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02 May 2014

Project No: 2014-020-001

Part B Permit Application Support

Prepared for:

Nagor Limited

Site 1 and Site 2 Tournament Way
Ivanhoe Industrial Estate
Ashby-de-la-Zouch
Leicestershire
LE65 2UU

Contents Amendment Record

This report has been issued and amended as follows:

Revision	Description	Date	Signed
1.0	Final	02 May 2014	Jill Cottrell

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Acknowledgement

Mabbett & Associates Ltd (Mabbett) have prepared this Part B Permit Application report in accordance with a scope of work presented in Mabbett Letter-Agreement dated 18 March 2014 (Ref.: 151-2014/LA/NS/pb). This report is based on information and data provided by Nagor Limited (Nagor) and data generated/collected by Mabbett. Should any of the information be incorrect, incomplete or subject to change, Mabbett may wish to revise the report accordingly.

The following Mabbett personnel completed this Part B Permit Application report:

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Environmental Engineer

The following Mabbett personnel reviewed and approved this Part B Permit Application report:

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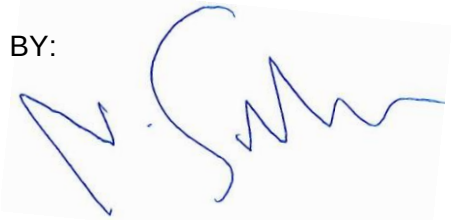

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Senior Environmental Engineer and
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Section 1.0 Introduction

1.1 Background

Nagor Limited (Nagor) provides this report for the purposes of the application to North West Leicestershire District Council (NWLDC) for a Part B Permit under the Environmental Permitting (England and Wales) (Amendment) Regulations 2013. This is to comply with the need to regulate the coating process activities under Part B Section 6.4 (a) (iv) of the Environmental Permitting Regulations, described as:

'*any process (other than for the re-painting or re-spraying of or of parts of aircraft or road or railway vehicles) for applying a substrate, or drying or curing after such application, printing ink or paint or any other coating material as, or in the course of, a manufacturing activity, where the process may result in the release into the air of particulate matter or of any volatile organic compound and is likely to involve the use in any twelve month period of five or more tonnes of organic solvents*'.

The entire site operated by Nagor has been referred to in this report as the '*Installation*'. The Installation comprises two separate buildings which are referred to by Nagor as Site 1 which includes shell manufacturing, texturing and curing and Site 2 which includes closure patching, gel filling, QA/QC, packaging and cutting. See Drawing L-1 Site and Installation Boundary in Appendix A. The part of the Site where the process to be permitted under PPC is proposed to take place has been referred to as the '*Stationary Technical Unit*'. For the purposes of this report the Stationary Technical Unit forms a portion of the overall Installation area and is the specific area to be assessed.

This report is provided to describe the proposed Stationary Technical Unit activities and the proposed techniques and measures to prevent and reduce waste arising and emissions of substances and/or energy (including leak or malfunction) to air.

At present the Stationary Technical Unit at the Nagor, Ashby-de-la-Zouch facility comprises the following operations:

- Moulding and Curing Process (involves numerous dipping, drying, curing and texturing stages).

In addition, the following Directly Associated Activities are also carried out on Site:

- Delivery, storage and handling of raw materials;
- Pre-treatment (including cleaning of mandrels and mixing of dispersions);
- Post-treatment (including closure patching and gel filling);
- Rinsing of product at various stages of the process; and
- General cleaning of product.

See Drawing L-2 Stationary Technical Unit and Directly Associated Activities Boundaries in Appendix A.

Section 2.0 Process Description

2.1 Non-technical Summary

Nagor manufactures medical devices for the aesthetic and reconstructive market. The product consists of three main components:

- Shell;
- Closure Patch; and
- Filling Gel.

Various solvent based materials are used within the manufacturing process to create a vulcanised elastomer product which is used to form the shells and closure patches. The shell and the closure patch (the latter of which is made up of three individual components, two of which are made from the same principle process detailed below but with different tooling) both utilise solvents; it is noted that the production of the shells utilises the largest quantity of solvents followed by the closure patches while the filling gel manufacturing process does not utilise any solvents.

The manufacturing of the shell component is a moulding process, whereby a two part mixture of dispersed polymers are chemically cross linked in the presence of a catalyst at high temperatures. A plastic mandrel is introduced into a bowl of dispersion (mixture of unreacted silicon elastomer and solvent). The plastic mandrel is then placed into a heating oven to evaporate the solvents from the elastomer (process of devolatilisation). This process is repeated up to four times for each mandrel until the shell has achieved the desired design. The tool is then placed in the heating curing oven to fully chemically cross link/vulcanise the shell prior to its removal from the tool using a manual stripping process. The shell is now available for use in the final product.

Further, various solvents are also utilised for general cleaning of equipment, clean-room furniture and the clean-room itself.

2.2 Technical Process Description

Nagor produce shells and filling gel at their Ashby-de-la-Zouch Site. The facility also cuts barrier sheets (produced in the companies Cumbernauld facility) into the required sizes for two of the three components of the closure patch. The final products produced are classified as medical devices for the aesthetic and reconstruction market.

The processes associated with the manufacturing of the shells, filling gel and overall finishing of the final product (cutting and application of the closure patch which are manufactured in the Cumbernauld facility and filling of the shell) are discussed individually below.

2.2.1 Shell

The shell material is manufactured through a polymerisation reaction which utilises a base elastomer, crosslinker and thinner material to form a liquid dispersion which is stored in small volume containers for use later in the process. Pre-shaped moulds, known as mandrels, are manually dipped into the liquid dispersion to create the desired shape of implant before being placed into a curing oven to set with the curing of the liquid dispersion being undertaken at elevated temperatures. The shells typically comprise four individual layers of cured dispersion material, with each layer being represented by one of the following chemical configurations (depending on the required specification):

- Dimethyl Dispersal Base, a crosslinker and xylene (a thinner); or
- Fluorosilicone Dispersion Base, a crosslinker and either tetrachloroethylene or nButyl Acetate (thinners).

Typically there is only one fluorosilicone layer (classed as a barrier layer) and three dimethyl layers with the barrier layer usually being the second laid down although this configuration can vary in terms of the choice of layers laid down and the total number based on the required product specification.

The chemicals (stored in 205 litre drums and 25 litre bottles) utilised to make the dispersions are stored out with the main production area and are piped into the mixing room. The required base, crosslinker and thinner material are metered into dedicated plastic containers (via dosing nozzles controlled by foot pumps) which upon completion of material transfer are sealed. The plastic containers are then mechanically shaken for three minutes to ensure a homogenous mix before being filtered through voile into a metal bucket/container to remove any pre-cured silicone and foreign material.

The metal buckets/containers are then covered in foil and stored on dedicated shelving in the flammable material cupboards within the '*Material on Hold*' area (located in the mixing room).

The shells (predominantly utilised for breast implants) produced by the Nagor, Ashby-de-la-Zouch facility are round in shape.

Typically 32 shells are processed per batch and once the required mandrels have been identified and sorted for use (based on the client order requirements i.e. size and shape) they are washed with filtered water and manually cleaned with Isopropanol Acetate prior to reuse in the dispersion moulding stage. After dipping into the liquid dispersion, they are placed in an oven at 53° C (temperature range between 50° C to 60 ° C) for 30 minutes to cure. In total, there are eight small ovens which can each hold a maximum of four mandrels. As noted, this process is repeated up to four times although it can be more if required, with at least one of the dips being made into a fluorosilicone dispersion (to form the barrier layer).

Following the final dispersion curing stage, the mandrels are removed from the ovens and undergo a further curing process (90 minutes at 145° C). Once this is complete the mandrels are removed from the oven and allowed to cool to ambient room temperature over approximately one hour. At this point up to 30 % of the mandrels are removed from the batch (designated as smooth shells), placed into work-in-progress holding areas before re-join the process at the shell stripping stage (see below for details). The remainder of the mandrels are then pre-heated in an oven for 20 minutes at 60 ° C prior to undergoing a texturing process.

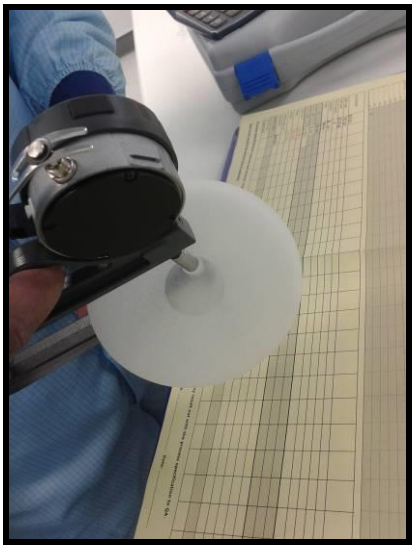
Note: The texturing process is undertaken to assist reduce the occurrence and impact of capsular contracture, which is the creation and hardening of a 'capsule' around the implant and which can lead to sever pain and discomfort for the patient. A number of clinical studies suggest that the texturing of the implant can disrupt the formation of these capsules around the implant.

The texturing process involves dipping the heated, coated mandrels into the dimethyl dispersion again to form an additional layer which can then undergo a texturing process. The application of the texture is achieved by shot-blasting the surface of the shells with sodium chloride particles (between 0.25 mm – 1.00 mm in diameter) for four full rotations of the mandrels in the texturing machine. The mandrels are then allowed to stand for 20 minutes and then they are moved back to the ovens to be cured for 45 minutes at 145° C. Following this curing stage, the shells are allowed to cool prior to being washed in warm filtered water.

The smooth and textured shells are then manually stripped from the mandrels before undergoing a final heat treatment for 90 minutes at 150° C. The shells are then moved from Site 1 to Site 2 where the manufacturing process resumes.

At this stage, the shells undergo three quality tests:

- Visual inspection to include aesthetic appearance and texture uniformity;
- Dimensional inspection (thickness); and
- Air testing for leaks (shell inflated with air and then submerged in water).



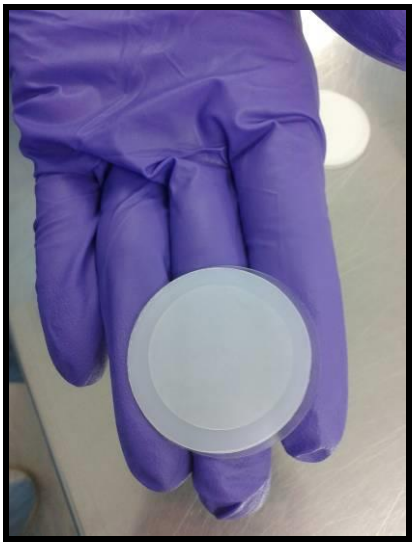
Following this inspection, the smooth shells are cleaned with IPA and the textured shells are placed in a washing machine on a cool cycle. All shells are dried (smooth shells dry on racks while the textured shells are tumbled dried) before being stored as work-in-progress until required.

2.2.2 Closure Patch

As the plastic mandrels leave a circular hole in the shell, a closure patch is required to fully seal the hole so that once the gel is inserted no leakages can occur.

The three components that make up the closure patch are:

- ID disc (cut from barrier sheet);
- Raw disc (cut from rubber compound to a specified thickness); and
- Barrier disc (cut from barrier sheet).



The ID and Barrier discs are made using barrier sheets, which are manufactured in the Cumbernauld facility, and are cut to the required shape (utilising specialist cutting tools) at the Ashby-de-la-Zouch facility. Nagor report that, on average, 70 barriers sheets per week are dispatched to the Ashby-de-la-Zouch facility for further processing. Between 80 and 100 closure patches can be made out of each barrier sheet.

Once selected to fill an order, the work-in-progress shells are moved to the finished goods manufacturing stage. Initially the shells are kitted which involves the selection of all the patch components required i.e. the ID disc, the raw disc (which is stored in a fridge to keep the product cool so as to reduce smudging and marking the patch) and the barrier disc under an MR004 form (Quality Form). The ID disc is then etched by laser with the shell details which includes product code, size and lot number.

The closure patch is then assembled and this comprises a number of stages (see Shell Assembly Manufacturing Process, 21 March 2014 in Appendix B):

- Place 40 mm barrier disc on the platform (dull side down) and clean the top side with IPA;
- Turn the 40 mm barrier disc over using tweezers so that the shiny side is down and wipe the dull side with IPA;
- Take the raw disc and remove the plastic protection from one side;
- Place the exposed side of the raw disc on the cleaned dull surface of the 40 mm barrier disc;
- Gently press down to remove any air from between the two meeting surfaces;
- Take the ID disc and place on platform (shiny side down) and wipe with IPA;
- Turn the ID disc over using the tweezers and clean the shiny side with IPA;
- Gently remove the plastic protection from the raw disc attached to the 40 mm barrier disc using tweezers;

- Place the ID disc (dull side down) to the exposed raw disc;
- Take a myler strip and place in position (this will allow for an injection point for the gel);
- Place the shell on the dome mandrel and place the closure patch assembly ensuring that there are no gaps, creases or air trap between the layers;
- Place assembled shell on the vulcanising platform; and
- Operate vulcanising equipment (3 minute cycle at 160° C).

The shells now complete with closure patch are leak tested in water and dried in a tumble dryer (in net bag) prior to gel filling.

2.2.3 Filling Gel

The gel compromises two components; a gel base and a gel crosslinker. Different specifications of gel can be prepared based on the desired '*firmness*' required for the product. The usual ratio is 3:1 but can vary (between 3:0.8 and 3:1.2). After preparation of the filling gel batch, four 0.72 gram samples and one shell filled with 360 grams of the mixed gel are prepared and placed into an oven for 270 minutes at a temperature of 165° C. The samples are then inspected for density (cohesion and penetrometer test) and if determined to be unsuitable the filling gel batch can be reworked (reworking can only occur once) before undergoing retesting. If the filling gel fails the density testing again then the gel is rejected.

Once the desired density has been achieved, the filling gel is injected (via the injection point made by the myler strip) by machine into the semi-complete shells. This is an empirical process and if additional gel is needed to increase the weight of the product then this is added manually using a needle.

The filled shells are then placed in a vacuum prior to moving to the de-airing area. De-airing of the product uses a blunt needle to remove any excess air and if air is still noted to be present within the filled shell, the vacuum/de-airing process can be undertaken up to three times before the product has to be rejected. Once all of the air is removed, the filled shell is inspected and weighed (allowed to be + or - 2 to 3 grams depending on the product) prior to being sealed with medical grade, room temperature vulcanising silicone adhesive.

The filled shells are then held for a minimum of 60 minutes following sealing prior to the final curing process (oven heated for 270 minutes at 150° C). The product is then cooled to room temperature on racking (normally 150 minutes).

The product then goes to QA/QC for a final visual inspection prior to cleaning with IPA and packaging (product placed in pouches and boxed and labelled).

2.2.4 Additional Information

There are currently four atmospheric discharge emission points at Site 1 and these release discharges from the following process areas:

- Dipping Ovens (emission of xylene, tetrachloroethylene and n-Butyl Acetate);
- Texturing Booth (emission of salt);
- Curing Ovens (hot air extraction); and
- Wash Station (IPA fume extraction).

There are currently three atmospheric discharge emission points at Site 2 and these release discharges from the following process areas:

- Curing Ovens (hot air extraction); and
- Wash Station of shells and utensils (two IPA fume extraction).

Currently no historic emission monitoring has been undertaken for these discharge points. However Nagor have committed to fully quantifying the physical parameters and contaminant loading associated with all relevant atmospheric discharges and an **Action Item** has been included on the PPC Action Plan for the Site to ensure this data is generated in a timely manner (See Appendix C Nagor Environmental Permitting Action Plan). Furthermore, an **Action Item** has been noted to generate a complete list of all atmospheric emission points detailing their source processes, unique identification tag, physical location, design specification etc.

2.3 Best Available Techniques

The manufacturing area within the installation has continually evolved as the demand for the product has increased in recent years. Historically, the quantities of solvents utilised at the site were noted to be less than the prescribed limits and as such no consideration of how to ensure compliance with Best Available Techniques (BAT) was given. An **Action Item** has been raised by Nagor to identify where gaps may exist between current practices and the requirements of indicative BAT for the manufacturing processes undertaken at the Installation. Where gaps are identified further work will be required to ensure suitable measures are taken to achieve BAT for all aspects of the permitted process.

2.4 Site Plans

The Nagor facility (central grid reference 318000N, 435090E) is located within the Ivanhoe Industrial Estate approximately 1.5 km north west of Ashby-de-la-Zouch town centre. The surrounding area is predominantly utilised for commercial/industrial purposes.

The Nagor facility comprises two units: Unit 7 (referred to by Nagor as Site 1) and Unit 11 (referred to by Nagor as Site 2). Both Units are located along Tournament Way (Unit 7 is located to the south of Tournament Way while Unit 11 is located to the north) which is located off to the east of the B6006 (Simsby Road).

Unit 7 is a small one-storey rectangular warehouse unit which is internally divided into two units (Nagor Ltd and Ashby Microsystems Ltd). The Unit is constructed of corrugated metal sheets and red bricks and has a corrugated sheet metal apex roof. The following rooms were identified in Unit 7:

- Ante room;
- Cleaning Room;
- Mixing Room;
- Dipping Room including dipping ovens, curing ovens and dispersion storage; and
- Clean Room including curing ovens, auto-texturing booth and hot water tank.

Unit 11 is a two-storey L-Shaped warehouse building constructed of red brick and corrugated metal sheet with a corrugated metal sheet apex roof. Unit 11 has a small car park and external chemical storage area (square red brick built building with slate apex roof located approximately 20 m to the south of the main building). Unit 11 is utilised as the companies Ashby-de-la-Zouch main office and includes offices and dispatch. Additional process rooms identified in Unit 11 include:

- Clean Room including curing ovens, gel filling, vacuum chamber, de-air and sealing and final inspection; and
- Clean Room Extension including vulcanisers and laser etching.

The Site is predominantly surrounded by industrial and commercial properties, although an area of rough grassland is located to the north of the site. Residential properties are located approximately 250 m to the south of the site.

Drawing L-1 Site and Installation Boundary diagram is included as Appendix A to this Permit Application Report.

Section 3.0 Raw Materials Inventory

The Installation utilises a variety of chemicals and as such, consideration regarding the purchase, storage and safe handling of these raw materials throughout the life of the Permit should be given. An **Action Item** has been noted to assist ensure that any gaps in relation to the current procedures relating to Raw Materials and the requirements of Indicative BAT are met in a timely manner.

Raw material data based on 2012-2013 consumption has been provided by Nagor and quantities are presented in the table below:

Raw Material Consumption Data 2012 - 2013

Chemical	Usage (kg/unit)	Container Size & Type	Process Usage i.e. Dispersion Thinner or Cross-linker etc.
Xylene	6,200	200 litre plastic drum	Shell Manufacturing - Thinner
Tetrachloroethylene	1,303	25 litre plastic drum	Shell Manufacturing - Thinner
nButyl Acetate	82.6	2.5 litre glass bottle	Shell Manufacturing - Thinner
Isopropanol Alcohol	4,108	200 litre plastic drum	General cleaning and cleaning of product
Sodium Chloride	2,800	25 kg bags	Texturing of Shells
Responsive Gel_PN 40004	10,132	204 kg steel drum	Gel Mixture
Primer_PN 40096	5.808	1 pint tins	Lubricant used on gel sheeting
LSR10-1-PART-A-B_PN 40029	100	Base - 18 kg drums Cross-linker – 2 kg plastic buckets	Custom Fabrication, Silicone Blocks
HS RTV Silicone Elastomer_PN 40021	204	204 kg steel drum	Shell Manufacturing
HS Firm Silicone Gel_PN 40135	12,146	204 kg steel drum	Gel Mixture
HS Firm Gel_PN 40022	320	180 kg base 20 kg x linker steel drum	Gel Mixture
Fluoro Dispersion_PN 40130	2,876	204 kg steel drum	Shell Manufacturing – Fluorosilicone Layer
Dimethyl Dispersion_PN 40000	12,444	204 kg steel drum	Shell Manufacturing – Dimethyl Layer

This usage information is based on actual consumption during the detailed time period. The volume of material held on Site at any one time will depend on the requirements of production planning and will likely vary over any given period. Nagor are committed to the optimisation of the process operations and work to minimise chemical raw materials usage on an on-going basis.

In order to quantify usage more accurately, Nagor have an implemented Quality Assurance Procedure for Purchasing and Order Processing, Section 5.0 (QP006 0116). This is an electronic system which utilises minimum and maximum quantities of raw materials, re-order quantities and stock balance (free and allocated). This minimises the quantities of excess chemicals stored on-site un-necessarily (see Appendix D Quality Manual Procedures).

Nagor maintain a raw materials inventory for the Installation. A modified version of this inventory is presented for reference in Appendix E to this Permit Application and contains the following information on each of the raw materials:

- Chemical trade name and supplier;
- Principal use and Description of process utilising chemical;
- Chemical constituents;
- Annual usage;
- Annual usage of individual chemical constituents;
- Packaging type and size;
- ID (CAS Number);
- Details of associated hazards;
- Chemical risk phrases;
- Health & Safety risk phrases; and
- Fate/disposal method.

Additional process or chemical specific information shall be included as required.

Production demands require that Nagor maintain a sufficient on-site chemical inventory to allow the process to continue without major interruptions in the event of a delay in delivery. The stock of chemicals held on site is adequate for the infrastructure and management procedures that are in place in order to comply with all relevant material handling requirements. Nagor confirmed that the chemical storage areas are located within impervious bunds for the stored chemicals and that the capacity is 110 % of the largest storage container or 25 % of the total storage volume etc.

The following table provides details of the indicative Best Available Technique requirements for the selection of chemical raw materials.

Indicative BAT Requirements	Nagor Response	Action Plan	Target Date
The Operator should create and maintain a full chemical raw material inventory.	A chemical raw material inventory has been prepared to accompany this Permit Application and is presented in Appendix E.	Ongoing.	Ongoing.
The Operator should have procedures for the regular review of new developments in raw materials and the implementation of any suitable ones that are less hazardous.	Nagor acknowledge that selection of raw materials represents an opportunity to control emissions at source. As part of their commitment to continual process improvement Nagor routinely review advances in chemical raw material selection on a regular basis in order to ensure that cost effective options for substituting existing chemical raw materials for less hazardous options are fully investigated and where applicable implemented.	Ongoing.	Ongoing.
The Operator should have quality-assurance procedures for controlling the content of raw materials.	Nagor operates dedicated procedures for the control of raw materials. The procedure includes visual, attribute and physical testing on the good received (depending on the nature of the product). All raw materials are purchased from ISO certified companies (which includes certificates of conformance and analysis). See Appendix D Control of Incoming Goods (QP017 0112).	Ongoing.	Ongoing.
The Operator should complete any longer-term studies needed into the less polluting options and should make any material substitutes identified.	Nagor are committed to continuous improvement and shall review options for substitution and implement alternative where economically and technically feasible. *See Appendix F Nagor Correspondence from Applied Silicone (Raw Material Supplier) dated 02 April 2014.*	Ongoing.	Ongoing.

Note: Due to the medical nature of the products being manufactured, any changes in the products being utilised require authority from the appropriate regulators. Therefore, it is unlikely that substitutions to the current chemicals utilised would be undertaken in the short term (see Appendix F Nagor correspondence from Applied Silicone, a raw material supplier detailing potential impacts of deviating from the current raw materials utilised) without a major external driver i.e. considerable financial benefit over the status-quo, significantly improved environmental performance, regulator requirements etc. However, as noted, Nagor are committed to the continual review of possible alternative chemical raw materials and will consider improvement where deemed to be technically and economically feasible.

Material Safety Data Sheets for all materials currently utilised are included as Appendix G to this Permit Application report.

Section 4.0 Environmental Management Systems

4.1 Environmental Management Systems

While Nagor have a number of procedures in place these have not yet been formalised into an accredited internal Environmental Management System. It has been confirmed that a longer term project is underway to investigate the benefits of achieving formal registration to ISO 14001. It is therefore considered likely that Nagor will look to produce an internal Environmental Management System (including an Environmental Policy) that aligned with ISO 14001 and which can developed, if required, to allow formal register under ISO 14001 at a future date. An **Action Item** has been raised to track the development and implementation of the internal Environmental Management System for the site and the processes undertaken.

Nagor do have a range of environmental procedures in place that although not formalised are utilised throughout the day-to-day running of the site and this includes spill procedures for 50 litre and 205 litre containers (see Appendix G).

4.2 Quality Management Systems

As a producer of medical devices, Nagor manage all aspects of the operations undertaken at Ashby-de-la-Zouch with a high level of quality control. While the systems in place are not formalised to ISO 9001 standard, they are formalised under ISO 13485 which is audited by BSI on an annual basis. Further, the systems in place are in line with the Quality System Regulation (21 CFR part 820), the Medical Device Directive (MDD93/42/EEC) and the Brazilian Good Manufacturing Practice Technical Regulation, Resolution RDC Number 16 (RDC 16). Key sections of the ISO 13485 Quality Management System formalised by Nagor include:

- Quality Policy;
- Resources;
- Quality System;
- Design Control;
- Purchasing;
- Product Identification and Traceability;
- Receiving Inspection and Testing;
- Final Inspection and Testing;
- Inspection Measuring and Test Equipment;
- Control of non-conforming Products;
- Corrective and Preventative Action;
- Quality Records;
- Training;
- Custom Made Devices;
- Quality Plans;
- Change Control.
- Responsibility and Authority;
- Management Representative and Review;
- Contract Review;
- Document and Data Control;
- Customer Supplied Product;
- Process Control;
- In Process Inspection and Testing;
- Inspection and Test Records;
- Inspection and Test Status;
- Non-conformity Review, Disposition and Rework;
- Handling, Storage, Packaging Preservation and Delivery;
- Internal Quality Audits;
- Statistical Techniques;
- Validation;
- Complaint Files; and

Nagor have confirmed to Mabbett that they are currently investigating the creation and implementation of an internal Quality Management System registered to ISO 9001. An **Action Item** has been raised to track the development and implementation of the internal Quality Management System for the site and the processes undertaken.

The following table provides details of the indicative Best Available Technique requirements for effective process management.

Indicative BAT Requirements	Nagor Response	Action Plan	Target Date
Effective operational and maintenance systems should be employed on all aspects of the process whose failure could impact on the environment, in particular there should be: ▪ documented procedures to control operations that may have an adverse impact on the environment; ▪ a defined procedure for identifying, reviewing and prioritising items of plant for which a preventative maintenance regime is appropriate; ▪ documented procedures for monitoring emissions or impacts; and ▪ preventative maintenance programme covering all plant, whose failure could lead to impact on the environment, including regular inspection of major 'non-productive' items such as tanks, pipework, retaining walls, bunds ducts and filters	Nagor has in place documented procedures to assist minimise their impact on the environment. Planned preventative and reactive maintenance is undertaken on all key plant and equipment that could result in a change to the facility's impact on the environment. *See Appendix I for Weekly Maintenance and Calibration Sheets.* At present, no procedures are in place for monitoring emissions to atmosphere and the overall environmental impact of the Installation. An **Action Item** has been raised to develop these procedures.	Develop formal monitoring procedures / criteria and undertake monitoring of relevant atmospheric emissions.	Q3 2014.
The maintenance system should include auditing of performance against requirements arising from the above and reporting the result of audits to top management.	Planned preventative and reactive maintenance is undertaken on all key plant and equipment that could result in a change to the facility's impact on the environment. *See Appendix I for Weekly Maintenance and Calibration Sheets.* Failure of plant and equipment and a record of maintenance interventions is logged and the data is reported to management as appropriate.	Ongoing.	Ongoing.
Training systems, covering the following items, should be in place for all relevant staff which Cover: ▪ awareness of the regulatory implications of the Permit for the activity and their work activities; ▪ awareness of all potential environmental effects from operation under normal and abnormal circumstances; ▪ awareness of the need to report deviation from the Permit; and ▪ prevention of accidental emissions and action to be taken when accidental emissions occur.	Induction training systems are in place for all new starts and ad-hoc training is also provided on an as required basis *(see Appendix H Environmental Management Procedures – Spill Procedures and Appendix D Quality Manual Section QM 028 – Training).*	Ongoing.	Ongoing.
The skills and competencies necessary for key posts should be documented and records of training needs and training received for these post maintained.	Job descriptions contain details of skills and competencies necessary for each post (*see Appendix D Quality Manual – Section QM 004 – Responsibilities and Authorities).*	Ongoing.	Ongoing.
The key posts should include contractors and those purchasing equipment and materials.	Contractors and those purchasing equipment and materials are also covered.	Ongoing.	Ongoing.
The potential environmental risks posed by the work of contractors should be assessed and instructions provided to contractors about protecting the environment while working on site.	Controls are in place to minimise the impact of all work undertaken by third party contractors.	Ongoing.	Ongoing.
Where industry standards or codes of practice for training exist (e.g. WAMITAB) they should be complied with.	Where appropriate, all industry codes and standards are adhered to.	Ongoing.	Ongoing.
There should be written procedures for handling, investigating, communicating and reporting actual or potential non-compliance with operating procedures or emission limits.	Actual and potential non-compliances or near misses are documented and where appropriate action is taken to rectify any issues.	Ongoing.	Ongoing.

Indicative BAT Requirements	Nagor Response	Action Plan	Target Date
There should be written procedures for handling, investigating, communicating and reporting environmental complaints and implementation of appropriate actions.	Environmental complaints are documented and where appropriate action is taken to rectify any issues.	Ongoing.	Ongoing.
There should be written procedures for investigating incidents, (and near misses) including identifying suitable corrective action and following up	Actual and potential non-compliances or near misses are documented and where appropriate action is taken to rectify any issues.	Ongoing.	Ongoing.
The company should preferably adopt an environmental policy and programme which: ▪ includes a commitment to continual improvement and prevention of pollution; ▪ includes a commitment to comply with relevant legislation, and with other requirements to which the organisation subscribes; and ▪ identifies, sets, monitors and reviews environmental objectives and key performance indicators independently of the Permit.	No formal EMS exists although internal procedures cover all activities that could result in a change to the facility's impact on the environment.	Ongoing.	Ongoing.
The company should preferably have procedures which incorporate environmental issues into the following areas (as supported by demonstrable evidence e.g. written procedures): ▪ the control of process change on the installation; ▪ design and review of new facilities (including provision for their decommissioning), engineering and other capital projects; ▪ capital approval; and ▪ purchasing policy.	No formal EMS exists although internal procedures cover all activities that could result in a change to the facility's impact on the environment.	Ongoing.	Ongoing.
The company should preferably have audits, at least annually, to check that all activities are being carried out in conformity with the above requirements. These should preferably be independent.	Annual, internal audits are undertaken by Nagor and all findings documented and actioned as appropriate (see Appendix D Quality Manual QM 027 – Internal Audits).	Ongoing.	Ongoing.
The company should preferably report annually on environmental performance, objectives and targets, and future planned improvements. This should preferably be a public environmental statement.	Internal reporting is undertaken on an annual basis.	Ongoing.	Ongoing.
The company should preferably have a registered or certified EMAS/ISO 14001 system (by an accredited certification body).	No formal EMS exists although internal procedures cover all activities that could result in a change to the facility's impact on the environment.	Ongoing.	Ongoing.
The company should preferably have a clear, logical and recorded system for keeping records of: ▪ policies; ▪ roles and responsibilities; ▪ targets; ▪ procedures; ▪ results of audits; and ▪ results of reviews.	Internal reporting is undertaken on an annual basis (see Appendix D Quality Manual – QM001).	Ongoing.	Ongoing.

Section 5.0 Monitoring

No historic emission monitoring has been undertaken for the Ashby-de-la-Zouch facility. An **Action Item** has been raised to track the completion of quantitative stack testing in order to speciate and quantify the concentration of emissions of relevant contaminants from the various manufacturing activities undertaken and the physical data associated with each release (volumetric flowrate, temperature, moisture content etc.). Details of the emissions monitoring exercise will be submitted to NWLDC upon completion.

Section 6.0 Emissions Inventory

No historic emission monitoring has been undertaken for the Ashby-de-la-Zouch facility. An **Action Item** has been raised to track the completion of quantitative stack testing in order to speciate and quantify the concentration of emissions of relevant contaminants from the various manufacturing activities undertaken and the physical data associated with each release (volumetric flowrate, temperature, moisture content etc.). Details of the emissions monitoring exercise will be submitted to NWLDC upon completion.

In addition, once data is available for the emission to atmosphere, a mass balance exercise will be undertaken to quantify fugitive emissions arising from the Ashby-de-la-Zouch facility.

Furthermore, an **Action Item** has been noted to generate a complete list of all atmospheric emission points detailing their source processes, unique identification tag, physical location, design specification etc.

Section 7.0 Impact Assessment

No historic emission monitoring has been undertaken for the Ashby-de-la-Zouch facility. An **Action Item** has been raised to track the completion of quantitative stack testing in order to speciate and quantify the concentration of emissions of relevant contaminants from the various manufacturing activities undertaken and the physical data associated with each release (volumetric flowrate, temperature, moisture content etc.). Details of the emissions monitoring exercise will be submitted to NWLDC upon completion.

In addition, once data is available for the emission to atmosphere, a mass balance exercise will be undertaken to quantify fugitive emissions arising from the Ashby-de-la-Zouch facility. An **Action Item** has been raised to track the completion of the mass balance exercise.

Furthermore, once emission concentration data is available, the impact of the facility will be quantified by direct comparison against the relevant BAT emissions limit values. Where required, it is anticipated that further work will be undertaken to optimise the site impact through improved/modified management procedures, production processes and/or engineering controls. Where appropriate, computerised, Air Dispersion Modelling will be utilised to assist determine the off-site impact. An **Action Item** has been raised to track the completion of quantifying the facilities impacts including the off-site impacts.

Section 8.0 Statutory Consultees

8.1 Local Authority

The Nagor facility falls within the North West Leicestershire District Council located at:

North West Leicestershire District Council
Environmental Health
Council Offices
Coalville
Leicestershire
LE67 3FJ

8.2 Health Board

NHS England (Leicestershire and Lincolnshire Area Team)
Fosse House
6 Smith Way
Grove Park
Enderby
Leicestershire.
LE19 1SX

8.3 SSSI/European Conservation Sites

There are no known SSSI within 2 km radius of the Nagor facility boundary. Information on the SSSI locations within this area was obtained from the DEFRA website:

http://magic.defra.gov.uk/MagicMap

8.4 COMAH

It is not anticipated that the Ashby-de-la-Zouch facility will fall under the COMAH regulations at this time. Consideration will however, be given to any future changes in the regulations and/or activities undertaken at the facility and where appropriate this classification will be revised.