the original Land and Groundwater Risk Assessment (prepared in 2015); this Addendum covers the risks to land and groundwater from the proposed variations.

Figure 1.1: Location of the Scheme

2. THE SCHEME

C1.2 Non-Technical Description

2.1. ERA's Terms of Reference (ToR) are:

> *Please provide a non-technical summary of the proposed changes.*

2.2. The proposed variations will comprise the addition of:

- A new micronisation facility with overlying laboratory and two offices;
- Three new reactors in the existing production lines, carrying out the same processes as those already authorised and operational;
- New cold rooms;
- The addition of a new temporary waste storage area in an adjacent site;
- Replacement of three existing LPG tanks with a single new tank, also at an adjacent site; and
- New offices and meeting rooms in the second floor overlying the existing administration block.

2.3. The micronisation facility will be used for size reduction of some of the products already synthesised on site; the resultant particle size of the products will typically be lower than 5 µm, which makes them more soluble. Micronisation will follow a jet milling process, where nitrogen is inserted into the microniser at high pressure, causing acceleration and collision of the particles, which causes the particles to break up into smaller pieces. The micronisation process is connected to dust filters as well as the existing scrubber, to mitigate emissions to air. Noise emissions from this facility will be mitigated by enclosing the micronisation room and technical area inside a concreted room.

2.4. The overlying micronisation laboratory will carry out research and development, and quality control related to the micronisation process. Emissions from the laboratory fume hoods will be treated using carbon filters, and emissions from the balance enclosure where weighing of powders is carried out will be treated using a high-efficiency filter.

2.5. The number of reactors at the site will increase from 9 to 12; this will increase the production capabilities of the Scheme as well as improve operational flexibility. The reactors will be placed in the existing production lines, and will carry out the same processes as those already authorised and operational. There will also be no changes to the types of raw materials used, or the types of

products and waste generated as a result of these new reactors. The reactors will also be connected to the existing scrubber.

2.6. The cold rooms will be used for storage of samples, raw materials, intermediates, and products at low temperature.

2.7. A new temporary waste storage area is also being added to enable better organisation of waste before it leaves the Scheme site. This area will house the existing waste streams produced by the Scheme; no new waste types are envisaged as a result of these proposals.

2.8. Three existing LPG tanks will also be replaced with a single 25,000 L storage tank to cater for a planned future expansion of the plant.

2.9. The above technical areas will include measures for spill containment (such as impermeable flooring, secondary containment and spill kits). This ensures that the risk of land and groundwater contamination is mitigated.

C1.3 The Proposed Variations

2.10. ERA's ToR are:

> *Please provide a summary of the variations which you are applying for.*
>
> *This should include:*
>
> - *a description of the change in operation requiring the variation;*
> - *an indication of the variations to the conditions of the permit that you wish to apply for.*

2.11. The proposed variations comprise:

- The addition of the stage 3 block, consisting of a micronisation facility at ground floor level, with an overlying laboratory and two offices at second floor level;
- Three new reactors in the existing production lines (one reactor in line 1, and two reactors in line 2);
- The addition of new cold rooms;
- The addition of a new temporary waste storage area;
- Replacement of three existing LPG tanks with a single bulk storage tank; and
- New offices and meeting rooms in the second floor overlying the existing administration block; there will be no technical activities in this area.

2.12. The addition of the micronisation facility, as part of Stage 3 of the Scheme, will enable the Scheme to reduce the particle size of the active ingredients produced (to micrometer levels, approximately 10^{-6} m), thus increasing the exposed product surface, and therefore the solubility and bioavailability of the products (and therefore increasing the fraction of the administered dose that reaches the systemic circulation as well as the speed with which this process occurs). This is particularly important for active ingredients having low solubility in water.

2.13. From a development planning perspective, the micronisation facility is covered by DN 0624/16. In terms of the IPPC permit, reference to the micronisation facility may need to be included as a permitted activity in Table 1.1.1 of the IPPC permit. It is noted that there are no new emission points from the micronisation unit, since air emissions from this area will be treated through HEPA filters and routed to the existing permitted scrubber. However, the overlying laboratory includes two new fume hoods that will exhaust through new vents after treatment (as described more fully in section C3.6); it is proposed that these are included as new emission points.

2.14. The production capabilities of the Scheme will be increased through the addition of new reactors (from the current 9 to 12); these will also increase operational flexibility. It is noted that these reactors will carry out the same processes as those already authorised and operational. However, in order to allow the Operator to make use of the notification procedure envisaged in condition 1.5.1 of the permit in case future changes to production equipment are required, it is proposed that the number of reactors is not restricted in Table 1.1.1. It is envisaged that the notification procedure may be used when: any new equipment would carry out the same processes as those already authorised, no new emission points to air are required, and no new land take is envisaged.

2.15. The footprint of an existing sampling room has been reduced to include three new cold rooms for storage of samples, raw materials, intermediates, and products. It is therefore suggested that these cold rooms are included in the list of directly associated activities (as utilities) in Table 1.1.1 of the IPPC permit. Additionally, the location from which exhaust air is released from the cold rooms (described in section C3.6) will need to be included as a new emission point in the IPPC permit.

2.16. A new temporary waste storage area is also being added to enable better organisation of waste before it leaves the Scheme site. This area, which is covered by development permit DN 23/17, houses waste produced by the Scheme prior to removal from site. The entire area will also be contained. It is envisaged that the permitted site boundary (Schedule 3B of the IPPC permit) will need to be extended to include this new area.

2.17. Three existing LPG tanks and vaporiser will also be replaced with a single 25,000 L bulk storage tank and vaporiser in the adjacent HF 50 block. The Operator has submitted a development planning application (PA 3638/18) to cover this new tank. It is envisaged that the permitted site boundary (Schedule

3B of the IPPC permit) will also need to be extended to include the area in which this bulk tank will be located.

2.18. The Scheme also envisages the construction of offices and meeting rooms on the second floor of the existing administration building. The construction of these elements is covered by DN 00617/17; however, since no technical activities will be carried out here it is understood that none of the conditions in the IPPC permit will need to be varied to accommodate this aspect.

2.19. Layout plans showing the proposed changes are included in **Chapter 3** (section C2.2; **Figure 3.1** and **Figure 3.2**).

C1.4 Site Maps and Reports

2.20. The IPPC application form requires the submission of the following information when a change in operation that would result in additional land being included within the site of the installation is proposed:

> *C.1.4.1: A site report, describing the condition of the site of that part of the installation in respect of which you are applying for a variation, and, in particular, identifying any substance in, on or under the land which may constitute a pollution risk. A baseline report assessing the state of the groundwater and land may also be required by the Authority.*
>
> *C1.4.2: A suitable map (or maps) showing the location of the site of the installation, and the area for which a variation of the IPPC permit is being applied for. The outline of the site and the area requiring the variation should be clearly marked in colour, and the surroundings of the site should be included in the map.*
>
> *C1.4.3: Suitable block plans, properly labelled, showing any changes to the location and nature of the various activities being proposed on that site.*

2.21. A Land and Groundwater Risk Assessment had been prepared for the Scheme in 2015, to cover the already permitted activities[2]. An Addendum to that Risk Assessment, covering the proposed variations, is included as **Volume 3** of this IPPC application. This Addendum includes an assessment of both the activities that will be located in areas outside the existing permitted site boundary (namely the new waste storage area and LPG tank), as well as new activities that will be carried out within the currently permitted site boundary.

[2] En-Sure Ltd, 2015. *Sterling Chemical Malta Ltd, Hal Far: Land and Groundwater Risk Assessment* (Version 1). San Ġwann, December 2015; iv + 41 pp. + 3 Appendices.

3. TECHNIQUES

C2.1 Environmental Management System

3.1. ERA requires the Applicant to:

> *Provide details of any changes to environmental management techniques resulting from your proposals.*

3.2. The Operator already has several EMS procedures and documents in place, including the following:

- Environmental Policy;
- EMS Manual;
- Identification of roles and responsibilities;
- Risk assessment;
- Training procedures;
- Maintenance plan;
- Various standard operating instructions with environmental relevance, such as on packaging and labelling of dangerous goods, fire response, and spill response;
- Other EMS procedures, such as on identifying compliance obligations, communication, management review, and waste management.

3.3. A copy of the above documentation has already been forwarded to ERA as part of the Operator's application for an extension to the deadline for certification of the Scheme to the ISO 14001 Environmental Management System standard.

3.4. The Scheme aims to apply for certification to the new ISO 14001:2015 standard, and already has an implementation programme for this in place (already forwarded to ERA as part of the mentioned minor variation application). This implementation process will include a review of the process of the entire facility, including the variations proposed by the current IPPC applications. However, it is noted that these variations are aimed at increasing the operational capabilities and flexibility of operations at the Scheme, and therefore no significant changes to the EMS techniques are expected as a result of these minor variations *per se*.

3.5. It is envisaged that the Scheme will obtain ISO 14001 certification by February 2019. A copy of the ISO 14001 certificate, as well as any other information required, will be forward to ERA once the certification process is completed.

C2.2 Proposed Activities

3.6. ERA's ToR require the Applicant to:

> *C2.2.1 Describe any proposed changes to the installation activities.*
>
> *C2.2.2 Describe the proposed techniques and measures to prevent and reduce waste and emissions of substances and heat (including during periods of start-up or shut-down, momentary stoppage, leak or malfunction) as a result of your proposals.*
>
> *C2.2.3 Submit a flow diagram summarising the proposed installation activities and indicating the changes.C2.2.5 Include an outline of the main alternatives considered to the proposed changes to the technology, techniques and measures.*

3.7. The application form (section C3.11) also requires the Applicant to:

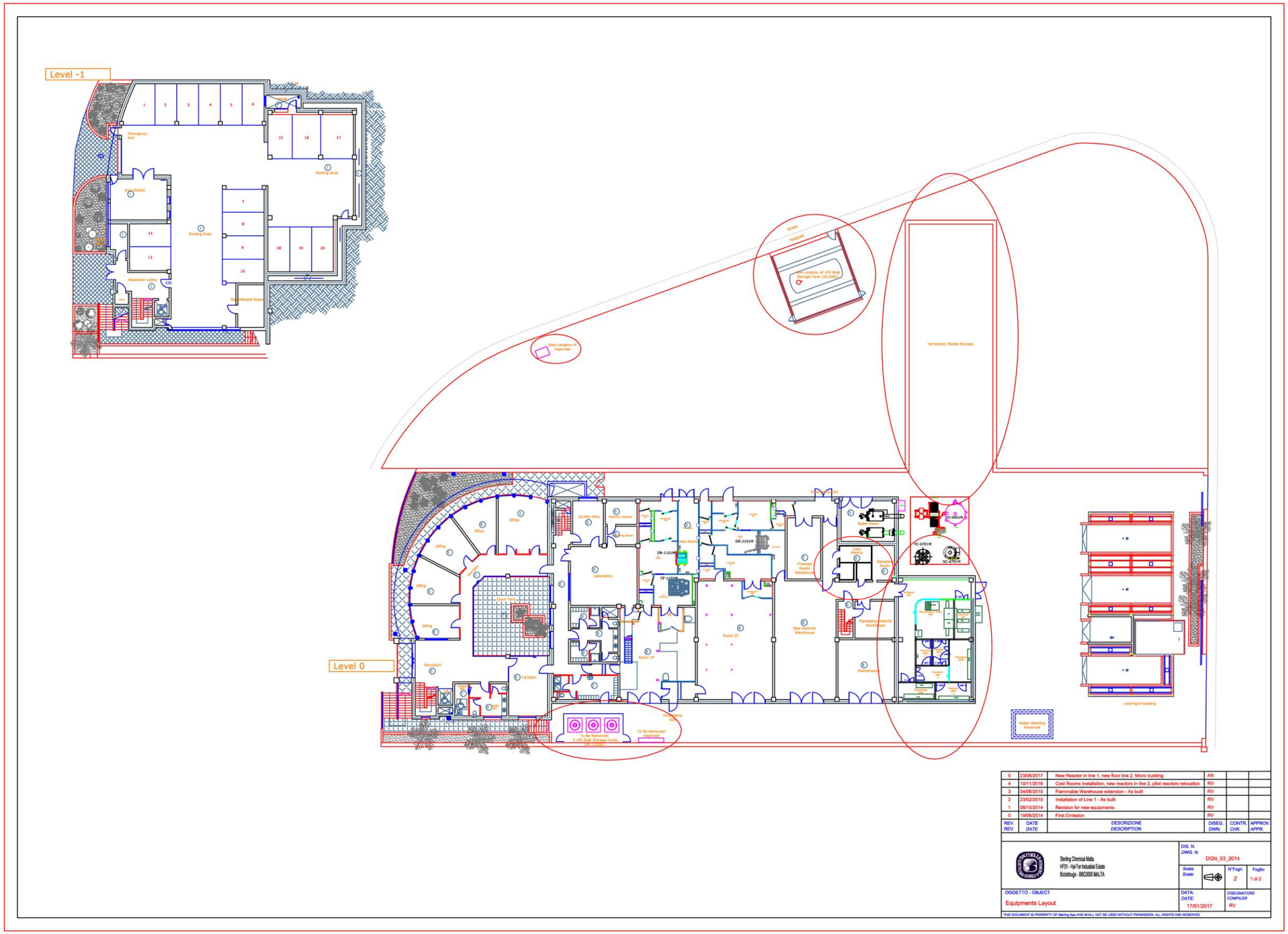
> *By means of a mass flow diagram, summarise the emissions and waste described in sections C3.1, C3.2, C3.3, C3.4, C3.6, and C3.8 of this application.*

3.8. As noted, the proposed variations comprise:

- The addition of the stage 3 block, consisting of a micronisation facility at ground floor level, with an overlying laboratory and two offices at second floor level;
- Three new reactors in the existing production lines (one reactor in line 1, and two reactors in line 2);
- The addition of new cold rooms;
- The addition of a new temporary waste storage area in block HF 50;
- Replacement of three existing LPG tanks with a single bulk storage tank in block HF 50; and
- New offices and meeting rooms in the second floor overlying the existing administration block; there will be no technical activities in this area.

3.9. The layout of the Scheme (with the above proposed variations circled in red) is shown in **Figure 3.1** and **Figure 3.2**. The following sub-sections describe the technical activities associated with the above variations in further detail.

Figure 3.1: Scheme layout (levels -1 and 0)



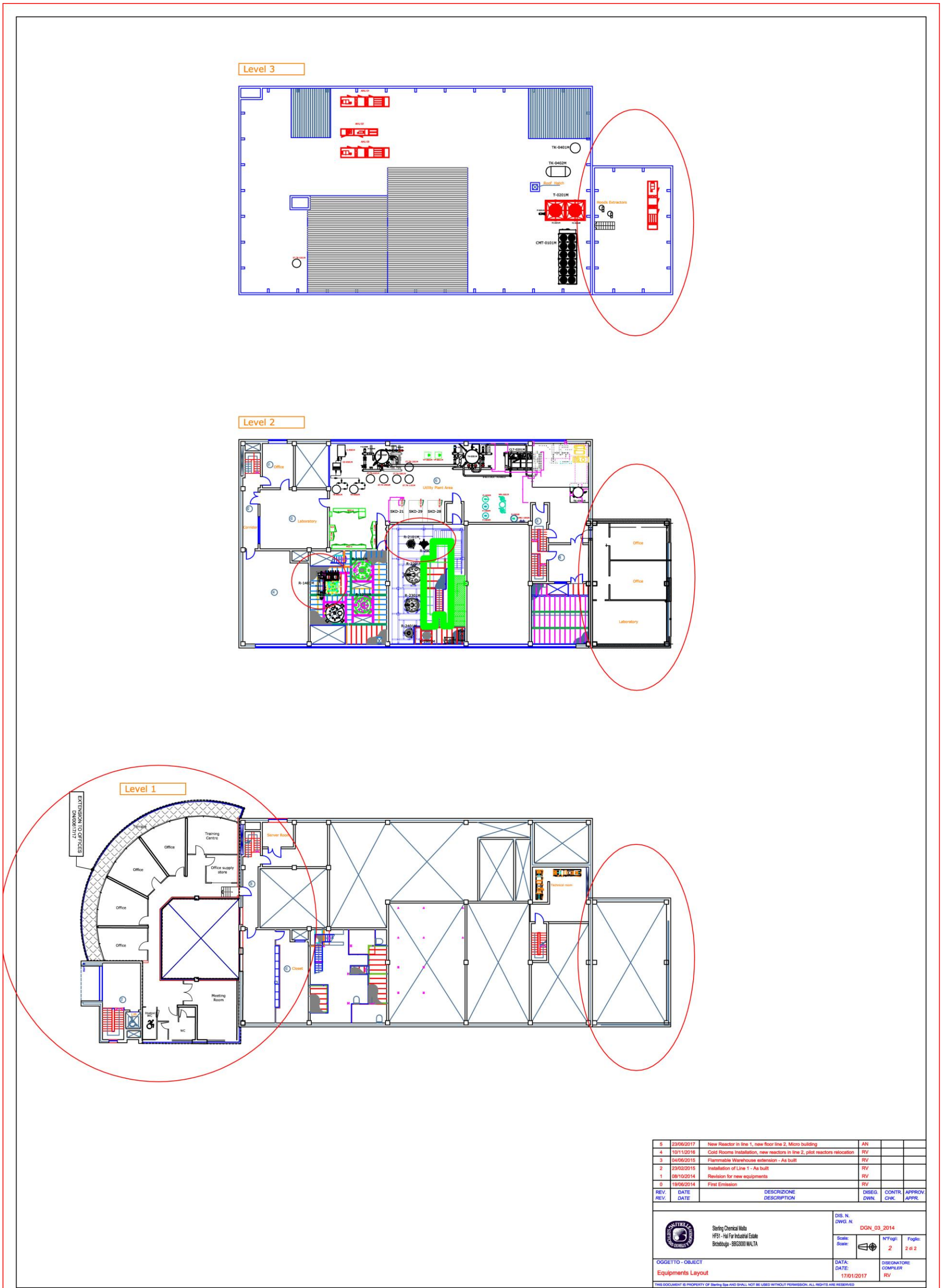
REV. REV.	DATE DATE	DESCRIZIONE DESCRIPTION	DISEG. DWN.	CONTR. CHK.	APPROV. APPR.
5	23/06/2017	New Reactor in line 1, new floor line 2, Micro building	AN		
4	10/11/2016	Cold Rooms Installation, new reactors in line 2, pilot reactors relocation	RV		
3	04/08/2015	Flammable Warehouse extension - As built	RV		
2	23/02/2015	Installation of Line 1 - As built	RV		
1	08/10/2014	Revision for new equipments	RV		
0	19/06/2014	First Emission	RV		

Sterling Chemical Malta
HF51 - Hal Far Industrial Estate
Birzebbuga - BBG3000 MALTA

DIS. N. / DWG. N.: DGN_03_2014
Scala: / Scale: 1:200
N°Fogli: / Sheets: 2
Foglio: / Page: 1 di 2

OGGETTO - OBJECT: Equipments Layout
DATA: / DATE: 17/01/2017
DISEGNATORE: / COMPILER: RV

Figure 3.2: Scheme layout (levels 1, 2 & 3)



Micronisation Facility

2.3. Micronisation refers to the size reduction of particles to the micron scale. In the pharmaceutical industry, size reduction of APIs is becoming important because:

- Research is creating APIs with very low solubility in water; reducing the particle size increases the surface area and therefore the solubility of the APIs;
- Particles of micrometer size may be used in inhalation therapy, as they would present a reduced systemic toxicity and quickly become available in the target organ (the lungs) at high concentration;
- Micronisation causes changes in the crystal structure of the product (breaking it down to an amorphous form), which increases the product's dissolution rate;
- Crystallisation (and particle size dimension reduction) may be difficult for large / complex products; micronisation enables better control of particle size and formulation homogeneity.

3.10. Size reduction of particles may be carried out using a range of milling systems, as described below:

- Crushers: Produce particles having a size below 2 cm (i.e. not sufficient to achieve micron scale);
- Mechanical mills (such as oscillating mills, cone mills, hammer mills, and pin mills): Particle size ranges from around 30 to 200 µm; and
- Jet mills: Particle size produced ranging from around 0.5 to 20 µm (typically <5 µm).

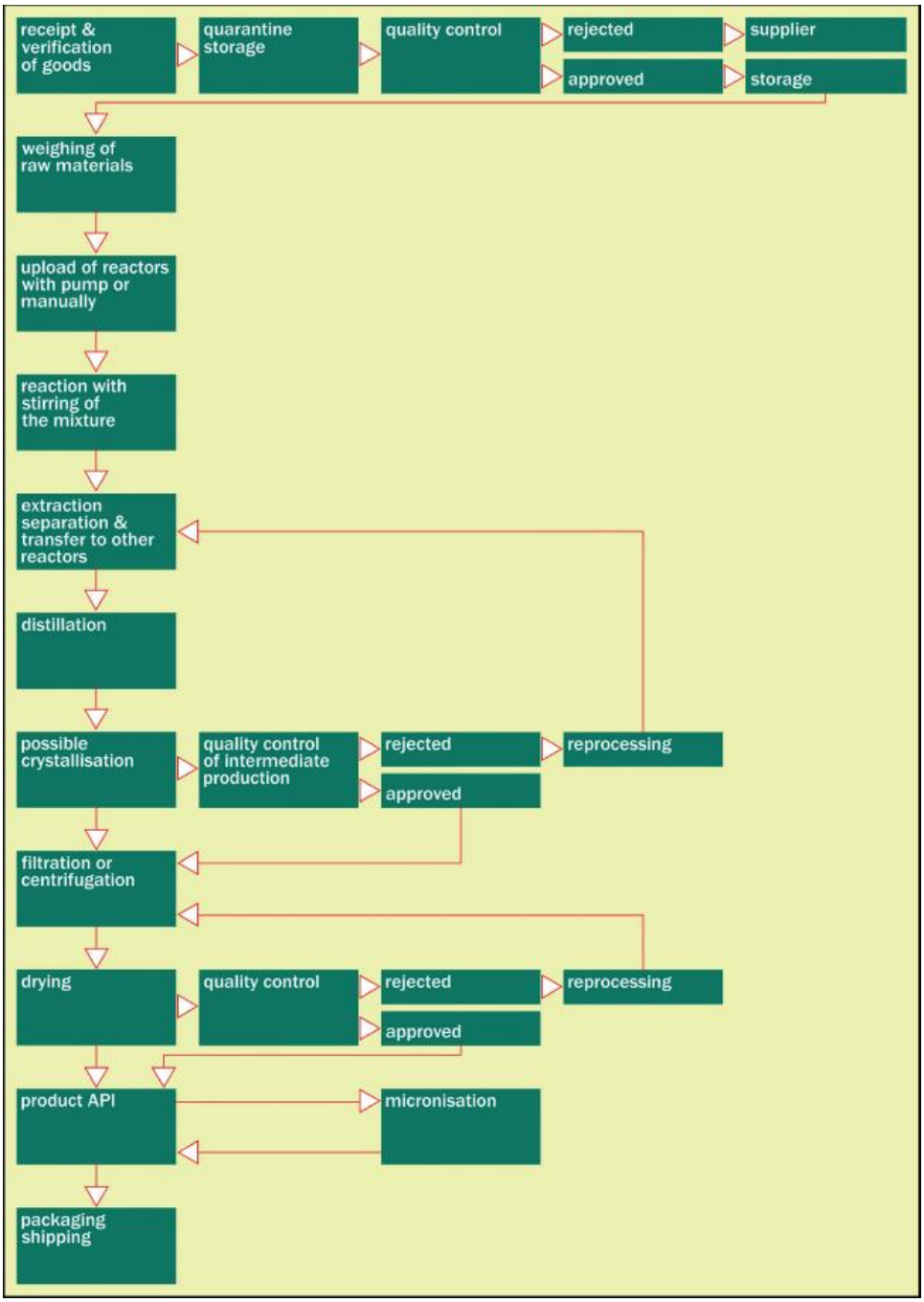
3.11. Considering the above alternatives, in view of the superior size reduction capabilities of a jet milling system, this option will be used in the Scheme. This process reduces particle size by using fluid energy (provided by pressurised nitrogen) rather than by mechanical means.

3.12. Jet milling also has the advantage of completely removing the risk of metallic contamination of the product (which is an issue with mechanical mills). Since an oxygen-free environment is used, the system is also suitable for the processing of heat-sensitive products without damage to the product or jet mill, and under safe conditions. The mill also has no moving parts, thus reducing the need for frequent maintenance (and increased risk of down-time).

3.13. Micronisation occurs at the end of the production process, after the APIs would already have been produced and dried in the existing production lines. **Figure 3.3** gives an overview of the production cycle to show the stage at which micronisation occurs. It is noted that no new API types are envisaged to be

produced as a result of the micronisation process[3]. Additionally, not all of the Scheme's products will undergo micronisation, but only those required by the Scheme's clients.

Figure 3.3: Overview of the production cycle, including micronisation stage



[3] The Scheme manufacturing profile includes steroids, anti-inflammatory drugs, hormones (contraceptives) and anti-cancer drugs. Typically the micronisation plant will process steroids and hormones.

3.14. The micronisation process starts by transferring the dry APIs produced in the Scheme's production line to the micronisation room; at this stage the APIs are in polyethylene (PET) bags or aluminium cans containing up to 10 kg of APIs each. These containers are opened inside an enclosed glove box and loaded into the micronisation hopper, from where they enter the milling chamber. This part of the process is connected to a High Efficiency Particulate Air (HEPA) filter for the control of dust emissions.

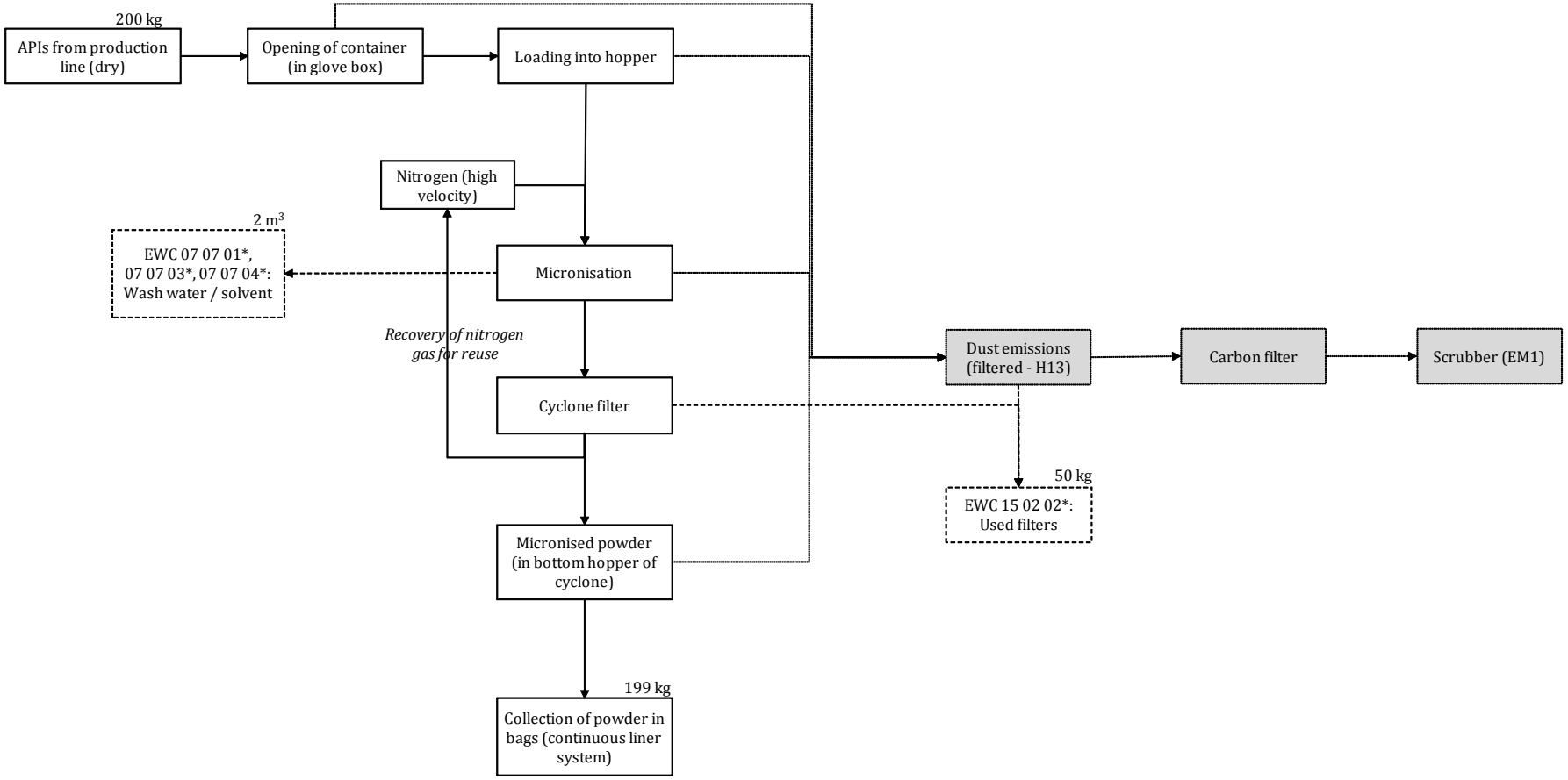
3.15. Nitrogen is then introduced into the mill at high pressure through jet nozzles placed around the circular chamber of the mill. This causes acceleration of the particles inside the milling chamber, where they are dragged in a circular motion causing them to collide repeatedly. This causes the particles to break up into progressively small particles until the accumulated energy is reduced to negligible values. This step of the process is also connected to a HEPA filter.

3.16. The micronised particles are then carried by the nitrogen gas into a cyclone filter. A series of fabric filters are located in the inner part of the cyclone filter. The nitrogen is filtered through these fabric filters and returned for reuse. Reverse jets of compressed air periodically shake the filters causing the product to be removed from the fabric. The micronised product is then collected in bags inside the bottom hopper of the cyclone filter. It is noted that the bottom part of the cyclone is enclosed inside a dedicated glove box, with the exhaust air being filtered through a HEPA filter. The extraction of the product bags from the glove box occurs through an enclosed continuous liner system to ensure there are no emissions of product.

3.17. The microniser to be used will be produced by Nuova Guseo; a manufacturer specification sheet is included in **Annex 1**. It is noted that the "Sanitary Version" model will be in place, which is specially designed for pharmaceutical use. Further information on the glove boxes to be used with the microniser is included in **Annex 2**.

3.18. A flow diagram of the micronisation process is included in **Figure 3.4**. It is noted that the process is 99.5% efficient, with minimal waste APIs being generated (namely through adherence to the cyclone filter or the inside of the microniser unit; the latter would be washed out when the equipment is cleaned).

Figure 3.4: Micronisation process flow diagram



3.19. The micronisation process occurs inside enclosed equipment, and the system for product collection is also enclosed to reduce emissions. Additionally, as mentioned, the various stages where dust emissions containing APIs can be generated will be connected to H13 HEPA dust filters. Emissions from the HEPA filters will then be routed to a carbon filter and the existing scrubber (emission point EM1). Additionally, in the event of a leak being detected from the microniser, a loss of pressure will be registered and the micronisation process will automatically be stopped.

3.20. The ground in this area is concreted, and the ground and skirting are being covered by an impermeable vinyl / resin layer to form a partial bund (**Figure 3.5**). The bund is "partial" because the doorways are not bunded; however, there are several rooms and a corridor separating the micronisation plant and the outdoor area, and minimal use of liquids in the area (given that only powders will be processed here).

Figure 3.5: Installation of micronisation plant flooring

3.21. The only liquids to be used in this area are:

- Solvents for cleaning of the equipment (maximum 100 L at a time), which will be collected and disposed of as hazardous waste; and
- Small quantities of acetone or water and soap for cleaning the room; the cleaning liquid is collected with an absorbent mop after use.

3.22. Precautions will be taken to reduce the risk of a dust explosion (since most pharmaceutical powders are explosive in the micronized form, and electrostatic

discharge is common in jet milling). Therefore nitrogen will be used as the process gas inside the micronizer. Additionally, all equipment inside the micronisation room will be ATEX rated.

3.23. The micronisation facility will also include the following areas (shown in the Level 0 drawing, **Figure 3.1**):

- Warehouse for storage of APIs (the layout plan code for this area in **Figure 3.1** is JMW);
- Staff changing rooms (JMP2 and JMA);
- A room for entry and exit of personnel (JMP1) and one for materials (JMM);
- A packaging room (JMPK); and
- A technical room (JMT) housing the air changing units and the control panel for the micronisation unit;

3.24. The micronisation laboratory on the second floor will carry out research and development, and quality control related to the micronisation process. As in the other laboratories at the Scheme, small quantities of chemicals / solvents will be consumed and associated waste generated. Laboratory wastes will be managed using the same procedures employed for the other existing laboratories on site.

3.25. This laboratory will include two fume hoods. Emissions from these fume hoods will be treated using carbon filters before being released at roof level; additionally a HEPA H13 filter will be installed on the suction hoods (balance enclosure) where the weighing of the powders is carried out. Further details are provided in section C3.6.

3.26. Floor drains will be installed in the laboratory such that spills will be collected and retained in the existing 25 m^3 underground reservoir (labelled as the 'water washing reservoir' in **Figure 3.1**).

New Reactors

2.3. The production capabilities of the Scheme will be increased through the addition of new reactors in lines 1 and 2; these will also improve operational flexibility. It is noted that these reactors are located in the existing production lines, and will carry out the same processes as those already authorised and operational. There will also be no changes to the types of raw materials used, or the types of products and waste generated as a result of these new reactors. The reactors will also be connected to the existing scrubber (emission point EM1).

3.27. As a result, the technical information submitted in the original IPPC application (notably in section B.2.2) also applies to these new reactors.

3.28. Technical drawings of the new reactors are included in **Annex 3**.

Cold Rooms

3.29. The footprint of a former sampling room has been reduced to include three new cold rooms for storage at low temperature of samples, raw materials, intermediates, and products.

3.30. The floor in this area is concreted and overlain by an impermeable vinyl layer (**Figure 3.6**). The floor also slopes inwards from the door such that in the event of a spill or washing of these areas, the liquid would be retained. Used washwater from this area is collected using absorbent pads, which are disposed of as hazardous waste, as is current practice.

3.31. Additionally, the cold rooms are located next to the raw materials warehouse, which includes a spill kit (**Figure 3.7**).

3.32. Exhaust air from the cold rooms is vented directly to the atmosphere; it is noted that only storage of substances is carried out in this area, and there is no exposure of substances to the atmosphere under normal conditions.

Figure 3.6: Cold room

Figure 3.7: Raw material warehouse spill kit

New Temporary Waste Storage Area

3.33. A new temporary waste storage area was added in March / April 2018 to enable better organisation of waste before it leaves the Scheme site. This is a temporary arrangement, since the Operator plans to construct a new external flammable warehouse in this area to replace the current arrangements; it is envisaged that the new warehouse will be operational by mid-2019. The Operator has commissioned an EIA Update Report and IPPC application to cover the new external flammable warehouse; these will be submitted to ERA in the next months.

3.34. The temporary waste storage area is used for storage of existing waste streams already produced by the Scheme, and there will be no addition of new waste types as a result of this addition.

3.35. Most of the liquid hazardous waste is stored on prefabricated containment systems to capture spills; nevertheless some temporary storage liquid hazardous waste outside containment systems is currently carried out while the site is being organised or the waste being prepared for shipment.

3.36. The ground in this area is made of concrete overlain by tarmac and is laid to fall towards a pipe at the northwestern corner of this area; the pipe leads to an external road that abuts the Wied Żnuber valley. In order to ensure that the area is fully contained, a sump will be installed before this pipe to contain any spills, and the pipe will be fitted with a locked valve to ensure that only discharges of clean rainwater occur; this measure will be implemented by end September 2018. A trained person will be responsible for inspecting the area and the accumulated rainwater prior to unlocking the valve.

3.37. A spill kit will also be installed in this area.

3.38. The waste stored in this area will be handled in accordance with existing waste management arrangements, including use of licensed waste carriers and permitted receiving facilities.

3.39. Further details on this area are included in section C3.1.

New LPG Tank

3.40. The Scheme currently operates three above-ground vertical storage tanks, each having a capacity of 2,250 L (water volume). The system includes a vaporiser to produce LPG gas for the Scheme's two existing steam generators.

3.41. The Operator is preparing for a future expansion of the Scheme, which will include an increase in the manufacturing capacity as well as the addition of a new boiler to service the new production lines. These elements will be the subject of a separate IPPC variation application to be submitted in the coming months.

3.42. As a result the Scheme requires the LPG storage capacity to be increased. Therefore the existing LPG tanks and vaporiser at the HF 51 site will be replaced

with a single 25,000 L (water volume) underground bulk storage tank and associated electric vaporiser at the adjacent HF 50 site. The existing LPG tanks and vaporiser will be dismantled and decommissioned, and sent for disposal / recycling at an authorised waste management facility; details of this process are not currently available but can be provided to ERA at a later stage if required.

3.43. The LPG vapour will be piped to the existing pipework to service the Scheme, and in future the pipework will also be extended to service the planned extension; as mentioned, the latter is a future project that will be included in an upcoming IPPC variation application. Above-ground pipework will be made of galvanised steel, and joints sealed with PTFE tape and non-hardening compound. Below-ground pipework will be made of plastic placed in a suitable trench. Pipework will be tested upon commissioning to ensure there are no leakages.

3.44. Drawings of the new LPG tank (showing also the planned future expansion, provided for context only) are provided in **Figure 3.8** to **Figure 3.10**.

3.45. The LPG tank and pipeline have been designed and sited to conform to Maltese and UK Codes of Practice, and the tank will be certified according to the Pressure Equipment Regulations, SL 427.29. The tank will have fire walls on two sides, and meet the requirements for safety distances on the other two sides. As shown in **Figure 3.9**) the LPG tank is surrounded by walls on each side to reduce the risk of accidental collision. The LPG tank and vaporiser are also located in a well-ventilated area to ensure no build-up of gas.

3.46. Additionally, the boiler rooms are fitted with gas sensors to detect leakage. Activation of the gas sensors will activate quick-closing valves in the boiler rooms, shutting down the release of gas; the valves can also be activated manually. A quick-closing valve will be installed at the vaporiser outlet. Isolating valves will also be installed on the steam generators and outside the boiler rooms.

3.47. An engineer's report covering this equipment is included in **Annex 4**.

Figure 3.8: Proposed LPG tank and pipework

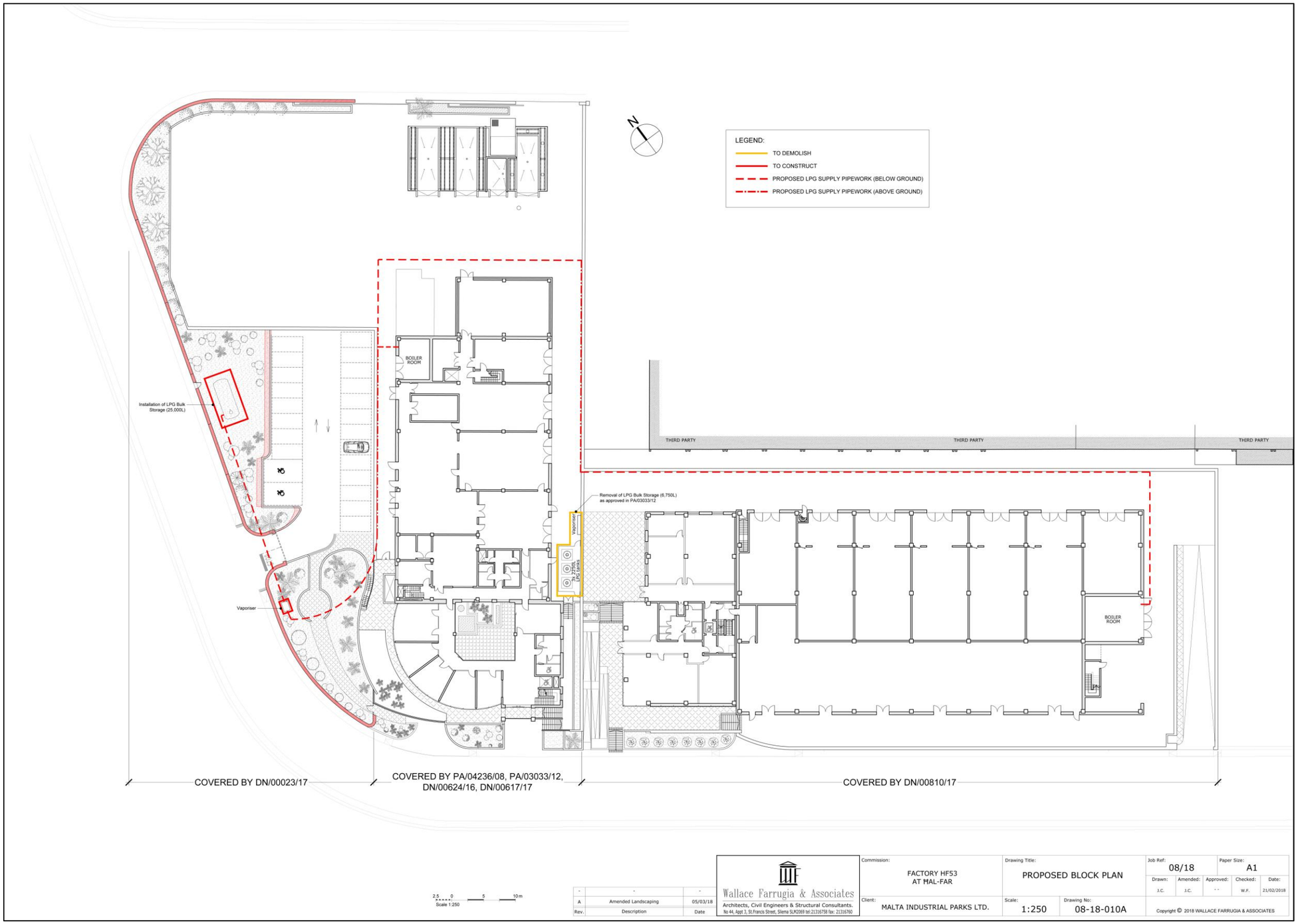


Figure 3.9: LPG tank – plan and sections

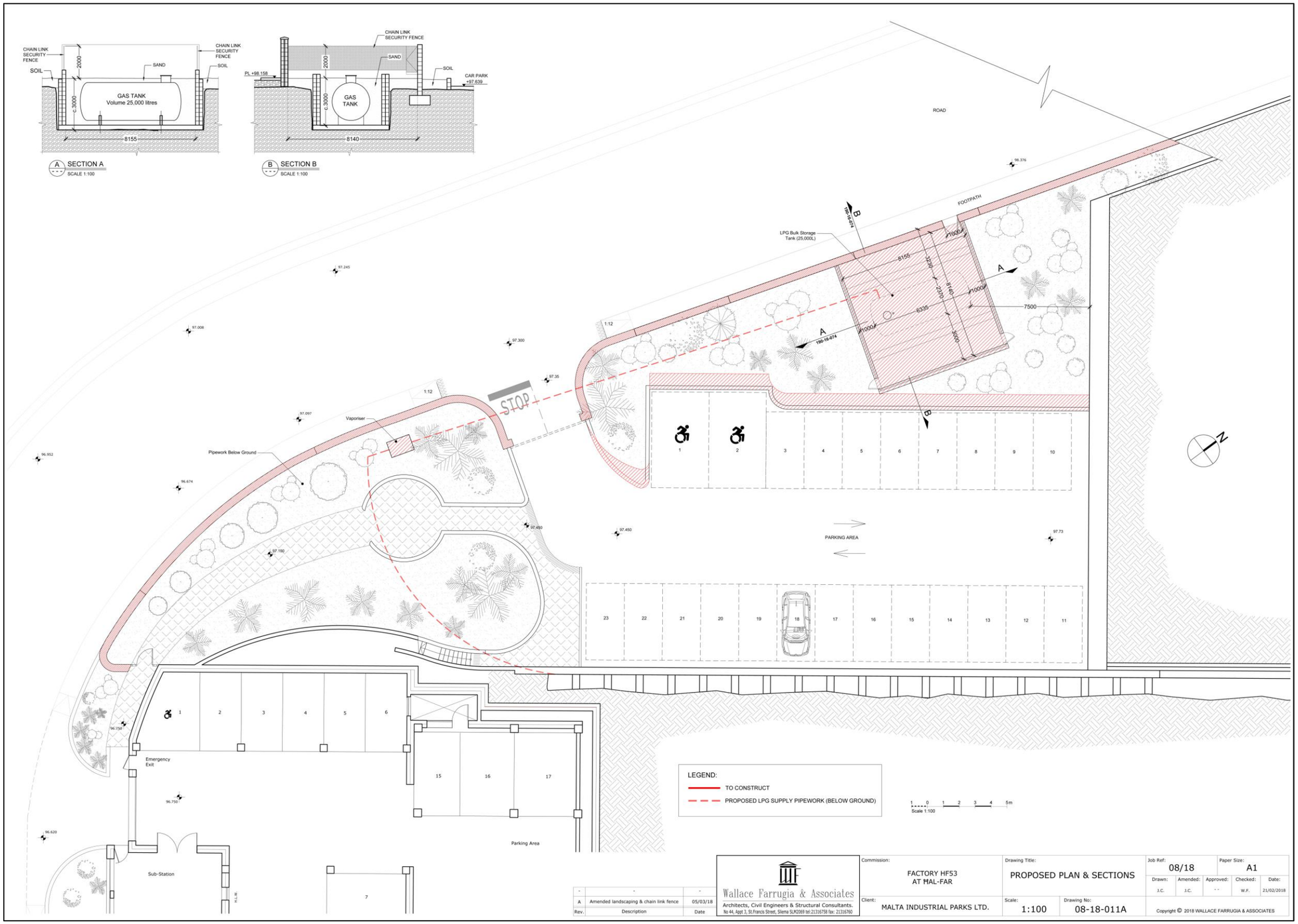
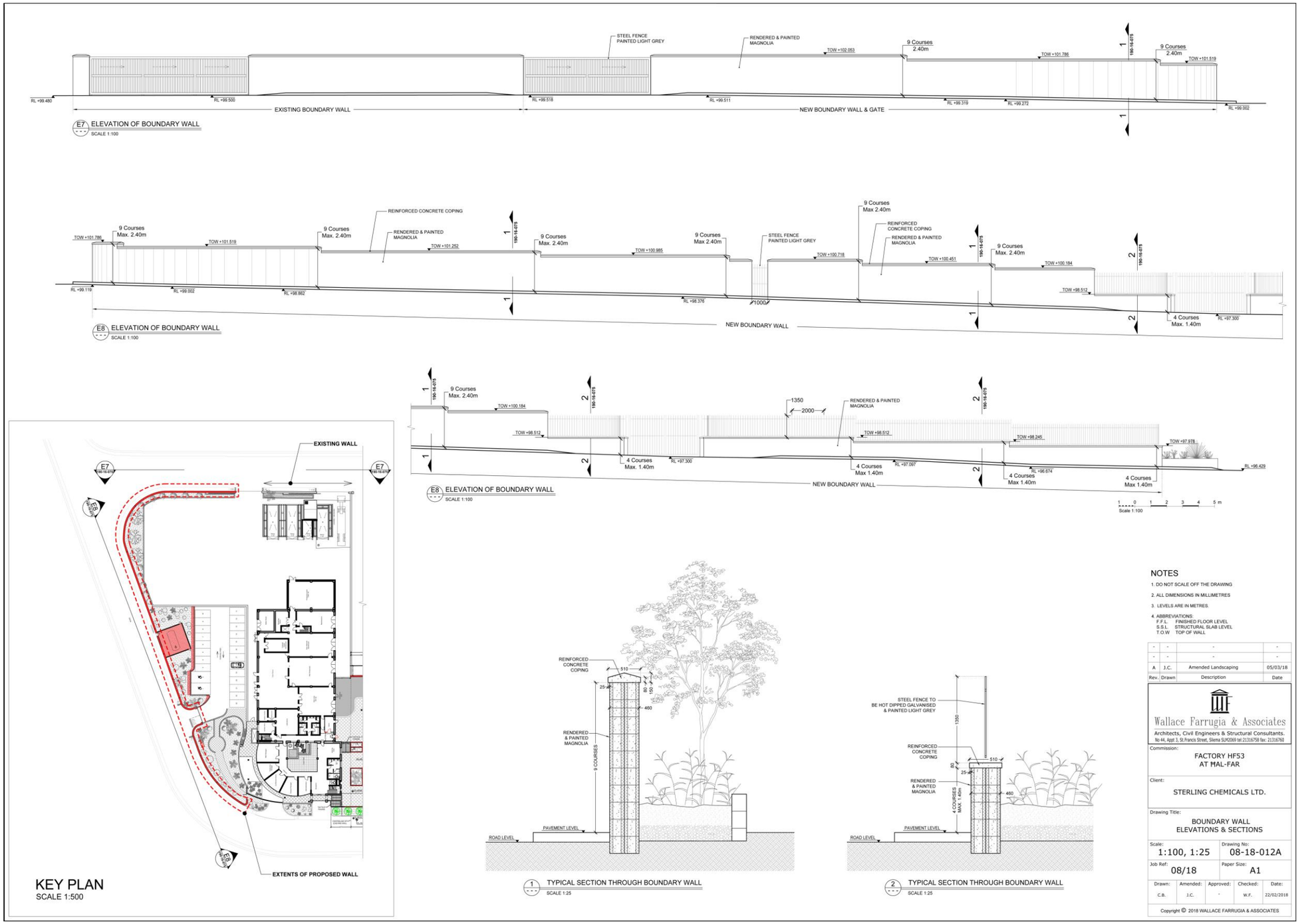


Figure 3.10: LPG tank boundary wall



C2.2.4 Best Available Technique Assessment

3.48. The IPPC application form (section C2.2.4) also requires the Applicant to:

> *Include a comparison of the proposed changes to the activities with relevant BAT conclusions published by the European Commission, where these have been published.*

3.49. No changes to the types of activities at the Scheme are proposed. Therefore the Best Available Technique (BAT) assessment submitted as part of the original application (Annex B.2.2-A3) remains valid. That BAT assessment included a comparison of the processes at the Scheme with the BREF for Manufacture of Organic Fine Chemicals (published in August 2006).

3.50. More recently, the European Commission adopted Implementing Decision (EU) 2016/902 establishing BAT conclusions for common waste water and waste gas treatment / management systems in the chemical sector. A comparison of the entire Scheme's operations (i.e. both existing and proposed activities) against these new BAT conclusions is included in **Annex 5**.

C2.3 Raw Materials

3.51. The IPPC application form asks the Applicant to:

> *Identify any changes to the raw and auxiliary materials, and any other substances (including fuels) proposed to be used as a result of your proposals.*
>
> *If any changes are proposed, give details of quantities proposed to be used annually and submit respective MSDS sheets.*
>
> *In addition, identify the storage location of these materials on a site layout plan and give details on:*
>
> - *Maximum storage capacity;*
> - *Containment measures (including bunding capacity, where applicable);*
> - *Protective measures (including security).*

3.52. There are no proposed changes to the types of raw and auxiliary materials (as well as other substances) as a result of these proposals. As is the current practice, the list of raw materials used in the previous year will continue to be reported as part of the Annual Environmental Report (AER) for the Scheme.

3.53. The micronisation process will only use nitrogen as a raw material; this is stored in the existing nitrogen tank in the external utilities area (labelled as TK-0601M in **Figure 3.1**). The starting material for the micronisation process will be the APIs produced in the production process.

3.54. As mentioned, the new reactors will carry out the same processes as those already authorised and operational, and there will also be no changes to the types of raw materials used, or to the existing storage arrangements.

3.55. The new cold rooms may be used for storage of raw materials requiring low temperatures. As mentioned, the floor in this area is concreted and overlain by an impermeable vinyl layer. The floor also slopes inwards from the door such that in the event of a spill or washing of these areas, the liquid would be retained. Additionally, the cold rooms are located next to the raw materials warehouse, which includes a spill kit.

3.56. As described in section C2.2, LPG will start to be stored in a single 25,000 L underground bulk storage tank instead of three existing storage tanks. This change is needed to accommodate a planned future expansion of the plant, which will be the subject of a separate IPPC variation application. Drawings of the new LPG tank are included in section C2.2.

3.57. It is anticipated that once the planned expansion comes into operation, LPG consumption will increase from around 170 m^3 annually to around 340 m^3 annually (phase 1) and 595 m^3 (phase 2).

3.58. Since LPG is gaseous at room temperature and pressure, containment to prevent land / groundwater contamination is not required. Nevertheless, measures will be in place to reduce the risk of LPG emissions or fire, as described in section C2.2. These include tank certification, appropriate placement of the LPG tank and vaporiser, gas sensors on the boilers, isolating valves, and the presence of surrounding walls around the LPG tank.

C2.4 Ozone Depleting Substances and Fluorinated Greenhouse Gases

3.59. The IPPC application forms require the Applicant to:

> *Identify any changes to the equipment using ozone depleting substances and fluorinated greenhouse gases, with a fluid charge of 3 kg or more.*
>
> *For each such equipment, identify the type of equipment (hermetically-sealed systems, fixed systems or mobile systems), its use (firefighting, refrigeration/air-conditioning or high-voltage switchgear), charge (in kg) and the type of substance (e.g. R22, R407c, R134a).*

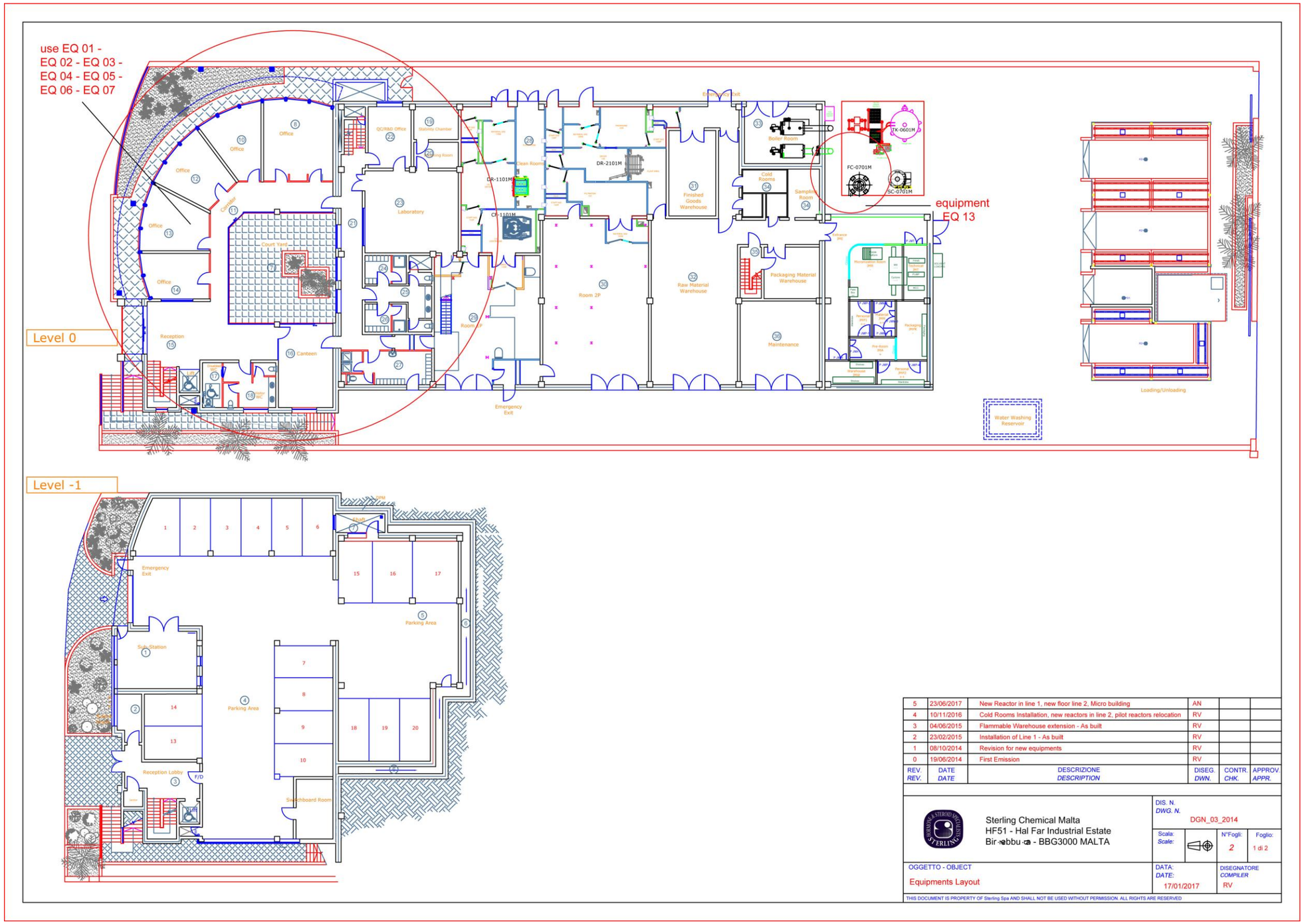
3.60. These variations require the addition of new equipment containing refrigerants (EQ 12 and EQ 13). The updated list of equipment containing refrigerants is presented in **Table 3.1**. The equipment is all fixed, but not hermetically sealed. The location of this equipment is shown in **Figure 3.11** to **Figure 3.14**.

Table 3.1: Equipment containing refrigerants

Equipment code	Type of equipment	Use	Charge (kg) / (tonnes $CO_{2\ eq.}$)	Type of refrigerant	Inspection frequency
EQ 1	Air-conditioner	Lab area	6.5 / 13.57	R410-A	Annual
EQ 2	Air-conditioner	Office 1st floor	8.5 / 17.45	R410-A	Annual
EQ 3	Air-conditioner	Lab QC 2nd floor	7 / 14.62	R410-A	Annual
EQ 4	Air-conditioner	Offices	2.4 / 5.01	R410-A	Annual
EQ 5	Air-conditioner	Offices	6.5 / 13.57	R410-A	Annual
EQ 6	Air-conditioner	Offices 2nd floor	3.5 / 7.31	R410-A	Annual
EQ 7	Air-conditioner	Offices	2.8 / 5.85	R410-A	Annual
EQ 8	Air-conditioner	Server room	2 / 4.18	R410-A	Annual
EQ 9	Refrigeration Chiller MTA	Clean room / production	109.5/ 228.58	R410-A	Every 6 months
EQ 10	Refrigeration Chiller MTA	Production area	136 / 523	R404-A	Every 3 months
EQ 11	Air compressor	Production area / laboratories	0.129 / 0.198	R134-A	Annual
EQ 12	Cold room compressor	Warehouse / storage	6/ 8.57	R134-A	Annual
EQ 13	Air-conditioner	Micronisation area	5.50/11.48	R410-A	Annual

3.61. The above equipment will be checked for leaks according to the frequency stipulated in Regulation 517/2014/EU. The inspection frequency will be as listed in **Table 3.1**.

Figure 3.11: Location of refrigerant-containing equipment (Level 0)



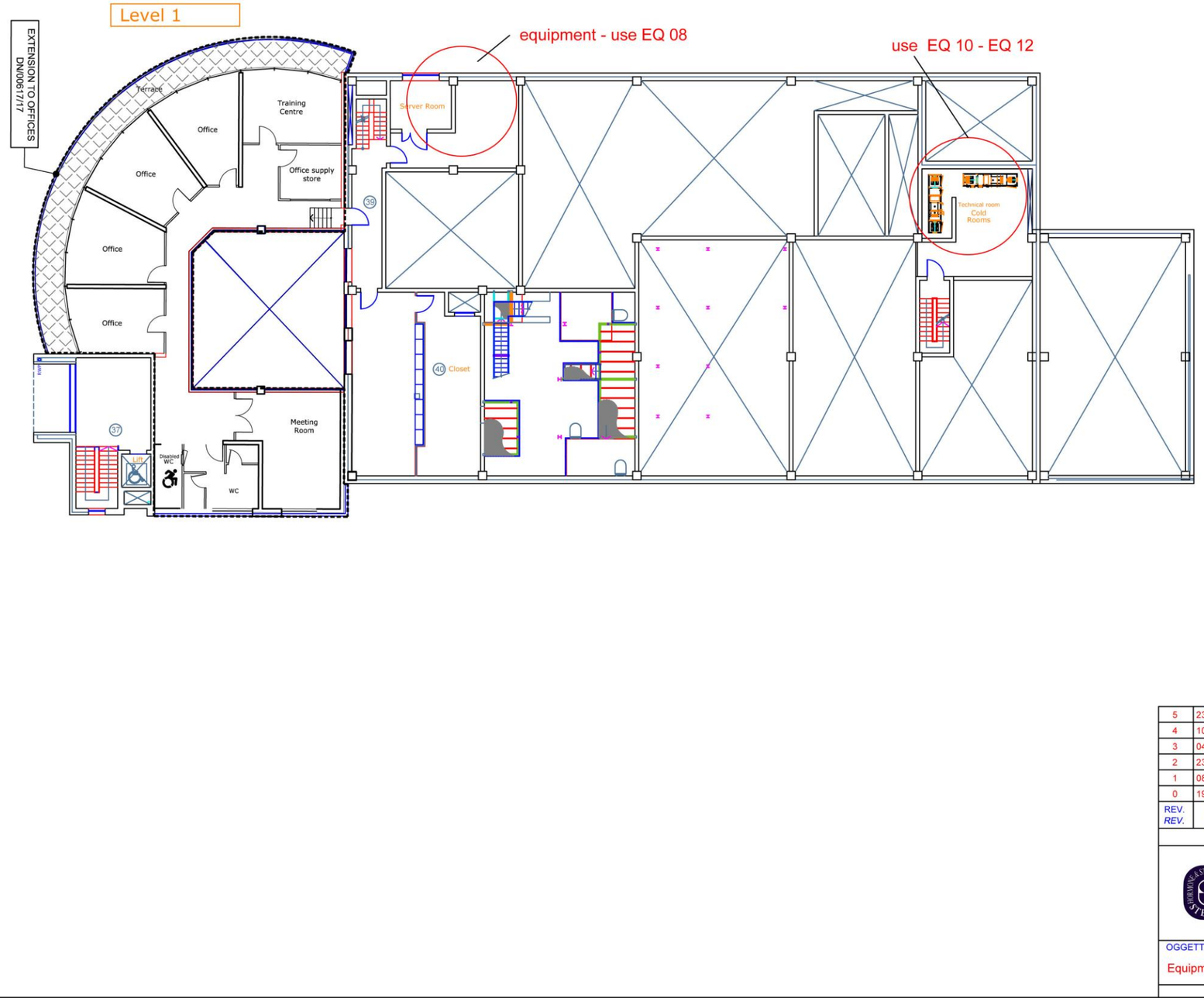
REV. REV.	DATE DATE	DESCRIZIONE DESCRIPTION	DISEG. DWN.	CONTR. CHK.	APPROV. APPR.
5	23/06/2017	New Reactor in line 1, new floor line 2, Micro building	AN		
4	10/11/2016	Cold Rooms Installation, new reactors in line 2, pilot reactors relocation	RV		
3	04/06/2015	Flammable Warehouse extension - As built	RV		
2	23/02/2015	Installation of Line 1 - As built	RV		
1	08/10/2014	Revision for new equipments	RV		
0	19/06/2014	First Emission	RV		

Sterling Chemical Malta
HF51 - Hal Far Industrial Estate
Birżebbuġa - BBG3000 MALTA

DIS. N. / DWG. N.: DGN_03_2014
Scala: / Scale:
N°Fogli: 2
Foglio: 1 di 2

OGGETTO - OBJECT: Equipments Layout
DATA: / DATE: 17/01/2017
DISEGNATORE / COMPILER: RV

Figure 3.12: Location of refrigerant-containing equipment (Level 1)



REV.	DATE	DESCRIZIONE / DESCRIPTION	DISEG. / DWN.	CONTR. / CHK.	APPR / APPR.
5	23/06/2017	New Reactor in line 1, new floor line 2, Micro building	AN		
4	10/11/2016	Cold Rooms Installation, new reactors in line 2, pilot reactors relocation	RV		
3	04/06/2015	Flammable Warehouse extension - As built	RV		
2	23/02/2015	Installation of Line 1 - As built	RV		
1	08/10/2014	Revision for new equipments	RV		
0	19/06/2014	First Emission	RV		

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HF51 - Hal Far Industrial Estate
Birżebbuġa - BBG3000 MALTA

DIS. N. / DWG. N.: DGN_03_2014
Scala: / Scale:
N°Fogli: 2
Foglio 2 di 2

OGGETTO - OBJECT: Equipments Layout
DATA: / DATE: 17/01/2017
DISEGNATORE / COMPILER: RV

Figure 3.13: Location of refrigerant-containing equipment (Level 2)

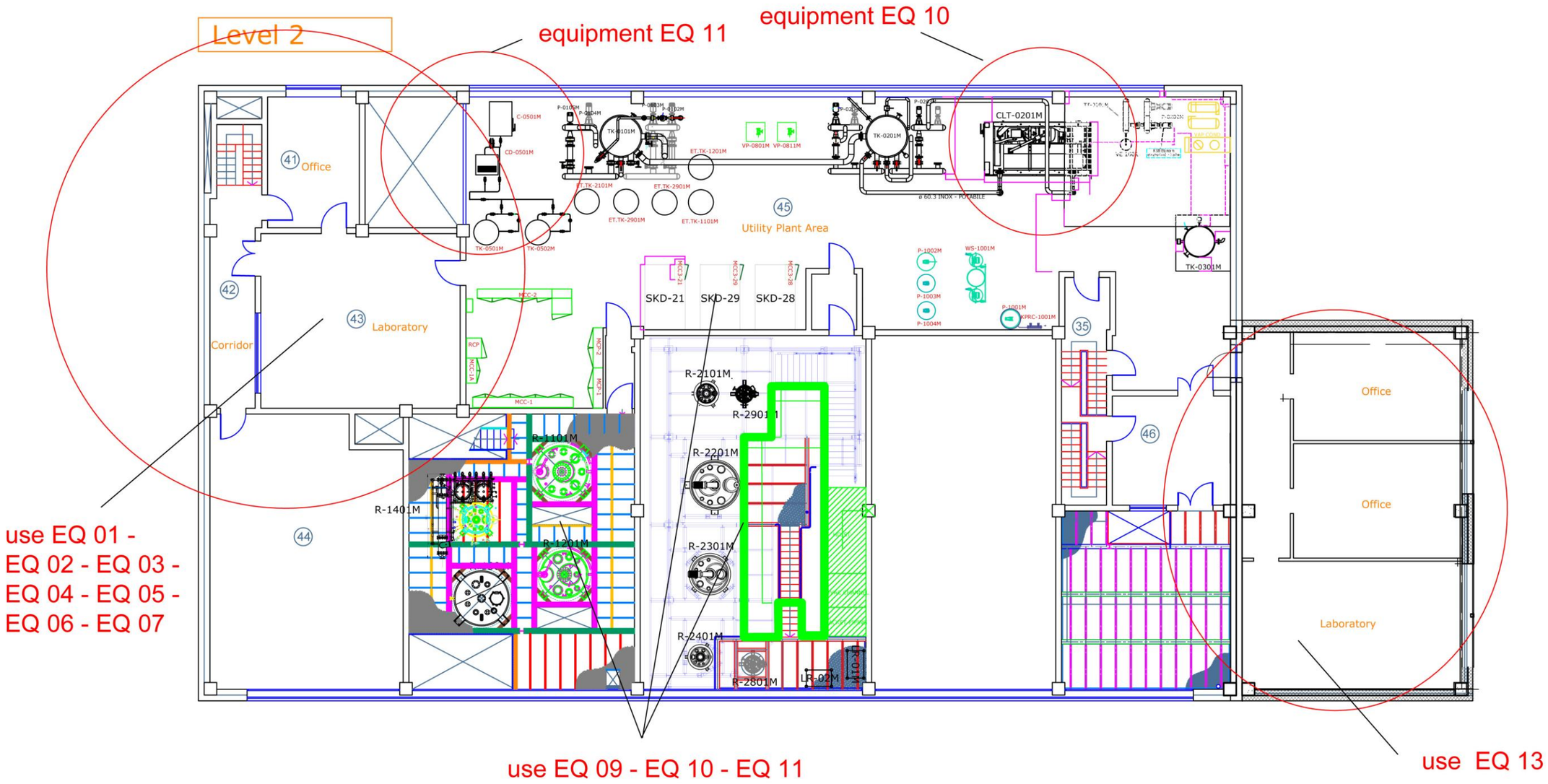
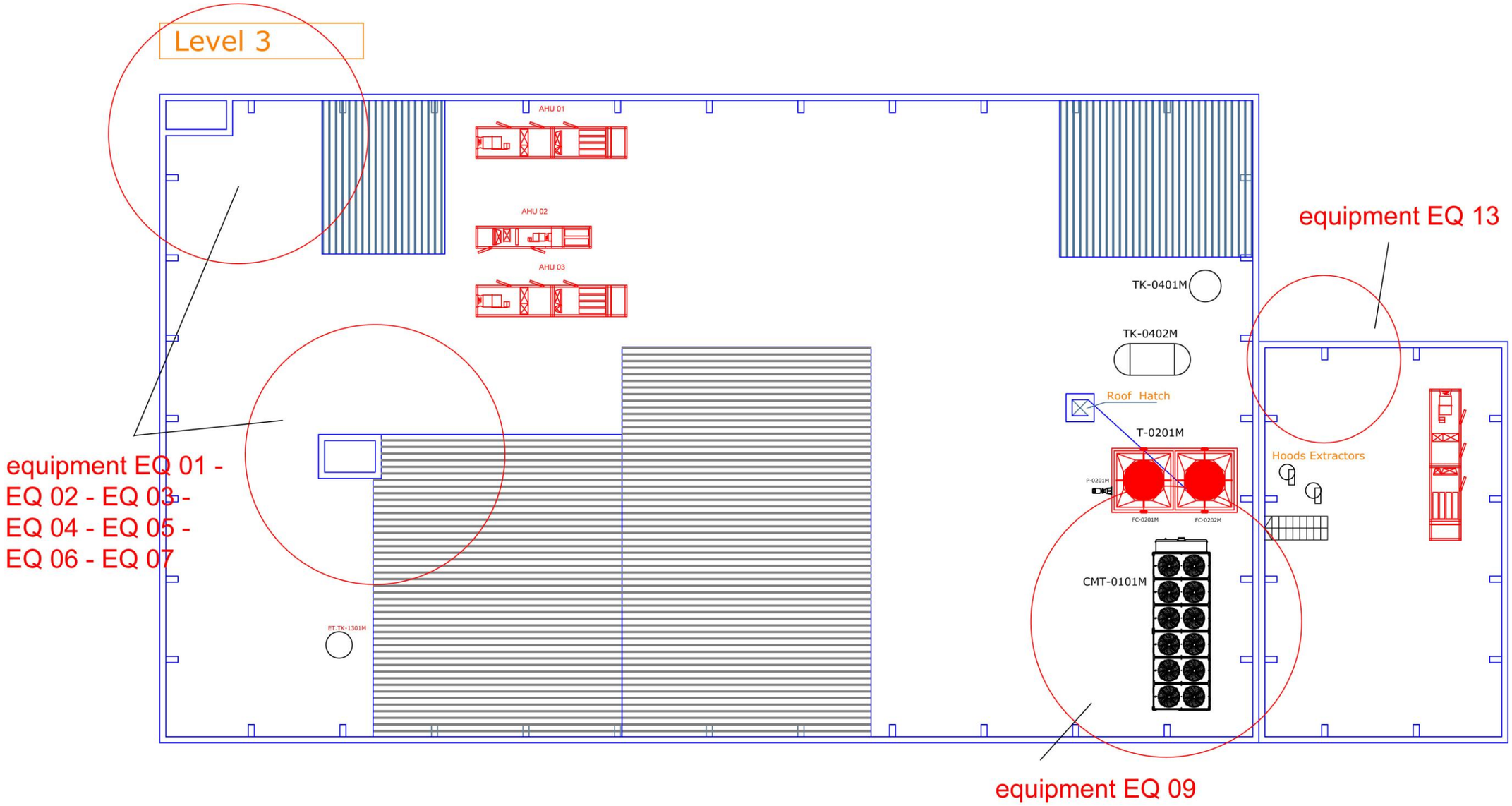


Figure 3.14: Location of refrigerant-containing equipment (Level 3)



C2.5 Maintenance

3.62. ERA's ToR require:

> *Describe any changes to the maintenance programme for the installation.*

3.63. The Scheme has a maintenance plan in place, which has been updated to include the new equipment (MN.SOP.001 rev.011 dated July 2018); a copy is included in **Annex 6**. Maintenance requirements are in accordance with manufacturer specifications and with applicable legal requirements.

C2.6 Energy

3.64. ERA's application form requires the Applicant to:

> *C2.6.1: Describe any changes to the annual energy consumption, highlighting the main energy-consuming equipment, and generation by source and end-use (including information on energy generated on site, if applicable).*
>
> *C2.6.2: Describe any changes to the proposed basic measures for improvement of energy efficiency.*

3.65. The microniser will be the main new electricity consumer in these variations. The electricity consumption of the microniser will not be greater than 50 kWh[4], and will be in use up to 320 hours per year, therefore the estimated annual electricity consumption will be not more than 16 MWh. The energy efficiency of the micronisation system has been ensured by not over-designing the microniser motors, as these are designed to cater for 110% of the actual energy requirement.

3.66. As with the existing reactors, the new reactors will obtain thermal energy from the existing natural gas boiler (each reactor has a jacket which can be heated by means of steam from the boiler, or cooled by means of chillers). However, the Scheme's boiler is already working at full power, and can only be used to produce steam for two reactors at the same time. Therefore, no increase in LPG gas consumption is foreseen.

3.67. The new reactors are rated at 3 kWh and will be used for around 24 hours each week; therefore, the additional annual electricity consumption as a result of this new equipment will be of around 11 MWh.

3.68. The cold rooms will also use electricity for cooling. The primary cooling system currently in use at the Scheme, and which will also be used for the cold rooms, is based on chilled water (equipment EQ 10 in section C2.4); this is a very efficient system. A system with an external compressor (EQ 12), which is less efficient, will also be available to cool the cold rooms; however, this will only be used if

[4] This is the maximum power that can be supported by the electrical panel; in reality, the microniser will consume a lower quantity of electricity than this amount.

there is a failure in the primary cooling system, and only until the more efficient chilled water system is back in operation.

3.69. Indoor lighting will be based on energy efficient systems (LED or similar) to minimise consumption.

3.70. As described in section C2.3, in future it is envisaged that LPG consumption by the steam generators will increase from around 170 m^3 annually to around 340 m^3 annually (phase 1) and 595 m^3 (phase 2).

3.71. No new energy generation sources are proposed in this variation application.

C2.7 Water

3.72. ERA's Terms of Reference (ToR) are:

> *Provide a breakdown of any changes to the proposed annual water consumption by source and end-use.*

3.73. Additional water will be needed primarily be used to wash the new reactors and the microniser after a production campaign has been completed. Purified mains water will be used for this purpose (as is current practice), and the contaminated washwater will be disposed of as hazardous waste, as also is the current practice.

3.74. It is envisaged that the water consumption at the Scheme will increase slightly, by about 25 m^3 annually.

C2.8 Risk Assessment

3.75. ERA's Terms of Reference (ToR) require the Applicant to:

> *Describe any changes to the documented system used to identify, assess and minimise the environmental risks and hazards of accidents and their consequences.*
>
> *Include any changes to emergency plans in case of fire, actions to be taken in case of failure of abatement equipment and other environmentally relevant incidents (e.g. spillages, gas leakage).*

3.76. The Scheme's emergency procedures are governed by document MIOS-4.4.7-I (rev 00): Emergency and evacuation procedure, issued in May 2015. There are also several related procedures, including:

- MIOS_ 4.4.7-A: Procedure to follow in case of fire, issued in January 2014;
- MIOS_ 4.4.7-B Operating instruction for fire extinguishers, fire hydrants and mobile foam units, issued in January 2014;
- MIOS_ 4.4.7-C: Procedure to follow in case of spill or release or contact with hazardous substances, issued in April 2015;

- MIOS_ 4.4.7-D: Procedure to follow in case of malfunction or breakdown of equipment, issued in May 2015;
- MIOS_ 4.4.7-E: Procedure to follow in case of injury or illness, issued in January 2014;
- MIOS_ 4.4.7-F: Procedure to follow for the safety of the plant and the employees, issued in October 2013;
- MIOS_ 4.4.7-G: Procedure to follow in case of earthquake, flood, power emergency, issued in February 2014;
- MIOS_ 4.4.7-H: Procedure to follow in case of emergency (covering notification and evacuation), issued in June 2013; and
- MIOS_ 4.4.7-I: Emergency and evacuation procedure (covering emergency procedures in more detail), issued in May 2015.

3.77. The above procedures, which have already been submitted to ERA as part of the Scheme's application for extension of the deadline to certify the Scheme's Environmental Management System (EMS), will also apply to the proposed variations (subject to any changes that may be made as part of the ISO 14001 certification process).

3.78. Additionally, an external company has been engaged to draw up fire detection and firefighting plans for the areas covered by these variations (excluding the new reactors, which are housed in the existing production line, and for which the existing system will be kept). It is noted that the following firefighting systems are / will be in place in the new areas:

- Micronisation facility: a fire extinguisher cabinet (fitted with portable fire extinguishers);
- Cold rooms: Following a review of the activities in this area, the fire consultants did not consider that the rooms needed a specific fire extinguisher cabinet as they are cold and damp rooms. Nevertheless, a fire extinguisher is already located right outside the corridor leading to the cold rooms;
- New floor overlying the existing administration block: a fire extinguisher cabinet; and
- New temporary waste storage area: portable foam fire extinguishers. There is also a water hose reel in the adjacent existing flammable warehouse area.

3.79. Fire prevention measures for the new LPG tank and associated activities, including gas detection systems are described in section C2.2. The firefighting measures for this area will be defined at a later stage by the fire consultants.

3.80. With regard to spill response, spill kits are already installed in the production areas and in the raw materials warehouse (which is located just outside the cold rooms). The use of a spill kit in the micronisation plant is not envisaged, due to GMP (Good Manufacturing Practice) restrictions owing to potential contamination of the product. However, in that area the product will be in powder form, and therefore mechanical means of collection would be used. A spill kit will also be installed near the main containment system in the new temporary waste storage area. Spill kits are not relevant to the new LPG tank since LPG is gaseous under room temperature and pressure.

3.81. An Addendum to the original Land and Groundwater Risk Assessment has also been prepared as part of this IPPC application; this is included as **Volume 3**. This Risk Assessment concludes that the risks to land and groundwater from the proposed variations range from none (where there is no pollutant linkage) to low and very low.

C2.9 Training

3.82. The IPPC Application Form requires the Applicant to:

> *Please indicate whether any changes to the staff training programme will be required. Please submit the name of the technically competent person on site who will be responsible for such training.*

3.83. The procedure governing the identification of training needs and implementation of a training programme is MPA_4.4.2 (rev 00, issued February 2014). This procedure was already identified as part of the original IPPC application (and has been resubmitted to ERA as part of the EMS certification deadline extension application), and will continue to apply.

3.84. This procedure aims to ensure that any persons working for or on behalf of the Scheme involved in activities that could have an impact on the environment are properly trained to carry out their assigned duties in a manner that will not cause deviation from the company environmental policy (whereas the policy includes a commitment to comply with applicable legal requirements and other environmental requirements to which the Company subscribes, i.e. including its IPPC permit).

3.85. The procedure also requires the implementation of an annual training plan, and maintenance of training records. Therefore the activities covered by these proposed variations will be included in the forthcoming training plan for the Scheme, and corresponding records kept.

4. EMISSIONS

C3.1 Waste

4.1. ERA's ToR require:

> *C3.1.1: Characterise (using the European Waste Catalogue code, in accordance with LN 184 of 2011 as amended) and quantify any changes to each waste stream from the installation.*
>
> *C3.1.2: Describe any changes to the proposed measures for waste management, storage and handling. If any are identified, also indicate the storage location of wastes on a site layout plan and give details on:*
>
> - *Maximum storage capacity;*
> - *Containment measures (including bunding capacity, where applicable);*
> - *Protective measures (including security).*

4.2. The original IPPC application (section B3.1) already includes the identification of the waste types generated by the Scheme. Additionally, transfers of waste off-site are reported annually to ERA as part of the AER of the Scheme.

4.3. Since the proposed variations are similar to the existing processes, no new waste types are envisaged. The waste quantities generated annually are likely to increase slightly; the estimated quantities generated as a result of the proposed variations are presented in **Table 4.1**.

Table 4.1: Estimated waste quantities

EWC code	Description	Estimated annual quantity generated (tonnes)
07 07 01*	Aqueous washing liquids and mother liquors	10
07 07 03*	Organic halogenated solvents, washing liquids, and mother liquors	5
07 07 04*	Other organic solvents, washing liquids, and mother liquors	24
15 02 02*	Absorbents, filter materials (including HEPA filters), wiping cloths, protective clothing contaminated by dangerous substances	12

4.4. As mentioned in section C2.2, a new temporary waste storage area has also been added to enable better organisation of waste before it leaves the Scheme site. This is a temporary arrangement, and will be replaced by a new external and fully contained built flammable warehouse by mid-2019.

4.5. The temporary waste storage area is used for storage of existing waste streams already produced by the Scheme, and there will be no addition of new waste types as a result of this addition. The primary waste streams stored here are liquid hazardous waste (**Table 4.2**), which are stored in 1 m^3 IBCs or in drums.

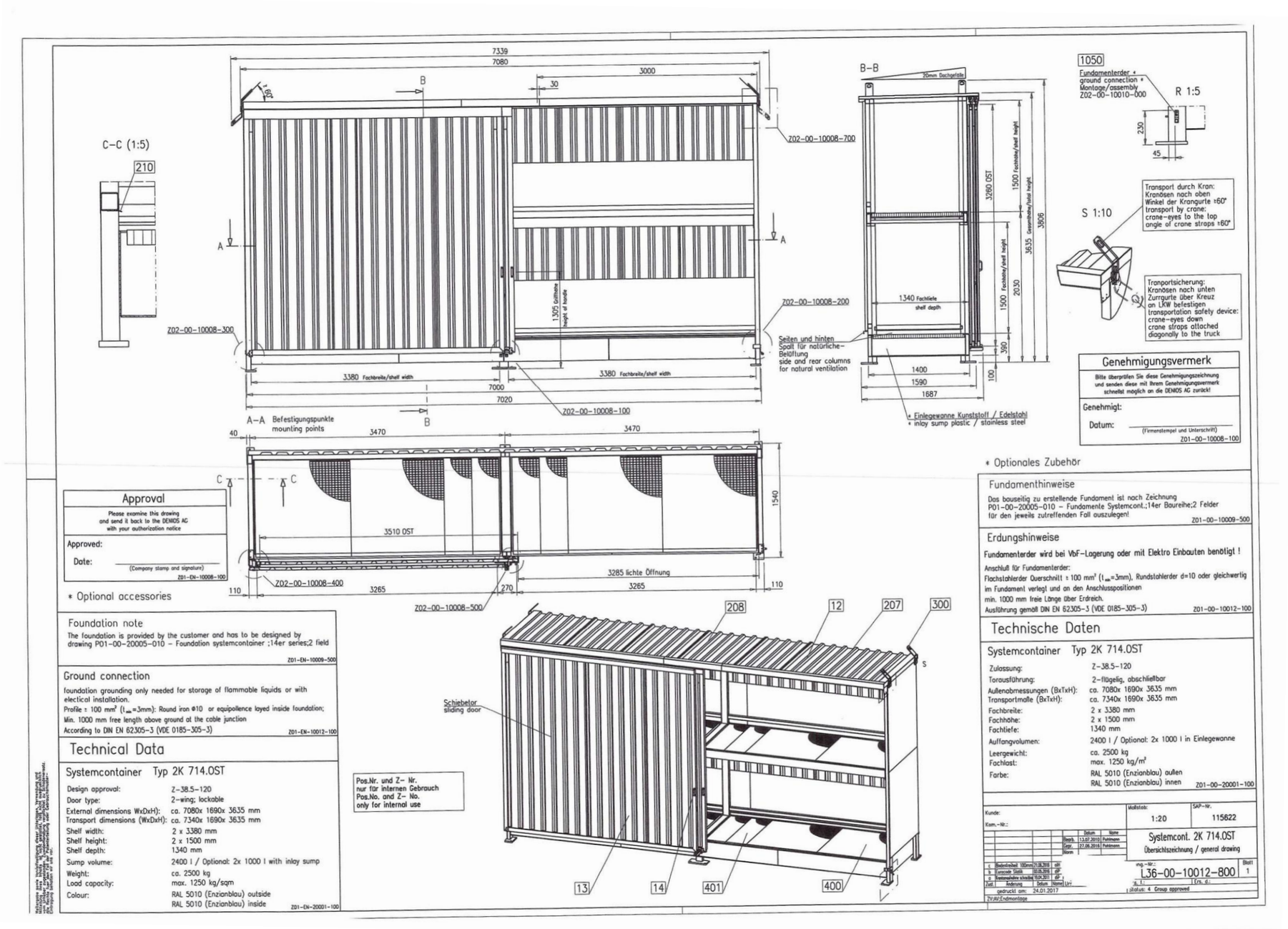
Table 4.2: Principal wastes stored in the temporary waste storage area

EWC code	Description
07 07 01*	Aqueous washing liquids and mother liquors
07 07 03*	Organic halogenated solvents, washing liquids and mother liquors
07 07 04*	Other organic solvents, washing liquids and mother liquors

4.6. A prefabricated containment system (shown in **Figure 4.1**) is installed in this area; the specifications of this system are presented in **Figure 4.2**. The system has a bund capacity of 2,400 L, enough to contain the contents of more than two full IBCs in case of a leak.

Figure 4.1: New temporary waste storage area showing main containment system

Figure 4.2: Containment system specifications



4.7. Other smaller prefabricated bunds are also available in the area, as shown in **Figure 4.3**. However, some temporary storage of liquid hazardous waste outside containment systems is still carried out while the waste is being organised or prepared for shipment.

Figure 4.3: Other prefabricated bunds

4.8. There is also some storage of non-hazardous solid waste in designated areas (e.g. empty IBCs or wood pallets, shown in **Figure 4.4**) or in closed skips (e.g. clean glass jars, **Figure 4.5**).

Figure 4.4: Wood storage

Figure 4.5: Storage in skips

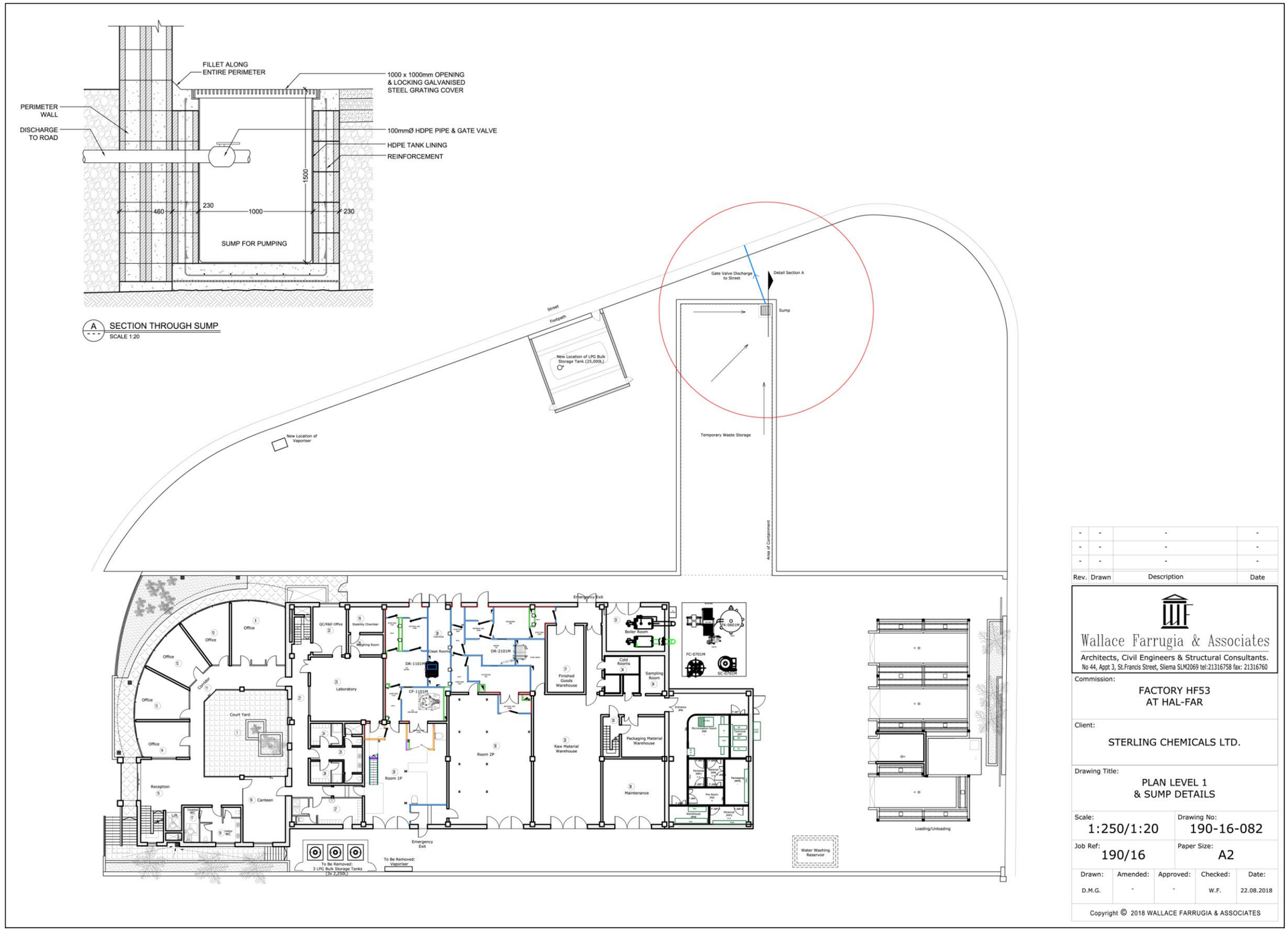
4.9. The ground in this area is made of concrete overlain by tarmac and is laid to fall towards a rainwater pipe at the northwestern corner of this area; the pipe leads to the external road that abuts the Wied Żnuber valley. In order to fully contain

this area, the pipe will be fitted with a locked gate valve to ensure that only discharges of clean rainwater occur to the road surface; the pipe will be preceded by a sump to enable any spillage to be collected and pumped out for disposal as hazardous waste. These arrangements are shown in **Figure 4.6**. A trained person will be responsible for inspecting the area and the accumulated rainwater prior to unlocking the valve. These measures will be implemented by end September 2018.

4.10. The maximum quantity of waste stored in this area is 17,700 kg, which is the capacity of a shipping container. Once this capacity is reached, the waste is removed from site.

4.11. All waste on site will continue to be transferred to licensed facilities using authorised waste carriers, and records will continue to be maintained and reported to ERA as per current practice.

Figure 4.6: Containment of new temporary waste management area



C3.5 Rainwater

4.12. ERA's ToR ask the Applicant to:

> *Describe any changes to how rainwater is handled on site. If any changes are proposed, attach a site drainage map indicating rainwater capture and harvesting/discharge.*

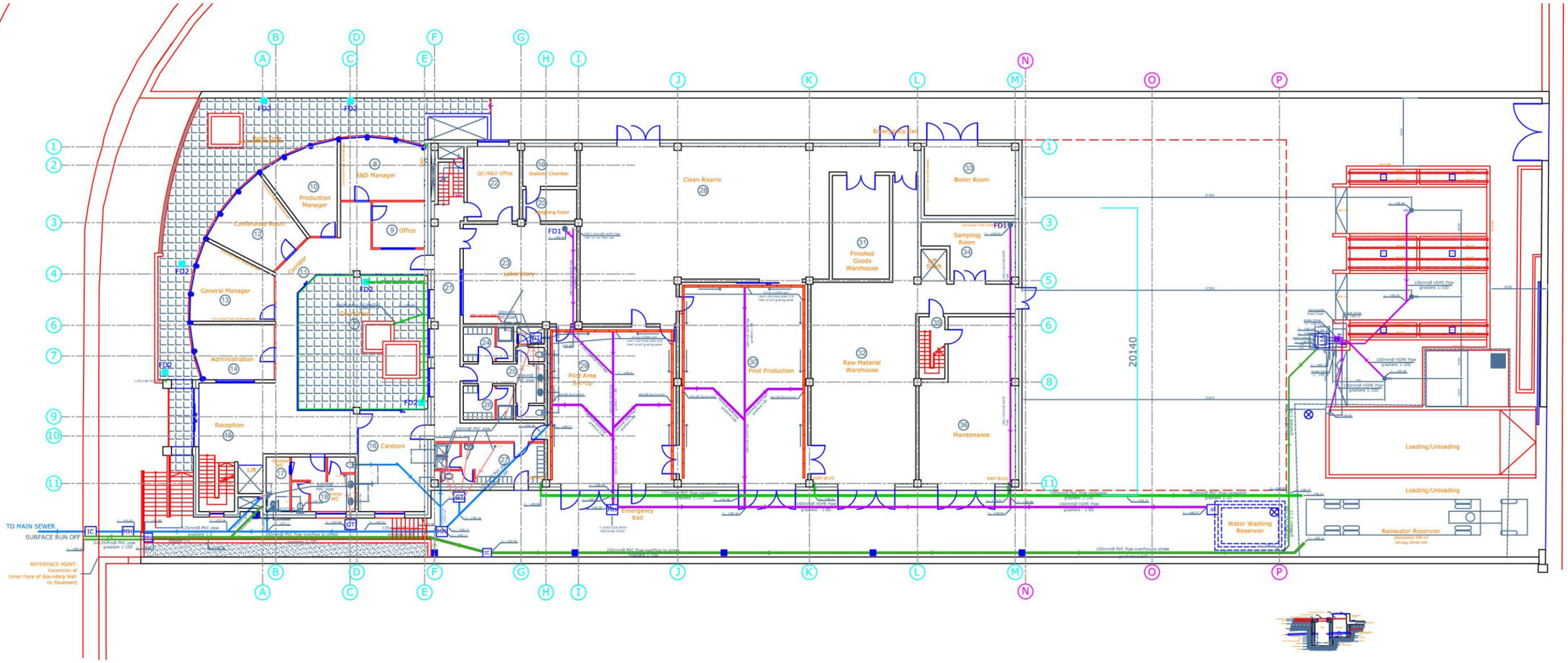
4.13. Clean rainwater from the new building roofs (namely the new stage 3 block and the new roof of the administration block) will, as is the current arrangement for the rest of the Scheme site's roofs, be collected in an existing underground reservoir having a capacity or 600 m^3. This reservoir is shown in **Figure 4.7**.

4.14. In accordance with the existing scenario, the water in this reservoir is primarily reserved for firefighting purposes.

4.15. As mentioned, the ground in the new temporary waste management area is currently laid to fall towards a rainwater pipe at the northwestern corner of this area. However, this area will be fitted with a sump leading to a locked gate valve (as shown previously, in **Figure 4.6**) to ensure that only discharge of clean rainwater occurs to the road surface.

4.16. With regard to the new LPG tank area, a soakaway will be installed in the flooring to allow for rainwater drainage; contamination of rainwater is not an issue in this area since LPG is gaseous at room temperature and pressure.

Figure 4.7: Rainwater reservoir



C3.6 Emissions to Air

4.17. ERA's application form requires the Applicant to:

> *Identify if there may be any changes in emissions of substances to air.*
>
> *If any are identified, submit details of each emission point, the nature and the proposed quantities of substances emitted from each point and treatment/abatement measures. A block plan of the site showing each emission point should be submitted.*
>
> *For each new boiler/generator, submit the following details: rated thermal input, energy output, date of manufacture, stack height, fuel type and annual fuel consumption.*

4.18. As mentioned, emissions to air from the microniser will be filtered using H13 HEPA filters, a carbon filter, and then routed to the scrubber; the scrubber is an existing authorised emission point to air (EM1). The HEPA filter's test certificate is included in **Annex 7**, which shows that the filtration efficiency is greater than 99.95%. It is noted that a differential pressure device is installed before and after each HEPA filter in order to monitor the operation of the filter; the filters will also be included in the Scheme's maintenance programme and replaced as per the maintenance schedule.

4.19. The micronisation laboratory on the second floor will include two fume hoods, which will exhaust through new vents (labelled as EM10 and EM11 in **Figure 4.8**). The content of the emissions will be small quantities of solvent and chemical emissions; such emissions will be treated through a carbon filter prior to release. Specification sheets for the carbon filters to be used are included in **Annex 8**. These emission points will be at a height of 2 m above roof level.

4.20. Additionally, in the micronisation laboratory a HEPA H13 filter will also be installed on the suction hoods (balance enclosure) where weighing of powders is carried out; the treated air exhausts inside the laboratory itself.

4.21. Emissions from the new reactors in production lines 1 and 2 will be routed to the existing scrubber EM1. As with the existing reactors, each reactor is connected to a heat exchanger to condense organic vapours; the entire reactor line is also connected to a second, larger heat exchanger, following which vapours are treated in a carbon filter and scrubber (EM1).

4.22. It is noted that the scrubber is oversized and can handle the increased flow arising from the new activities. As shown in **Figure 4.8**, the scrubber can handle a flow rate of up to 5,000 m^3/h, which is more than sufficient even if all vents (existing and proposed) are used simultaneously; this scenario is highly improbable due to many processes being discontinuous. Emissions from the scrubber will continue to be monitored and reported to ERA as required.

4.23. Exhaust air from the cold rooms is vented directly to the atmosphere (new emission point EM12). It is noted that only storage of substances is carried out in this area, and there is no exposure of substances to the atmosphere (and therefore no releases of dangerous substances to air) under normal conditions.

4.24. **Figure 4.9** shows the location of all the emission points from the Scheme (both permitted and proposed). It is noted that the Scheme includes only one cooling tower (EM7); therefore the formerly proposed cooling tower EM8 is not shown **Figure 4.9**.

4.25. No new boilers / generators are proposed as part of the current application.

Figure 4.8: P&ID schematic for the scrubber

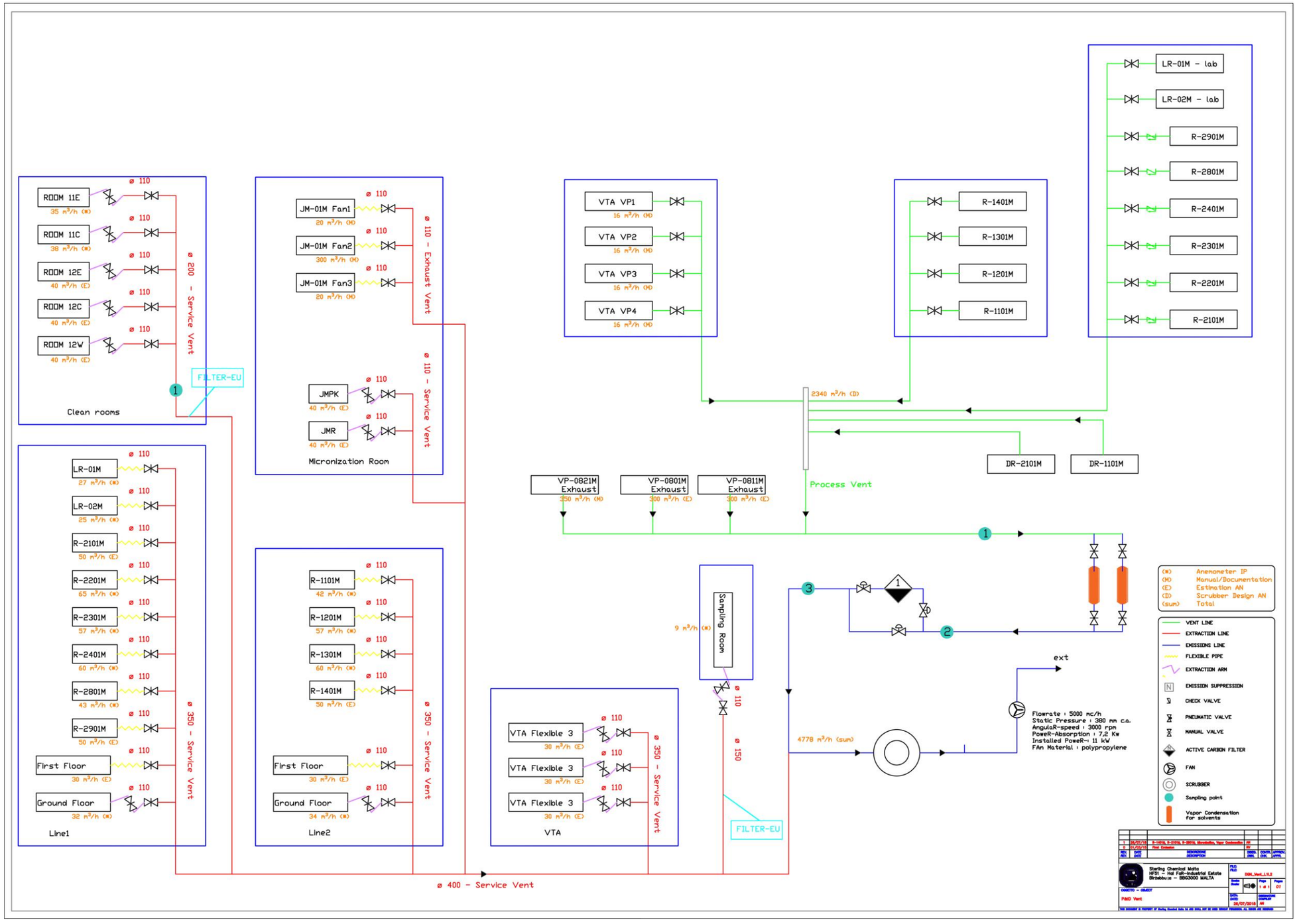
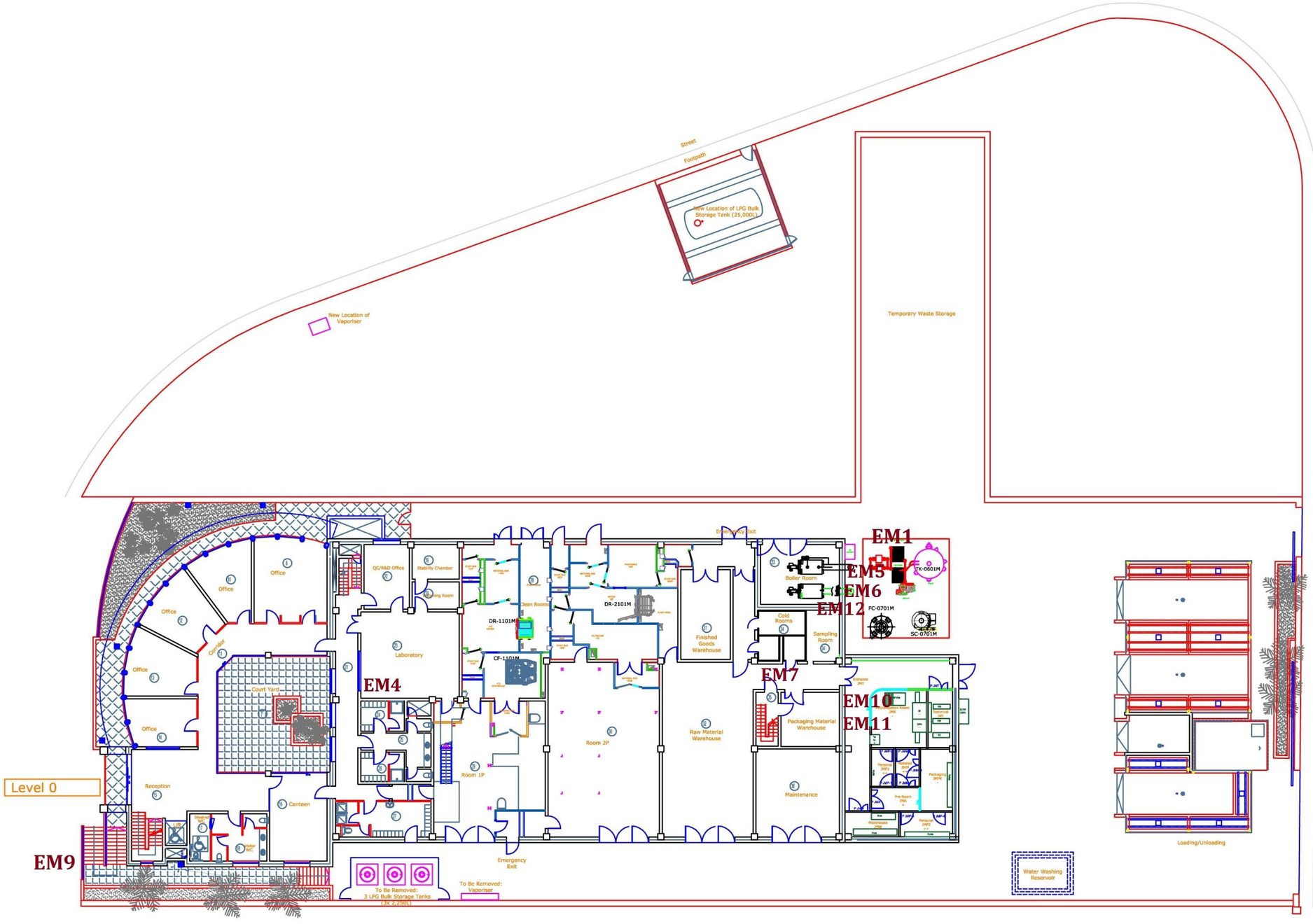


Figure 4.9: Emission points from the Scheme



C3.9 Noise

4.26. The IPPC application form requires the Applicant to:

> *Describe:*
>
> ***C3.9.1:*** *The main sources of noise and vibration (including infrequent sources) of the new proposal;*
>
> ***C3.9.2:*** *The proposed techniques and measures for control of noise;*
>
> ***C3.9.3:*** *The nearest noise sensitive locations and distance away from the site (a site map may be submitted for this purpose); and*
>
> ***C3.9.4:*** *Relevant environmental noise measurement surveys which have been undertaken (monitoring shall be according to the latest revisions of ISO1996 and the rating of industrial noise affecting residential areas shall be according to BS 4142; monitoring shall be carried out exclusively using type 1 sound level meter).*

4.27. The main new generators of noise are the micronisation room and the associated technical area; emissions of noise from these areas will be abated by enclosing these two rooms in concrete.

4.28. Since the site is located in an industrial area surrounded by industrial uses, impacts on noise sensitive receptors are not expected.

4.29. The IPPC permit already requires noise monitoring to be carried out every five years. Noise monitoring was first carried out in December 2015 and submitted to ERA as part of the 2016 Annual Environmental Report. The next monitoring session is scheduled for 2020; however, as requested by ERA such monitoring will be carried out once the microniser is commissioned.

C3.10 Monitoring

4.30. ERA's application form requires the Applicant to:

> *Describe the proposed measures for monitoring emissions arising from the proposal, including any environmental monitoring. The following must be specified:*
>
> ***C3.10.1:*** *The location of each proposed monitoring point (plotted on a suitably-labelled block plan of the site);*
>
> ***C3.10.2:*** *The substances (in each environmental medium) which are proposed to be monitored;*

C3.10.3: *The frequency with which monitoring is proposed to take place;*

C3.10.4: *The proposed measurement methodology, which should be a standard methodology, such as EN or ISO standard, or equivalent;*

C3.10.5: *The proposed procedure for evaluation of the results.*

4.31. The relevant emissions associated with these proposals are emissions to air and noise emissions.

4.32. With regard to emissions to air, the proposed variations will mostly be connected to the existing scrubber, which is already authorised and subject to monitoring.

4.33. There will be new emission points to air from the micronisation laboratory fume hoods (EM10 and EM11); these will generate minimal quantities of airborne emissions, which are also treated prior to release. As requested by ERA, a one-time air emission monitoring exercise from these emission points will be carried out. Monitoring will be carried out for VOCs, which are the main emission types from these points.

4.34. Additionally, exhaust air from the cold rooms is vented directly to the atmosphere (new emission point EM12). However, since there under normal conditions are no releases of dangerous substances to air from this area, it is considered that monitoring from this point is unnecessary.

4.35. As mentioned, emissions of noise from the micronisation facility will be mitigated, and a noise monitoring programme already exists. The next monitoring session will be carried out once the microniser is commissioned, Since the site is located in an industrial area some distance away from noise sensitive receptors, it is considered that the existing noise monitoring frequency (every five years) can be retained, subject to the above study not revealing significant noise impacts, and no new noise-generating equipment being commissioned in the interim.

5. IMPACT ON THE ENVIRONMENT

5.1. ERA's ToR require:

> ***C4.1 Environmental effects***
>
> *Provide an assessment of the potential significant environmental effects (including transboundary effects) of the foreseeable emissions from the proposal.*
>
> ***C4.2 Effects on other sites***
>
> *Provide an assessment of whether the proposal is likely to have a significant effect on another site in Malta and, if it is, provide an assessment of the implications of the installation for that site.*

5.2. As described in this Application, the potential emissions arising from the proposed variations are:

- Emissions to air; and
- Noise emissions.

5.3. The surrounding land uses are mapped in **Figure 5.1**. The predominant land uses in the surrounding area are industrial, predominantly manufacturing activities (including pharmaceutical production, detergent manufacture, production of climate control systems, and printing presses) and storage / warehousing. Some cultivated agricultural land is found along both sides of the Wied Żnuber valley, located to the west of the Scheme site. There are no residential properties within 250 m of the Scheme site.

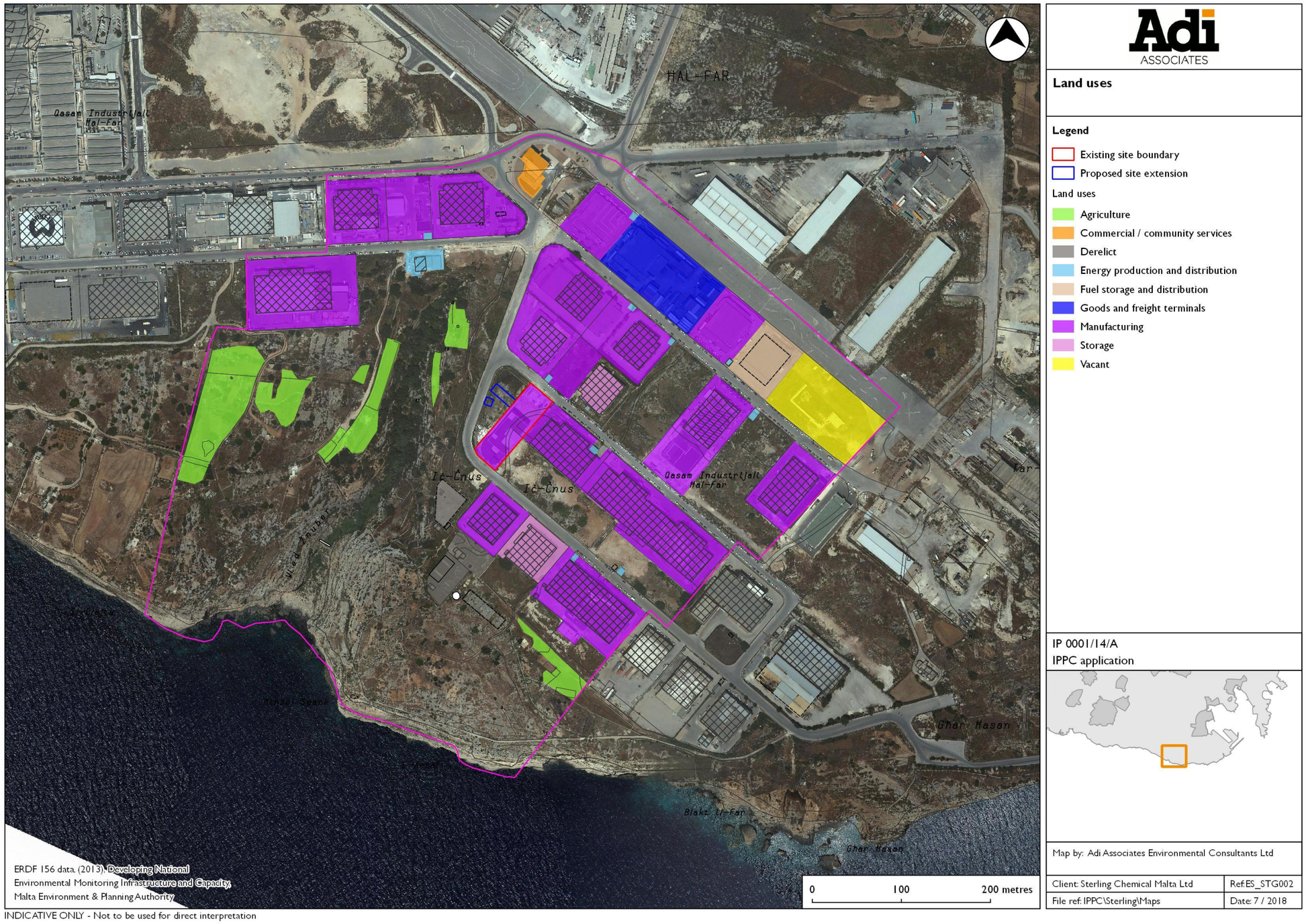
5.4. Emissions to air from the proposed variations are described in section C3.6 of this application. As mentioned, air emissions will largely be mitigated through the use of HEPA filters and an existing scrubber (which can handle the increased flow). The only new emission points are minor: from the laboratory fume hoods (which will be abated), and the cold rooms (which will not release dangerous substances under normal operating conditions). Therefore the environmental impacts of air emissions from the Scheme are expected to be low.

5.5. Noise emissions are described in section C3.9 of this application. Such emissions will mainly arise from the micronisation room and the associated technical area, and will be mitigated by enclosing these areas inside concreted rooms. Due to this mitigation as well as the nature of the surrounding land uses, impacts on noise sensitive receptors are not expected.

5.6. As noted in the IPPC application form (**Volume 1**), no emissions to land and groundwater are proposed. The addendum to the Land and Groundwater Risk

Assessment (**Volume 3**), identifies the risks to land and groundwater as ranging from none (where there is no pollutant linkage) to low and very low.

Figure 5.1: Surrounding land uses



INDICATIVE ONLY - Not to be used for direct interpretation

Adi ASSOCIATES

Land uses

Legend

- Existing site boundary
- Proposed site extension

Land uses

- Agriculture
- Commercial / community services
- Derelict
- Energy production and distribution
- Fuel storage and distribution
- Goods and freight terminals
- Manufacturing
- Storage
- Vacant

IP 0001/14/A
IPPC application

Map by: Adi Associates Environmental Consultants Ltd

Client: Sterling Chemical Malta Ltd	Ref:ES_STG002
File ref: IPPC\Sterling\Maps	Date: 7 / 2018

Annex 1: Micronisation unit

nuova guseo®

MICRONIZZATORI
JET-MILLS

SERIE "MICRONETTE"

Micronizzatori a getto "Micronette„

Applicazioni

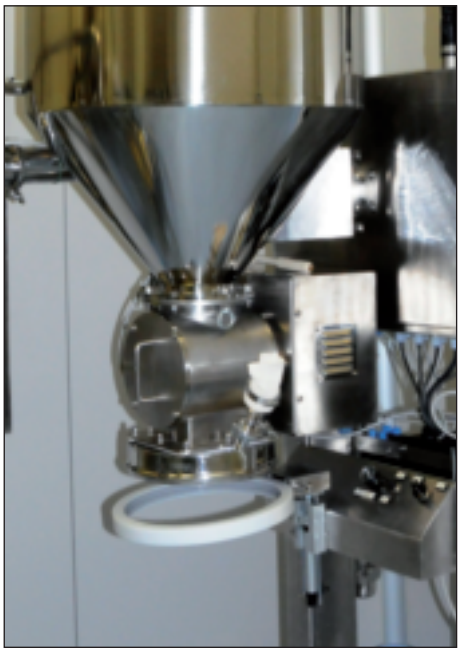
Tra i vari sistemi di comminuzione attualmente conosciuti il micronizzatore a getto è, senza dubbio, il più idoneo al trattamento di prodotti chimico/farmaceutici. Con l'impiego di detto mulino è possibile, grazie al suo particolare principio di funzionamento, soddisfare molteplici richieste granulometriche fino ad ottenere, senza l'ausilio di organi macinanti e classificanti, particelle micronizzate al 100% inferiori a 5 micron; risultato quest'ultimo non ottenibile con mulini convenzionali di diversa concezione. Il micronizzatore a getto garantisce inoltre la totale assenza di inquinamento da parti metalliche.
Agrochimici, fungicidi, insetticidi, fertilizzanti, pigmenti, materie plastiche, metalli, cosmetici, sostanze chimiche e alimentari, farmaci sono i principali prodotti per i quali si consiglia l'impiego del micronizzatore a getto. Sostanze termolabili, abrasive, esplosive, possono essere trattate senza che il prodotto ed il micronizzatore stesso subisca danneggiamento alcuno ed in assoluta sicurezza.
Per l'impiego nella micronizzazione di sostanze ad uso farmaceutico è stata appositamente progettata e realizzata una particolare "Versione Sanitaria". Soluzioni che garantiscono un rapido smontaggio senza l'ausilio di utensili meccanici e particolari accorgimenti che rendono l'apparecchiatura facilmente accessibile in ogni sua parte, permettendone un'accurata pulizia, sono caratteristiche peculiari dei modelli Versione Sanitaria". Tali caratteristiche, unite al principio stesso di funzionamento del micronizzatore a getto, consentono di mantenere inalterata la purezza della sostanza.

Principio di funzionamento

Le particelle di prodotto, immesse nella camera di macinazione attraverso un iniettore Venturi, vengono bruscamente accelerate da un flusso di aria compressa ad altissima velocità iniettato mediante ugelli situati alla periferia della camera circolare del mulino. Queste vengono trascinate in un moto vorticoso che le induce a scontrarsi ripetutamente tra loro riducendone progressivamente il diametro e la massa fintanto che l'energia dalle stesse accumulata scende a valori trascurabili. Le particelle di prodotto micronizzato vengono convogliate dal flusso di aria esausta ad un apposito ciclone-filtro. All'interno di questo un set di moduli filtranti realizzati in tessuto speciale permette lo scarico dell'aria depolverata, mentre il prodotto micronizzato viene trattenuto sulla superficie esterna degli stessi. Un breve soffio di aria compressa insufflato all'interno dei moduli li scuote periodicamente e rimuove il prodotto che viene raccolto nella parte inferiore del ciclone-filtro. La totale assenza di organi macinanti in movimento e di dispositivi di classificazione permette una facile conduzione dell'impianto ed una drastica riduzione dei costi di manutenzione.

Applications

Among the different milling systems known at present, the jet mill is, without doubt, the most suitable for the micronizing of chemical and pharmaceutical products.
Thanks to its very well established and particular working principle it is able to meet numerous demands of fineness until to obtain, without the help of moving and classifying parts, micronized particles typically 100% below 5 micron. This is a result that cannot be achieved by more conventional mills having different conception. Besides the mill grants the total absence of metallic part pollution. The jet mill is ideal for the formulation and development of Agrochemicals, Fungicides, Insecticides, Fertilizers, Pigments, Polymers, Plastics, Metals, Cosmetics, Chemicals, Foodstuffs, Drugs, etc. Heat-sensitive products, Abrasives and Explosives can be micronized without causing damage to product or jet mill and in absolute safety conditions. Besides, the specially designed "Sanitary Version" of the GUSEO jet mill is particularly suitable and widely used for the high-purity and contamination-free grinding of materials having pharmaceutical use. Solutions granting a quick disassembling without the need for mechanical tools as well as particular devices making the equipment of easy access in each part for an accurate cleaning are special characteristics of "Sanitary Version" models.



Working principle

Product particles are fed into the milling chamber through a Venturi injector. High-velocity air is introduced into the mill through jet nozzles placed around the circular chamber of the mill. Particles are consequently accelerated inside the milling chamber and dragged in a vortical movement causing them to collide repeatedly. They break up into progressively small particles until the accumulated energy is reduced to negligible values. The exhausted air carries micronized particles into a suitable cyclone-filter. At the inner of the cyclone-filter the air is dedusted through a set of filtering bags, in special fabric, and discharged to the outside. Reverse jets of compressed air periodically shake filtering elements causing product removal from fabric. Micronized product collection takes place into the bottom hopper of the cyclone-filter. Due to the absence of moving parts and classifying devices the mill is practically maintenance free and therefore substantial cost saving is achieved.

Fluido di micronizzazione

Quale fluido di micronizzazione viene generalmente utilizzata aria compressa essiccata e disoleata, ma è possibile impiegare anche altri gas quali Azoto ed Argon oppure Vapore quando il prodotto non è sensibile al calore. Tutte le apparecchiature e gli accessori necessari per il funzionamento ad aria compressa sono disponibili. Linee complete per funzionamento in ciclo chiuso inertizzato possono inoltre essere fornite a richiesta.

Micronizing fluid

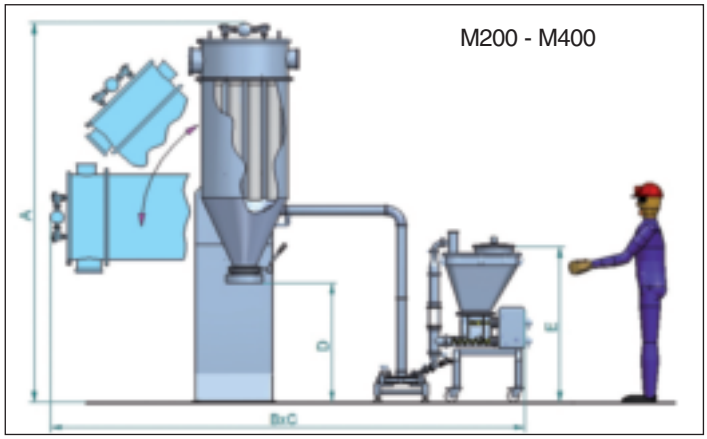
Dry and oil free compressed air is generally used as vector fluid, but it is possible to employ also other gases as Nitrogen and Argon, or even Steam if the product is not heat-sensitive. All necessary equipment and ancillaries for compressed air running are available too. Additionally, complete lines for closed circuit operation with inert gases are supplied on request.

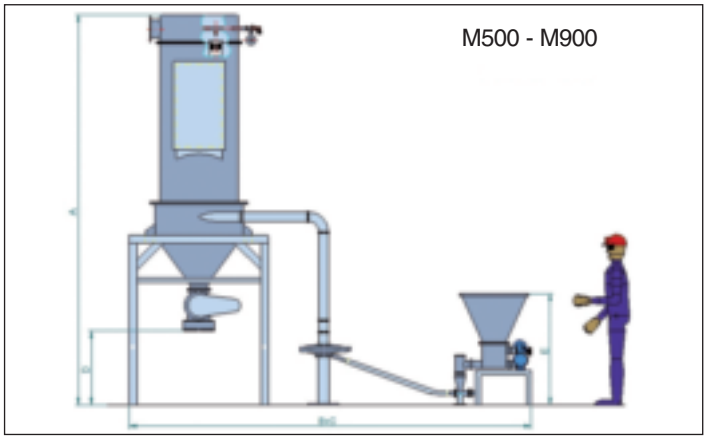
Materiale di costruzione

Il micronizzatore MICRONETTE è disponibile in più versioni atte a soddisfare le specifiche esigenze produttive ed è realizzato con acciai semplici di qualità o AISI 304 ed AISI 316 in funzione del tipo e della natura della sostanza da trattare. All'occorrenza, possono essere realizzati rivestimenti con materiali speciali al fine di eliminare particolari inconvenienti quali abrasione, impaccamento ecc.

Manufacturing materials

The jet mill MICRONETTE is available in several versions to meet specific production requirements. It is manufactured in good quality steel or stainless steel AISI 304 and AISI 316, depending on the type of material being processed.
If necessary, special linings can be fitted to minimize abrasion or prevent product adhering to internal surfaces.





	M200	M300	M400	M500	M600	M750	M900
A	2200	3200	4300	4925	6280	6280	6675
B	2500	3800	5400	5705	5970	6160	6780
C	850	1180	1800	1505	2000	2500	2860
D	800	1000	1000	800	800	800	800
E	1200	1300	1300	1400	1500	1500	1600
m^3/h 7 bar	100	240	600	760	1400	2300	3400

I dati sopra indicati sono soggetti a modifica in funzione della richiesta del cliente. Immagini a scopo illustrativo. Il costruttore si riserva di modificare dettagli costruttivi senza preavviso.

Data mentioned above are subject to modification according to customer's demand. Photos only for illustrative purpose. Details can be changed without notice.

Nuova Guseo è in grado di fornire una vasta gamma di altre apparecchiature per la macinazione fine ed ultrafine, mescolatori orizzontali e verticali, dispositivi di alimentazione-dosaggio, classificazione, filtrazione, trasporto e trattamento in genere di solidi. A richiesta sono disponibili cataloghi specifici.
Prove dimostrative possono essere eseguite presso Nuova Guseo o direttamente negli stabilimenti del Cliente.

Nuova Guseo is also in a position to supply a wide range of different equipment for fine and ultra-fine grinding, horizontal and vertical mixers, screw / vibrating feeders, classifiers, filters, conveyors and solid handling systems. Specific catalogues are available on request. Grinding test can be carried out at Nuova Guseo's or Customer's premises.

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Annex 2: Glove boxes

nuova guseo®

GLOVE BOXES

GLOVE BOXES

Stazione di scarico per centrifughe e filtri essiccatori (interno)
Centrifuges and dryer filters discharging Box (inside view)

Isolatore con dispositivo di pesata e carico sostanze liquide in fusti
Glove box with weighing device for charging of liquid into drums

Isolatore a doppia camera per attività di pesata e dispensa
Double chamber isolator for weighing and dispensing activities

TRIPLA PROTEZIONE

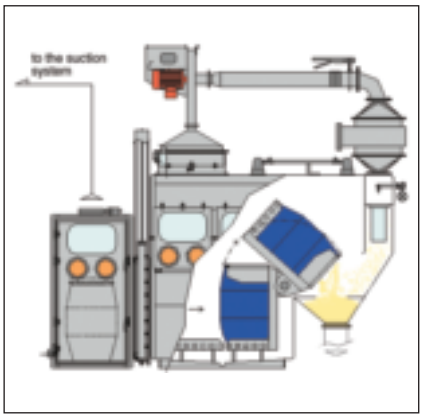
Negli ultimi anni si è visto riporre, da parte dell'industria chimico-farmaceutica, una sempre maggiore attenzione nel problema del contenimento, in particolare dovuta all'aumento della tossicità dei prodotti trattati.

Questa tendenza ha portato in primo piano le tecnologie legate ad una specifica metodica di produzione: **l'isotecnia** o tecnica dei volumi confinati, che consente di ottenere preparazioni contenenti sostanze altamente attive (es. antibiotici, ormoni, citostatici) in condizioni di sicurezza. La produzione in isotecnia avviene all'interno di glove boxes, che sono a tutti gli effetti delle piccole camere che assicurano il confinamento di una serie di operazioni garantendo un triplice livello di protezione:

- PROTEZIONE OPERATORE;
- PROTEZIONE PRODOTTO;
- PROTEZIONE AMBIENTE ESTERNO.

La protezione dell'operatore dalla contaminazione di sostanze tossiche e/o attive è garantita dall'assenza di contatto diretto, tra l'operatore stesso e la sostanza manipolata durante le varie fasi del processo. Grazie all'impiego di ampie "visive" munite di flange guantate o, in alternativa, di sistemi a mezzo scafandro, l'operatore può, infatti, effettuare tutta una serie di operazioni quali, ad esempio; l'apertura di contenitori, la pesata e la dispensa, la macinazione, il campionamento, il tutto senza venire direttamente a contatto con la sostanza trattata.

Stazione di ribaltamento fusti con pre-camera (esterno)
Drum overturning Glove Box with pre-chamber (outside view)



Stazione di ribaltamento fusti con pre-camera (schema di flusso)
Drum overturning Glove Box with pre-chamber (flow sheet)

La protezione del prodotto da contaminazioni provenienti dall'ambiente esterno è garantita da un sistema di filtrazione assoluta (Hepa) posto all'aspirazione. Tale dispositivo assicura che l'aria esterna venga a contatto con la sostanza da trattare solo dopo opportuna filtrazione, garantendo così l'assoluto controllo degli inquinanti aerotrasportati.

La protezione dell'ambiente esterno è garantita da un ulteriore sistema di filtrazione assoluta (Hepa) posto allo scarico. Tale dispositivo assicura l'adeguato trattamento dell'atmosfera interna prima dell'espulsione a salvaguardia dell'ambiente ed anche dell'operatore.

Per alcune particolari applicazioni le Glove Boxes possono essere dotate di pre-camera, che può essere a sua volta provvista di un sistema di filtrazione dedicato. Al suo interno un diverso livello di pressione (positiva o negativa, secondo il progetto) agisce da barriera tra l'ambiente esterno e la zona contaminata interna alla cabina di lavoro.

L'alto grado di finitura (Ra interna<0,4 micron) consente di evitare accumuli della sostanza trattata, mentre il controllo dei flussi d'aria limita il contatto del prodotto con le superfici interne della Glove Box; il tutto al fine di facilitare le operazioni di pulizia al cambio prodotto. Gli eventuali residui possono essere facilmente rimossi mediante un sistema di lavaggio interno ed il liquido di lavaggio viene convogliato, attraverso un fondo drenante, allo scarico dove potrà essere recuperato per il successivo trattamento.

Alcuni modelli sono stati espressamente progettati per il trattamento di sostanze potenzialmente esplosive, conformemente a quanto previsto in materia dalla direttiva 94/9CE "ATEX", e sono corredate di relativa dichiarazione di conformità.

Tutte le realizzazioni sono accuratamente studiate nei minimi dettagli e possono essere realizzate al fine di soddisfare ogni specifica esigenza del cliente.

TRIPLE PROTECTION

In the past years there has been an ever increasing attention given to containment aspects by the pharmaceutical & chemical industries, in particular due to the increase of the toxicity of treated products

*This trend has brought to the fore the technologies related to a specific method of production: **isolation technology**, which allows to obtain preparations containing highly active substances (i.e. antibiotics, hormones, cytostatic) in safety conditions. The production as per isolation technology takes place inside glove boxes, which are to all effects of small rooms providing for the segregation of a series of operations by granting, at the same time, a triple protection level:*

- *PROTECTION OF THE OPERATOR;*
- *PROTECTION OF THE PROCESSED PRODUCT;*
- *PROTECTION OF THE ENVIRONMENT.*

The **protection of the operator** *from dangerous product contamination is granted by the total absence of direct contact with the product during the different phases of the process. Thanks to the use of large viewing panels equipped with glove ports or half suits, the operator can carry out a series of activities such as container opening, sacking, weighing and dispensing, as well as milling and sampling without coming in direct contact with the treated substance.*

The **protection of the product** *from external polluting substances is granted by an absolute filtration system (Hepa type) placed on the suction. This device allows the product to enter into contact with the external air only after a suitable filtration that grants the absolute control of the aero-pollutants.*

Isolatore con dispositivo di carico/scarico materia prima a "liner continuo"
Glove Box with charging/discharging device of raw material to "continuos liner"

Isolatore con riciclo di gas inerte ad alto contenimento
Glove Box with high containment inert gas recycle

The **protection of the environment** *is granted by another absolute filtration system (Hepa type) placed on the air release. This device allows the expulsion of the inner air only after treatment in order to protect both environment and operator.*

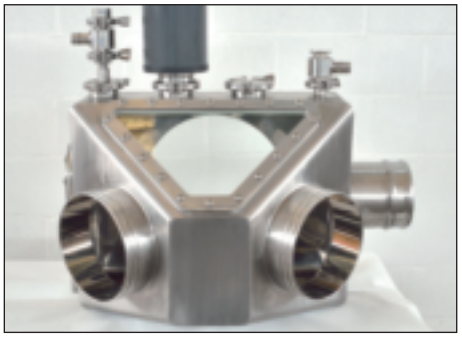
For particular applications the Glove Boxes can be equipped with pre-chamber, this can be equipped with absolute filtration system too, at the inner of which a different pressure level (positive or negative depending on the project) acts like a barrier between environment and the internal contaminated area.

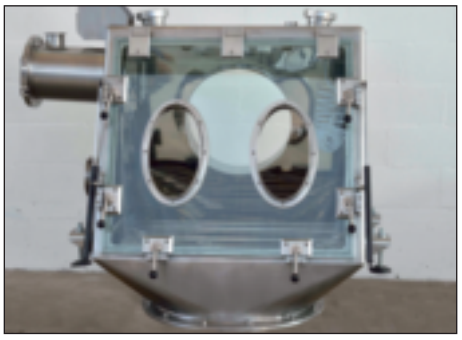
The high finishing degree (inner Ra<0,4 micron) avoids the heap of treated substances while the control of the air flows minimise the contact of product with the internal surface of the Glove Boxes; all this in order to facilitate the cleaning operations at product change. Possible deposits can be easily removed by an internal washing system and the contaminated liquid is conveyed into a draining bottom allowing to reclaim it for the subsequent waste processing.

Some models have been properly designed for the treatment of potential explosive substances according to the 94/9/EC "ATEX" directive and are supplied with relevant conformity declaration.

All the constructions are carefully studied in detail and can be manufactured to meet with Customer specific needs.

Isolatore per unità di micronizzazione pilota
Glove Box with pilot scale micronization unit





Stazione per lo svuotamento fusti mediante sonda di aspirazione
Drum emptying Glove Box by suction probe

APPLICAZIONI

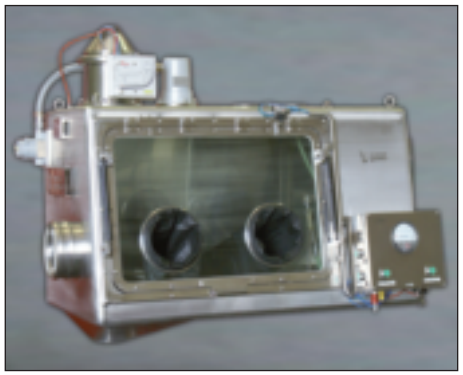
Numerosi sono i processi per i quali l'applicazione delle Glove Boxes può rendersi necessaria:

- CARICO DI REATTORI
- CARICO DI ESSICCATORI ANCHE ROTANTI
- SCARICO DI CENTRIFUGHE AUTOMATICHE
- CARICO / SCARICO FILTRI ESSICATORI
- CONFEZIONAMENTO
- PESATA E DISPENSA
- MACINAZIONE / MICRONIZZAZIONE

APPLICATIONS

There are many processes for which the application of the glove box may be necessary:

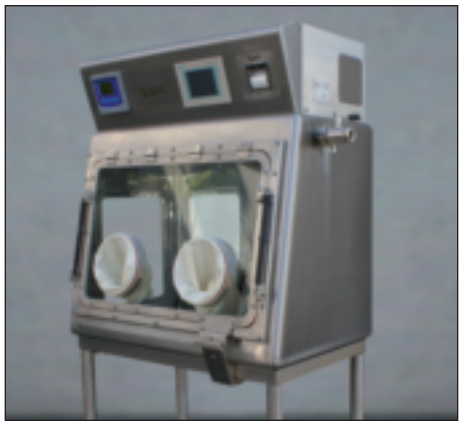
- *REACTOR CHARGING*
- *DRYER CHARGING, ALSO FOR ROTATING TYPE*
- *AUTOMATIC CENTRIFUGE DISCHARGE*
- *FILTER DRYER CHARGING / DISCHARGING*
- *SACKING*
- *WEIGHING AND DISPENSING*
- *MILLING / MICRONIZING*



Isolatore per il carico di additivi pericolosi
Charging glove box for dangerous additive

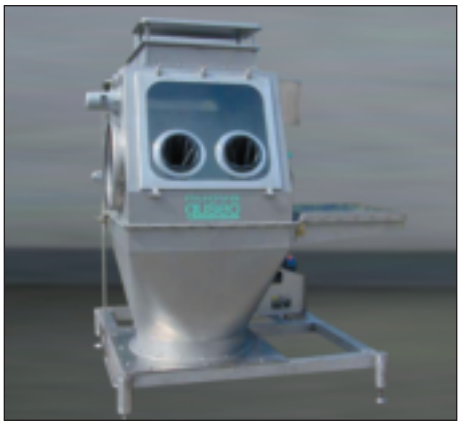
Interno isolatore di carico additivi con rulliera e griglia
Internal detail of charging glove box with roller conveyor and grill

Dettaglio di porta interna a tenuta ermetica
Detail of hermetical internal door

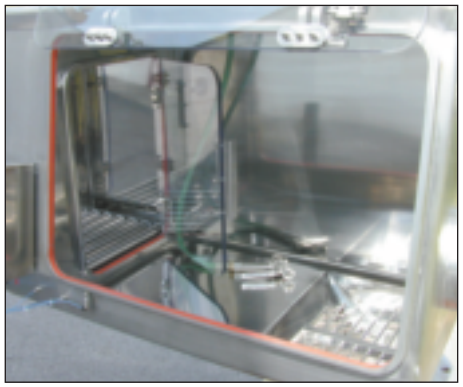


Isolatore per attività di laboratorio in atmosfera inerte
Glove box for laboratory activities in inert atmosphere

Isolatore statico per lo scarico da filtro essiccatore
Static glove box for filter dryer discharge



Isolatore per carico di carboni attivi
Charging glove box for activated carbon



Particolare: finitura, pistola per il cleaning
Finishing degree detail, spray gun for cleaning operation

Esempio di sinottico su touch panel
Example of synoptic display on touch panel

Isolatore per il carico reattore da laboratorio
Laboratory reactor charging glove box

Nuova Guseo è in grado di fornire una vasta gamma di altre apparecchiature per la macinazione fine ed ultrafine, mescolatori orizzontali e verticali, dispositivi di alimentazione-dosaggio, classificazione, filtrazione, trasporto e trattamento in genere di solidi. A richiesta sono disponibili cataloghi specifici.
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en-sure monitoring

Annex 3: New reactors

DATI DI PROGETTO – DESIGN DATA				RECIPIENTE VESSEL	CAMICIA JACKET
ENTE NOTIFICATO	NOTIFIED BODY	–	–	TUV 0948	
CODICE DI CALCOLO	DESIGN CODE	–	–	EN 13445	
TABELLA ART.3 PAR.1 – APPENDIX II PED	TABLE ART.3 PAR.1 – APPENDIX II PED	–	–	1	2
CATEGORIA (D.E. 2014/68/UE)	CATEGORY (D.E. 2014/68/UE)	–	–	IV	II
VALUTAZIONE DI CONFORMITA' PED	PED CONFORMITY ASSESSMENT	–	–	MODULO G	
VALUTAZIONE DI CONFORMITA' ATEX	ATEX CONFORMITY ASSESSMENT	–	–	II 2G/D T4	
MAX. PRESSIONE AMMISSIBILE	MAX ALLOWABLE PRESSURE	PS	Bar g	6 / −1	12 / −1
PRESSIONE DI ESERCIZIO	OPERATING PRESSURE	PO	Bar g	0.49 / −1	–
PRESSIONE DI PROVA IDRAULICA PRIMA DELLA SMALTATURA	HYDRAULIC PRESSURE TEST BEFORE GLASSING	PT	Bar g	12.4	16.3
PRESSIONE DI PROVA IDRAULICA DOPO SMALTATURA	HYDRAULIC PRESSURE TEST AFTER GLASSING	PT	Bar g	7.7	16.3
TEMPERATURA AMMISSIBILE MIN/MAX	MIN/MAX ALLOWABLE TEMPERATUR	TS	°C	−25/+200	−25/+200
TEMPERATURA DI ESERCIZIO	OPERATING TEMPERATURE	TO	°C	–	–
SOVRASPESSORE DI CORROSIONE	CORROSION ALLOWANCE	–	mm	0	1 (DOVE INC.)
OVALIZZAZIONE MAX FASCIAME/FONDI	MAX. OUT OF ROUNDNESS SHELL/HEADS	–	%	≤1	≤1
CARICHI CICLICI	CYCLIC LOADING	–	–	≤ 500	
FLUIDO – TIPO	FLUID – NATURE	–	–	COMPOSTI ORGANICI	
FLUIDO – STATO FISICO	FLUID – PHISICAL STATE	–	–	LIQ.+VAP.	LIQ.+VAP.
FLUIDO – PESO SPECIFICO	FLUID – SP. GRAVITY	–	kg/dm³	~1.5	~1
FLUIDO – GRUPPO (D.E. 2014/68/UE Art.13)	FLUID – GROUP (D.E. 2014/68/UE Art.13)	–	–	1	2
CAPACITA' TOTALE	TOTAL CAPACITY	–	l	1485	63
SUPERFICIE DI SCAMBIO	HEAT TRANSFER SURFACE	–	m²	–	4.9
PESO TOTALE VUOTO	EMPTY WEIGHT	–	kg	1850	
PESO PIENO D'ACQUA	WEIGHT FULL OF WATER	–	kg	3398	
No. DI FABBRICA	SERIAL No.	–	–	50220	
ANNO DI COSTRUZIONE	YEAR OF CONSTRUCTION	–	–	2017	
COLLAUDO	INSPECTION BODY	–	–	D.E.2014/68/UE PED	
ISPEZIONE	TEST BY	–	–	CLIENTE–CUSTOMER	
FINITURA SUPERFICI ESTERNE	PAINTING OF EXTERNAL SURFACES	–	–	SABB. Sa 2 1/5 + 2 MANI DI VERNICE EPOSSIDICA Sp. 80+80 µ COLORE DA DEFINIRE	①

NOTE

1) TUTTE LE DIMENSIONI SONO IN mm. SALVO DIVERSA INDICAZIONE.
2) LE FLANGE FISSE AVRANNO FORATURA SFALSATA RISPETTO AGLI ASSI PRINCIPALI.
3) TOLLERANZE DI FABBRICAZIONE SECONDO DIN 28006 FG. 2.
4) PRESCRIZIONI SUI MATERIALI:
ISPESL RACC. M – AD MERKBLAETTER (W1–W4–W7–W13)
5) GLI SPESSORI INDICATI PER LE PARTI FORMATE SONO I MINIMI DOPO FORMATURA/LAVORAZIONE.
6) PARTI FORMATE A FREDDO CON CERTIFICATI DI NORMALIZZAZIONE.
7) RAGGIO MINIMO DI SBOCCHELLATURA : 50 mm.
8) TUTTE LE PARTI VETRIFICATE SONO NORMALIZZATE PIU' VOLTE DURANTE IL CICLO DI SMALTATURA.
9) TUTTE LE SUPERFICI INTERNE DELLA CALDAIA COMPRESE LE SEDI DELLE GUARNIZIONI E COPERCHI SONO VETRIFICATE CON GK15–W (BIANCO) TUTTI GLI ACCESSORI SONO VETRIFICATI CON GK15–B (BLU)
10) CONTROLLO VETRIFICAZIONE:
–COLLAUDO DIELETTRICO SEC. ISO 2746: 20000 V DOPO VETRIFICAZIONE E 12000 V PRIMA DELLA SPEDIZIONE.
–CONTROLLO QUALITA' SEC. DIN EN ISO 28721–1.
–CONTROLLO STATIFLUX.
11) No. MAX DI RIPARAZIONI CON VITE M 5 IN TANTALIO: SENZA PORI
12) DOPO LA SMALTATURA NON DOVRA' ESSERE ESEGUITA NESSUNA SALDATURA SULLA CALDAIA.
13) I MORSETTI E LA BULLONERIA SARANNO ZINCATI E PASSIVATI.
14) NUMERO E TIPO DEI MORSETTI SARANNO INDICATI SULLA TARGA.
16) DIMENSIONI DELLE FLANGE LIBERE IN ACCORDO ALLA NORMA DIN 28150, RATING (p/T) PN 10 SECONDO EN 1092–1.
RATING (p/T) DELLE ALTRE FLANGE SEC. EN 1092–1)

NOTES

1) UNLESS OTHERWISE INDICATED ALL DIMENSIONS ARE IN mm.
2) FIXED FLANGE DRILLING TO BE STRADDLE MAIN AXIS.
3) CONSTRUCTION TOLERANCES ACCORDING TO DIN 28005 SHEET 2.
4) PRESCRIPTION ON MATERIALS:
ISPESL RACC. M – AD MERKBLAETTER (W1–W4–W7–W13)
5) THE THICKNESS INDICATED ARE MINIMUM AFTER FORMING.
6) PARTS COLD FORMED WITH NORMALIZED CERTIFICATE
7) MINIMUM RADIUS OF SWAGING: 50 mm.
8) ALL GLASS–LINED PARTS ARE NORMALISED SEVERAL TIMES DURING LINING.
9) ALL INTERNAL VESSEL SURFACES, INCLUDING GASKETS SEATS, AND COVERS ARE GLASSLINED WITH GK 15–W (BIANCO) ALL THE ACCESSORIS ARE GLASSLINED WITH GK15–B (BLUE)
10) GLASS–LINING TEST:
–SPARK TEST ACC. TO ISO 2746: 20000 V AFTER LINING AND 12000 V BEFORE SHIPMENT.
–QUALITY CONTROLL ACC. TO DIN EN ISO 28721–1
–STATIFLUX TEST.
11) MAXIMUM NUMBER OF REPAIRING M5 TANTALUM PLUGS:PLUGS FREE
12) DO NOT WELD AFTER GLASS–LINING NEAR GLASS–LINED WALLS.
13) THE CLAMPS ARE GALVANIZED AND PASSIVATED.
14) NUMBER AND TYPE OF CLAMPS TO BE INDICATE ON NAME PLATE.
16) DIMENTION OF SPLIT FLANGE ACC. TO DIN 28150. RATING (p/T) PN 10 ACC. TO EN 1092–1
RATING (p/T) OF OTHER FLANGE ACC. TO EN 1092–1)

GlassKem s.r.l. Torre di Mosto (VE) Italy — GK_ATX–01 x II 2 GD IIB T120 — 0948

ITEM	–	DESIGN CODE	VSR
SERIAL N°	50037–F	YEAR	2017
PED CATEGORY	IV	TESTING DATE	
FLUID GROUP	VESSEL 1 / JACKET 1	WEIGHT kg	1850
		VESSEL	JACKET
MIN/MAX ALLOWABLE PRESS.	PS/Bar g	−1/+6	−1/+12
MIN/MAX ALLOWABLE TEMP.	TS/C°	−25/+200	−25/+200
TEST PRESSURE	PT/Bar g	7.7	16.3
TOTAL CAPACITY	V/l	1485	63
CLAMPS MAIN FLANGE	Q.TY	–	TYPE –
CLAMPS MANHOLE	Q.TY	–	TYPE –

POS. ITEM	BETRIEB SERVIZIO	N° PZ. QUANT.	DN ND	PN RATING	TIPO TYPE	A	B	C	D	E	F	G	H	L	M	N	P
N54	SPIA VISIVA LIGHT GLASS	1	80	10	① SEE DWG	84	–	–	–	–	–	–	–	–	–	–	–
N53	SPIA VISIVA LIGHT GLASS	1	80	10	① SEE DWG	84	–	–	–	–	–	–	–	–	–	–	–
N52	PASSAGGIO AGITATORE AGITATOR ENTRY	1	125	10	① SEE DWG	128	188	–	–	–	20	–	–	–	12	–	154
N51	SCARICO OUTLET	1	100	10	① SEE DWG	104	158	180	220	130	18	16	8	18	9.5	24	130
N12	SERVIZIO SEMITUBO HALF PIPE SERVICE	1	40	16	② EN 1092–01	49.5	88	110	150	48.3	2	18	4	18	3.68	–	–
N11	SERVIZIO SEMITUBO HALF PIPE SERVICE	1	40	16	② EN 1092–01	49.5	88	110	150	48.3	2	18	4	18	3.68	–	–
N10	SERVIZIO SERVICE	1	100	10	① SEE DWG	104	158	180	220	130	18	16	8	18	9.5	24	130
N9	SERVIZIO SERVICE	1	100	10	① SEE DWG	104	158	180	220	130	18	16	8	18	9.5	24	130
N7	FRANGIONDA BAFFLE	1	200	10	① SEE DWG	203	268	295	340	230	22	21	8	22	12	32	229
N6	SERVIZIO SERVICE	1	100	10	① SEE DWG	104	158	180	220	130	18	16	8	18	9.5	24	130
N5	SERVIZIO SERVICE	1	200	10	① SEE DWG	203	268	295	340	230	22	21	8	22	12	32	229
N3	SERVIZIO SERVICE	1	100	10	① SEE DWG	104	158	180	220	130	18	16	8	18	9.5	24	130
N2	SERVIZIO SERVICE	1	100	10	① SEE DWG	104	158	180	220	130	18	16	8	18	9.5	24	130
N1	PASSO D'UOMO MANHOLE	1	350x450	10	② SEE DWG	–	–	–	–	–	–	–	–	–	–	–	–

DISTINTA BOCCHELLI – NOZZLE TABLE

3.1 = CERTIFICATO DI FERRIERA 3.1 EN 10204. – WORKS CERTIFICATE 3.1 EN 10204. – WERKZEUGNIS 3.1 EN 10204.

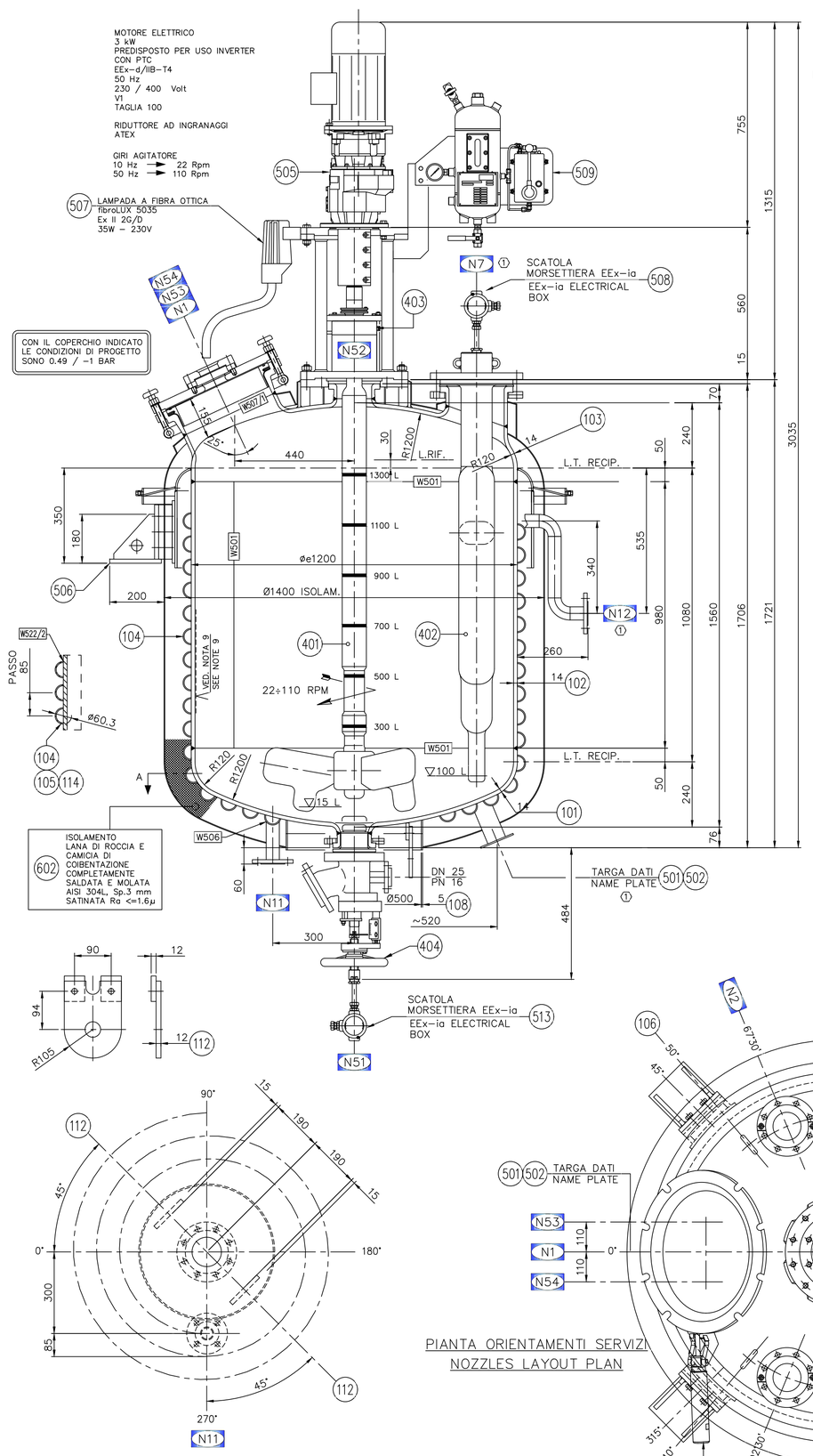
VEDERE DUCUMENTAZIONE SEPARATA PER PREPARAZIONE DEI LEMBI, WPS E WPAR
FOR WELDING AND TESTING ACTIVITY SEE WPS & WPAR

GRUPPO DEI MATERIALI–MATERIALS GROUP acc. to EN ISO 15608 : 1.1	EFFICIENZA DEI GIUNTI WELDED JOINTS EFFICIENCY : 0.85
GRUPPO DI CONTROLLO TESTING GROUP acc. to EN 13445–5 : 3b	ESTENSIONE DEL CONTROLLO NDT EXTENT OF NDT to EN 13445–5 Tab.6.6.2–1 : 10%
NORME DI RIFERIMENTO PER I CONTROLLI NDT REFERENCE NORM SEE EN 13445–5 Tab. 6.6.3–1	

TABELLA SALDATURE – WELDING TABLE

W501 | W522 | W506 | W506/2 | W507/1 | W507/2 | W521 | W523

PREPARAZIONE DEI LEMBI PER SALDATURA
BEVELS PREPARATION FOR WELDING



VISTA ELEVAZIONI BOCCHELLI
ELEVATION NOZZLES VIEW

N1	A	FLANGIONE P.d'U FLANGE	DN 350x450 SPEC.	1	P245GH EN 10222–2	3.1	
	B	CERNIERA PER GRUPPO APERTURA COPERCHIO HINGE		2	AISI 304L	–	CER–FLA–28145
	C	NERVATURE PER APERTURA RIB		8	P265GH EN 10028–2	–	
	D	GRUPPO COPERCHIO P.d'U COVER	DN 350x450	1	AISI 304L	3.1	
		N2–N3–N6–N9–N10					
o	A	BOCCHELLO NOZZLE	DN 100	5	P235GH TC1 EN 10216–2	3.1	BOC–AP–28139
	B	FLANGIA IN 2 META' SPLIT LOOSE FLANGE	DN 100 PN 10 – F	5	1.4404	3.1	FL2–10–28150
	C	GUARNIZIONE GASKET	DN 100	5	BUSTA PTFE CON INSERTO FIBRA ARAMIDICA	–	GUA–FD–28148
	D	ASTA FILETTATA STUD BOLT	M16x120	40	A2 70	3.1	
	E	DADO ESAGONALE NUT	M16 UNI 5587	40	A2 70	3.1	
N5 N7	A	BOCCHELLO NOZZLE	DN 200	2	P235GH TC1 EN 10216–2	3.1	BOC–AP–28139
	B	FLANGIA IN 2 META' SPLIT LOOSE FLANGE	DN 200 PN 10 – F	2	1.4404	3.1	FL2–10–28150
	C	GUARNIZIONE GASKET	DN 200	2	BUSTA PTFE CON INSERTO FIBRA ARAMIDICA	–	GUA–FD–28148
	D	ASTA FILETTATA STUD BOLT	M20x120	16	A2 70	3.1	
	E	DADO ESAGONALE NUT	M20 UNI 5587	16	A2 70	3.1	
N51	A	BOCCHELLO NOZZLE	DN 100	1	P235GH TC1 EN 10216–2	3.1	BOC–AP–28139
	B	FLANGIA IN 2 META' SPLIT LOOSE FLANGE	DN 100 PN 10 – F	1	S355JRG2 EN 10025	3.1	FL2–10–28150
	C	GUARNIZIONE GASKET	DN 100	1	BUSTA PTFE CON INSERTO FIBRA ARAMIDICA	–	GUA–FD–28148
	D	ASTA FILETTATA STUD BOLT	M16x110	8	A2 70	3.1	
	E	DADO ESAGONALE NUT	M16 UNI 5587	8	A2 70	3.1	
N52	A	BOCCHELLO NOZZLE	DN 125	1	P235GH TC1 EN 10216–2	3.1	BOC–AP–28139
	B	FLANGIA SOTTOLANTERNA FLANGE	SPECIALE TUTTI I FORI FILETTATI E 250	1	P235GH EN 10216–2	3.1	FLA–LAN–28137
	C	GUARNIZIONE GASKET	DN 125	1	BUSTA PTFE CON INSERTO FIBRA ARAMIDICA	–	GUA–FD–28148
	D	VITE TE SCREW	M20x65 UNI 5737	8	A2 70	3.1	
	E	RONDELLA WASHER	A21 UNI 1751	8	ACC. PER MOLLE	–	
N53	A	GUARNIZIONE GASKET	DN 80	2	BUSTA PTFE CON INSERTO FIBRA ARAMIDICA	3.1	GUA–FD–28148
	B	VETRO GLASS	Ø125x25	2	BOROSILICATO	3.1	DIN 7080
	C	GUARNIZIONE GASKET	DN 80	2	KLINGERSILL	3.1	GUA–VIS–28120
N54	D	COPERCHIO COVER	DN 80	2	AISI 304L	3.1	
	E	VITE TCI SCREW	M16x... UNI 5931	16	A2 70	3.1	
N11 N12 ①	A	FLANGIA PIANA FLANGE	DN 40 PN 16	2	P265GH EN 10028–2	3.1	SER–CAM–28151
	B	TRONCHETTO PIPE	ø48.3 x 3.68	2	P235GH TC1 EN 10216–2	3.1	
	C	DEFLETTORE PROTECTION PLATE		2	ACC. INOX	/	
①	D	CURVA 90° ELBOW	DN 40 L.R. SCH STD	2	P235GH TC1 EN 10216–2	3.1	
602		COIBENTAZIONE INSULATION		1	ISOLAMENTO LANA DI ROCCIA CAMICIA AISI 304L	/	
601		COPERTURA SUPERIORE COVER		1	AISI 304L	/	
516		FLANGIA CIECA BLIND FLANGE	DN 200	1	AISI 304L / PTFE	/	
515		FLANGIA DI RIDUZIONE REDUCTION FLANGE	DN 100/80	1	AISI 304L / PTFE	/	
514		FLANGIA CIECA BLIND FLANGE	DN 100	2	AISI 304L / PTFE	/	
513		SONDA DI TEMPERATURA TEMPERATURE PROBE	2xPt100 3+3	1	VEDI DIS./SEE DWG.	/	TPG–PT100–02
① 512		FLANGIA CON TRI–CLAMP TRI–CLAMP FLANGE	DN 100	2	AISI 316L	/	
511		PESCANTE CON SPRAY BALL DIP PIPE WITH SPRAY BALL	DN 100	2	PTFE	/	
① 510		ANELLO SOSTEGNO ISOLAMENTO SUPERIORE INSULATION RING		1	AISI 304L	/	
509		DISPOSITIVO DI PRESSURIZZAZIONE PRESSURE POT	J.CRANE	1	AISI 316L	3.1	
508		SONDA DI TEMPERATURA TEMPERATURE PROBE	2xPt100 3+3	1	VEDI DIS./SEE DWG.	/	TPG–PT100–01
507		LAMPADA DI ILLUMINAZIONE LAMP		1	VEDI DIS./SEE DWG.	/	MAX MULLER
506		MENSOLA DI SOSTEGNO SUPPORT BRACKET	SMONTABILE	4	RINFORZO P265GH EN 10028–2 MENSOLA S275JR EN 10025	/	
505		GRUPPO DI AGITAZIONE DRIVE ASSEMBLY	100 IMP	1	VEDI DIS./SEE DWG.	/	GA–060–00630–A
504		GRUPPO APERTURA COPERCHIO SPRING DEVICE		1	AISI 304L	/	
503		VIROLA DI SUPPORTO SHELL		1	P265GH EN 10028–2	/	
502		TARGA DATI NAME PLATE		1	AISI 304	/	TDE–AP–CE–ATEX
501		SUPPORTO TARGA NAME PLATE SUPPORT		1	AISI 304	/	
404		VALVOLA DI SCARICO OUTLET VALVE	DN 100/80 CON LAV.	1	VEDI DIS./SEE DWG.	/	
403		GRUPPO TENUTA MECCANICA MECHANICAL ASSEMBLY	ø60	1	VEDI DIS./SEE DWG.	/	
402		FRANGIONDA A SPADA BAFFLE	DN 200	1	P235GH TC1 EN 10216–2	/	
401		AGITATORE AGITATOR	KEM–LOCK d3=60	1	P235GH TC1 EN 10216–2	/	
202		FASCIAME CAMICIA JACKET SHELL		1	P275NH EN 10028–3	3.1	
201		FONDO CAMICIA JACKET HEAD		1	P265GH EN 10028–2	3.1	
114		CHIUSURA SEMITUBO COVER	TIPO 60	2	P265GH EN 10028–2	3.1	GK–AGT–10
113		MONCONE SUPERIORE DI SUPPORTO UPPER APRON		1	P265GH EN 10028–2	3.1	
112		GOLFARI DI MANOVRA LIFTING LUGS	SMONTABILI	2	P265GH EN 10028–2	3.1	
111		ANELLO ATTACCO COPERTURA RING	DN 350x450	1	AISI 304L	/	
110		ANELLO ATTACCO COPERTURA RING	DN 100	5	AISI 304L	/	
109		ANELLO ATTACCO COPERTURA RING	DN 200	2	AISI 304L	/	
108		ANELLO SOSTEGNO ISOLAMENTO INFERIORE INSULATION RING		1	AISI 304L	/	
107		NERVATURE PER FL. SOTTOLANTERNA RIB	80x93x10	8	P265GH EN 10028–2	3.1	
106		OCCHIOLO DI SOLLEVAMENTO LIFTING LUG	TIPO 18	3	AISI 304L	3.1	OCC–SOL–28145
105		SEMITUBO SUL FASCIAME HALF PIPE	Sp.4	1	P265GH EN 10028–2	3.1	
104		SEMITUBO SUL FONDO HALF PIPE	Ø60.3x3.91	1	P235GH TC1 EN 10216–2	3.1	
103		FONDO SUP. CALDAIA VESSEL TOP HEAD		1	P265GH EN 10028–2	3.1	
102		FASCIAME CALDAIA VESSEL SHELL		1	P275NH EN 10028–3	3.1	
101		FONDO INF. CALDAIA VESSEL BOTTOM HEAD		1	P265GH EN 10028–2	3.1	

POS. ITEM	DESCRIZIONE DESCRIPTION	Nr. PEZZI QUANTITY	MATERIALE MATERIALS	COLL. TEST	NOTE/DIS No. NOTES/DWG No.

REV.	DATA DATE	PREPARATO PREPARED BY	CONTROLLATO CONTROLLED BY	APPROVATO APPROVED BY	DESCRIZIONE DESCRIPTION
1	24–07–2017	L.C.	L.C.	L.C	MODIFICATO DOVE INDICATO
0	20–07–2017	L.C.	L.C.	L.C	PRIMA EMISSIONE

No. PEZZI QUANT.	1	CLIENTE CUSTOMER	STERLING CHEMICAL MALTA LTD
DESTINAZIONE LOCATION			BIRZEBBUGGIA MALTA
DATA DATE	20–07–2017	DIS. DRAWN	L.C.
CONTR. CHK. D	L.C.	TOLLERANZE GENERICHE SENZA INDICAZIONE SEC. ISO 2768–mK. [TUTTI QUI SPIGOLI DEVONO ESSERE ARROTONDATI CON R= 0.2]	SCALA SCALE 1:10

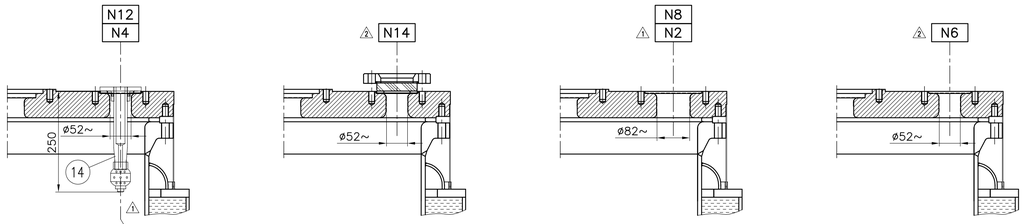
GlassKem s.r.l. Torre di Mosto (VE) Italy

TITOLO TITLE: REATTORE SMALTATO BE 1000 DIN 28136 CON COPERTURA FONDO SUPERIORE

PARTICOLARE PART: ASSIEME ASSEMBLY — FORMATO FORMAT A1

COMMESSA No. JOB No. 50220 — DISEGNO No. DRAWING Nr. R_BE_01000_003

REV. Ø 1



PESCANTE DN 50 PTFE/vetro [FDA]
con ugello di lavaggio
LECHLER modello 583.269.55.AL
materiale PTFE [FDA]

	bar	1	2	3	4
360°	L/min	103	145	178	205

NOTE

1) PRESCRIZIONI SUI MATERIALI:
ISPESL RACC. M – AD MERKBLAETTER W – VSM 53165
2) GLI SPESSORI INDICATI PER LE PARTI FORMATE SONO I MINIMI DOPO FORMATURA/LAVORAZIONE.
3) RAGGIO MINIMO DI SBOCCHELLATURA : 50 mm.
4) LE FLANGE FISSE AVRANNO FORATURA SFALSATA RISPETTO AGLI ASSI PRINCIPALI.
5)
6) LE PARTI FORMATE (FONDI, MONCONI) SARANNO FORMATE A CALDO O A FREDDO CON TRATTAMENTI TERMICI DOPO FORMATURA SEC. HP7/2
7) TUTTE LE PARTI VETRIFICATE SONO NORMALIZZATE Piu' VOLTE DURANTE IL CICLO DI SMALTATURA.
8) TUTTE LE SUPERFICI INTERNE DELLA CALDAIA COMPRESE LE SEDI DELLE GUARNIZIONI E COPERCHI SONO VETRIFICATE CON SMALTO **WWG 9125 BIANCO PER CALDAIA E AGITATORE.**
132 BIANCO PER COPERCHIO E APERTURA RAPIDA.
TUTTI GLI ALTRI ACCESSORI SONO VETRIFICATI CON SMALTO **DURAVIT 258 BLU.**
9) CONTROLLO VETRIFICAZIONE: SEC. UNI EN 15159–1
–COLLAUDO DIELETTRICO SEC. UNI EN 14430: 20000 V DOPO VETRIFICAZIONE E 12000 V PRIMA DELLA SPEDIZIONE.
–CONTROLLO STATIFLUX.
10) SMALTATURA SENZA DIFETTI SEC. UNI EN 15159–1.
11) TOLLERANZE DI FABBRICAZIONE SECONDO DIN 28006 FG. 2.
12) TUTTE LE DIMENSIONI SONO IN mm. SALVO DIVERSA INDICAZIONE.
13) DOPO LA SMALTATURA NON DOVRA' ESSERE ESEGUITA NESSUNA SALDATURA SULLA CALDAIA.
15) PUNZONARE IL N.F. SU TUTTE LE PARTI SMONTABILI.
16) L'UTENTE E' TENUTO A SEGUIRE LE PRESCRIZIONI CONTENUTE NEL MANUALE D'USO E MANUTENZIONE.
17) VALORE RIPORTATO SULLA TARGA PER PROVA IDRAULICA IN IMPIANTO PROVA NON ESEGUITA DAL COSTRUTTORE.
18) "STRESS CATEGORY" II SEC. AD–W10.
19) PARTI IN ACCIAIO INOX: SATINATURA Ra <= 1.6 µm
PARTI IN ACCIAIO AL. CARBONIO: 1 MANO DI VERNICE EPOSSIDICA ALL'ACQUA, CON PIGMENTAZIONE ANTICORROSIVA ATTIVA (FOSFATI DI ZINCO), ACQUAEPOX PRIMER DELLA ELCROM **COLORE RAL 5002 BLU, Spessore 80 µ.**

NOTES

1) PRESCRIPTION ON MATERIALS:
ISPESL RACC. M – AD MERKBLAETTER W – VSM 53165.
2) THE THICKNESS INDICATED ARE MINIMUM AFTER FORMING.
3) MINIMUM RADIUS OF SWAGING: 50 mm.
4) FIXED FLANGE DRILLING TO BE STRADDLE MAIN AXIS.
5)
6) SHAPED PARTS WILL BE HOT FORMED OR COLD FORMED AND NORMALISED AFTER FORMING ACCORDING TO HP7/2.
7) ALL GLASS–LINED PARTS ARE NORMALISED SEVERAL TIMES DURING LINING.
8) ALL INTERNAL VESSEL SURFACES, INCLUDING GASKETS SEATS, AND COVERS ARE GLASSLINED WITH **WWG 9125 WHITE FOR VESSEL AND AGITATOR.**
132 WHITE FOR COVER AND QUICK OPENING DEVICE.
ALL OTHER ACCESSORIES ARE GLASSLINED WITH **DURAVIT 258 BLUE.**
9) GLASS–LINING TEST: SEC. UNI EN 15159–1.
–SPARK TEST ACC. TO UNI EN 14430: 20000 V AFTER LINING AND 12000 V BEFORE SHIPMENT.
–STATIFLUX TEST.
10) FREE OF DEFECTS GLASSLINED ACCORDING TO UNI EN 15159–1.
11) CONSTRUCTION TOLERANCES ACCORDING TO DIN 28006 SHEET 2.
12) UNLESS OTHERWISE INDICATED ALL DIMENSIONS ARE IN mm.
13) DO NOT WELD AFTER GLASS–LINING NEAR GLASS–LINED WALLS.
15) STAMP SERIAL No. ON ALL DEMOUNTABLE PARTS.
16) THE USER HAS TO FOLLOW THE INSTRUCTIONS OF OPERATING MANUAL.
17) VALUE MARKED ON THE NAME–PLATE FOR HYDROTEST IN PLANT. HYDROTEST NOT CARRIED OUT BY MANUFACTURER.
18) "STRESS CATEGORY" II ACC. TO AD–W10.
19) STAINLESS STEEL PARTS: SATIN FINISH Ra <= 1.6 µm
CARBON STEEL PARTS: 1 COAT OF PAINT EPOXY PRIMER, WATER BASED, WITH ANTICORROSIVE PIGMENTS (ZINC PHOSPHATES), TYPE ACQUAEPOX ELCROM **COLOR RAL 5002 BLUE, 80 µ D.F.T.**

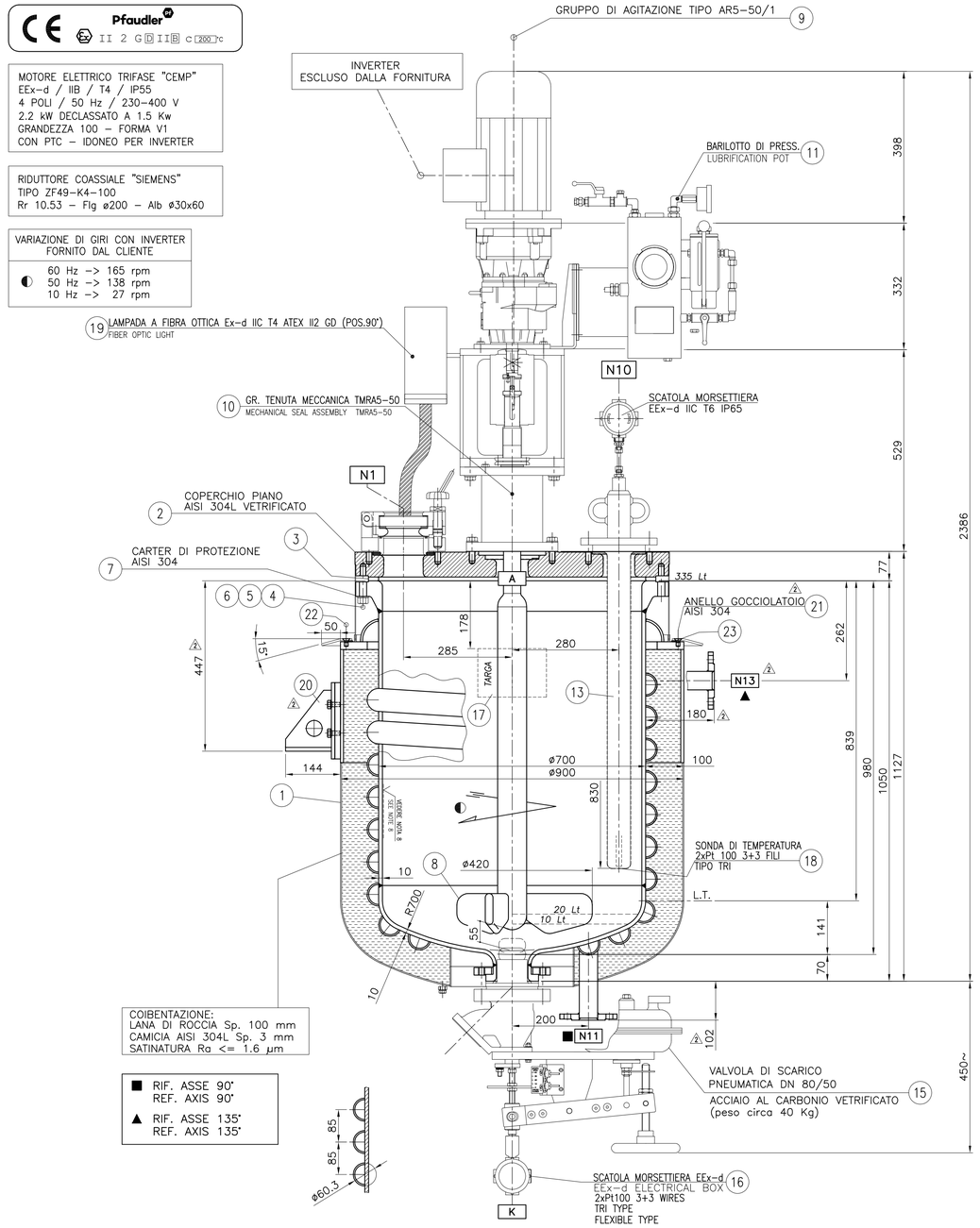
N1	1	COPERCHIO DI CARICO DN 100 PN 10 COVER		SA–240 304L	3.1	9–7–1821–02–02
	8	VITE T.C.E. M 16 x 40 UNI 5931 SCREW		A2/A4–70	W2–St	
N4 N12	2	GUARNIZIONE A BUSTA ENVELOPE GASKET	DN 50 forma D	PTFE/ASBESTOS FREE	FDA	RMS–040
N14	1	GUARNIZIONE A BUSTA ENVELOPE GASKET	DN 50 forma D	PTFE/ASBESTOS FREE	FDA	RMS–040
	1	VETRO SPIA SIGHT GLASS	ø100x20	VETRO BOROSILICATO	3.1	DIN 7080
	1	GUARNIZIONE PIANA FLAT GASKET	DN 50 speciale	KLINGERSIL 4400		ø 100, ø80, sp.3
	1	FLANGIA TENUTA VETRO FLANGE	DN 50 PN16	AISI 304	3.1	8–5–1559–02
	4	ASTA FILETTATA STUD BOLT	M16x85	A2/A4 70		
	4	DADO CIECO BLIND NUT	M16	A2/A4 70		DIN 1587
	4	RONDELLA PIANA WASHER	ø\ 17	AISI 304		UNI 6592
N10	1	GUARNIZIONE A BUSTA ENVELOPE GASKET	DN 80 forma D	PTFE/ASBESTOS FREE	FDA	RMS–040
	8	ASTA FILETTATA STUD BOLT	M16x80	A2/A4 70		
	8	DADO CIECO BLIND NUT	M16	A2/A4 70		DIN 1587
	8	RONDELLA PIANA WASHER	ø\ 17	AISI 304		UNI 6592
A	1	GUARNIZIONE A BUSTA ENVELOPE GASKET	DN 80 forma A	PTFE/ASBESTOS FREE	FDA	RMS–040
	8	VITE SCREW	T.E. M16x50	A2/A4 70		UNI 5739
	8	RONDELLA PIANA WASHER	ø\ 17	AISI 304		UNI 6592
K	1	BOCCHELLO NOZZLE	DN 80	P235GH TC1 EN 10216–2	3.1	044767–SC
	1	FLANGIA IN 2 META' SPLIT FLANGE	DN 80 "FORMA B"	S355J2G3 EN10025	W13–W10 3.1	RMS–020
	1	GUARNIZIONE GASKET	DN 80 "FORMA D"	PTFE/ASBESTOS FREE	––	RMS–040
	8	ASTA FIL. STUD BOLT	M 16 x 100	A2–A4/70	W2–St	
	8	DADO ESAG. NUT	M 16 UNI 5587	A2–A4/70	W2–St	
N11 N13	2	FLANGIA PIANA FLANGE	DN 40 PN 16	P250 GH EN 10222–2	W1–W10 3.1	EN 1092–1
	2	TRONCHETTO PIPE	ø 48.3 x 3.06	P235 GH TC1 EN 10216–2	W4–W10 3.1	
	2	DISCO DI CHIUSURA SEMITUBO COVER	Sp.4	P275 NH EN 10028–3	W1–W10 3.1	

CE Pfaudler II 2 G D IIB c 280 c

MOTORE ELETTRICO TRIFASE "CEMP"
EEx–d / IIB / T4 / IP55
4 POLI / 50 Hz / 230–400 V
2.2 kW DECLASSATO A 1.5 Kw
GRANDEZZA 100 – FORMA V1
CON PTC – IDONEO PER INVERTER

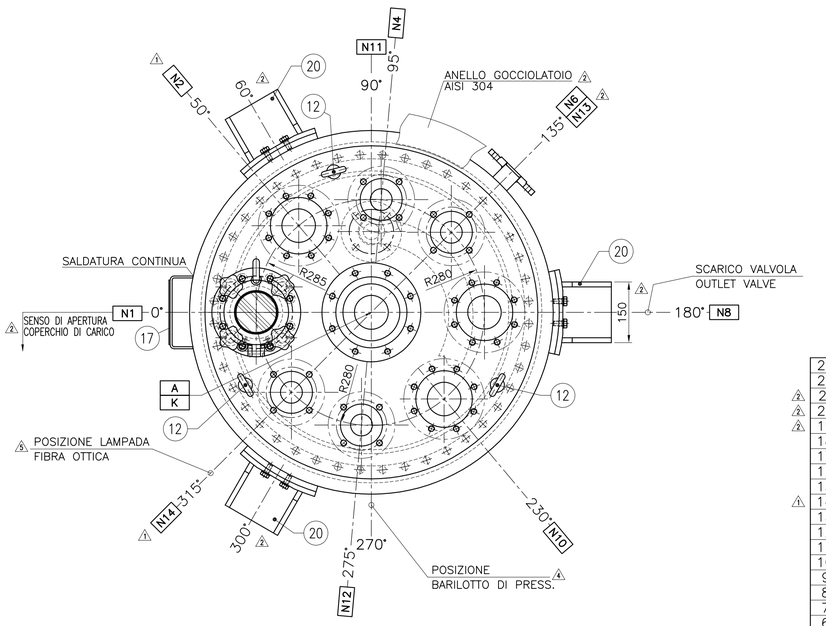
RIDUTTORE COASSIALE "SIEMENS"
TIPO ZF49–K4–100
Rr 10.53 – Flg ø200 – Alb ø30x60

VARIAZIONE DI GIRI CON INVERTER FORNITO DAL CLIENTE
◐ 60 Hz –> 165 rpm
50 Hz –> 138 rpm
10 Hz –> 27 rpm



COIBENTAZIONE:
LANA DI ROCCIA Sp. 100 mm
CAMICIA AISI 304L Sp. 3 mm
SATINATURA Ra <= 1.6 µm

■ RIF. ASSE 90°
REF. AXIS 90°
▲ RIF. ASSE 135°
REF. AXIS 135°



PIANTA ORIENTAMENTI – LAYOUT PLAN

23	1	GUARNIZIONE SEZIONE 12x4 GASKET		100%PTFE	––	
22	12	VITE T.C.E.I. UNI 5931 M10X16 SCREW		A2/A4–70	W2–St	
21	1	ANELLO GOCCIOLATOIO RING		AISI 304	––	8–7–1766–02
20	3	MENSOLA SUPPORT BRACKET		AISI 304	––	8–7–1764–02
19	1	LAMPADA FIBROLUX 5035 LUNGHEZZA FIBRA OTTICA 1m LAMP		ACC. INOX	––	MAX MULLER
18	1	SONDA DI TEMPERATURA TEMPERATURE PROBE		––	––	9–9–912–02
17	1	TARGA DATI PED NAME PLATE		AISI 304		TD.100.SO.LPD02
16	1	SONDA DI TEMPERATURA TEMPERATURE PROBE	TIPO C 2xPt100 3+3 Fili	––	––	9–912–07–B
15	1	VALVOLA DI SCARICO PNEUMATICA PNEUMATIC OUTLET VALVE	DN 80/50 tipo TS	ACC. AL CARBONIO VETRIFICATO		VPLP–B–U0–80
14	2	PESCANTE CON UGELLO DI LAVAGGIO DIP–PIPE WITH SPRAY–BALL	DN 50	PTFE/vetro – PTFE	FDA	9–8–1305–02
13	1	FRANGIONDA BAFFLE	DN 80 TIPO 4	ACC. AL CARBONIO VETRIFICATO		9–3–1070–03
12	3	GOLFARE DI SOLLEVAMENTO LIFTING LUG	M16	AISI 316		DIN 580
11	1	BARILOTTO DI PRESSURIZ. PRESSURIZATION TANK		–––		9–9–994–11
10	1	GRUPPO TENUTA MECCANICA MECHANICAL SEAL UNIT	J.CRANE	SCATOLA CARBON STEEL	FDA	.....
9	1	GRUPPO DI AGITAZIONE MIXING SYSTEM	tipo AR5–50/1	–––		8–8–1321–02–1–01
8	1	AGITATORE AGITATOR	IMPELLER 3–PALE	ACC. AL CARBONIO VETRIFICATO		9–0–1148–02–22
7	1	CARTER DI PROTEZIONE HOUSING		AISI 304		8–4–856–03–03
6	44	ROSETTA PIANA WASHER	ø\ 17	AISI 304		UNI 6592
5	44	DADO ESAGONALE NUT	M16	A2/A4 70		UNI 5587
4	44	ASTA FILETTATA STUD BOLT	M16x100	A2/A4 70		
3	1	GUARNIZIONE A BUSTA DI PTFE PTFE ENVELOPE GASKET	DN 700 POS. 7	PTFE/ASBESTOS FREE	FDA	RMS–041–SP
2	1	COPERCHIO COVER	DN 700	AISI 304L VETRIFICATO	3.1	AE–250–MT–42001029–B
1	1	CALDAIA COIBENTATA INSULATED JACKETED VESSEL		ACC. AL CARBONIO VETRIFICATO	W1–W10–W11 W13–3.1	AE–250–MT–42001029–A

POS. ITEM POS.	N. PEZZI QUANT. MENGE	DESCRIZIONE DENOMINATION BEZEICHNUNG	MATERIALE MATERIALS WERKSTOFF	COLLI TEST ABN. ZEUGN.	NOTE/DIS. No. NOTES/DRWG. Nr. BEMERKUNGEN

DATI DI PROGETTO DESIGN DATA BERECHNUNGSDATEN		RECIPIENTE VESSEL BEHAELTER	SEMITUBO HALF PIPE DOPP.MANT.
FLUIDO FLUID PRODUKT	GRUPPO–GROUP–GRUPPE (ACC. TO ART.13 "PED")	1	2
	STATO FISICO–PHISICAL STATE–PHYS.ZUSTAENDE	LIQUIDO+ VAPORE	LIQUIDO+ VAPORE
	PESO SPECIFICO–SP.GR.–SPEZIF.GEWICHT Kg/dm³	1.5	1.05
CAPACITA' TOTALE – TOTAL CAPACITY – GESAMTINHALT	[V] l	335	21
SUPERFICIE DI SCAMBIO – HEAT TRANSFER SURFACE – HEIZ/KUEHLFLAECHE	m²	1.7	
TABELLA – TABLE – DIAGRAM (ACC. TO ART.4 PAR.1/APPENDIX II "PED")		1	
CATEGORIA – CATEGORY – KATEGORIEN (ACC. TO APPENDIX II "PED")		IV	
MODULO – MODULE – MODUL (ACC. TO ART.14 PAR.2 "PED")		G	
No. DI FABBRICA – SERIAL No. FABRIK. Nr.	12579	ANNO DI COSTRUZIONE YEAR OF CONSTR. BAUJAHR	2016
ORGANISMO NOTIFICATO NOTIFIED BODY	TALLONI TEST COUPONS–PRUEFSTUECK ESAME RADIOGRAFICO RADIOGRAPHIC TEST–ROENTGEN QUALIFICA PROCEDIMENTO WELDING PROCESS QUALIF.–SCHWEISSVERFAHREN GEPRUEFT QUALIFICA SALDATORI WELDER QUALIFICATION–SCHWEISSER GEPRUEFT	PED/SGS	N° IDENTIFICAZIONE KENNZEICHNUMMER IDENT. NUMBER	1381
SABBIATURA DELLE SUPERFICI ESTERNE : SAND BLAST ON EXTERNAL SURFACES : SANDSTRAHLUNG DER AUSSENFLAECHE :		SA 2 1/2	
PITTURAZIONE DELLE SUPERFICI ESTERNE : PAINTING OF EXTERNAL SURFACES : ANSTRICH DER AUSSENFLAECHEN :		nota 19)	
ESTERNO SOLO DOVE INCAMICIATO ◐ EXTERNAL ONLY WHERE JACKET AUSSER NUR DUER DOPPELMANTEL ZONE		MISURATA ALLA "CHIAVE" IN VERTICALE ● MEASURED AT VERTICAL POSITION OBEN MIT STEHENDER BEHALTER GEMESSEN	

N13	1	40	16	VED.DIS. SEE DWG	SERVIZIO SEMITUBO–JACKET SERVICE DOPPELMANTEL STUTZEN		
N11	1	40	16	VED.DIS. SEE DWG	SERVIZIO SEMITUBO–JACKET SERVICE DOPPELMANTEL STUTZEN		
K	1	80	16	VED.DIS. SEE DWG	SCARICO OUTLET		
A	1	80	16	VED.DIS. SEE DWG	AGITATORE AGITATOR		
N14	1	50	16	VED.DIS. SEE DWG	CONTROSPIA–LIGHT GLASS SCHAUGLAS–LEUCHTE		
N12	1	50	16	VED.DIS. SEE DWG	PESCANTE CON UGELLO DI LAVAGGIO DIP–PIPE WITH SPRAY–BALL		
N10	1	80	16	VED.DIS. SEE DWG	FRANGIONDA–BAFFLE ENTRY STROEMGSTOERER		
N8	1	80	16	VED.DIS. SEE DWG	SERVIZIO–SERVICE BETRIEB		
N6	1	50	16	VED.DIS. SEE DWG	SERVIZIO–SERVICE BETRIEB		
N4	1	50	16	VED.DIS. SEE DWG	PESCANTE CON UGELLO DI LAVAGGIO DIP–PIPE WITH SPRAY–BALL		
N2	1	80	16	VED.DIS. SEE DWG	SERVIZIO–SERVICE BETRIEB		
N1	1	100	16	VED.DIS. SEE DWG	PASSO DI MANO – HANDHOLE HANDLOCH		
POS. ITEM POS.	N° PZ. QUANT. MENGE	DN ND NW	PN RATING ND	TIPO TYPE MOD.	SERVIZIO SERVICE BETRIEB		

SALDATURA–WELDING–SCHWEISSUNGEN			
PREPARAZIONE DEI LEMBI WPS E WPAR SECONDO MANUALE EDGE PREPARATION WPS AND WPAR ACCORDING TO WELDING–BOOK SCHWEISSKANTEN VORBEREITUNG WPS UND WPAR GEM. SCHWEISSBUCH N° WB–(EN 15614–1) TÜV.			
EFFICIENZA GIUNTI JOINT EFFICIENCY–SCHWEISSFAKTOR		0.85	
TALLONI TEST COUPONS–PRUEFSTUECK		NACH HP 5/2	
ESAME RADIOGRAFICO RADIOGRAPHIC TEST–ROENTGEN		NACH HP 5/3	
QUALIFICA PROCEDIMENTO WELDING PROCESS QUALIF.–SCHWEISSVERFAHREN GEPRUEFT	EN15614–1 / HP 2/1		
QUALIFICA SALDATORI WELDER QUALIFICATION–SCHWEISSER GEPRUEFT	EN ISO 9606–1 / HP3		

		Vessel	Jacket/Half-pipe
maximum allowable pressure	[PS] bar	–1/+6	–1/+6
min/max allowable temperature	[TS] °C	–25/+200	–25/+200
Hydrostatic test pressure	[PT] bar	12.3	8.8
Recurrent hydrostatic test pressure	bar	7.7	8.8
Volume	[V] L	335	21
Main opening clamps	N°.	.	Type .
Manhole/Handhole clamps	N°.	.	Type .

Pfaudler Pf
Pfaudler Srl
30027 – San Donà di Piave
Venezia – ITALY

CE
Item .
Serial N°. 12579 Year of manufacture 2016
Identification N°. 1381 PED Category IV Hy Test Date
Fluid Group 1 Empty Weights [kg] 1170

1	MODIFICATO SECONDO RICHIESTE CLIENTE AS BUILT ACCORDING TO CUSTOMER REQUIREMENTS	Emanuel C.	02/01/17			
0	EMESSO PER APPROVAZIONE ISSUED FOR APPROVAL EMISSION ZUR GENEHMIGUNG	Emanuel C.	30/12/16			
NR.	MODIFICA ANDERUNG	FIRMA GEZ.	DATE DATUM	NR.	MODIFICA ANDERUNG	FIRMA GEZ.
5	MODIFICATO SECONDO RICHIESTE CLIENTE POSIZIONE BARILOTTO A 270°	Emanuel C.	30/12/16			
4	MODIFICATO SECONDO RICHIESTE CLIENTE	Emanuel C.	30/11/16			
3	MODIFICATO TARGA DATI PED IN INGLESE	Emanuel C.	21/12/16			
2	MODIFICATO SECONDO RICHIESTE CLIENTE	Emanuel C.	29/11/16			
1	MODIFICATO SECONDO RICHIESTE CLIENTE	Emanuel C.	25/11/16			

Pfaudler Pf

TITOLO–TITLE–TITEL

REATTORE VETRIFICATO TIPO AE–250

GLASS–LINED REACTOR TYPE AE–250

ITEM .

ORDINE NR. P. ORDER Nr. AUFTRAG Nr. 957/A1

DESTINAZIONE LOCATION BESTIMMUNGSORT BIRZEBBUGIA (MALTA)

CLIENTE CUSTOMER KUNDE STERLING CHEMICAL MALTA LTD

SCALA 1 : SCALE MASSTAB 1:7.5

DIS. DRAWN. GEZ. CBIN E.
APPR. APP'D GESEHEN
DATA DATE DATUM 25/11/16

COMMESSA – JOB Nr. – KOMM. Nr. 42001029

Nr. PEZZI QUANT. STUECKZAHL 1

FORMATO A1

DISEGNO No. – DRAWING. Nr. – ZEICHNUNG Nr. AE–250–MT–42001029

CONTR. CHK. D. GEPRUEFT

CODICE – PART No. PKRAE00250PH023 REV. 5

PESI – WEIGHTS – GEWICHT

I PESI SONO COMPRENSIVI DI GRUPPO D'AGITAZIONE E ACCESSORI
THE WEIGHTS INCLUDE ALSO DRIVE ASSEMBLY AND ACCESSORIES
GEWICHT MIT ANTRIEB UND ZUBEHOR

TOTALE A VUOTO–EMPTY GESAMTGEWICHTLEER Kg~ 1170 ±5%

PIENO D'ACQUA–FULL OF WATER GEWICHT VOLL WASSER Kg~ 1526 ±5%

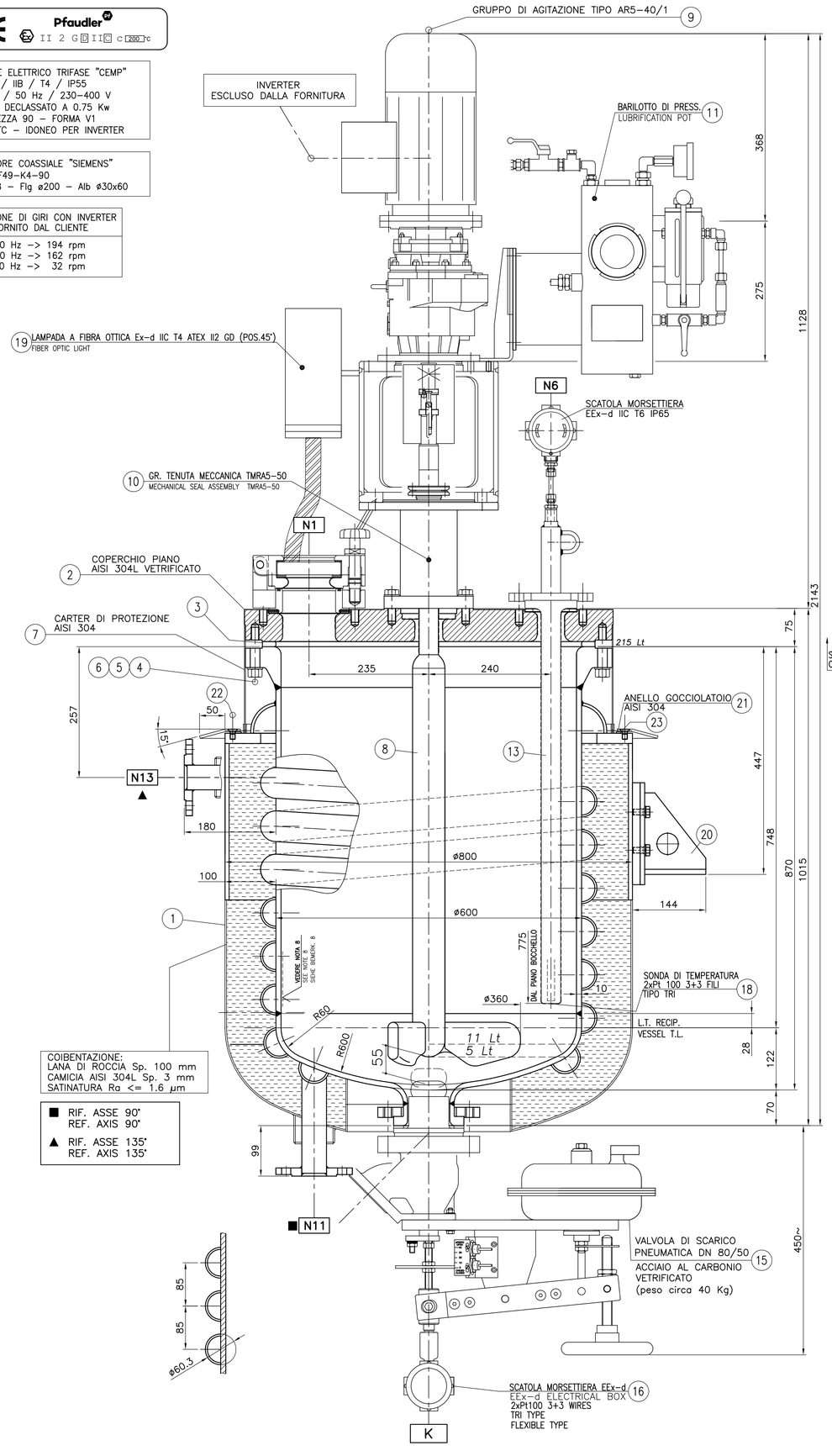
CE Pfaudler II 2 G D IIC c 200 °c

MOTORE ELETTRICO TRIFASE "CEMP"
EEx-d / IIB / T4 / IP55
4 POLI / 50 Hz / 230-400 V
1.1 kW DECLASSATO A 0.75 Kw
GRANDEZZA 90 – FORMA V1
CON PTC – IDONEO PER INVERTER

RIDUTTORE COASSIALE "SIEMENS"
TIPO ZF49-K4-90
Rr 8.88 – Flg ø200 – Alb ø30x60

VARIAZIONE DI GIRI CON INVERTER FORNITO DAL CLIENTE

60 Hz ->	194 rpm
◐ 50 Hz ->	162 rpm
10 Hz ->	32 rpm



COIBENTAZIONE:
LANA DI ROCCIA Sp. 100 mm
CAMICIA AISI 304L Sp. 3 mm
SATINATURA Ra <= 1.6 µm

■ RIF. ASSE 90°
REF. AXIS 90°

▲ RIF. ASSE 135°
REF. AXIS 135°

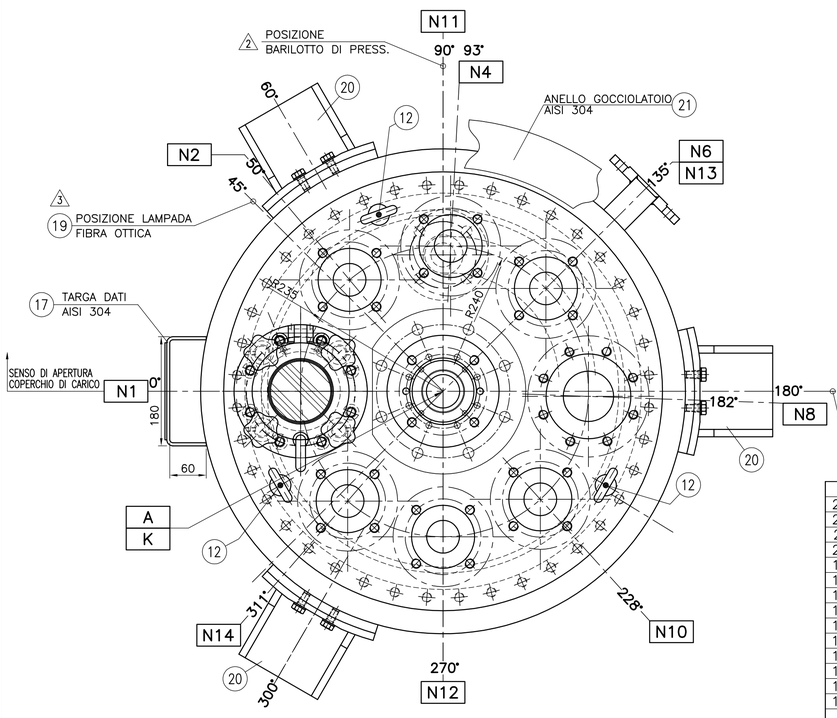
NR	DESCRIZIONE	DATA	FIRMA
1	MODIFICATO TARGA DATE IN INGLESE / PLATE DATE IN ENGLISH	30/12/16	CIBIN E.
0	EMESSO PER APPROVAZIONE / ISSUED FOR APPROVAL GENEHMIGUNGSZWECKEN	03/12/16	CIBIN E.
3	MODIFICATO SECONDO RICHIESTA DEL CLIENTE: FIBRA OTTICA a 45°	30/12/16	CIBIN E.
2	MODIFICATO SECONDO RICHIESTA DEL CLIENTE: FIBRA OTTICA a 90°	21/12/16	CIBIN E.
NR	MODIFICA / MODIFICATION / ABÄNDERUNG	DATA / DATE / DATUM	FIRMA / SIGN. / UNTERSCHRIFT

NOTE

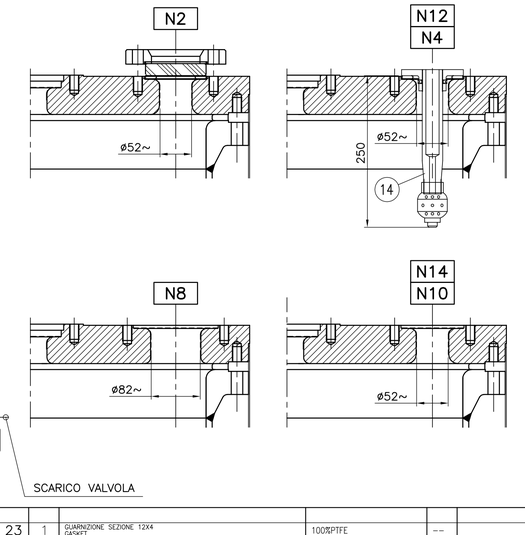
1) PRESCRIZIONI SUI MATERIALI:
ISPESL RACC. M – AD MERKBLAETTER W – VSM 53165
2) GLI SPESSORI INDICATI PER LE PARTI FORMATE SONO I MINIMI DOPO FORMATURA/LAVORAZIONE.
3) RAGGIO MINIMO DI SBOCCHELLATURA : 50 mm.
4) LE FLANGE FISSE AVRANNO FORATURA SFALSATA RISPETTO AGLI ASSI PRINCIPALI.
5)
6) LE PARTI FORMATE (FONDI, MONCONI) SARANNO FORMATE A CALDO O A FREDDO CON TRATTAMENTI TERMICI DOPO FORMATURA SEC. HP7/2
7) TUTTE LE PARTI VETRIFICATE SONO NORMALIZZATE PIU' VOLTE DURANTE IL CICLO DI SMALTATURA.
8) TUTTE LE SUPERFICI INTERNE DELLA CALDAIA COMPRESE LE SEDI DELLE GUARNIZIONI E COPERCHI SONO VETRIFICATE CON SMALTO **WWG 9125 BIANCO PER CALDAIA E AGITATORE.**
132 BIANCO PER COPERCHIO E APERTURA RAPIDA.
TUTTI GLI ALTRI ACCESSORI SONO VETRIFICATI CON SMALTO **DURAVIT 258 BLU.**
9) CONTROLLO VETRIFICAZIONE: SEC. UNI EN 15159–1
–COLLAUDO DIELETTRICO SEC. UNI EN 14430: 20000 V DOPO VETRIFICAZIONE E 12000 V PRIMA DELLA SPEDIZIONE.
–CONTROLLO STATIFLUX.
10) SMALTATURA SENZA DIFETTI SEC. UNI EN 15159–1.
11) TOLLERANZE DI FABBRICAZIONE SECONDO DIN 28006 FG. 2.
12) TUTTE LE DIMENSIONI SONO IN mm. SALVO DIVERSA INDICAZIONE.
13) DOPO LA SMALTATURA NON DOVRA' ESSERE ESEGUITA NESSUNA SALDATURA SULLA CALDAIA.
15) PUNZONARE IL N.F. SU TUTTE LE PARTI SMONTABILI.
16) L'UTENTE E' TENUTO A SEGUIRE LE PRESCRIZIONI CONTENUTE NEL MANUALE D'USO E MANUTENZIONE.
17) VALORE RIPORTATO SULLA TARGA PER PROVA IDRAULICA IN IMPIANTO PROVA NON ESEGUITA DAL COSTRUTTORE.
18) "STRESS CATEGORY" II SEC. AD–W10.
19) PARTI IN ACCIAIO INOX: SATINATURA Ra <= 1.6 µm
PARTI IN ACCIAIO AL CARBONIO: 1 MANO DI VERNICE EPOSSIDICA ALL'ACQUA, CON PIGMENTAZIONE ANTICORROSIVA ATTIVA (FOSFATI DI ZINCO), ACQUAEPOX PRIMER DELLA ELCROM **COLORE RAL 5002 BLU, Spessore 80 µ.**

NOTES

1) PRESCRIPTION ON MATERIALS:
ISPESL RACC. M – AD MERKBLAETTER W – VSM 53165.
2) THE THICKNESS INDICATED ARE MINIMUM AFTER FORMING.
3) MINIMUM RADIUS OF SWAGING: 50 mm.
4) FIXED FLANGE DRILLING TO BE STRADDLE MAIN AXIS.
5)
6) SHAPED PARTS WILL BE HOT FORMED OR COLD FORMED AND NORMALISED AFTER FORMING ACCORDING TO HP7/2.
7) ALL GLASS–LINED PARTS ARE NORMALISED SEVERAL TIMES DURING LINING.
8) ALL INTERNAL VESSEL SURFACES, INCLUDING GASKETS SEATS, AND COVERS ARE GLASSLINED WITH **WWG 9125 WHITE FOR VESSEL AND AGITATOR.**
132 WHITE FOR COVER AND QUICK OPENING DEVICE.
ALL OTHER ACCESSORIES ARE GLASSLINED WITH **DURAVIT 258 BLUE**
9) GLASS–LINING TEST: SEC. UNI EN 15159–1.
–SPARK TEST ACC. TO UNI EN 14430: 20000 V AFTER LINING AND 12000 V BEFORE SHIPMENT.
–STATIFLUX TEST.
10) FREE OF DEFECTS GLASSLINED ACCORDING TO UNI EN 15159–1.
11) CONSTRUCTION TOLERANCES ACCORDING TO DIN 28006 SHEET 2.
12) UNLESS OTHERWISE INDICATED ALL DIMENSIONS ARE IN mm.
13) DO NOT WELD AFTER GLASS–LINING NEAR GLASS–LINED WALLS.
15) STAMP SERIAL No. ON ALL DEMOUNTABLE PARTS.
16) THE USER HAS TO FOLLOW THE INSTRUCTIONS OF OPERATING MANUAL.
17) VALUE MARKED ON THE NAME–PLATE FOR HYDROTEST IN PLANT. HYDROTEST NOT CARRIED OUT BY MANUFACTURER.
18) "STRESS CATEGORY" II ACC. TO AD–W10.
19) STAINLESS STEEL PARTS: SATIN FINISH Ra <= 1.6 µm
CARBON STEEL PARTS: 1 COAT OF PAINT EPOXY PRIMER, WATER BASED, WITH ANTICORROSIVE PIGMENTS (ZINC PHOSPHATES), TYPE ACQUAEPOX ELCROM **COLOR RAL 5002 BLUE, 80 µ D.F.T.**



PIANTA ORIENTAMENTI – LAYOUT PLAN



N1	1	COPERCHIO DI CARICO DN 100 PN 10 / COVER		SA–240 304L	3.1	9–7–1821–02–02
	8	VITE T.C.E. M 16 x 40 UNI 5931 / SCREW		A2/A4–70	W2–S1	
N4 N12	2	GUARNIZIONE A BUSTA / ENVELOPE GASKET	DN 50 forma D	PTFE/ASBESTOS FREE	FDA	RMS–040
N2	1	GUARNIZIONE A BUSTA / ENVELOPE GASKET	DN 50 forma D	PTFE/ASBESTOS FREE	FDA	RMS–040
	1	VETRO SPIA / SIGHT GLASS	ø100x20	VETRO BOROSILICATO	3.1	DIN 7080
	1	GUARNIZIONE PIANA / FLAT GASKET	DN 50 speciale	KLINGERSIL 4400		ø¢ 100, ø80, sp.3
	1	FLANGIA TENUTA VETRO / FLANGE	DN 50 PN16	AISI 304	3.1	8–5–1559–02
	4	ASTA FILETTATA / STUD BOLT	M16x85	A2/A4 70		
	4	DADO CIECO / BLIND NUT	M16	A2/A4 70		DIN 1587
	4	RONDELLA PIANA / WASHER	ø¢ 17	AISI 304		UNI 6592
N6	1	GUARNIZIONE A BUSTA / ENVELOPE GASKET	DN 80 forma D	PTFE/ASBESTOS FREE	FDA	RMS–040
	4	ASTA FILETTATA / STUD BOLT	M16x80	A2/A4 70		
	8	DADO CIECO / BLIND NUT	M16	A2/A4 70		DIN 1587
	8	RONDELLA PIANA / WASHER	ø¢ 17	AISI 304		UNI 6592
A	1	GUARNIZIONE A BUSTA / ENVELOPE GASKET	DN 50 forma A	PTFE/ASBESTOS FREE	FDA	RMS–040
	8	VITE / SCREW	T.E. M16x50	A2/A4 70		UNI 5739
	8	RONDELLA PIANA / WASHER	ø¢ 17	AISI 304		UNI 6592
K	1	BOCCHELLO / NOZZLE	DN 80	P235GH TC1 EN 10216–2	3.1	044767–SC
	1	FLANGIA IN 2 META' / SPLIT FLANGE	DN 80 "FORMA B"	S355J2G3 EN10025	W13–W10 3.1	RMS–020
	1	GUARNIZIONE / GASKET	DN 80 "FORMA D"	PTFE/ASBESTOS FREE	——	RMS–040
	8	ASTA FIL. / STUD BOLT	M 16 x 100	A2–A4/70	W2–S1	
	8	DADO ESAG. / NUT	M 16 UNI 5587	A2–A4/70	W2–S1	
N11 N13	2	FLANGIA PIANA / FLANGE	DN 40 PN 16	P250 GH EN 10222–2	W1–W10 3.1	EN 1092–1
	2	TRONCHETTO / PIPE	ø 48.3 x 3.06	P235 GH TC1 EN 10216–2	W1–W10 3.1	
	2	DISCO DI CHIUSURA SEMITUBO / COVER	Sp.4	P275 NH EN 10028–3	W1–W10 3.1	
23	1	GUARNIZIONE SEZIONE 12X4 / GASKET		100%PTFE	––	
22	12	VITE T.C.E. UNI 5931 M10X16 / SCREW		A2/A4–70	W2–S1	
21	1	ANELLO GOCCIOLATOIO / RING		AISI 304	––	8–7–1767–02
20	3	MENSOLA / SUPPORT BRACKET		AISI 304	––	8–7–1765–02
19	1	LAMPADA FIBROLUX 5035 LUNGHEZZA FIBRA OTTICA 1m / LAMP		ACC. INOX	––	MAX MULLER
18	1	SONDA DI TEMPERATURA / TEMPERATURE PROBE		––	––	9–9–912–02
17	1	TARGA DATI PED / NAME PLATE		AISI 304		TD100S0IP002
16	1	SONDA DI TEMPERATURA / TEMPERATURE PROBE	TIPO C 2xPt100 3+3 Fili	––	––	9–912–07–8
15	1	VALVOLA DI SCARICO PNEUMATICA / PNEUMATIC OUTLET VALVE	DN 80/50 tipo TS	ACC. AL CARBONIO VETRIFICATO		VPLP–B–U0–80
14	2	PESCANTE CON UGELLO DI LAVAGGIO DIP–PIPE WITH SPRAY–BALL	DN 50 TIPO 4	PTFE/vetro – PTFE	FDA	9–8–1305–02
13	1	FRANGIONDA / BAFFLE	DN 50 TIPO 3	ACC. AL CARBONIO VETRIFICATO		9–3–1070–02
12	3	GOLFARE DI SOLLEVAMENTO / LIFTING LUG	M16	AISI 316		DIN 580
11	1	BARILOTTO DI PRESURIZ. / PRESSURIZATION TANK		–––		9–9–994–11
10	1	GRUPPO TENUTA MECCANICA / MECHANICAL SEAL UNIT	J.CRANE	SCATOLA CARBON STEEL	FDA	8–8–1260–02–08
9	1	GRUPPO DI AGITAZIONE / MIXING SYSTEM	tipo AR5–40/1	–––		8–8–1320–02–1–01
8	1	AGITATORE / AGITATOR	IMPELLER 3–PALE	ACC. AL CARBONIO VETRIFICATO		9–0–1214–02–25
7	1	CARTER DI PROTEZIONE / HOUSING		AISI 304		8–4–856–03–04
6	40	ROSETTA PIANA / WASHER	ø¢ 17	AISI 304		UNI 6592
5	40	DADO ESAGONALE / NUT	M16	A2/A4 70		UNI 5587
4	40	ASTA FILETTATA / STUD BOLT	M16x100	A2/A4 70		
3	1	GUARNIZIONE A BUSTA DI PTFE / PTFE ENVELOPE GASKET	DN 600 POS. 8	PTFE/ASBESTOS FREE	FDA	RMS–041–SP
2	1	COPERCHIO / COVER	DN 600	AISI 304L VETRIFICATO	3.1	AE–160–MT–42001029–B
1	1	CALDAIA COIBENTATA / INSULATED JACKETED VESSEL		ACC. AL CARBONIO VETRIFICATO	W1–W10–W11 HP7/1–2/1	AE–160–MT–42001029–A

POS. ITEM POS.	N. PEZZI QUANT. MENGE	DESCRIZIONE DENOMINATION BEZEICHNUNG	MATERIALE MATERIALS WERKSTOFF	COLL. TEST ABN. ZEUGN.	NOTE/DIS. No. NOTES/DRWG. Nr. BEMERKUNGEN

SALDATURA–WELDING–SCHWEISSUNGEN

PREPARAZIONE DEI LEMBI WPS E WPAR SECONDO MANUALE
EDGE PREPARATION WPS AND WPAR ACCORDING TO WELDING–BOOK
SCHWEISSKANTEN VORBEREITUNG WPS UND WPAR GEM. SCHWEISSBUCH
N° WB–(EN 15614–1) TÜV.

EFFICIENZA GIUNTI / JOINT EFFICENCY–SCHWEISSFAKTOR	0.85
TALLONI / TEST COUPONS–PRUEFSTUECK	NACH HP 5/2
ESAME RADIOGRAFICO / RADIOGRAPHIC TEST–ROENTGEN	NACH HP 5/3
QUALIFICA PROCEDIMENTO / WELDING PROCESS QUALIF.–SCHWEISSVERFAHREN GEPRUEFT	EN15614–1 / HP 2/1
QUALIFICA SALDATORI / WELDER QUALIFICATION–SCHWEISSER GEPRUEFT	EN ISO 9606–1 / HP3

POS. ITEM POS.	N° PZ. QUANT. MENGE	DN ND NW	PN RATING ND	TIPO TYPE MOD.	SERVIZIO SERVICE BETRIEB
N13	1	40	16	VED.DIS. SEE DWG	SERVIZIO SEMITUBO–JACKET SERVICE DOPPELMANTEL STUTZEN
N11	1	40	16	VED.DIS. SEE DWG	SERVIZIO SEMITUBO–JACKET SERVICE DOPPELMANTEL STUTZEN
K	1	80	16	VED.DIS. SEE DWG	SCARICO / OUTLET
A	1	50	16	VED.DIS. SEE DWG	AGITATORE / AGITATOR
N14	1	50	16	VED.DIS. SEE DWG	SERVIZIO–SERVICE BETRIEB
N12	1	50	16	VED.DIS. SEE DWG	PESCANTE CON UGELLO DI LAVAGGIO DIP–PIPE WITH SPRAY–BALL
N10	1	50	16	VED.DIS. SEE DWG	SERVIZIO–SERVICE BETRIEB
N8	1	80	16	VED.DIS. SEE DWG	SERVIZIO–SERVICE BETRIEB
N6	1	50	16	VED.DIS. SEE DWG	FRANGIONDA–BAFFLE ENTRY STROEMSTOERER
N4	1	50	16	VED.DIS. SEE DWG	PESCANTE CON UGELLO DI LAVAGGIO DIP–PIPE WITH SPRAY–BALL
N2	1	50	16	VED.DIS. SEE DWG	CONTROSPIA–LIGHT GLASS SCHAUGLAS–LEUCHTE
N1	1	100	16	VED.DIS. SEE DWG	PASSO DI MANO – HANDHOLE HANDLOCH

DATI DI PROGETTO DESIGN DATA BERECHNUNGSDATEN	RECIPIENTE VESSEL BEHAELTER	SEMITUBO HALF PIPE DOPP.MANT.
GRUPPO–GROUP–GRUPPE (ACC. TO ART.13 "PED")	1	2
STATO FISICO–PHISICAL STATE–PHYS.BESCHAFFENHEIT	LIQUIDO+ VAPORE	LIQUIDO+ VAPORE
PESO SPECIFICO–SP.GR.–SPEZIF.GEWICHT Kg/dm³	1.5	1.05
CAPACITA' TOTALE – TOTAL CAPACITY – GESAMTINHALT [V]l	215	16
SUPERFICIE DI SCAMBIO – HEAT TRANSFER SURFACE – HEIZ/KUEHLFLAECHE m²	1.2	
TABELLA – TABLE – DIAGRAM (ACC. TO ART.4 PAR.1/APPENDIX II "PED")	1	
CATEGORIA – CATEGORY – KATEGORIEN (ACC. TO APPENDIX II "PED")	IV	
MODULO – MODULE – MODUL (ACC. TO ART.4 PAR.2 "PED")	G	
No. DI FABBRICA – SERIAL No. FABRIK. Nr.	12580	
ORGANISMO NOTIFICATO / NOTIFIED BODY	PED/SGS	
ANNO DI COSTRUZIONE / YEAR OF CONSTR. BAUJAHR	2016	
N° IDENTIFICAZIONE / IDENT. NUMBER KENNUMMER	1381	

DATI DI PROGETTO DESIGN DATA BERECHNUNGSDATEN	RECIPIENTE VESSEL BEHAELTER	SEMITUBO HALF PIPE DOPP.MANT.
CODICE DI CALCOLO – DESIGN CODE – BERECHNUNGSNORM		AD 2000
MAX. PRESSIONE AMMISSIBILE – MAX ALLOWABLE PRESSURE – MAX ZUL. DRUCK [PS]bar	–1/+6	–1/+6
PRESS. DI PROVA / HYDROSTATIC TEST PRESSURE PRUEFUEBERDRUCK – PRIMA DELLA SMALTATURA / BEFORE GLASSING [PT]bar	12.3	––
PRESS. DI PROVA / HYDROSTATIC TEST PRESSURE PRUEFUEBERDRUCK – DOPO SMALTATURA / AFTER GLASSING NACH EMAILLIERUNG [PT]bar	7.7 [17]	8.8
TEMPERATURA DI PROGETTO – DESIGN TEMPERATURE–MIN MAX ZUL. TEMPERATUR [TS]°C	–25/+200	–25/+200
SOVRAPRESSORE DI CORROSIONE – CORROSION ALLOWANCE – KORROSIONSZUSCHLAG mm	1	1 INT.
DURATA PROVA – CICLI / VARIAZIONE DI PRESSIONE LIFE FORESEEING – CYCLES / PRESSURE RANGE VORAUSSICHTLICHE LEBENSDAUER – BETRIEBSZYKLEN/DRUCKSCHWANKUNGSBREITE	20000 CYCLES	20000 CYCLES DELTA 7 BAR
DIVALUTAZIONE MAX FASCIAME./FONDI MAX. OUT OF ROUND SHELL/HEADS MAX. UNRUNDHEIT MANTEL/BODEN %	1/1	1/1

RENDIMENTO SALDATURE / WELDING EFFICIENCY SCHWEISSFAKTOR	1
TRATTAMENTO TERMICO / HEAT TREATMENT WAERMEBEHANDLUNG	NO
RADIOGRAFIA / RADIOGRAPHIC TEST ROENTGEN	NO
PROVA IDRAULICA / HYDROSTATIC TEST PRUEFUNG	SI

PESI – WEIGHTS – GEWICHT
I PESI SONO COMPRENSIVI DI GRUPPO D'AGITAZIONE E ACCESSORI
THE WEIGHTS INCLUDE ALSO DRIVE ASSEMBLY AND ACCESSORIES
GEWICHT MIT ANTRIEB UND ZUBEHOR

SABBIATURA DELLE SUPERFICI ESTERNE / SAND BLAST ON EXTERNAL SURFACES / SANDSTRAHLUNG DER AUSSENFLAECHE	SA 2 1/2	
PITturazione DELLE SUPERFICI ESTERNE / PAINTING OF EXTERNAL SURFACES / BESTRICH DER AUSSENFLAECHEN	nota 19)	
ESTERNO SOLO DOVE INCAMICIATO / ONLY EXTERNAL OF SHELL AT JACKET / AUSSER NUR FUER DOPPELMANTEL ZONE	MISURATA ALLA SCIANATA IN VERTICALE / AT THE TOP IN VERTICAL POSITION / OBEN MIT STEHENDER BEHAELTER GEMESSEN	
TOTALE A VUOTO–EMPTY / GESAMTGEWICHTLEER	Kg~ 968	±5%
PIENO D'ACQUA–FULL OF WATER / GEWICHT VOLL WASSER	Kg~ 1199	±5%

Pfaudler Srl
30027 - San Donà di Piave
Venezia - ITALY

Item	.		
Serial N°.	12580	Year of manufacture	2016
Identification N°. 1381	PED Category	IV	Hy Test Date
	Fluid Group	1	Empty Weights [kg] 968
		Vessel	Jacket/Half-pipe
maximum allowable pressure [PS] bar		–1/+6	–1/+6
min/max allowable temperature [TS] °C		–25/+200	–25/+200
Hydrostatic test pressure [PT] bar		12.3	8.8
Recurrent hydrostatic test pressure bar		7.7	8.8
Volume [V] L		215	16
Main opening clamps N°. .		Type .	
Manhole/Handhole clamps N°. .		Type .	

Pfaudler

TITOLO–TITLE–TITEL

REATTORE VETRIFICATO TIPO AE–160

GLASS–LINED REACTOR TYPE AE–160

ITEM	.
ORDINE NR. / P. ORDER Nr.	957/A1
AUFTRAG Nr.	
DESTINAZIONE / LOCATION BESTIMMUNGSORT	BIRZEBBUGIA (MALTA)
CLIENTE / CUSTOMER KUNDE	STERLING CHEMICAL MALTA LTD

SCALA / SCALE / MASSTAB	1:5
DIS. / DRAWN. / GEZ.	CIBIN E.
CONTR. CHK. D. GEPRUEFT	
APPR. / APP'D / GESEHEN	
DATA / DATE / DATUM	03/12/16
COMMESSA – JOB Nr. – KOMM. Nr	42001029
Nr. PEZZI / QUANT. / STUECKZAHL	1
FORMATO	A1
DISEGNO No. – DRAWING. Nr. – ZEICHNUNG Nr.	AE–160–MT–42001029
CODICE – PART No.	PKRAE00160FH008
REV.	3

Annex 4: Engineer's report on new LPG tank

NB ENGINEERING SERVICES LTD.

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J.G. Baldacchino Street,
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Email: nikibel@onvol.net Vat: MT1580-8323

The Replacement of an Existing Bulk LPG Storage Tank Facility
with a
New, Larger One due to Factory Expansion.

Client: Sterling Chemicals Ltd
Industrial Estate, Hal Far.

March, 2018

To: The CEO
Malta Resources Authority

Design Basis
The basis of the design for the bulk LPG storage tank and pipeline will be the MRA COP's and the Codes of Practice of the UK. The bulk storage tanks will be EU Certified according to the PED Directive for pressurized storage vessels.

We shall use the above codes for the tank sitting, separation distances, pipework design, testing requirements and safety features we feel will offer the most safest installation possible, considering the equipment being used.

Proposal

The above Client currently operates a bulk lpg system which consists of three in number, above ground, vertical storage tanks, each with a capacity of 2250 ltrs water volume. The system has incorporated a vaporizer to produce lpgas for two in number steam boilers. The factory is currently undergoing an expansion process, and the steam plant shall double in capacity. It is therefore necessary to increase the lpg storage facility. The Client has acquired additional land from MIP, and a new lpg storage facility is being prepared on a site adjacent to the existing. Drawing Numbers 08-18-011, 08-18-010 and 08-18-012 show the proposed position for consideration.

A new, underground tank shall be installed, with a water volume capacity of 25000 ltrs. It shall be sited adjacent to the public road, with adequate fire walls on two sides, and safety distances as per COP's A3 on the other ends. An electric vaporizer shall be installed some distance away, again following the recommended distances. The fuel vapor shall be piped to the existing pipework, and an extension of the same pipework will be carried out to the new boiler room.

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2. A gas sensor in the boiler rooms, adjacent to the burners
3. The general fire alarm of the building.

The pipework system will be tested at a minimum of 6.0 barg after installation. After testing, the pipe will be painted bright yellow, and indicative signs will be installed.

Conclusion

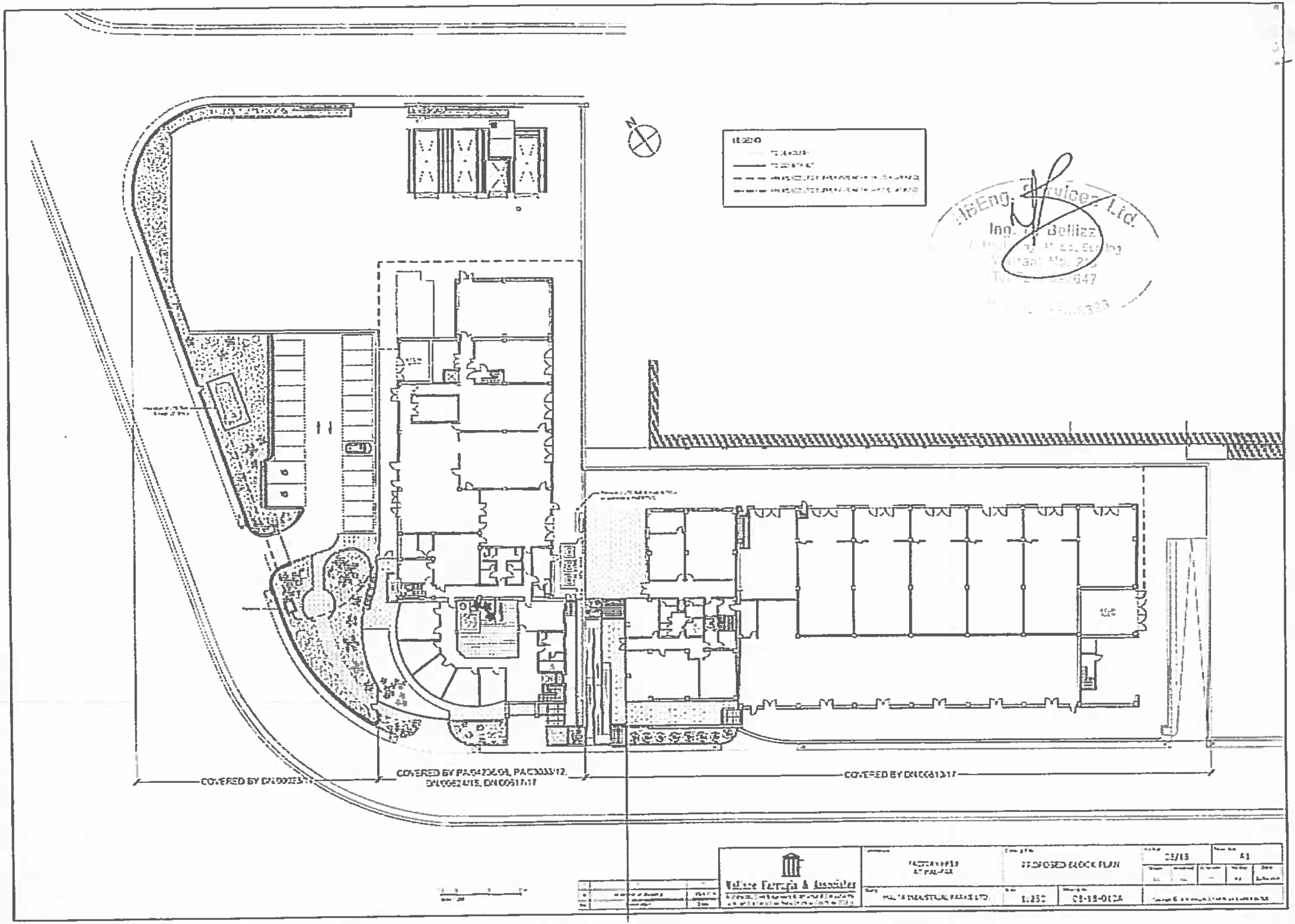
In conclusion, the safety features we intend to incorporate in this system are the following:

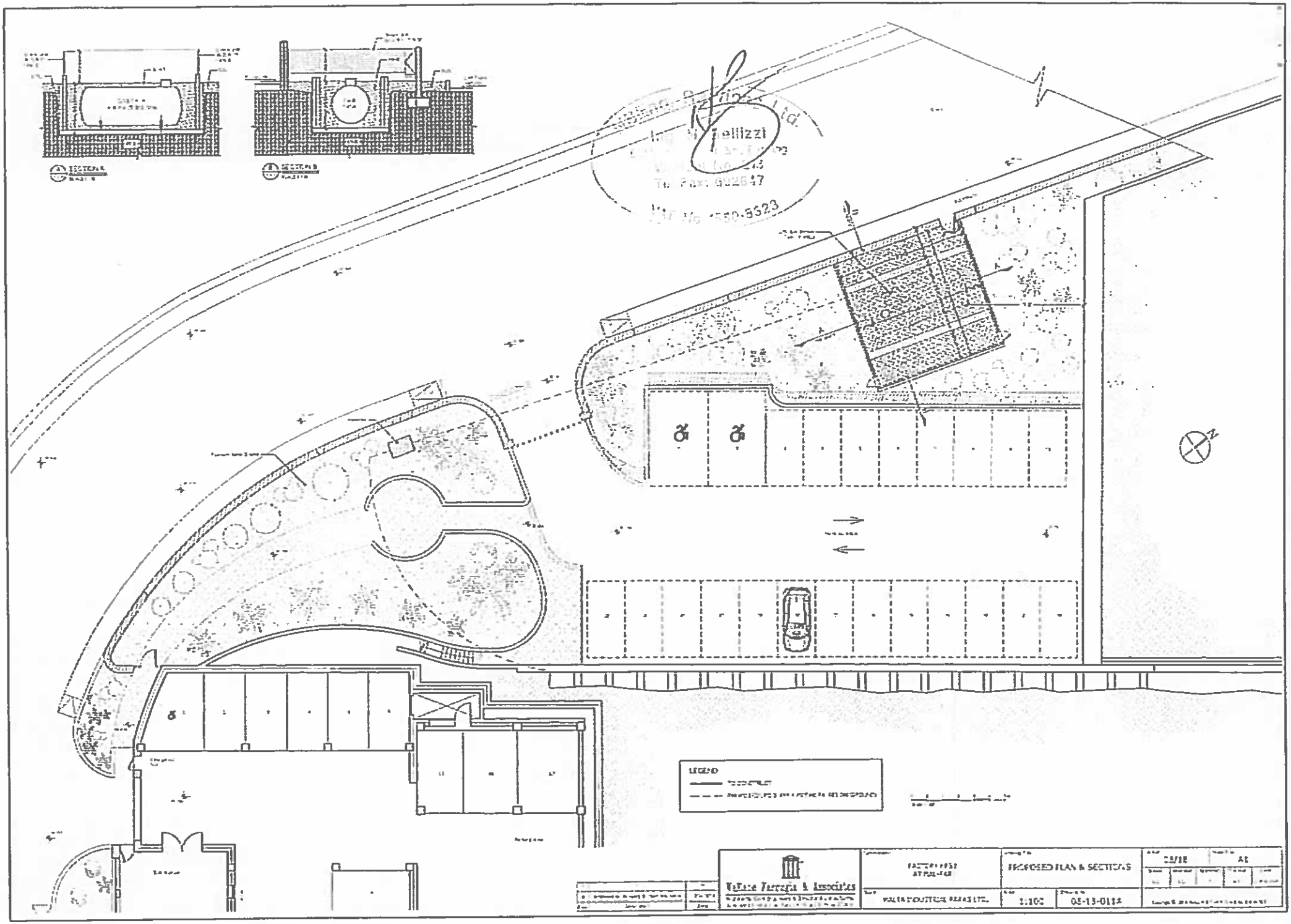
1. Adequate siting, and foundations. (as per MRA COP's A3)
2. An OPSO/UPSO downstream of the second stage regulators for both boiler rooms.
3. Quick closing valves installed and activated by one manual push in each boiler room, and by either of the gas sensors.
4. Tank certified under PED Directive
5. Above ground pipework in galvanized steel, PTFE tape and non-hardening compound. Below ground pipework in plastic material, adequately placed in a trench as per COP's
6. Testing completed pipework system to significantly high pressures- to ensure no leakages.
7. Isolating valves on the boiler, and another isolating valve prior to entry of the building.

With the above system, we feel that the lpg proposal is secure and should offer ample security to both its user and the premises owner.

Ing. Nicholas Bellizzi
Warrant No. 213
19.03.2018

NBEng. Services Ltd.
Ing. N. Bellizzi
Warrant No. 213
Tel/Fax: 692647
VAT No 1580-8323


LEGEND
PROPOSED BLOCK PLAN
A1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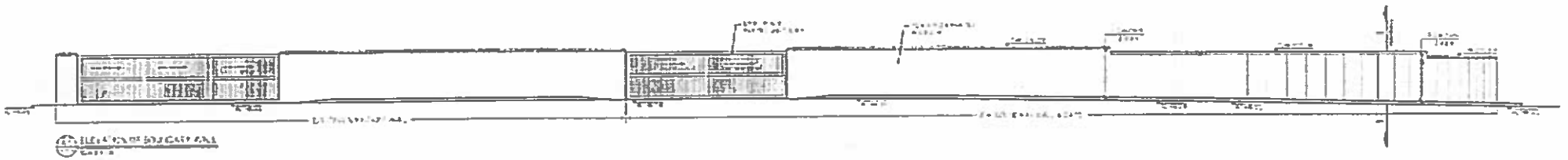
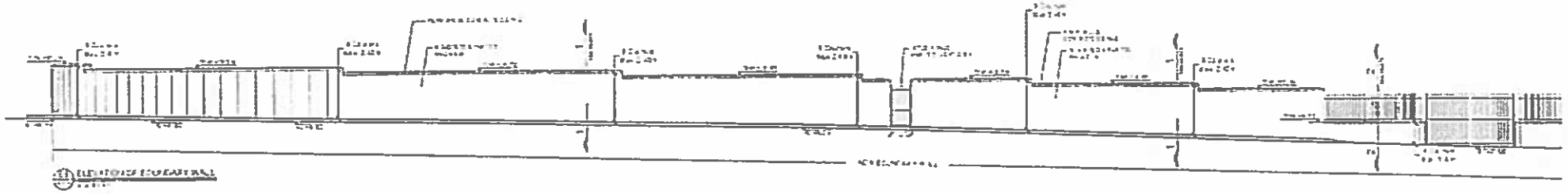
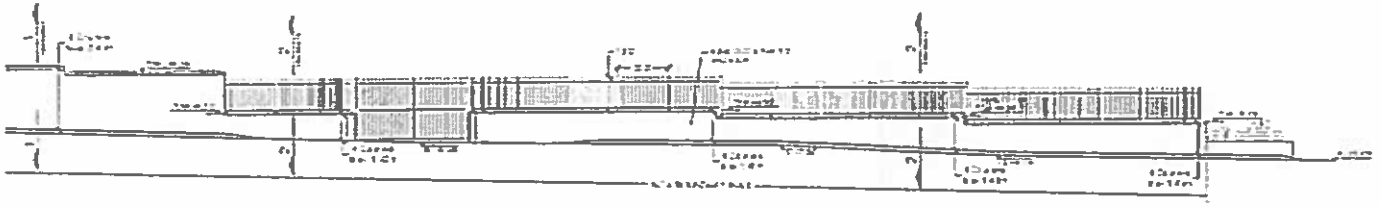
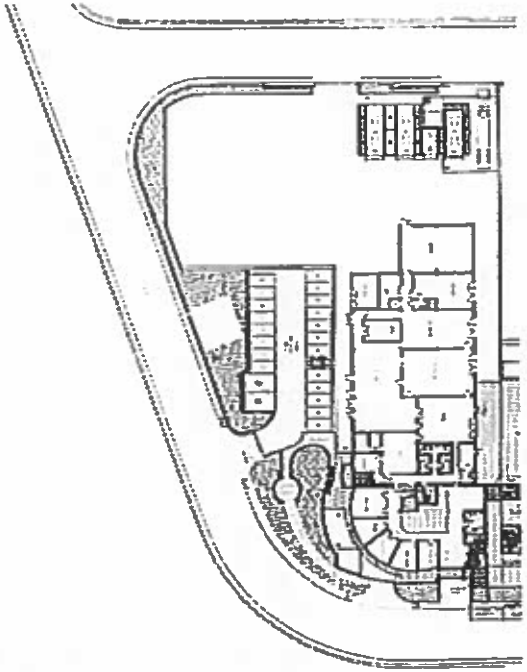
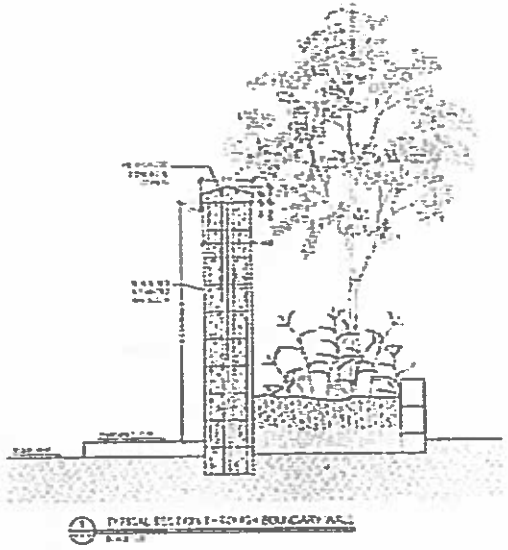
PROPOSED PLAN & SECTIONS
1:100
05-13-0114

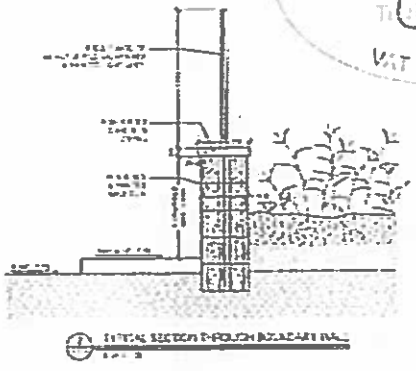












Annex 5: BAT assessment

BAT Conclusions for common waste water and waste gas treatment/ management systems in the chemical sector (Commission Implementing Decision (EU) 2016/902)

BAT conclusion		Status at the Scheme
1. Environmental management systems		
BAT 1 **Environmental Management System**	In order to improve the overall environmental performance, BAT is to implement and adhere to an environmental management system (EMS) that incorporates all of the following features: i. commitment of the management, including senior management; ii. an environmental policy that includes the continuous improvement of the installation by the management; iii. planning and establishing the necessary procedures, objectives and targets, in conjunction with financial planning and investment; iv. implementation of procedures paying particular attention to: a) structure and responsibility; b) recruitment, training, awareness and competence; c) communication; d) employee involvement; e) documentation; f) effective process control; g) maintenance programmes; h) emergency preparedness and response; i) safeguarding compliance with environmental legislation; v. checking performance and taking corrective action, paying particular attention to: a) monitoring and measurement (see also the Reference Report on Monitoring of emissions to Air and Water from IED installations — ROM); b) corrective and preventive action; c) maintenance of records; d) independent (where practicable) internal or external auditing in order to determine whether or not the EMS conforms to planned arrangements and has been properly implemented and maintained; vi. review of the EMS and its continuing suitability, adequacy and effectiveness by senior management; vii. following the development of cleaner technologies; viii. consideration for the environmental impacts from the eventual decommissioning of the plant at the design stage of a new plant, and throughout its operating life;	An EMS is currently being set up and implemented that meets the requirements of the ISO 14001:2015 standard.

BAT conclusion			Status at the Scheme
	ix. application of sectoral benchmarking on a regular basis; x. waste management plan (see BAT 13). Specifically for chemical sector activities, BAT is to incorporate the following features in the EMS: xi. on multi-operator installations/sites, establishment of a convention that sets out the roles, responsibilities and coordination of operating procedures of each plant operator in order to enhance the cooperation between the various operators; xii. establishment of inventories of waste water and waste gas streams (see BAT 2). In some cases, the following features are part of the EMS xiii. odour management plan (see BAT 20); xiv. noise management plan (see BAT 22).		
	Applicability	The scope (e.g. level of detail) and nature of the EMS (e.g. standardised or non-standardised) will generally be related to the nature, scale and complexity of the installation, and the range of environmental impacts it may have.	
BAT 2 **Inventory of waste water and waste gas streams**	In order to facilitate the reduction of emissions to water and air and the reduction of water usage, BAT is to establish and to maintain an inventory of waste water and waste gas streams, as part of the environmental management system (see BAT 1), that incorporates all of the following features: i. information about the chemical production processes, including: (a) chemical reaction equations, also showing side products; (b) simplified process flow sheets that show the origin of the emissions; (c) descriptions of process-integrated techniques and waste water/waste gas treatment at source including their performances; ii. information, as comprehensive as is reasonably possible, about the characteristics of the waste water streams, such as: (a) average values and variability of flow, pH, temperature, and conductivity; (b) average concentration and load values of relevant pollutants/parameters and their variability (e.g. COD/TOC, nitrogen species, phosphorus, metals, salts, specific organic compounds); (c) data on bioeliminability (e.g. BOD, BOD/COD ratio, Zahn-Wellens test, biological inhibition potential (e.g. nitrification)); iii. information, as comprehensive as is reasonably possible, about the characteristics of the waste gas streams, such as: a. average values and variability of flow and temperature; b. average concentration and load values of relevant pollutants/parameters and their variability (e.g. VOC, CO, NO_X, SO_X, chlorine, hydrogen chloride); c. flammability, lower and higher explosive limits, reactivity;		All hazardous wastewater streams are recorded, collected and discarded appropriately, and reported to ERA as part of the Annual Environmental Report (AER) for the Scheme. There is no on-site wastewater treatment at the Scheme. Air emissions monitoring is carried out as required by the IPPC permit, and reported to ERA as part of the Annual Environmental Report (AER) for the Scheme.

<table>
<tr><th colspan="2">BAT conclusion</th><th>Status at the Scheme</th></tr>
<tr><td></td><td>d. presence of other substances that may affect the waste gas treatment system or plant safety (e.g. oxygen, nitrogen, water vapour, dust).</td><td></td></tr>
<tr><td colspan="3">2. Monitoring</td></tr>
<tr><td>BAT 3

Monitoring of key process parameters</td><td colspan="2">For relevant emissions to water as identified by the inventory of waste water streams (see BAT 2), BAT is to monitor key process parameters (including continuous monitoring of waste water flow, pH and temperature) at key locations (e.g. influent to pre-treatment and influent to final treatment).</td><td>All hazardous wastewater streams are collected and discarded appropriately, and reported to ERA as part of the Annual Environmental Report (AER) for the Scheme. There is no on-site wastewater treatment at the Scheme or discharges to water bodies.</td></tr>
<tr><td>BAT 4

Monitoring of emissions to water</td><td colspan="2">BAT is to monitor emissions to water in accordance with EN standards with at least the minimum frequency given below. If EN standards are not available, BAT is to use ISO, national or other international standards that ensure the provision of data of an equivalent scientific quality.
<table>
<tr><th>Substance/parameter</th><th>Standard(s)</th><th>Minimum monitoring frequency (1) (2)</th></tr>
<tr><td>Total organic carbon (TOC) (3)</td><td>EN 1484</td><td rowspan="6">Daily</td></tr>
<tr><td>Chemical oxygen demand (COD) (3)</td><td>No EN standard available</td></tr>
<tr><td>Total suspended solids (TSS)</td><td>EN 872</td></tr>
<tr><td>Total nitrogen (TN) (4)</td><td>EN 12260</td></tr>
<tr><td>Total inorganic nitrogen (N_{inorg}) (4)</td><td>Various EN standards available</td></tr>
<tr><td>Total phosphorus (TP)</td><td>Various EN standards available</td></tr>
</table>
<table>
<tr><th colspan="2">Substance/parameter</th><th>Standard(s)</th><th>Minimum monitoring frequency (1) (2)</th></tr>
<tr><td colspan="2">Adsorbable organically bound halogens (AOX)</td><td>EN ISO 9562</td><td rowspan="7">Monthly</td></tr>
<tr><td rowspan="6">Metals</td><td>Cr</td><td rowspan="6">Various EN standards available</td></tr>
<tr><td>Cu</td></tr>
<tr><td>Ni</td></tr>
<tr><td>Pb</td></tr>
<tr><td>Zn</td></tr>
<tr><td>Other relevant, if relevant</td></tr>
<tr><td rowspan="5">Toxicity (5)</td><td>Fish eggs (Danio rerio)</td><td>EN ISO 15088</td><td rowspan="5">To be decided based on a risk assessment, after an initial characterisation</td></tr>
<tr><td>Daphnia
(Daphnia magna Straus)</td><td>EN ISO 6341</td></tr>
<tr><td>Luminescent bacteria
(Vibrio fischeri)</td><td>EN ISO 11348-1
EN ISO 11348-2 or
EN ISO 11348-3</td></tr>
<tr><td>Duckweed (Lemna minor)</td><td>EN ISO 20079</td></tr>
<tr><td>Algae</td><td>EN ISO 8692
EN ISO 10253
EN ISO 10710</td></tr>
</table>
(1) Monitoring frequencies may be adapted if the data series clearly demonstrate a sufficient stability.
(2) The sampling point is located where the emission leaves the installation.</td><td>Not applicable. There are no emissions to water bodies from the Scheme. All hazardous wastewater streams are collected and discarded off-site.</td></tr>
</table>

BAT conclusion			Status at the Scheme
	(3) TOC monitoring and COD monitoring are alternatives. TOC monitoring is the preferred option because it does not rely on the use of very toxic compounds. (4)TN and N_{inorg} monitoring are alternatives. (5) An appropriate combination of these methods can be used.		
BAT 5 **Monitoring of diffuse VOC emissions**	BAT is to periodically monitor diffuse VOC emissions to air from relevant sources by using an appropriate combination of the techniques I-III or, where large amounts of VOC are handled, all of the techniques I-III. i. sniffing methods (e.g. with portable instruments according to EN 15446) associated with correlation curves for key equipment; ii. optical gas imaging methods; iii. calculation of emissions based on emissions factors, periodically validated (e.g. once every two years) by measurements. Where large amounts of VOCs are handled, the screening and quantification of emissions from the installation by periodic campaigns with optical absorption-based techniques, such as Differential absorption light detection and ranging (DIAL) or Solar occultation flux (SOF), is a useful complementary technique to the techniques I to III. (See also Section 6.2.)		VOC measurements and calculations are carried out as required by the IPPC permit, and reported to ERA as part of the AER.
BAT 6 **Odour emission monitoring**	BAT is to periodically monitor odour emissions from relevant sources in accordance with EN standards.		The Scheme is not a significant source of odour emissions, and so odour monitoring is not required.
	Description	Emissions can be monitored by dynamic olfactometry according to EN 13725. Emission monitoring may be complemented by measurement/estimation of odour exposure or estimation of odour impact.	
	Applicability	The applicability is restricted to cases where odour nuisance can be expected or has been substantiated.	
3. Emissions to water			
3.1 Water usage and waste water generation			
BAT 7 **Reduction of volume and/or pollutant load of waste water streams**	In order to reduce the usage of water and the generation of waste water, BAT is to reduce the volume and/or pollutant load of waste water streams, to enhance the reuse of waste water within the production process and to recover and reuse raw materials.		It is not possible to change the production process as this is strictly dependent on the product. Additionally, due to the nature of the Scheme and the need to avoid contamination of the API product, reuse / recovery of raw materials or waste water is not possible. However, water usage at the Scheme is not high, and is reported to ERA as part of the AER.
3.2. Waste water collection and segregation			
BAT 8 **Segregation of contaminated waste streams**	In order to prevent the contamination of uncontaminated water and to reduce emissions to water, BAT is to segregate uncontaminated waste water streams from waste water streams that require treatment.		Contaminated wastewater streams are segregated from uncontaminated rainwater.
	Applicability	The segregation of uncontaminated rainwater may not be applicable in the case of existing waste water collection systems.	
BAT 9 **Buffer storage capacity**	In order to prevent uncontrolled emissions to water, BAT is to provide an appropriate buffer storage capacity for waste water incurred during other than normal operating conditions based on a risk assessment (taking into account e.g. the nature of the pollutant, the effects on further treatment, and the receiving environment), and to take appropriate further measures (e.g. control, treat, reuse).		The Scheme includes mitigation measures for protection of land and groundwater in the event of a spill, as outlined in the Land and Groundwater Risk

<table>
<tr><th colspan="3">BAT conclusion</th><th>Status at the Scheme</th></tr>
<tr><td></td><td>Applicability</td><td>The interim storage of contaminated rainwater requires segregation, which may not be applicable in the case of existing waste water collection systems.</td><td>assessment prepared for the Scheme.</td></tr>
<tr><td colspan="4">3.3 Waste water treatment</td></tr>
<tr><td>BAT 10

Integrated waste water management</td><td colspan="2">In order to reduce emissions to water, BAT is to use an integrated waste water management and treatment strategy that includes an appropriate combination of the techniques in the priority order given below.

<table>
<tr><th colspan="2">Technique</th><th>Description</th></tr>
<tr><td>a)</td><td>Process-integrated techniques (1)</td><td>Techniques to prevent or reduce the generation of water pollutants.</td></tr>
<tr><td>b)</td><td>Recovery of pollutants at source (1)</td><td>Techniques to recover pollutants prior to their discharge to the waste water collection system.</td></tr>
<tr><td>c)</td><td>Waste water pre-treatment (1) (2)</td><td>Techniques to abate pollutants before the final waste water treatment.

Pre-treatment can be carried out at the source or in combined streams</td></tr>
<tr><td>d)</td><td>Final waste water treatment (3)</td><td>Final waste water treatment by, for example, preliminary and primary treatment, biological treatment, nitrogen removal, phosphorus removal and/or final solids removal techniques before discharge to a receiving water body.</td></tr>
</table>
(1) These techniques are further described and defined in other BAT conclusions for the chemical industry.
(2) See BAT 11.
(3) See BAT 12.

<table>
<tr><td>Description</td><td>The integrated waste water management and treatment strategy is based on the inventory of waste water streams (see BAT 2).</td></tr>
<tr><td>BAT-associated emission levels (BAT-AELs):</td><td>see Section 3.4</td></tr>
</table></td><td>All hazardous wastewater streams are collected and discarded appropriately at licensed facilities.

It is not possible to change the production process or reduce water consumption as this is strictly dependent on the product; however, water consumption at the Scheme is not high and is reported to ERA as part of the AER.

Additionally, due to the nature of the Scheme and the need to avoid contamination of the API product, reuse / recovery of raw materials or waste water is not possible.</td></tr>
<tr><td>BAT 11

Pre-treatment of waste water</td><td colspan="2">In order to reduce emissions to water, BAT is to pre-treat waste water that contains pollutants that cannot be dealt with adequately during final waste water treatment by using appropriate techniques.

Description:

Waste water pre-treatment is carried out as part of an integrated waste water management and treatment strategy (see BAT 10) and is generally necessary to:

— protect the final waste water treatment plant (e.g. protection of a biological treatment plant against inhibitory or toxic compounds);

— remove compounds that are insufficiently abated during final treatment (e.g. toxic compounds, poorly/non-biodegradable organic compounds, organic compounds that are present in high concentrations, or metals during biological treatment);

— remove compounds that are otherwise stripped to air from the collection system or during final treatment (e.g. volatile halogenated organic compounds, benzene);

— remove compounds that have other negative effects (e.g. corrosion of equipment; unwanted reaction with other substances; contamination of waste water sludge).

In general, pre-treatment is carried out as close as possible to the source in order to avoid dilution, in particular for metals. Sometimes, waste water streams with appropriate characteristics can be segregated and collected in order to undergo a dedicated combined pre-treatment.</td><td>Not applicable. Pre-treatment of the hazardous wastewater streams is not required by the receiving facility.</td></tr>
<tr><td>BAT 12</td><td colspan="2">In order to reduce emissions to water, BAT is to use an appropriate combination of final waste water treatment techniques.</td><td>Not applicable. The Scheme does not include an on-</td></tr>
</table>

BAT conclusion		Status at the Scheme
Final waste water treatment techniques	Description: Final waste water treatment is carried out as part of an integrated waste water management and treatment strategy (see BAT 10). Appropriate final waste water treatment techniques, depending on the pollutant, include:	site wastewater treatment plant. All hazardous wastewater streams are collected and discarded off-site at licensed facilities, and there are no direct emissions to a receiving water body from the Scheme.

Technique		Typical pollutants abated	Applicability
Preliminary and primary treatment			
a)	Equalisation	All pollutants	Generally applicable.
b)	Neutralisation	Acids, alkalis	
c)	Physical separation, e.g. screens, sieves, grit separators, grease separators or primary settlement tanks	Suspended solids, oil/grease	
Biological treatment (secondary treatment), e.g.			
d)	Activated sludge process	Biodegradable organic compounds	Generally applicable.
e)	Membrane bioreactor		
Nitrogen removal			
f)	Nitrification/denitrification	Total nitrogen, ammonia	Nitrification may not be applicable in case of high chloride concentrations (i.e. around 10 g/l) and provided that the reduction of the chloride concentration prior to nitrification would not be justified by the environmental benefits. Not applicable when the final treatment does not include a biological treatment.
Phosphorus removal			
g)	Chemical precipitation	Phosphorus	Generally applicable
Final Solids removal			
h)	Coagulation and flocculation	Suspended solids	Generally applicable.
i)	Sedimentation		
J)	Filtration (e.g. sand filtration, microfiltration, ultrafiltration)		
k)	Flotation		

(1) The descriptions of the techniques are given in Section 6.1.

3.4. *BAT-associated emission levels for emissions to water*

The BAT-associated emission levels (BAT-AELs), for emissions to water given in Table 1, Table 2 and Table 3 apply to direct emissions to a receiving water body from:

BAT conclusion		Status at the Scheme

(i) the activities specified in Section 4 of Annex I to Directive 2010/75/EU;

(ii) independently operated waste water treatment plants specified in Section 6.11 of Annex I to Directive 2010/75/EU provided that the main pollutant load originates from activities specified in Section 4 of Annex I to Directive 2010/75/EU;

(iii) The combined treatment of waste water from different origins provided that the main pollutant load originates from activities specified in Section 4 of Annex I to Directive 2010/75/EU.

The BAT-AELs apply at the point where the emission leaves the installation.

Table 1: **BAT-AELs for direct emissions of TOC, COD and TSS to a receiving water body**

Parameter	BAT-AEL (yearly average)	Conditions
Total organic carbon (TOC) (1) (2)	10-33 mg/l (3) (4) (5) (6)	The BAT-AEL applies if the emission exceeds 3,3 t/yr.
Chemical oxygen demand (COD) (1) (2)	30-100 mg/l (3) (4) (5) (6)	The BAT-AEL applies if the emission exceeds 10 t/yr
Total suspended solids (TSS)	5,0-35 mg/l (7) (8)	The BAT-AEL applies if the emission exceeds 3,5 t/yr.

(1) No BAT-AEL applies for Biochemical oxygen demand (BOD). As an indication, the yearly average BOD_5 level in the effluent from a biological waste water treatment plant will generally be ≤ 20 mg/l.
(2) Either the BAT-AEL for TOC or the BAT-AEL for COD applies. TOC is the preferred option because its monitoring does not rely on the use of very toxic compounds.
(3) The lower end of the range is typically achieved when few tributary waste water streams contain organic compounds and/or the waste water mostly contains easily biodegradable organic compounds.
(4) The upper end of the range may be up to 100 mg/l for TOC or up to 300 mg/l for COD, both as yearly averages, if both of the fol- lowing conditions are fulfilled:
— Condition A: Abatement efficiency ≥ 90 % as a yearly average (including both pre-treatment and final treatment).
— Condition B: If a biological treatment is used, at least one of the following criteria is met:
— A low-loaded biological treatment step is used (i.e. ≤ 0,25 kg COD/kg of organic dry matter of sludge). This implies that the BOD5 level in the effluent is ≤ 20 mg/l.
— Nitrification is used.
(5) The upper end of the range may not apply if all of the following conditions are fulfilled:
— Condition A: Abatement efficiency ≥ 95 % as a yearly average (including both pretreatment and final treatment).
— Condition B: same as Condition B in footnote (4).
— Condition C: The influent to the final waste water treatment shows the following characteristics: TOC > 2 g/l (or COD > 6 g/l) as a yearly average and a high proportion of refractory organic compounds.
(6) The upper end of the range may not apply when the main pollutant load originates from the production of methylcellulose.
(7) The lower end of the range is typically achieved when using filtration (e.g. sand filtration, microfiltration, ultrafiltration, membrane bioreactor), while the upper end of the range is typically achieved when using sedimentation only.
(8) This BAT-AEL may not apply when the main pollutant load originates from the production of soda ash via the Solvay process or from the production of titanium dioxide.

BAT conclusion	Status at the Scheme

Table 2: **BAT-AELs for direct emissions of nutrients to a receiving water body**

Parameter	BAT-AEL (yearly average)	Conditions
Total nitrogen (TN) (1)	5,0-25 mg/l (2) (3)	The BAT-AEL applies if the emission exceeds 2,5 t/yr
Total inorganic nitrogen (N_{inorg}) (1)	5,0-20 mg/l (2) (3)	The BAT-AEL applies if the emission exceeds 2,0 t/yr.
Total phosphorus (TP)	0,50-3,0 mg/l (4)	The BAT-AEL applies if the emission exceeds 300 kg/yr.

(1) Either the BAT-AEL for total nitrogen or the BAT-AEL for total inorganic nitrogen applies.
(2) The BAT-AELs for TN and N_{inorg} do not apply to installations without biological waste water treatment. The lower end of the range is typically achieved when the influent to the biological waste water treatment plant contains low levels of nitrogen and/or when nitrification/denitrification can be operated under optimum conditions.
(3))The upper end of the range may be higher and up to 40 mg/l for TN or 35 mg/l for N_{inorg}, both as yearly averages, if the abatement efficiency is ≥ 70 % as a yearly average (including both pre-treatment and final treatment).
(4) The lower end of the range is typically achieved when phosphorus is added for the proper operation of the biological waste water treatment plant or when phosphorus mainly originates from heating or cooling systems. The upper end of the range is typically achieved when phosphorus-containing compounds are produced by the installation.

Table 3: **BAT-AELs for direct emission of AOX and metals to a receiving water body**

Parameter	BAT-AEL (yearly average)	Conditions
Adsorbable organically bound halogens (AOX)	0,20-1,0 mg/l (1) (2)	The BAT-AEL applies if the emission exceeds 100 kg/yr.
Chromium (expressed as Cr)	5,0-25 µg/l (3) (4) (5) (6)	The BAT-AEL applies if the emission exceeds 2,5 kg/yr.
Copper (expressed as Cu)	5,0-50 µg/l (3) (4) (5) (7)	The BAT-AEL applies if the emission exceeds 5,0 kg/yr.
Nickel (expressed as Ni)	5,0-50 µg/l (3) (4) (5)	The BAT-AEL applies if the emission exceeds 5,0 kg/yr.
Zinc (expressed as Zn)	20-300 µg/l (3) (4) (5) (8)	The BAT-AEL applies if the emission exceeds 30 kg/yr

(1) The lower end of the range is typically achieved when few halogenated organic compounds are used or produced by the installation.
(2) This BAT-AEL may not apply when the main pollutant load originates from the production of iodinated X-ray contrast agents due to the high refractory loads. This BAT-AEL may also not apply when the main pollutant load originates from the production of propylene oxide or epichlorohydrin via the chlorohydrin process due to the high loads.

<table>
<tr><th colspan="2">BAT conclusion</th><th>Status at the Scheme</th></tr>
<tr><td></td><td>(3) The lower end of the range is typically achieved when few of the corresponding metal (compounds) are used or produced by the installation.
(4) This BAT-AEL may not apply to inorganic effluents when the main pollutant load originates from the production of inorganic heavy metal compounds.
(5) This BAT-AEL may not apply when the main pollutant load originates from the processing of large volumes of solid inorganic raw materials that are contaminated with metals (e.g. soda ash from the Solvay process, titanium dioxide).
(6) This BAT-AEL may not apply when the main pollutant load originates from the production of chromium-organic compounds.
(7) This BAT-AEL may not apply when the main pollutant load originates from the production of copper-organic compounds or the production of vinyl chloride monomer/ethylene dichloride via the ox chlorination process.
(8) This BAT-AEL may not apply when the main pollutant load originates from the production of viscose fibres.

The associated monitoring is in BAT 4.</td><td></td></tr>
<tr><td colspan="3">4. Waste</td></tr>
<tr><td>BAT 13

Waste Management Plan</td><td colspan="2">In order to prevent or, where this is not practicable, to reduce the quantity of waste being sent for disposal, BAT is to set up and implement a waste management plan as part of the environmental management system (see BAT 1) that, in order of priority, ensures that waste is prevented, prepared for reuse, recycled or otherwise recovered.</td><td>The EMS will include this waste management plan.</td></tr>
<tr><td>BAT 14

Reduction of volume of waste water sludge</td><td colspan="2">In order to reduce the volume of waste water sludge requiring further treatment or disposal, and to reduce its potential environmental impact, BAT is to use one or a combination of the techniques given below.

<table>
<tr><th>Technique</th><th>Description</th><th>Applicability</th></tr>
<tr><td>a) Conditioning</td><td>Chemical conditioning (i.e. adding coagulants and/or flocculants) or thermal conditioning (i.e. heating) to improve the conditions during sludge thickening/dewatering.</td><td>Not applicable to inorganic sludges. The necessity for conditioning depends on the sludge properties and on the thickening/dewatering equipment used.</td></tr>
<tr><td>b) Thickening/dewatering</td><td>Thickening can be carried out by sedimentation, centrifugation, flotation, gravity belts, or rotary drums. Dewatering can be carried out by belt filter presses or plate filter presses.</td><td>Generally applicable.</td></tr>
<tr><td>c)Stabilisation</td><td>Sludge stabilisation includes chemical treatment, thermal treatment, aerobic digestion, or anaerobic digestion.</td><td>Not applicable to inorganic sludges. Not applicable for short-term handling before final treatment.</td></tr>
<tr><td>d) Drying</td><td>Sludge is dried by direct or indirect contact with a heat source.</td><td>Not applicable to cases where waste heat is not available or cannot be used.</td></tr>
</table></td><td>Not applicable. The Scheme does not include an on-site wastewater treatment plant.</td></tr>
<tr><td colspan="3">5. Emissions to air</td></tr>
<tr><td colspan="3">5.1. Waste gas collection</td></tr>
<tr><td>BAT 15

Treatment of air emissions</td><td colspan="2">In order to facilitate the recovery of compounds and the reduction of emissions to air, BAT is to enclose the emission sources and to treat the emissions, where possible.

Applicability: The applicability may be restricted by concerns on operability (access to equipment), safety (avoiding concentrations close to the lower explosive limit) and health (where operator access is required inside the enclosure).</td><td>Emissions to air are treated as described in the IPPC application.</td></tr>
<tr><td colspan="3">5.2. Waste gas treatment</td></tr>
<tr><td>BAT 16

Integrated waste gas management plan</td><td colspan="2">In order to reduce emissions to air, BAT is to use an integrated waste gas management and treatment strategy that includes process-integrated and waste gas treatment techniques.

Description: The integrated waste gas management and treatment strategy is based on the inventory of waste gas streams (see BAT 2) giving priority to</td><td>Emissions to air are treated as described in the IPPC application, and monitored in accordance with the IPPC permit.</td></tr>
</table>

<table>
<tr><th colspan="2">BAT conclusion</th><th>Status at the Scheme</th></tr>
<tr><td></td><td>process-integrated techniques.</td><td></td></tr>
<tr><td colspan="3">5.3. Flaring</td></tr>
<tr><td>BAT 17

Usage of flaring solely for safety reasons</td><td>In order to prevent emissions to air from flares, BAT is to use flaring only for safety reasons or non-routine operational conditions (e.g. start-ups, shutdowns) by using one or both of the techniques given below.

<table>
<tr><th colspan="2">Technique</th><th>Description</th><th>Applicability</th></tr>
<tr><td>a)</td><td>Correct plant design</td><td>This includes the provision of a gas recovery system with sufficient capacity and the use of high-integrity relief valves.</td><td>Generally applicable to new plants. Gas recovery systems may be retro- fitted in existing plants.</td></tr>
<tr><td>b)</td><td>Plant management</td><td>This includes balancing the fuel gas system and using advanced process control.</td><td>Generally applicable.</td></tr>
</table></td><td>Not applicable. Flaring is not used at the Scheme.</td></tr>
<tr><td>BAT 18

Flare management</td><td>In order to reduce emissions to air from flares when flaring is unavoidable, BAT is to use one or both of the techniques given below.

<table>
<tr><th></th><th>Technique</th><th>Description</th><th>Applicability</th></tr>
<tr><td>a)</td><td>Correct design of flaring devices</td><td>Optimisation of height, pressure, assistance by steam, air or gas, type of flare tips (either enclosed or shielded), etc., aimed to enable smokeless and reliable operation and to ensure the efficient combustion of ex- cess gases.</td><td>Applicable to new flares. In existing plants, applicability may be restricted due to e.g. maintenance time avail-ability during the turnaround of the plant.</td></tr>
<tr><td>b)</td><td>Monitoring and recording as part of flare management</td><td>Continuous monitoring of the gas sent to flaring, measurements of gas flow and estimations of other parameters (e.g. composition, heat con- tent, ratio of assistance, velocity, purge gas flow rate, pollutant emissions (e.g. NOX, CO, hydrocarbons, noise)). The recording of flaring events usually includes the estimated/ measured flare gas composition, the estimated/measured flare gas quantity and the duration of operation. The recording allows for the quantification of emissions and the potential prevention of future flaring events.</td><td>Generally applicable.</td></tr>
</table></td><td>Not applicable. Flaring is not used at the Scheme.</td></tr>
<tr><td colspan="3">5.4 Diffuse VOC emissions</td></tr>
<tr><td>BAT 19

Mitigation measures to reduce diffuse VOC emission to air</td><td>In order to prevent or, where that is not practicable, to reduce diffuse VOC emissions to air, BAT is to use a combination of the techniques given below.

<table>
<tr><th colspan="2">Technique</th><th>Applicability</th></tr>
<tr><td colspan="3">Techniques related to plant design</td></tr>
<tr><td>a)</td><td>Limit the number of potential emissions sources</td><td rowspan="2">Applicability may be restricted in the case of existing plants due to</td></tr>
<tr><td>b)</td><td>Maximise process-inherent containment features</td></tr>
</table></td><td>Emissions of VOCs are directed towards treatment systems, which are also monitored as required by the IPPC permit.

Equipment is selected according to its intended use. In relation to high-integrity equipment, corrosion-resistant equipment is in place, and also some agitators have mechanical seals.

Equipment is tested upon commissioning and certified as having been installed correctly in line</td></tr>
</table>

<table>
<tr><th colspan="4">BAT conclusion</th><th>Status at the Scheme</th></tr>
<tr><td></td><td colspan="3"><table>
<tr><td>c)</td><td>Select high-integrity equipment (see the description in Section 6.2)</td><td rowspan="2">operability requirements.</td></tr>
<tr><td>d)</td><td>Facilitate maintenance activities by ensuring access to potentially leaky equipment</td></tr>
<tr><td colspan="3">Techniques related to plant/equipment constructions, assembly and commissioning</td></tr>
<tr><td>e)</td><td>Ensure well-defined and comprehensive procedures for plant/equipment construction and assembly. This includes using the designed gasket stress for flanged joint assembly (see the description in Section 6.2)</td><td rowspan="2">Generally applicable.</td></tr>
<tr><td>f)</td><td>Ensure robust plant/equipment commissioning and handover procedures in line with the design requirements</td></tr>
<tr><td colspan="3">Techniques related to plant operation</td></tr>
<tr><td>g)</td><td>Ensure good maintenance and timely replacement of equipment</td><td rowspan="3">Generally applicable.</td></tr>
<tr><td>h)</td><td>Use a risk-based leak detection and repair (LDAR) programme (see the description in Section 6.2)</td></tr>
<tr><td>i)</td><td>As far as it is reasonable, prevent diffuse VOC emissions, collect them at source, and treat them</td></tr>
</table>
The associated monitoring is in BAT 5.</td><td>with manufacturer guidance.

A maintenance programme is also in place, as described in the IPPC application. Reactors use a vacuum / suction system, so in case of damage air would go into the reactor rather than leaking out. Maintenance of reactors includes vacuum testing to ensure the integrity of the equipment. If the test fails then all the equipment is checked until the source is identified.</td></tr>
<tr><td colspan="5">5.5. Odour emissions</td></tr>
<tr><td>BAT 20

Odour Management Plan</td><td colspan="3">In order to prevent or, where that is not practicable, to reduce odour emissions, BAT is to set up, implement and regularly review an odour management plan, as part of the environmental management system (see BAT 1), that includes all of the following elements:

i. a protocol containing appropriate actions and timelines;

ii. a protocol for conducting odour monitoring;

iii. a protocol for response to identified odour incidents;

iv. an odour prevention and reduction programme designed to identify the source(s); to measure/estimate odour exposure; to characterise the contributions of the sources; and to implement prevention and/or reduction measures.

The associated monitoring is in BAT 6.

<table><tr><td>Applicability</td><td>The applicability is restricted to cases where odour nuisance can be expected or has been substantiated</td></tr></table></td><td>Not applicable. The Scheme is not a significant source of odour emissions.</td></tr>
<tr><td>BAT 21

Mitigation measures for the reduction of odours from waste water collection/treatment and from sludge treatment</td><td colspan="3">In order to prevent or, where that is not practicable, to reduce odour emissions from waste water collection and treatment and from sludge treatment, BAT is to use one or a combination of the techniques given below.

<table><tr><th colspan="2">Technique</th><th>Description</th><th>Applicability</th></tr><tr><td>a)</td><td>Minimise residence times</td><td>Minimise the residence time of waste water and sludge in collection and storage systems, in particular under anaerobic conditions.</td><td>Applicability may be restricted in the case of existing collection and storage systems.</td></tr><tr><td>b)</td><td>Chemical treatment</td><td>Use chemicals to destroy or to reduce the formation of odorous compounds (e.g. oxidation or precipitation of hydrogen sulphide).</td><td>Generally applicable.</td></tr></table></td><td>Not applicable. The Scheme is not a significant source of odour emissions. Additionally, there is no on-site wastewater or sludge treatment.</td></tr>
</table>

<table>
<tr><th colspan="2">BAT conclusion</th><th>Status at the Scheme</th></tr>
<tr><td></td><td>
<table>
<tr><td>c)</td><td>Optimise aerobic treatment</td><td>This can include:
(i) controlling the oxygen content;
(ii) frequent maintenance of the aeration system;
(iii) use of pure oxygen;
(iv) Removal of scum in tanks.</td><td>Generally applicable.</td></tr>
<tr><td>d)</td><td>Enclosure</td><td>Cover or enclose facilities for collecting and treating waste water and sludge to collect the odorous waste gas for further treatment.</td><td>Generally applicable.</td></tr>
<tr><td>e)</td><td>End-of-pipe treatment</td><td>This can include:
(i) biological treatment;
(ii) Thermal oxidation.</td><td>Biological treatment is only applicable to compounds that are easily soluble in water and readily bioeliminable.</td></tr>
</table>
</td><td></td></tr>
<tr><td colspan="3">5.6. Noise emissions</td></tr>
<tr><td>BAT 22

Noise Management Plan</td><td>In order to prevent or, where that is not practicable, to reduce noise emissions, BAT is to set up and implement a noise management plan, as part of the environmental management system (see BAT 1), that includes all of the following elements:

(i) a protocol containing appropriate actions and timelines;

(ii) a protocol for conducting noise monitoring;

(iii) a protocol for response to identified noise incidents;

(iv) a noise prevention and reduction programme designed to identify the source(s), to measure/estimate noise exposure, to characterise the contributions of the sources and to implement prevention and/or reduction measures.

Applicability: The applicability is restricted to cases where noise nuisance can be expected or has been substantiated.</td><td>Noise monitoring is carried out as required by the IPPC permit; should any noise impacts be identified the appropriate abatement action will be taken. The next survey is planned after the micronisation plant is commissioned.</td></tr>
<tr><td>BAT 23

Mitigations of Noise Emissions</td><td>In order to prevent or, where that is not practicable, to reduce noise emissions, BAT is to use one or a combination of the techniques given below.
<table>
<tr><th colspan="2">Techniques</th><th>Description</th><th>Applicability</th></tr>
<tr><td>a)</td><td>Appropriate location of equipment and buildings</td><td>Increasing the distance between the emitter and the receiver and using buildings as noise screens.</td><td>For existing plants, the relocation of equipment may be restricted by a lack of space or excessive costs.</td></tr>
<tr><td>b)</td><td>Operational measures</td><td>This includes:
i. improved inspection and maintenance of equipment;
ii. closing of doors and windows of enclosed areas, if possible;
iii. equipment operation by experienced staff;
iv. avoidance of noisy activities at night, if possible;
v. provisions for noise control during maintenance activities.</td><td>Generally applicable.</td></tr>
<tr><td>c)</td><td>Low-noise equipment</td><td>This includes low-noise compressors, pumps and flares.</td><td>Applicable only when the equipment is new or replaced.</td></tr>
<tr><td>d)</td><td>Noise-control equipment</td><td>This includes:
(i) noise-reducers;
(ii) equipment insulation;
(iii) enclosure of noisy equipment;
(iv) soundproofing of buildings.</td><td>Applicability may be restricted due to space requirements (for existing plants), health, and safety issues.</td></tr>
</table>
</td><td>The Scheme includes noise mitigation measures including:
- Siting of the Scheme in an industrial area;
- Use of low-noise pumps;
- Enclosing the micronisation plant and technical area in a concreted room.

Should noise impacts be identified in the upcoming noise monitoring survey, further mitigation will be considered.</td></tr>
</table>

BAT conclusion					Status at the Scheme
	e)	Noise abatement	Inserting obstacles between emitters and receivers (e.g. protection walls, embankments and buildings).	Applicable only to existing plants; since the design of new plants should make this technique unnecessary. For existing plants, the insertion of obstacles may be restricted by a lack of space.	

Annex 6: Maintenance plan

Title: **Maintenance Plan**	Code: **MN.SOP.001** Rev: **11**

Prepared by			
Sterling Chemical Malta Ltd.	**Process Engineer**		
Company	Name	Signature	Date

Reviewed by			
Sterling Chemical Malta Ltd.	**QA Assistant**		
Company	Name	Signature	Date

Reviewed by			
Sterling Chemical Malta Ltd.	**Production Manager**		
Company	Name	Signature	Date

Approved by			
Sterling Chemical Malta Ltd.	**QA Manager**		
Company	Name	Signature	Date

Expiry Date _____

Re-Approvals Form

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EXPIRES ON _____

QUALITY ASSURANCE _____

TABLE OF CONTENTS

1. REVISION MATRIX

Revision	Date	Subject and Reason for Change
01	06/11/2013	Introduction of R-2801M, Filters F-2101M, F-2201M, F-2801M. Changed the frequency of replacement of water capsule filters. Date Rev. 00 Withdrawn 08/11/13
02	01/08/2014	Introduction of filters FT01, FT02, FT04, F-1201. Introduction of miller M001. Introduction of freezers and refrigerators. Date Rev. 01 Withdrawn 05/08/14
03	29/08/2014	Changed the maintenance frequency of the AHUs filters, depending on the filter grade. Date Rev. 02 Withdrawn 02/09/13
04	29/01/2015	Changed the maintenance frequency of clean rooms interlock system. Date Rev. 03 Withdrawn 02/02/15
05	13/03/2015	Changed the format on service equipment section. Introduction of reactors R-1101M, R-1201M, R-1301M, automation system DCS-01M, centrifuge CF-1101M, dryer DR-1101M, clean rooms air conditioning HVAC-02M. Introduction of chiller CMT-0101M, Pumps P-0103M, P-0104M, P-0105M and steam generator B-0411M. Removal of chiller CH-01 and tank BTK-RET, boiler B-0301M and Pump P-0102M. Introduction of the wash water level alarm. Date Rev. 04 Withdrawn 17/03/15
06	20/10/2015	Procedure configuration has been updated as per G.SOP.001 in force. Introduction of the verification of the alarm sounder of the clean rooms, of the BMS and of the DCS-01M. Date Rev. 05 Withdrawn 22/10/15
07	02/09/2016	Update of section R-1201M in order to introduce the verification of the sampler system with code SM-1201M integrated on reactor R-1201M. Date Rev. 06 Withdrawn ..... Signature.....Date.....
08	09/01/2017	Installation of the new Cold Rooms C RW-01, CRW-02 and CRW- 03. Installation of the new Fume Hood FH03 on QC2 Laboratory. Date Rev. 07 Withdrawn ..... Signature.....Date.....
09	27/02/2017	Installation of Filter F-2301M. Date Rev. 08 Withdrawn ..... Signature.....Date.....
10	18/09/2017	Installation of Reactors R-2101M and R-2901M in line 2. Installation of Fume Hood FH04 in QC1 Laboratory. Date Rev. 09 Withdrawn ..... Signature.....Date.....

Revision	Date	Subject and Reason for Change
11	05/07/2018	Introduction of new equipment for the Isolated Micronizer JM-01M and dedicated HVAC system HVAC-JM01M and HVAC Production Date Rev. 10 Withdrawn ..... Signature..... Date.....
12		Date Rev. 11 Withdrawn ..... Signature..... Date.....
13		Date Rev. 12 Withdrawn ..... Signature..... Date.....
14		Date Rev. 13 Withdrawn ..... Signature..... Date.....
15		Date Rev. 14 Withdrawn ..... Signature..... Date.....
16		Date Rev. 15 Withdrawn ..... Signature..... Date.....
17		Date Rev. 16 Withdrawn ..... Signature..... Date.....
18		Date Rev. 17 Withdrawn ..... Signature..... Date.....
19		Date Rev. 18 Withdrawn ..... Signature..... Date.....
20		Date Rev. 19 Withdrawn ..... Signature..... Date.....

2. INTRODUCTION

The awareness in issues of maintenance has increased in relatively recent time. A convergence of positions taken by various studies and experience has placed maintenance as a planned process which must be integrated with all the various characteristic features from the moment of design to the moment of operation.

Scheduled maintenance on the one hand establishes in advanced the frequency, method and resources for the maintenance activities, while on the other hand is a process that integrates with the entire usability of the facility and thus characterizes both the performance levels required and the consequential management costs.

The purpose of this maintenance plan is to provide a working tool through which the maintenance knowledge acquired in the design phase, where settings had been analysed and established, can be transferred to the operative stage as an application of a rational maintenance program.

3. METHODS AND DIAGNOSTIC TOOLS

The standard, Uni 10604, stipulates that any maintenance should be the result of the application of diagnostics: it is therefore necessary to use methods of diagnosis that ensure objectivity and comparability.

The level of *general diagnosis* is characterized by simple methods of detection such as:

- Visual detection.
- Detection using simple hand tools.
- Check-lists and simple schedules.
- Information from previous analysis.

The objective of diagnosis at a general level is to obtain general information on the state of the plant as well as, providing a framework for the prediction of failures based on knowledge of the plant characteristics, times and methods of anomalies.

At the level of *specific diagnosis* characterization is done using instrumental detection methods based on written analytical methods, including:

- Destructive tests using instruments.
- Non-destructive tests using instruments.
- Analytical methods such as fault trees, diagnostic trees, etc.
- Computerized diagnosis through expert systems.

This diagnosis will be made consistently with the available resources, or if the need arises, will be entrusted to a third party.

4. MAINTENANCE COMPANY POLICY

The maintenance of the systems within the company was the subject of a thorough technical and economic analysis, this analysis showed that the optimal solution applicable (and currently applied) consists of a combination of recovery methods, detection and corrections.
This company policy is applied through:

- ✓ SCHEDULED MAINTENANCE
- ✓ INSPECTIVE PREVENTIVE MAINTENANCE
- ✓ EXTRAORDINARY MAINTENANCE
- ✓ INCIDENTAL MAINTENANCE

SCHEDULED MAINTENANCE is carried out after a period of time previously established on the basis of statistical data of a fault (such data can be obtained from the manufacturer and can also be based on experience) and how the machine had been operated. It is performed by outside contractors or by internal operators in the case of simple tasks on devices that have a greater degree of criticality.

INSPECTIVE PREVENTIVE MAINTENANCE is an activity of verifying the state of use and/or functionality of a machine; it assumes that a fault is the final result of deterioration preceded by a series of signals detectable visually or through an instrument, and provides objective criteria for maintenance interventions. It is carried out by the operators of the facility, within the limit of their competence and duty, during the course of normal business activities and is part of the method of use.

EXTRAORDINARY MAINTENANCE interventions provide functional recovery following the detection of a fault that is not predictable in the planning phase and is then carried out with a frequency depending on the contingency.

INCIDENTAL MAINTENANCE consists of planned interventions as a result of failure or malfunction and is carried out, except for primary interventions by specialized external companies.

In the case of a planned downtime of the whole plant or part of the plant, it is possible to suspend scheduled maintenance of the plant or the inactive part. However, these periods of inactivity must not be less than one month, must be removed from the production program and agreed with the management. Before the next reboot of the plant or the inactive portion of the plant, it is required to perform the necessary repair and maintenance activities.

Furthermore, Quality Assurance verify that all maintenance activities are carried out in accordance with the dedicated procedure, P.SOP.010 and other applicable procedures of the company quality system.

5. SERVICE MAINTENANCE

The maintenance service within the company is carried out by a task force dedicated to this service, consisting of two operators and one manager.
The tasks of this unit are:

⇒ Carrying out maintenance operations which are easy to perform and do not pose a risk to the health and safety of the worker.

⇒ Apply the requirements of Good Manufacturing Practices (GMP) to the extent applicable and in particular maintain an adequate level of efficiency of the plants in order to minimize the probability of failure.

⇒ Detection of anomalies, identifying appropriate corrective actions in a timely manner.

⇒ Provide assistance and advice to companies carrying out external interventions.

The personnel assigned in these functions and that usually operate the facility are adequately trained and informed through:

- Operative Manuals.
- Internal Procedures.
- Material Safety Data Sheets of the substances involved in the production process.
- Refresher training on the proper use of the facility.

In addition, detailed information on each machine present inside the company is available in the technical archive.

All maintenance activities that go beyond the specific tasks of the servicing or the specific skills of the operators are entrusted to specialized and qualified external companies that are aware of the risks present within the company.

6. TECHNICAL ARCHIVE

The archive includes technical support documentation for maintenance activities, and in particular information concerning the structure, operating characteristics and construction of the system.

It must be promptly updated in case of changes and/or new installations, so that at all times its contents accurately reflect the structure of the installation within the company.
The following table displays the contents of the archive:

SUBJECT	***CONTENT***
EQUIPMENT DATA SHEETS	Identification and historical data of equipment and plants present within the company.
USER AND MAINTENANCE MANUALS	Operating Annuals for equipment and plants.
CATALOGUES FROM SUPPLIERS	Suppliers advertising materials.
STANDARD OPERATING PROCEDURES	SOPs, qualification data of plants, planned interventions, procedures for "change control", procedures for specific interventions.
FACILITY VERIFICATIONS	Documents relating to verification of installations subject to legal regulations.
SAFETY DATA SHEETS	Safety data sheets for materials used in maintenance and substances which workers may come into contact with during operations.
PROJECTS ARCHIVE	Project documentation of the installations (drawings, studies, technical reports, meeting minutes, etc..).
FACILITY VALIDATION	Design qualification, installation qualification, operational qualification.
CALIBRATION PROGRAM	Type, method and frequency of calibration of measuring instruments installed in support of the system and are considered critical from a procedural point of view.
LIST OF SPARE PARTS	Identification data of the systems, machines and components subject to wear and tear.

7. SCHEDULED MAINTENANCE

In this chapter, a section is dedicated to each element of the facility. Each subsection contains the Maintenance table of the components involved that describes the action to be performed and the frequency. The tables will be compiled during each intervention.

7.1. SECTION 0101M

7.1.1. CMT-0101M Chiller +5°C

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check control and safety equipment.			Half-yearly	
Check refrigerant through sight glasses and check for leaks.			Half-yearly	
Check fills and water circuits.			Half-yearly	
Check functionality of the flow state.			Half-yearly	
Check tightness of all electrical terminals.			Annual	

7.1.2. TK-0101M Tank +5°C

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visually check the cleanliness of the tank, where necessary close the outlet valve and fill with a combination of water and pickling solution. Leave for 30 minutes then drain and rinse.			Annual	
Open and close the isolating valves.			Annual	

7.1.3. P-0101M Primary Tank Pump TK-0101M

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y Filter on the suction of the pump.			Annual	
Open and close the isolating valves.			Annual	

7.1.4. P-0103M Primary Tank Pump TK-0101M

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y Filter on the suction of the pump.			Annual	
Open and close the isolating valves.			Annual	
Test the pressure regulator.			Annual	

7.1.5. P-0104M Secondary Tank Pump TK-0101M

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y Filter on the suction of the pump.			Annual	
Open and close the isolating valves.			Annual	
Test the pressure regulator.			Annual	

7.1.6. P-0105M Secondary Tank Pump TK-0101M

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y Filter on the suction of the pump.			Annual	
Open and close the isolating valves.			Annual	
Test the pressure regulator.			Annual	

7.2. SECTION 0201M

7.2.1. T-0201M Cooling Tower

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Inspect state of the nozzles.			Half-yearly	
Lubricate crankshaft bearing fan.			Half-yearly	
Wash basin and water filter.			Annual	
Adjust valve and water level.			Annual	
Check and adjust ventilator belts.			Annual	

7.2.2. CLT-0201M Chiller -25°C

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check control and safety equipment.			Half-yearly	
Check refrigerant through sight glasses and check for leaks.			Half-yearly	
Check fills and water circuits.			Half-yearly	
Check functionality of the flow state.			Half-yearly	
Check tightness of all electrical terminals.			Annual	

7.2.3. TK-0201M Tank -25°C

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visually check the cleanliness of the tank, where necessary close the outlet valve and fill with a combination of water and pickling solution. Leave for 30 minutes then drain and rinse.			Annual	
Open and close the isolating valves.			Annual	

7.2.4. P-0201M Water tower circulation pump

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y Filter on the suction of the pump.			Annual	
Open and close the isolating valves.			Annual	

7.2.5. P-0202M Water tower primary pump

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y Filter on the suction of the pump.			Annual	
Open and close the isolating valves.			Annual	

7.2.6. P-0203M Primary pump refrigeration unit CLT-0201M

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y Filter on the suction of the pump.			Annual	
Open and close the isolating valves.			Annual	

7.2.7. P-0204M Secondary pump refrigeration unit CLT-0201M

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y Filter on the suction of the pump.			Annual	
Open and close the isolating valves.			Annual	
Check the pressure regulator.			Annual	

7.3. SECTION 0301M

7.3.1. TK-0301M Hot water tank

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visually check the cleanliness of the tank, where necessary close the outlet valve and fill with a combination of water and pickling solution. Leave for 30 minutes then drain and rinse.			Annual	
Open and close the isolating valves.			Annual	

7.3.2. P-0301M Hot water pump

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y Filter on the suction of the pump.			Annual	
Open and close the isolating valves.			Annual	

7.4. SECTION 0401M

7.4.1. B-0401M Steam generator

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check control and safety equipment.			Half-yearly	
Clean combustion components of the burner			Half-yearly	
Open and close the isolating valves.			Annual	
Verify absence scaling or oxidation on the burner			Annual	
Check integrity status of refractory materials and interior insulation			Annual	
Check tightness of all electrical terminals.			Annual	

7.4.2. B-0411M Steam generator

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check control and safety equipment.			Half-yearly	
Clean combustion components of the burner			Half-yearly	
Open and close the isolating valves.			Annual	
Verify absence scaling or oxidation on the burner			Annual	
Check integrity status of refractory materials and interior insulation			Annual	
Check tightness of all electrical terminals.			Annual	

7.4.3. TK-0401M Condensate tank

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visually check the cleanliness of the tank, where necessary close the outlet valve and fill with a combination of water and pickling solution. Leave for 30 minutes then drain and rinse.			Annual	
Open and close the isolating valves.			Annual	

7.5. SECTION 0501M

7.5.1. C-0501M Compressor

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check control and safety equipment.			Half-yearly	
Clean the compressor.			Half-yearly	
Check filters.			Half-yearly	
Check tension-belt			Annual	
Check tightness of all electrical terminals.			Annual	
Open and close the isolating valves.			Annual	

7.5.2. CD-0501M Compressed air dryer

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Clean finned surfaces of the condenser.			Annual	
Inspect and clean the filter drain condensate.			Annual	

7.6. SECTION 0701M

7.6.1. SC-0701M Scrubber

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Verify tightness of the suction circuit.			Annual	
Verify tank cleanliness.			Annual	
Clean filter of pump suction.			Annual	
Grease bearings lubrication on fan shaft.			Annual	
Check fan belt tension.			Annual	

7.7. SECTION 0801M

7.7.1. Vacuum pumps (VP-080xM)

Duplicate page if necessary

Page ___ of ____

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TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Inspect and cleaning fittings, couplings, heat exchanger and cooling system.			Annual	
Replace grease bearings.			Annual	
Nitrogen flushing inspection.			Annual	
Replace gearbox oil.			Annual	
Visual inspection of the exchanger seal.			Annual	
Visual inspection of the tank leaks.			Annual	

7.8. SECTION 1001M

7.8.1. WS-1001M Water Softener System

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Dismantle the Pilot head and verify the internal components.			Annual	
Check and clean the accessories.			Annual	
Simulate regeneration phase.			Annual	
Water hardness setting of outgoing water.			Annual	

7.8.2. P-1001M

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Dismantle the dosing head and clean membrane.			Annual	
Replace retention valves.			Annual	
Measure the flow meter.			Annual	
Dismantle and clean the tank level sensor.			Annual	

7.8.3. P-1002M

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Dismantle the dosing head and clean membrane.			Annual	
Replace retention valves.			Annual	
Measure the flow meter.			Annual	
Dismantle and clean the tank level sensor.			Annual	

7.8.4. P-1003M

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Dismantle the dosing head and clean membrane.			Annual	
Replace retention valves.			Annual	
Measure the flow meter.			Annual	
Dismantle and clean the tank level sensor.			Annual	

7.8.5. P-1004M

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Dismantle the dosing head and clean membrane.			Annual	
Replace retention valves.			Annual	
Measure the flow meter.			Annual	
Dismantle and clean the tank level sensor.			Annual	

7.9. SECTION R-1101M

7.9.1. R-1101M Reactor

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for oil leakages from the mechanical seal.			Half-yearly	
Visual inspection of the internal coatings and structural integrity of the reactor body.			Annual	
Check the moving parts, seals and the parts of the glass structure subjected to elevated temperatures.			Annual	
Change the lubricating oil of the motor.			Annual	
Replace the oil of the mechanical seal.			Annual	
Visual check of the hatch gasket.			Annual	
Control enamel interior.			Annual	
Check for leaks in the thermoregulation system.			Annual	
Open and close the valves of the thermoregulation system.			Annual	
Visual check for leaks of the pump P-1101M			Annual	
Clean Y Filter on the suction of the pump P-1101M			Annual	
Check the correct operation of the thermoregulation system.			Annual	

7.10. SECTION R-1201M

7.10.1. R-1201M Reactor

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for oil leakages from the mechanical seal.			Half-yearly	
Visual inspection of the internal coatings and structural integrity of the reactor body.			Annual	
Check the moving parts, seals and the parts of the glass structure subjected to elevated temperatures.			Annual	
Change the lubricating oil of the motor.			Annual	
Replace the oil of the mechanical seal.			Annual	
Visual check of the hatch gasket.			Annual	
Control enamel interior.			Annual	
Check for leaks in the thermoregulation system.			Annual	
Open and close the valves of the thermoregulation system.			Annual	
Visual check for leaks of the pump P-1201M			Annual	
Clean Y Filter on the suction of the pump P-1201M			Annual	
Check the correct operation of the thermoregulation system.			Annual	

7.11. SECTION R-1301M

7.11.1. R-1301M Reactor

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for oil leakages from the mechanical seal.			Half-yearly	
Visual inspection of the internal coatings and structural integrity of the reactor body.			Annual	
Check the moving parts, seals and the parts of the glass structure subjected to elevated temperatures.			Annual	
Change the lubricating oil of the motor.			Annual	
Replace the oil of the mechanical seal.			Annual	
Visual check of the hatch gasket.			Annual	
Control enamel interior.			Annual	
Check for leaks in the thermoregulation system.			Annual	
Open and close the valves of the thermoregulation system.			Annual	
Visual check for leaks of the pump P-1301M			Annual	
Clean Y Filter on the suction of the pump P-1301M			Annual	
Check the correct operation of the thermoregulation system.			Annual	

7.12. SECTION R-2101M

7.12.1. R-2101M Reactor

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for oil leakages from the mechanical seal.			Half-yearly	
Visual inspection of the internal coatings and structural integrity of the reactor body.			Annual	
Check the moving parts, seals and the parts of the glass structure subjected to elevated temperatures.			Annual	
Change the lubricating oil of the motor.			Annual	
Replace the oil of the mechanical seal.			Annual	
Visual check of the hatch gasket.			Annual	
Control enamel interior.			Annual	
Check for leaks in the thermoregulation system.			Annual	
Open and close the valves of the thermoregulation system.			Annual	
Visual check for leaks of the pump P-2101M			Annual	
Clean Y Filter on the suction of the pump P-2101M			Annual	
Check the correct operation of the thermoregulation system.			Annual	

7.13. SECTION R-2201M

7.13.1. R-2201M Reactor

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for oil leakages from the mechanical seal.			Half-yearly	
Visual inspection of the internal coatings and structural integrity of the reactor body.			Annual	
Check the moving parts, seals and the parts of the glass structure subjected to elevated temperatures.			Annual	
Change the lubricating oil of the motor.			Annual	
Replace the oil of the mechanical seal.			Annual	
Visual check of the hatch gasket.			Annual	
Control enamel interior.			Annual	
Check for leaks in the thermoregulation system.			Annual	
Open and close the valves of the thermoregulation system.			Annual	

7.14. SECTION R-2301M

7.14.1. R-2301M Reactor

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for oil leakages from the mechanical seal.			Half-yearly	
Visual inspection of the internal coatings and structural integrity of the reactor body.			Annual	
Check the moving parts, seals and the parts of the glass structure subjected to elevated temperatures.			Annual	
Change the lubricating oil of the motor.			Annual	
Replace the oil of the mechanical seal.			Annual	
Visual check of the hatch gasket.			Annual	
Control enamel interior.			Annual	
Check for leaks in the thermoregulation system.			Annual	
Open and close the valves of the thermoregulation system.			Annual	

7.15. SECTION R-2401M

7.15.1. R-2401M Reactor

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for oil leakages from the mechanical seal.			Half-yearly	
Visual inspection of the internal coatings and structural integrity of the reactor body.			Annual	
Check the moving parts, seals and the parts of the glass structure subjected to elevated temperatures.			Annual	
Change the lubricating oil of the motor.			Annual	
Replace the oil of the mechanical seal.			Annual	
Visual check of the hatch gasket.			Annual	
Control enamel interior.			Annual	
Check for leaks in the thermoregulation system.			Annual	
Open and close the valves of the thermoregulation system.			Annual	

7.16. SECTION R-2801M

7.16.1. R-2801M Reactor

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for oil leakages from the mechanical seal.			Half-yearly	
Visual inspection of the internal coatings and structural integrity of the reactor body.			Annual	
Check the moving parts, seals and the parts of the glass structure subjected to elevated temperatures.			Annual	
Change the lubricating oil of the motor.			Annual	
Replace the oil of the mechanical seal.			Annual	
Visual check of the hatch gasket.			Annual	
Control enamel interior.			Annual	
Check for leaks in the thermoregulation system.			Annual	
Open and close the valves of the thermoregulation system.			Annual	

7.17. SECTION R-2901M

7.17.1. R-2901M Reactor

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for oil leakages from the mechanical seal.			Half-yearly	
Visual inspection of the internal coatings and structural integrity of the reactor body.			Annual	
Check the moving parts, seals and the parts of the glass structure subjected to elevated temperatures.			Annual	
Change the lubricating oil of the motor.			Annual	
Replace the oil of the mechanical seal.			Annual	
Visual check of the hatch gasket.			Annual	
Control enamel interior.			Annual	
Check for leaks in the thermoregulation system.			Annual	
Open and close the valves of the thermoregulation system.			Annual	
Visual check for leaks of the pump P-2901M			Annual	
Clean Y Filter on the suction of the pump P-2901M			Annual	
Check the correct operation of the thermoregulation system.			Annual	

7.18. SECTION FILTERS

7.18.1. F-2101M Buckner Filter

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the structural integrity of the filter.			Annual	
Visual inspection of the glass components.			Annual	
Visual check of the gaskets.			Annual	

7.18.2. F-2201M Buckner Filter

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the structural integrity of the filter.			Annual	
Visual inspection of the stainless steel components.			Annual	
Visual check of the gaskets.			Annual	

7.18.3. F-2301M Buckner Filter

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the structural integrity of the filter.			Annual	
Visual inspection of the stainless steel components.			Annual	
Visual check of the gaskets.			Annual	

7.18.4. F-2801M Buckner Filter

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the structural integrity of the filter.			Annual	
Visual inspection of the glass components.			Annual	
Visual check of the gaskets.			Annual	

7.18.5. F-1201 Buckner Filter

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the structural integrity of the filter.			Annual	
Visual inspection of the glass components.			Annual	
Visual check of the gaskets.			Annual	

7.18.6. FT04 Buckner Filter

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the structural integrity of the filter.			Annual	
Visual inspection of the glass components.			Annual	
Visual check of the gaskets.			Annual	

7.18.7. FT01 Lens Filter

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the structural integrity of the filter.			Annual	
Visual inspection of the glass components.			Annual	
Visual check of the gaskets.			Annual	

7.18.8. FT02 Sparkler Filter

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the structural integrity of the filter.			Annual	
Visual inspection of the glass components.			Annual	
Visual check of the gaskets.			Annual	
Check of any deformations: compare the length of the rods and carefully observe the sealing surfaces (any hump or lack of material on the seals may allow the liquid or dirt to pass through).			Annual	
Check the functionality of the safety valve			Annual	

7.19. SECTION PILOT REACTORS

7.19.1. LR-01

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the glass parts and structural integrity of the reactor body.			Annual	
Check the moving parts, seals and the parts of the glass structure subjected to elevated temperatures.			Annual	

7.19.2. LR-02

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the glass parts and structural integrity of the reactor body.			Annual	
Check the moving parts, seals and the parts of the glass structure subjected to elevated temperatures.			Annual	

7.20. SECTION DR-1101M

7.20.1. DR-1101M Static Dryer

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the internal coating and structural integrity of the dryer.			Annual	
Check the condition of the door seal.			Annual	
Check tightness of the connections and check for leaks.			Annual	
Clean the inside of the condensate collection tank.			Annual	
Internal cleaning of the expansion vessel.			Annual	
Check the vacuum level by closing the root valve and measuring the loss of vacuum after 30 minutes (Max Leak Rate = 100 mbarg\h) Initial Value……..Final Value…….			Annual	

7.20.2. P-1701M Circulation pump in dryer sleeve

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y filter on the suction of the pump.			Annual	
Open and close the shutoff valves.			Annual	

7.21. SECTION DR-2101M

7.21.1. DR-2101M Static Dryer

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the internal coating and structural integrity of the dryer.			Annual	
Check the condition of the door seal.			Annual	
Check tightness of the connections and check for leaks.			Annual	
Clean the inside of the condensate collection tank.			Annual	
Internal cleaning of the expansion vessel.			Annual	
Check the vacuum level by closing the root valve and measuring the loss of vacuum after 30 minutes (Max Leak Rate = 100 mbarg\h) Initial Value……..Final Value…….			Annual	

7.21.2. P-2701M Circulation pump in dryer sleeve

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y filter on the suction of the pump.			Annual	
Open and close the shutoff valves.			Annual	

7.22. SECTION CF-1101M

7.22.1. CF-1101M Vertical Axis Centrifuge

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check the grease of the bearings on top and bottom of the basket.			Annual	
Check the bearings on top and bottom of the basket.			Annual	
Check the drive belts.			Annual	
General check of the inertization panel ILP.			Annual	
Check the oil filter of the Hydraulic unit HYU.			Annual	
Check tightness of all electrical connections.			Annual	
Replace the drive belts.			Every ten years	

7.23. SECTION MILLER

7.23.1. M001 Miller

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check of the tightening of the mechanical connections.			Annual	
Check of the integrity of the electrical connections and of the functionality of the motor.			Annual	
Grease and verify that the bearings operate freely.			Annual	
Check the joint integrity.			Annual	
Check the sealing integrity.			Annual	
Check the grid basket integrity.			Annual	

7.23.2. JM-01M Jet Miller Micronizer

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check the sealing static gaskets of flanges and replace them if necessary.			Every two months	
Visual inspection of LIP radial mechanical seals and replace them if necessary.			Every two months	
Verify the electric continuity and earthing of equipment.			Half-yearly	
Visual inspection of screw-driver and lump-breaker and replace them if necessary.			Half-yearly	
Visual inspection of the ejector nozzle of the micronizer.			Annual	
Check conditions of the drive units (screw-driver, lump-breaker, fans)			Annual	
Visual check of the door gaskets of the isolators			Annual	
Visual check of the gloves of the isolators			Annual	
Visual check of the continuous liner system and relative O-rings			Annual	
Check the correct operation of the micronization system.			Annual	
Verification of the efficiency of the instruments of control and supervision of the process			Annual	

7.24. SECTION AUTOMATION

7.24.1. BMS Automation System

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check the operations of the alarm sounder			Half-yearly	
Check tightness of all electrical connections.			Annual	
Check for any system errors.			Annual	
Verify drives.			Annual	
Verify input and output signals.			Annual	

7.24.2. DCS-01M Automation System

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check the operations of the alarm sounder			Half-yearly	
Check tightness of all electrical connections.			Annual	
Check for any system errors.			Annual	
Verify drives.			Annual	
Verify input and output signals.			Annual	

7.25. SECTION HVAC

7.25.1. AHU1-CP1 Circulation pump HVAC system

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visually check for any leaks.			Annual	
Clean the Y filter on the aspiration control of the pump.			Annual	
Open and close the shutoff valves.			Annual	

7.25.2. AHU3-CP1 Circulation pump HVAC system

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visually check for any leaks.			Annual	
Clean the Y filter on the aspiration control of the pump.			Annual	
Open and close the shutoff valves.			Annual	

7.25.3. AHU1 Air supply/exhaust unit

TYPE OF INTERVENTION		Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace the filters on the supply unit.	G4 - Panel Filters			Every two months	
	F9 – Rigid Bag Filters			Half-yearly	
	H14 – Absolute Filters			Every six years	
Replace the filters on the exhaust unit.	G4 - Panel Filters			Every two months	
	F9 – Pleated Cell Filters			Half-yearly	
	H13 – Absolute Filters			Annual	
Check controls and safety equipment.				Half-yearly	
Check fan belt tension.				Annual	
Clean grills on air input\output.				Annual	

7.25.4. AHU2 Air supply unit

TYPE OF INTERVENTION		Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace the filters on the supply unit.	G4 - Panel Filters			Every two months	
	F9 – Rigid Bag Filters			Half-yearly	
	H14 – Absolute Filters			Every six years	
Check controls and safety equipment.				Half-yearly	
Check fan belt tension.				Annual	
Clean grills on air input\output.				Annual	

7.25.5. AHU3 Air supply/exhaust unit

TYPE OF INTERVENTION		Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace the filters on the supply unit.	G4 - Panel Filters			Every two months	
	F9 – Rigid Bag Filters			Half-yearly	
	H14 – Absolute Filters			Every six years	
Replace the filters on the exhaust unit.	G4 - Panel Filters			Every two months	
	F9 – Pleated Cell Filters			Half-yearly	
	H13 – Absolute Filters			Annual	
Check controls and safety equipment.				Half-yearly	
Check fan belt tension.				Annual	
Clean grills on air input\output.				Annual	

7.25.6. Clean rooms interlock system

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check the functionality of door indicator lights.			Half-yearly	
Check the functionality of door electric interlocks.			Half-yearly	
Check the operations of the alarm sounder			Half-yearly	

7.25.7. UTA-JM001M - Circulation pump HVAC system

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visually check for any leaks.			Annual	
Clean the Y filter on the aspiration control of the pump.			Annual	
Open and close the shutoff valves.			Annual	

7.25.8. UTA-JM001M UTA-JM002M Air supply/exhaust unit

TYPE OF INTERVENTION		Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace the filters on the supply unit.	G4 - Panel Filters			Every two months	
	F9 – Rigid Bag Filters			Half-yearly	
	H14 – Absolute Filters			Every six years	
Replace the filters on the exhaust unit.	H13 – Absolute Filters			Annual	
Check controls and safety equipment.				Half-yearly	
Check bearings and lubricants of the fans.				Annual	
Clean grills on air input\output.				Annual	

7.25.1. Clean rooms interlock system

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check the functionality of door indicator lights.			Half-yearly	
Check the functionality of door electric interlocks.			Half-yearly	
Check the operations of the alarm sounder			Half-yearly	

7.25.2. UTA-P1001M - Circulation pump HVAC system

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visually check for any leaks.			Annual	
Clean the Y filter on the aspiration control of the pump.			Annual	
Open and close the shutoff valves.			Annual	

7.25.3. UTA-P1001M UTA-P1002M Air supply/exhaust unit

TYPE OF INTERVENTION		Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace the filters on the supply unit.	G4 - Panel Filters			Every two months	
	F9 – Rigid Bag Filters			Half-yearly	
Replace the filters on the exhaust unit.	G4 - Panel Filters			Every two months	
	F9 – Pleated Cell Filters			Half-yearly	
Check controls and safety equipment.				Half-yearly	
Check bearings and lubricants of the fans.				Annual	
Clean grills on air input\output.				Annual	

7.26. SECTION COLD ROOMS

7.26.1. Cold Room CRW-01

TYPE OF INTERVENTION		Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace the filters on the supply unit.	F9 – Rigid Bag Filters			Half-yearly	
Check controls and safety equipment.				Half-yearly	
Check fan belt tension.				Annual	
Clean grills on air input\output.				Annual	
Check of the GSM Phone Alarm System				Annual	

7.26.2. Cold Room CRW-02

TYPE OF INTERVENTION		Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace the filters on the supply unit.	F9 – Rigid Bag Filters			Half-yearly	
Check controls and safety equipment.				Half-yearly	
Check fan belt tension.				Annual	
Clean grills on air input\output.				Annual	
Check of the GSM Phone Alarm System				Annual	

7.26.3. Cold Room CRW-03

TYPE OF INTERVENTION		Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace the filters on the supply unit.	F9 – Rigid Bag Filters			Half-yearly	
Check controls and safety equipment.				Half-yearly	
Check fan belt tension.				Annual	
Clean grills on air input\output.				Annual	
Check of the GSM Phone Alarm System				Annual	

7.26.4. CRW Condensing Unit

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Clean the external grid.			Half-yearly	
Visual check of all equipment.			Half-yearly	
Check controls and pipework.			Annual	
Check the oil flow and level by sight glasses.			Annual	

7.27. Service Circuits

7.27.1. Steam/Condensate circuit

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check calibration of pressure regulator.			Annual	
Check the efficiency of the condensate drains.			Annual	
Check for leaks in the circuit.			Annual	
Clean Y filters.			Annual	

7.27.2. Cold water circuit (+5°C)

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check calibration of pressure regulator.			Annual	
Check for leaks in the circuit.			Annual	
Clean Y filters.			Annual	

7.27.3. Chilled water circuit (-25°C)

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check calibration of pressure regulator.			Annual	
Check for leaks in the steam circuit.			Annual	
Clean Y filters.			Annual	

7.27.4. Hot water circuit

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for leaks in the circuit.			Annual	
Clean Y filters.			Annual	

7.27.5. Nitrogen circuit

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for leaks in the circuit.			Annual	
Replace cartridge filters.			Annual	

7.27.6. Reactors water supply circuit

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace softened water filters.			Every three months	
Check for leaks in the circuit.			Annual	

7.27.7. Storage tanks, wash water and process wastewater

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Verification, through an hydrostatic pressure measuring instrument, of any losses from the tank.			Every two years	
Verification of the level sensor alarm.			Every two years	

7.28. Service Equipment

7.28.1. Hoists

Lubricate the gear. Spread the lubricant and keep the gear thoroughly covered with the cart.	Visually check hoist integrity.	Check integrity and state of hook.	Maintenance Date	Operator Signature	Frequency
PR-01 (Maintenance Workshop)					
Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
PR-1P (Production area 1P)					
Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
PR-1101M (Room 11C)					
Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
PR-2101M (Room 12C)					
Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual

Maintenance Director Signature

Date

7.28.2. Transpallets

Duplicate this page if necessary Page ___ of ____

ID	Top up oil pump.	Lubricate roller bearings and steering wheels.	Lubricate the guide of the control lever that drives the pump.	Maintenance Date	Operator Signature	Frequency
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual

Maintenance Director Signature

Date

7.28.3. Flexible Pipes

Duplicate this page if necessary

Page ___ of ____

ID	Check integrity of tubing.	Check screws on attachment ties.	Maintenance Date	Operator Signature	Frequency
	Ok ☐ No ☐	Ok ☐ No ☐			Half-yearly
	Ok ☐ No ☐	Ok ☐ No ☐			Half-yearly
	Ok ☐ No ☐	Ok ☐ No ☐			Half-yearly
	Ok ☐ No ☐	Ok ☐ No ☐			Half-yearly
	Ok ☐ No ☐	Ok ☐ No ☐			Half-yearly
	Ok ☐ No ☐	Ok ☐ No ☐			Half-yearly
	Ok ☐ No ☐	Ok ☐ No ☐			Half-yearly
	Ok ☐ No ☐	Ok ☐ No ☐			Half-yearly
	Ok ☐ No ☐	Ok ☐ No ☐			Half-yearly
	Ok ☐ No ☐	Ok ☐ No ☐			Half-yearly
	Ok ☐ No ☐	Ok ☐ No ☐			Half-yearly
	Ok ☐ No ☐	Ok ☐ No ☐			Half-yearly
	Ok ☐ No ☐	Ok ☐ No ☐			Half-yearly
	Ok ☐ No ☐	Ok ☐ No ☐			Half-yearly
	Ok ☐ No ☐	Ok ☐ No ☐			Half-yearly
	Ok ☐ No ☐	Ok ☐ No ☐			Half-yearly

Maintenance Director Signature

Date

7.28.4. Fume hood QC1 and QC2

ID: FH01 (QC2)

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace the pre-filters.			Half-yearly	
Replace the Active Carbon filters.			Annual	
Front air flow measurement using methods and acceptance criteria regulated by the following technical standards: DIN 12924 Teil 1-4 and BS 7258 Part 1-4.			Annual	

ID: FH02 (QC1)

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace the pre-filters.			Half-yearly	
Replace the Active Carbon filters.			Annual	
Front air flow measurement using methods and acceptance criteria regulated by the following technical standards: DIN 12924 Teil 1-4 and BS 7258 Part 1-4.			Annual	

ID: FH03 (QC2)

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace the pre-filters.			Half-yearly	
Replace the Active Carbon filters.			Annual	
Front air flow measurement using methods and acceptance criteria regulated by the following technical standards: DIN 12924 Teil 1-4 and BS 7258 Part 1-4.			Annual	

ID: FH04 (QC1)

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace the pre-filters.			Half-yearly	
Replace the Active Carbon filters.			Annual	
Front air flow measurement using methods and acceptance criteria regulated by the following technical standards: DIN 12924 Teil 1-4 and BS 7258 Part 1-4.			Annual	

7.28.5. Maintenance of freezers and refrigerators

Duplicate this page if necessary Page ___ of ____

ID	Check the door seal	Clean the condenser coil	Manual defrost the unit	Maintenance Date	Operator Signature	Frequency
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual
	Ok ☐ No ☐	Ok ☐ No ☐	Ok ☐ No ☐			Annual

Maintenance Director Signature

Date

7.29. SAMPLING ROOM MAINTENANCE

7.29.1. Sampling room extractor hood

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace G4 filter on suction hood.			Half-yearly	

7.30. BUILDING MAINTENANCE

7.30.1. MAINTENANCE OF BUILDINGS INTERIOR

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the integrity of walls and roofs, absence of cracks, coating uniformity, absence of moisture patches.			Half-yearly	
Visually check glass integrity			Half-yearly	
Visually check doors integrity			Half-yearly	
Verify functionality of door handles			Half-yearly	
Check environment lumination			Half-yearly	
Check circuit breakers functionality			Half-yearly	
Verify functionality of emergency lighting			Half-yearly	
Check load applied to electric outlets			Half-yearly	

8. APPENDIX A: REPLACEMENT LABELS ON SOFTENED WATER FILTERS

SOFTENED WATER FILTER

SUBSTITUTION

MN.SOP.001
Rev 11
Date 09/07/2018

FILTER	
TOT. LITER COUNTERS on Installation	
DATE INSTALLATION	
DATE OF NEXT SUBSTITUTION	
PRODUCTION SIGNATURE	
QA SIGNATURE	

9. APPENDIX B: LABELS FOR FUME HOOD CAPS AND FILTERS SUBSTITUTION

FUMEHOOD/FILTERS CHECK MN.SOP.001
Rev 11
Date 09/07/2018

Date of check	
Date of next check	
Date of carbon filter change	
Date of next carbon filter change	
Date of substituting pre-filters	
Date of next pre-filters substitution	
PROCESS ENGINEER SIGNATURE	
QA SIGNATURE	

10. APPENDIX C: LABELS FOR PROCESS FLUIDS AND SERVICES

Label Color		Fluid
Text	Background	
White	Green	Chilled Water
White	Green	Cooling Water
White	Green	Hot Water
White	Green	Softened Water
White	Grey	Steam
White	Blue	Compressed Air
White	Yellow/beige	Nitrogen
White	Brown	Reactors Loading/Discharge
White	Yellow	Process Vacuum
White	Yellow	Service Vacuum
White	Yellow	Emergency Relievers
White	Yellow	Service Vents

11. APPENDIX D: DATA COLLECTION SHEET

Preventive Maintenance Checks: Fault Management

Reference Test and fault detected

Rif. Document	Rif. Equipment	Id	Part of equipment	Description of Intervention	Maintenance Date

Type of Maintenance (Internal/External)	Planned Frequency of Intervention (months)	External Company (if applicable)	Start Date	Planned Closing Date	Closing Date

Anomaly Noticed	

Maintenance Op.	Date	Process Engineer	Date	Approval	Date

Description of Recovery Work	

Maintenance Op.	Date	Process Engineer	Date	Approval	Date

Description of Materials Required for Restoration	

Maintenance Op.	Date	Process Engineer	Date	Approval	Date

Annex 7: HEPA filters test certificate

EMCEL Filters Limited
Blatchford Road | Horsham | West Sussex | United Kingdom | RH13 5RA
Tel: (01403) 253215 | Fax: (01403) 259881
Email: info@emcelfilters.co.uk | Web: www.emcelfilters.co.uk

CERTIFICATE OF CONFORMITY

Batch No. 47235.01

Customer:	Nuova Guseo s.r.l.
Order No:	1372
Drawing No:	E2234-40 Gr135 Issue 1
Description:	Cylindrical Leaf Seal HEPA Filter
Customer Ref:	CFE-H14-197D0300L-/RIF.CO.L59/CE (2 off) CFE-H14-197D0300L-/RIF.CO.L70/CE (3 off)
Serial No:	47235-01-01 to 47235-01-05
Quantity:	5 off

have been tested and/or inspected in accordance with the conditions and requirements of the contract or Purchase Order and unless otherwise noted conform in all respects to the specification(s) and drawing(s) relevant thereto.

Signed:

Print Name: Mr J D Robson

Authorised by:

Print Name: Mr R Clark

Date: 09 February 2018

EMCEL Filters Limited
Blatchford Road | Horsham | West Sussex | United Kingdom | RH13 5RA
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CERTIFICATE OF CONFORMITY

Batch No. 47235.03

Customer:	Nuova Guseo s.r.l.
Order No:	1372
Drawing No:	E2234-40 Gr134 Issue 1
Description:	Cylindrical Leaf Seal HEPA Filter
Customer Ref:	CFE-H14-236D0375L-/RIF.CO.L59/CE (1 off) CFE-H14-236D0375L-/RIF.CO.L70/CE (1 off)
Serial No:	47235-03-01 to 47235-03-02
Quantity:	2 off

have been tested and/or inspected in accordance with the conditions and requirements of the contract or Purchase Order and unless otherwise noted conform in all respects to the specification(s) and drawing(s) relevant thereto.

Signed:

Print Name: Mr J D Robson

Authorised by:

Print Name: Mr R Clark

Date: 09 February 2018

EMCEL Filters Limited
Blatchford Road | Horsham | West Sussex | United Kingdom | RH13 5RA
Tel: (01403) 253215 | Fax: (01403) 259881
Email: info@emcelfilters.co.uk | Web: www.emcelfilters.co.uk

CERTIFICATE OF TEST

Customer: Nuova Guseo s.r.l.

This is to certify that the item manufactured to your

Order No: 1372

Drawing No: E2234-40 Gr135 Issue 1

Product Description: Cylindrical Leaf Seal HEPA Filter

EMCEL Batch No: 47235.01

Serial No: 47235-01-02

Has been volumetrically tested to BS EN ISO 14644 Part 3 using an aerosol of Ondina oil

Aerosol Airflow Test Rate	74 cfm
Type Of Aerosol	Thermally generated poly dispersed ondina el oil
Challenge	32 µg/l
Penetration	0.0031 %
Efficiency	99.9969 %
Tested By	A. Macias
Date of Test	08/02/18
Instrument No	Smoke Generator P636, Photometer P685
Required Efficiency	99.995 %
Pass/Fail	PASS

Signed

Mr J D Robson
Quality Assurance Manager

Original to customer, copy to be retained by EMCEL Filters Limited. Details of results will be filed by batch number and held for 3 years.

EMCEL Filters Limited is proud to be affiliated with:

EMCEL Filters Limited
Blatchford Road | Horsham | West Sussex | United Kingdom | RH13 5RA
Tel: (01403) 253215 | Fax: (01403) 259881
Email: info@emcelfilters.co.uk | Web: www.emcelfilters.co.uk

CERTIFICATE OF TEST

Customer: Nuova Guseo s.r.l.

This is to certify that the item manufactured to your

Order No: 1372

Drawing No: E2234-40 Gr135 Issue 1

Product Description: Cylindrical Leaf Seal HEPA Filter

EMCEL Batch No: 47235.01

Serial No: 47235-01-01

Has been volumetrically tested to BS EN ISO 14644 Part 3 using an aerosol of Ondina oil

Aerosol Airflow Test Rate	74 cfm
Type Of Aerosol	Thermally generated poly dispersed ondina el oil
Challenge	34 µg/l
Penetration	0.0022 %
Efficiency	99.9978 %
Tested By	A. Macias
Date of Test	08/02/18
Instrument No	Smoke Generator P636, Photometer P685
Required Efficiency	99.995 %
Pass/Fail	PASS

Signed

Mr J D Robson
Quality Assurance Manager

Original to customer, copy to be retained by EMCEL Filters Limited. Details of results will be filed by batch number and held for 3 years.

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CERTIFICATE OF TEST

Customer: Nuova Guseo s.r.l.

This is to certify that the item manufactured to your

Order No: 1372

Drawing No: E2234-40 Gr134 Issue 1

Product Description: Cylindrical Leaf Seal HEPA Filter

EMCEL Batch No: 47235.03

Serial No: 47235-03-01

Has been volumetrically tested to BS EN ISO 14644 Part 3 using an aerosol of Ondina oil

Aerosol Airflow Test Rate	160 cfm
Type Of Aerosol	Thermally generated poly dispersed ondina el oil
Challenge	46 µg/l
Penetration	0.0037 %
Efficiency	99.9963 %
Tested By	A. Macias
Date of Test	08/02/18
Instrument No	Smoke Generator P636, Photometer P685
Required Efficiency	99.995 %
Pass/Fail	PASS

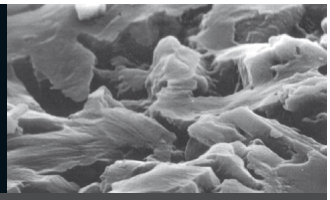
Signed

Mr J D Robson
Quality Assurance Manager

Original to customer, copy to be retained by EMCEL Filters Limited. Details of results will be filed by batch number and held for 3 years.

EMCEL Filters Limited is proud to be affiliated with:

Annex 8: Carbon filter specification sheet



Norit Electronic Version

Datasheet

Gas & Air

Norit R 2030 CO2

Norit R 2030 CO2 is a steam activated extruded carbon with a diameter of 3 mm. Due to the superior mechanical hardness and favourable adsorption properties, this is an excellent carbon type for the removal of carbon dioxide out of cold storage warehouses.

SPECIFICATIONS

Butane adsorption at p/p_0 = 0.1	**min. 13**	**g/100 g**
Butane adsorption at p/p_0 = 0.1	**max. 18**	**g/100 g**
Abrasion index	**max. 8**	**mg/min**
Moisture (as packed)	**max. 5**	**mass-%**

GENERAL CHARACTERISTICS

Butane adsorption at p/p_0 = 0.1	16	g/100 g
Total surface area (B.E.T.)	800	m^2/g
Apparent density	520	kg/m^3
Ball-pan hardness	99.9	-
Abrasion index	3	mg/min
Particle size > 2.36 mm	99	mass-%
Moisture (as packed)	1	mass-%
Ignition temperature, above	450	°C

Document No.

R203C

Product / Application

Extruded activated carbon

Version

13 July 2007

Norit Nederland BV

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NOTES

1 All analyses based on Norit Standard Test Methods (NSTM)
2 Specifications are guaranteed values based on lot to lot quality control, as covered by Norit's ISO 9001:2000 certification.
3 General characteristics reflect average values of product quality.
4 Detailed information on **pressure drop characteristics** in air can be found in Technical Bulletin TB 136: Pressure drop characteristics of Norit extruded activated carbon grades.

PACKAGING

Norit R 2030 CO2 is available in:
- Polyethylene bags of 25 kg, 44 bags per pallet, stretch wrapped on 115 x115 cm pallets (1100 kg net weight per pallet)

Product availabilities depend on the type of packaging.

This datasheet (Issue 13 July 2007) replaces previous issues.