Rentokil Initial Supplier Management Standard

Full Version – Issue 5 – September 2019

Supplier Selection & Assessment

Introduction

Rentokil-Initial (RI) has identified a need for a rigorous approach to supplier management, which is designed to encompass the entire relationship with the supplier, from initial supplier assessment and selection, through to the establishment of a supply agreement / contract and ongoing performance management of the supplier in question.

Audit Preparation and Planning

In order for everyone to gain the most value from an audit the supplier should have a clear understanding of the audit requirements prior to the audit itself.

Suppliers will be informed of RI's expectations in advance of the audit. This will ensure that RI has time for adequate planning and enable a productive audit. Suppliers may want to organise themselves to ensure that there is a good understanding of the Standard.

There is a requirement for the supplier to plan carefully for the audit, to have the appropriate documentation ready and to have appropriate staff available at all times during the on-site audit.

The scope of the audit, which must be understood by the supplier, shall cover the agreed products or product categories. All products within a certain area of the site and using the same production processes would normally be included within the scope of the audit. Different types of products made on the same site or products clearly intended for different geographical regions may be excluded from the scope. Other exclusions would require to be justified and should be confirmed prior to an audit visit.

The supplier shall ensure that production at the time of the audit covers products within the intended scope of the audit. Where possible, the widest range of these products shall be in production for the auditor to assess. Where the product range is large or diverse, the auditor has the discretion to continue the audit until sufficiently satisfied that the intended scope of the audit has been assessed.

The On -site Audit

The on-site audit consists of the following:

- The opening meeting – to confirm the scope and process of the audit.
- Production facility inspection – to review practical implementation of the systems, documentation and interview personnel. This stage might be repeated more than once to verify information.
- Review of all supporting and service areas, e.g. Customer Services, Maintenance, Logistics, etc
- Final review of findings by the auditor – preparation for the closing meeting
- Closing meeting – to review audit findings with the company and outline the next steps.

During the audit process, the auditor will require to interview members of staff from all levels of the organisation that could have an impact on product quality. It is possible that confidential interviews with staff will be requested with regards to asking questions related to Corporate Social Responsibility (including Modern Slavery).

All information viewed during the audit is regarded as confidential between the auditor and the site, except as detailed in the audit report. No non-RI brand names or similar identifiers of product will be released in the audit report.

Audit Reporting

Following each audit a full report will be issued. Within 2 working days of the audit a list will be supplied showing all non-conformances identified during the audit. This will be provided in a standard format which will need to be completed by the supplier and returned to Rentokil-Initial within 2 weeks of receiving it. It will contain the action plan stating corrective actions, time lines & persons responsible.

The detailed audit report section shall include comments where criteria have been met, particularly where improvement or enhancement is evident, and objective evidence to support any non- conformities that have been identified. Photographs may be used to demonstrate non-conformances or observations.

Audit reports shall remain the property of RI and shall not be released, in whole or part, to a third party unless the supplier has given prior consent (unless otherwise required by law). This may be by a consent form, or may be contained within a contract between Rentokil Initial and the supplier.

Ongoing Audit Frequency and Supplier Approval

A follow up audit might be required if there have been a significant number of non-conformances, or some serious non-conformances, or where the response to the audit is considered inadequate.

If a factory changes significantly in any way, for example a significant change of senior or technical management, production of different product types or supply to a new geographical area then a re-audit will be required as soon as possible to establish continuing conformity.

Non-conformances

During the audit, the auditor will determine the degree of any non-compliance to each clause and sub-clause and each of these will be categorized as:

- **Critical** - Failure to meet a product safety standard or a legal standard; where this failure puts the customer and or the Rentokil Initial brand integrity, at risk. Such a non-conformance might result in the cessation of an audit.
- **Major** – A deficiency which requires prompt attention to prevent a potential product safety or quality failure or legal issue from arising;
- **Minor** – A deficiency to this standard which, whilst not an immediate high risk, has the potential to affect product quality.

Each relevant main clause will be scored according to whether there are any non-conformances within that clause:

All sub-clauses satisfactory: 2
Minor non-conformance(s): 1
Major non-conformance(s): -3

Any critical non-conformances will result in no score for the audit.

Opportunities For Improvement (OFI) may also be identified during the audit and included within the Audit Report. These are generally recommendations to consider a way of improving a process, and are not considered a non-conformance at the time of the audit.

For audits where a site has not previously worked with RI and is being audited as part of the initial approval process, the site will be rated from a Corporate Social Responsibility and Quality perspective as 'Low Risk', 'Medium Risk' or 'High Risk' for future production. The scoring is for a guideline only. The rating will usually be based on non-conformances being addressed in a timely manner.

For audits where a site is currently providing products for RI, there will be a rating as 'Low Risk', 'Medium Risk' or 'High Risk' relating the ongoing production and for the potential to consider the site for new business or increased levels of production.

All processes within the manufacture of a 'product' will be subject to the audit and this may in some cases involve the audit at one or more premises by RI e.g. when a product is transferred to a different location for a finishing process. In the event that one or more premises are audited under one product audit, the report shall clearly indicate this information.

Product Groups

When conducting the audit it is important that the correct product group is selected prior to the audit due to the wide range of products sourced by Rentokil Initial. Some requirements may be essential for some types of product but not particularly important for others. This Standard divides products into three product groups

Group 1 - ***Products that have product specific safety legislation and are required to be manufactured under hygienic conditions either by law or to prevent microbiological or other contamination that has the potential to cause serious injury or death during normal or foreseeable use of the product***
Product types within this group include Cosmetics & Biocides.

Group *2* - ***All other products other than garment Manufacture.***

Group 3- ***Garment Manufacture.***

Appendix 1 Rentokil-Initial Requirements

This appendix details 40 clauses (including two split clauses) to be audited during the Supplier Audit. Under each clause is a number of sub-clauses, each numbered for reference purposes. Column 2 of the table details to which product group(s) an individual sub-clause applies.

1 Corporate Social Responsibility – Internal Controls

Clause	Product Group	Requirements
1.1	All	There will be a code of conduct that defines the behaviours expected of employees in their dealings with their colleagues and other stakeholders. Note: Membership to SEDEX is recommended
1.2	All	There will be defined policies in place, that applies to all employees and its agents, to ensure the ethical code of conduct, e.g.: anti-bribery and corruption policy, anti-harassment policy, conflict of interest policy, etc
1.3	All	There will be a process to ensure that staff have read and understood the documents above
1.4	All	There shall be appropriate training and refresher training of staff at all levels to ensure compliance to the above, with a particular focus on staff who have direct contact with external stakeholders
1.5	All	Adequate training and procedures need to be in place to prevent a breach of the General Data Protection Regulations.

2 Corporate Social Responsibility – Through the Supply Chain

Clause	Product Group	Requirements
2.1	All	The company shall be familiar with the RI Supplier Code of Conduct, and will have taken appropriate steps to ensure that the company is compliant to the requirements within this code
2.2	All	The company shall have a clear policy showing what steps are taken to ensure that Corporate Social Responsibility is adequately controlled throughout their Supply Chain. If the company has made a public statement, e.g. relating to the Modern Slavery Act, this should be shared with the auditors.
2.3	All	The company shall understand the key risk areas within their Supply Chain (not just relating to their direct suppliers, but including second tier and third tier suppliers, and in some instances beyond) with regard to Corporate Social Responsibility.
2.4	All	The following shall be defined as requirements throughout the Supply Chain: ● Respect for Human Rights ● A minimum age of people employed to work by the company ● Children are not to be employed ● The use of forced labour clearly forbidden ● Employees normal working hours will be defined ● Wages and benefits comply with local law (or are in line with industry norms, where these are higher than the legal minimum wage)

		• It shall be ensured that all staff are adequately covered by social insurance • Passports and identification cards are not to be withheld from staff • Recruitment fees are not to be charged to new employees and held as a debt against them • Employees are to be free to resign from their employment at any time, giving reasonable notice, without penalty • Minimum Health & Safety standards are met Note: If the company has been formally audited relating to any of the above, the results of the audits are to be shared during the RI audit
2.5	All	The supply chain shall be audited to demonstrate compliance with the above e.g. the minimum expectation would be the use of a questionnaire. Where key materials or components are purchased from high risk areas, there shall be a process to identify the risk, and where appropriate there shall be a contractual agreement and a higher level of checks carried out, e.g. audits.

3 Design & Production Capabilities & Capacity

Clause	Product Group	Requirements
3.1	All	An organisational chart will be supplied which provides a breakdown of the key areas and the number of personnel in each
3.2	All	The supplier shall demonstrate minimum manufacturing capability to produce the product under consideration in the most economical way. This shall include but not limited to consideration of: • Adequate equipment, minimum machine size and performance • Value added processes • Appropriate assembly capabilities for the products under consideration
3.3	All	The supplier shall demonstrate adequate production capacity to be assessed via machine capability (throughput), number of machines available, and in combination with overall capacity utilisation. The amount of spare capacity shall be assessed via • The number of shift patterns , • number of days worked • Ability to leverage additional labour • Potential for expansion (space/land)
3.4	All	Design & Technology: The company shall demonstrate the obvious relevant capability and/or have a proven history in manufacturing similar products under consideration. Where in-house expertise does not exist the company shall demonstrate links to industry experts to support essential functions.
3.5	All	Where applicable to the product concerned, the company shall demonstrate a history of design innovation via in-house or sub-contract resources.
3.6	All	The company shall have in-house test facilities and knowledge to verify the product is fit for purpose against specification.
3.7	All	The company shall demonstrate the capability to produce accurate prototypes, technical demonstrators or samples in-house or via proven external links in a cost effective and timely fashion.
3.8	All	The point at which the accountability for a new product moves from Design to Operations shall be clearly defined

4 Senior Management Commitment and Continual Improvement

Clause	Product Group	Requirements
4.1	All	If ISO9001 certified, an appropriate Management Review process shall be in place, with clear inputs and outputs, including actions with names and times against them.. If not ISO9001 certified the supplier / site needs to be able to demonstrate clear examples of Continual Improvement Key KPIs should be in place with improving annual targets
4.2	All	The company's senior management shall provide the human and financial resources required to implement and improve the processes of the QMS, Risk Assessments and to address legal, product safety and product quality matters.

5 Product Claims

Clause	Product Group	Requirements
5.1	All	Any claims about a product e.g. fire retardant, antimicrobial properties, environmental claims, etc shall be fully validated to ensure that products meet the stated claim. Validation data from an accredited third party or due diligent testing by RI may be required
5.2	All	The company will have assessed and fully understand how product claims could be affected by failures in operational processes.
5.3	All	There will be a procedure to ensure that where non conforming materials/components could affect the Product Claims, the materials/components can not be used without agreement from RI.
5.4	All	The company shall undertake product-in-use evaluations, testing and/or reliability trials and/or shelf-life evaluations, to validate and verify that production of a safe and legal product is maintained, taking account of the category of consumers at risk.

6 Product Legislative and Safety Requirements

Clause	Product Group	Requirements
6.1	1&2	The company shall have a general understanding of all relevant product related legislation relevant to the regions / countries where the product is supplied to.
6.2	1&2	The company shall have and use a system, which may comprise both internal and external resources, to demonstrate knowledge of all relevant legislation, product standards, product safety issues, scientific and technical developments, and industry /customer codes of practice in the regions of intended sale relevant to the products in scope. Such regulatory data shall be kept and updated in a Technical File Folder.
6.3	1&2	A process shall exist for incorporating changes in relevant product related legislation, standards etc into the company's procedures in a timely fashion which shall be before any official implementation date of the relevant change

6.4	1&2	A process shall exist to ensure that all suppliers and sub-suppliers are compliant to relevant product / component legislation, included ensuring that they regularly check for updated legislation
6.5	1&2	Relevant staff shall understand legislation, including how they might negatively impact legislation and where relevant will know how to access applicable legislation, standards, codes of practice and similar documents

7 Documentation Control

Clause	Product Group	Requirements
7.1	All	All documents in use shall be the current versions, authorised and dated and a procedure shall be in place to ensure obsolete documentation is removed from use.
7.2	All	Documents shall be clearly legible, unambiguous, in appropriate languages and sufficiently detailed to enable their correct application by staff. They shall be readily accessible to relevant staff at all times.

8 Specifications & Technical Information

Clause	Product Group	Requirements
8.1	All	A specification covering each product shall be documented, dated and authorised. This shall include all relevant information. Any changes to the product design shall be documented and dated
8.2	All	Finished products that are out of specification must not be shipped to RI unless covered by a concession issued by RI.

9 Product Control

Clause	Product Group	Requirements
9.1	All	Where samples are used as part of product control, they shall: - be stored in a secure and clean area - used for reference appropriately - maintained appropriately - replaced when required This would include samples formally approved by RI

10 Purchasing, Supplier Approval and Performance Monitoring

Clause	Product Group	Requirements
10.1	All	The site shall have a documented supplier approval procedure, including a list of approved suppliers
10.2	All	Procedures shall be established which include clear criteria for ongoing assessment, which may take the form of monitoring performance through one or more of the following, although there may be other acceptable methods: • in-house checks

		• certificates of analysis • supplier audits • traceability checks Records of this monitoring shall be retained for at least the lifetime of the product.
10.3	1&2	There shall be a process in place to ensure that unapproved suppliers are not used.

11 Process Control

Clause	Product Group	Requirements
11.1	All	Process monitoring shall be established and adequately controlled to ensure products are produced within the correct process specification with corrective action taken when there is any deviation from this.
11.2	All	Adequate production records shall be kept for a defined period of time
11.3	All	There shall be controls in place to ensure that batches are not started if all materials are not available, and that only the correct materials are used.

12A Quality Control – Inspection

Clause	Product Group	Requirements
12.1	1&2	There shall be a process to define the criticality of incoming goods with regards to quality, product regulations and product safety.
12.2	All	There shall be an effective system for assuring the quality of incoming goods before release into production, stock or delivery to customers. The reasons for any raw materials not formally released need to be sound. Dependence on CofCs or CofAs needs to be supported by some process of assurance of accuracy.
12.3	All	There needs to be an internal concession process to control the use of any component or material that is not to specification. All concessions must be recorded and preserved for reference
12.4	All	A procedure shall be in place, to ensure that only products conforming to specification are dispatched.

12B Quality Control – Records and definitions

Clause	Product Group	Requirements
12.5	All	All inspection results will be recorded, including all non conforming and re-inspection results. The records will include corrective actions taken and will be preserved for reference
12.6	All	Sampling plans, where required, shall be documented and approved and reviewed when changes in production methods or materials occur There will be a defined list of defect classifications easily to hand for all relevant personnel

12.7	All	Inspections shall be carried out in suitable conditions and with sufficient space and lighting
12.8	All	Inspection results which are outside the defined acceptance level shall be reviewed in a timely manner by a competent person and the need for corrective action assessed, documented and completed
12.9	All	If it has been decided that any part of normal Quality Control is not required, e.g. formal release of materials or goods, or production stages without inspection or testing, the decision must be based on sound reasons (for product group 1 - a risk assessment and reviewed annually)
12.10	All	Where any stage of production is carried out by third parties, this shall be clearly recorded & the same controls as outlined above are required to be in place. Additional controls such as third party visits, incoming inspection, etc will be required unless it can be demonstrated otherwise

13 Product Analysis/Testing

Clause	Product Group	Requirements
13.1	All	Companies shall adopt a product testing programme to support Quality Control where appropriate
13.2	1&2	For tests which are critical to product safety or legality, the laboratory used shall have gained recognised laboratory accreditation
13.3	All	Where testing is submitted to third parties, the required testing shall be clearly defined including, for example, reference to number, date and version of the test standard or method to be used.
13.4	1	Where testing laboratories are present on a manufacturing site, they shall be located, designed and operated to eliminate potential risks to product safety. Controls shall be documented, implemented and shall include consideration of the following: • design and operation of drainage and ventilation systems • access and security of the facility • movement of laboratory personnel • protective clothing arrangements • processes for obtaining product samples • disposal of laboratory waste

14 Calibration and Control of Measuring and Monitoring Devices

Clause	Product Group	Requirements
14.1	All	All measuring equipment shall be appropriately calibrated, which will include: - a list of calibrated equipment - a defined calibration period - a robust process to ensure that all equipment is calibrated within the defined period - calibration labels on the equipment - records of calibration results

		- measuring equipment outside of the calibration process should be defined as such
14.2	All	Where internal calibration is carried out, the test shall be appropriate to the measurement that the equipment is used for
14.3	All	Procedures shall be in place for actions to be taken if equipment is found not to be operating within specified tolerances and/or limits.

15 Traceability

Clause	Product Group	Requirements
15.1	All	The products that constitute a lot / batch shall be defined and documented and the traceability shall be available for each lot / batch
15.2	All	Companies shall be able to identify the immediate source of all raw materials, components and packaging materials. Dual or multiple sourcing must not be a barrier to clear traceability
15.3	All	Identification of lots/batches of raw materials including packaging, processing aids, intermediate/semi-processed products, part-used materials, finished products and materials pending investigation, shall be adequate to ensure traceability
15.4	All	Final products and packaging shall be suitably marked to allow easy identification
15.5	All	The traceability system shall be maintained when rework or any reworking operation is performed.
15.6	All	Changes in materials, processes or components shall be traceable if they could affect the safety, quality or legality of the product and formally agreed by the customer if contractually required.
15.7	1&2	For continuous production processes, methods of defining traceability levels must be documented and based on the risk assessment

16 Control of Non Conforming Materials.

Clause	Product Group	Requirements
16.1	All	Clear procedures for the control and identification of non-conforming materials and products, including rejection, segregation, acceptance by concession or regarding for an alternative use, shall be in place and understood by all authorised personnel
16.2	All	The company shall have a procedure in place, including clear accountability, for the secure and timely disposal of non-conforming materials. Specific requirements of the customer and any legal requirements must be considered.
16.3	1&2	Where relevant, there will be controls to ensure that stock that exceeds its shelf life is not picked for production or shipping

17 Corrective and Preventive Action

Clause	Product Group	Requirements
17.1	All	The company shall operate an effective system for the capture, recording and timely investigation of non conformities or matters reported as possible non conformities.

17.2	All	An appropriate staff member shall be identified and allocated the responsibility and accountability for each corrective action. This shall be documented.
17.3	All	The company shall ensure that effective corrective actions are taken to prevent reoccurrence of the problem and shall monitor and record their completion within an appropriate and agreed timescale

18 Retained Production Samples

Clause	Product Group	Requirements
18.1	1&2	The company shall retain a fully representative sample of each batch / lot of finished goods, and raw materials or components that could impact a product recall, with accountability clearly defined. Inspection records of production first/last piece sample shall be preserved should the sample not be available
18.2	1&2	Procedures shall be in place to determine the retention time of retained samples. This should normally be the foreseeable lifetime of the product and take into consideration legislative requirements.
18.3	1&2	Retained samples shall be securely held and stored in suitable conditions to maintain their original status. Removal and replacement of retained samples shall be logged.

19 Foreign Body Detection and Control

Clause	Product Group	Requirements
19.1	1&2	The company shall ensure that all necessary steps are taken to identify and prevent the risks of foreign body contamination. At all production stages, all items, including packaging, shall be securely protected from contamination, deterioration and damage
19.2	1	Tools and other sharp objects used in production shall be controlled, Methods such as, but not limited to the following, may be used • Snap-off-blade knives prohibited • Tools permanently attached to benches • Items controlled by a listing & registration procedure • Needle policy where all parts of broken needles have to be returned prior to new issue.
19.3	1	Where they constitute a risk to product, a management system that shall include written procedures shall be in place for all glass, brittle plastic and ceramics to ensure the necessary precautions are taken. Breakages shall be recorded and records retained
19.4	1	The use of wood within raw material handling, preparation, processing, packing and storage areas shall be eliminated except for wooden pallets where any risks should be evaluated and controlled

20 Product Packaging Materials

Clause	Product Group	Requirements

20.1	All	All packaging shall be fit for purpose with regard to: · Protecting the product from damage · Maintaining the integrity of the product · Protecting the consumer from injury · Preventing contamination
20.2	1	Where there is a risk of product contamination from transit packaging that could compromise product safety, legality and quality, such packaging shall be removed from production areas.

21 Final Product Packing and Control

Clause	Product Group	Requirements
21.1	All	The company shall define and validate the packing procedure for products taking particular account of customer requirements. This shall include methods of ensuring correct products / components are correctly packaged with and placed in the correct outer packaging
21.2	All	The company shall verify that information shown on primary (consumer) package labels and outer cartons, and any other packaging, is accurate and is adequate for regulatory and traceability purposes,

22 Change Control

Clause	Product Group	Requirements
22.1	All	There shall be a defined process to ensure that product specification changes are not made without consultation with RI
22.2	All	The company shall have a clearly defined process for defining the impact of significant changes, e.g. new equipment, new suppliers, organisational change, new legislation, etc
22.3	1&2	The company shall be aware of all relevant parts of RI's Change Control process, i.e. what type of change requires notification to RI, what support is required for a change, the approval required before a change can be implemented, etc

23 Stock Control & Storage

Clause	Product Group	Requirements
23.1	All	There shall be adequate space in all storage areas to ensure that all goods and materials can be freely accessed
23.2	All	Where chemicals are stored, there shall be appropriate controls in place, e.g. segregation, shelf life control, FIFO, etc
23.3	All	Procedures shall be in place for disposal of excess stock or obsolete inventory where such situations routinely occur with clear accountability identified.
23.4	All	Controls shall be in place to ensure that the risk of mispicking a product or component is as low as practical

24 Equipment & Equipment Maintenance

Clause	Product Group	Requirements
24.1	All	A documented system of planned / preventive maintenance shall be in place, covering all equipment / plant which can impact product safety, legality or quality and shall include records of: • Periodic maintenance schedules & completion • Contingency plans for failure of essential equipment • Findings / actions taken will be recorded and used for trend analysis • Measurement of late maintenance checks
24.2	1&2	Spare parts shall be stored in an organised and controlled manner. The level of spare parts stored shall be based on a risk assessment of the potential impact on product safety and quality and may include costs & lead times.
24.3	All	Engineering workshops shall be controlled, organized, clean and tidy to allow safe, efficient and quality work.
24.4	1	In addition to any planned maintenance programme, where there is a risk of product contamination by foreign bodies arising from equipment failure, the equipment shall be inspected at predetermined intervals, inspection results documented and any necessary corrective action taken
24.5	1	On completion of any maintenance work, machinery and equipment shall be clean and free from contamination hazards. A documented hygiene clearance procedure shall exist, which where appropriate shall include a risk assessment before the area can be used for production again.
24.6	3	Where required, there shall be a broken needle policy

25 Product Transport and Distribution

Clause	Product Group	Requirements
25.1	All	The company shall ensure that the transport and any subsequent storage of products is within its control, including at subcontracted warehouses. Dispatch shall be undertaken in such a way as to prevent the risk of contamination and damage
25.2	All	All transportation shall be checked & recorded that they are in good repair and in a clean / hygienic condition. It is good practise to take a photograph of the container when fully loaded to be kept electronically should there be a future claim.
25.3	All	Controls shall be in place to protect the integrity of the product from any internal and external conditions.

26 Customer Service / Complaints handling

Clause	Product Group	Requirements
26.1	All	A system shall be in place to capture and investigate all complaints relating to product safety, quality or legality.

26.2	All	The root cause of customer complaints shall be established and corrective action shall be carried out promptly and effectively by trained, competent staff & the effectiveness reviewed
26.3	All	There will be an appropriate system for planning to ensure that delivery dates will be respected
26.4	All	Delivery performance shall be monitored and measured

27 Management of Product Withdrawal and Product Recall

Clause	Product Group	Requirements
27.1	All	The supplier shall have a product recall procedure in place. The systems shall ensure that Rentokil Initial are advised immediately on any issues in terms of customer safety, product quality or legality
27.2	1&2	The product recall system, including all aspects of traceability, shall be tested and reviewed annually. The results of the test shall be used to demonstrate improvements as deemed necessary,

28 Internal Audits

Clause	Product Group	Requirements
28.1	All	Scheduled Internal audits shall cover all aspects of the Quality Management processes and be carried out by trained competent auditors
28.2	All	Corrective actions shall be documented and formally agreed by the person responsible for the action and implemented within appropriate and agreed timescales. All corrective actions shall be verified to ensure satisfactory completion

29 Building Interiors

Clause	Product Group	Requirements
29.1	All	The quality and finish of site buildings and facilities, including drainage when required shall be suitable for the intended purpose with due regard to the risk of product safety, legality and quality, and shall be maintained to an appropriate standard.
29.2	All	Any roof leaks in areas of production or storage shall be recorded with adequate corrective / preventive actions in place. There will be clear ownership of both controlling the leak and for the actions to prevent future leaks
29.3	All	General working conditions shall be appropriate to supporting quality & safety, which shall include, but not limited to: - adequate lighting throughout - adequate ventilation - adequate heating - adequate furniture
29.4	1	Potential contamination risk from buildings and overhead structures, including building voids shall be controlled through regular documented inspections, and corrective action shall be taken to prevent the risk of product contamination.

29.5	1	Walls, floors, ceilings, pipe-work and overhead structures shall be designed, constructed, finished and maintained to reduce condensation and mould growth, and shall have access to facilitate cleaning.

30 Pest Control

Clause	Product Group	Requirements
30.1	All	The company shall be responsible for identifying and controlling the risk of pest infestation on the site. If no pest control is conducted the company shall have a full justification for its absence. Where a Pest Control contract is in place, a log book shall be kept to show the plan of Pest Control and the history.
30.2	All	In the event of infestation, immediate action shall be taken to eliminate the hazard and this shall be documented. Action shall be taken to identify, evaluate and authorise the release of any product potentially affected

31 Staff Facilities

Clause	Product Group	Requirements
31.1	All	Staff facilities such as washrooms, canteens and break areas shall be clean and tidy, with systems in place to ensure that they remain clean and tidy
31.2	All	Where employees live in company dormitories or company sponsored properties, the living conditions are to be adequate and staff are to be free to leave the factory location during non-working hours
31.3	1	Staff facilities such as washrooms, canteens and break areas shall be designed and operated so as to minimise the risk of product contamination.
31.4	1	Where smoking is allowed under national law, designated controlled smoking areas shall be isolated from production areas to an extent that ensures smoke cannot reach the product. Adequate arrangements for dealing with smokers' waste shall be provided both internally and externally
31.5	1&2	Storage facilities of sufficient size to accommodate all reasonable personal items shall be provided for all personnel who work in areas where they are unable to keep possessions with them
31.6	1	Where specific work-wear is required, Designated changing facilities shall be provided for all personnel: staff, visitor or contractor. These shall be sited to allow direct access to the production, packing or storage areas without recourse to any external area. Where this is not possible, a risk assessment shall be carried out and procedures implemented accordingly
31.7	1	Suitable and sufficient hand-cleaning facilities shall be provided at access to, and at other appropriate points within, production areas. Information on how to clean hands shall also be provided near hand cleaning points.

31.8	1	All food brought into manufacturing premises by staff shall be stored in a clean and hygienic state. No food shall be taken into storage, processing or production areas

32 Housekeeping and Cleaning

Clause	Product Group	Requirements
32.1	All	The supplier's internal premises must be clean, tidy and well organised
32.2	All	The supplier's external premises must be well maintained in good order.
32.3	1&2	All Cleaning practices shall be designed and completed so as to minimise the risk of contamination
32.4	1	Cleaning and, where necessary, disinfection procedures shall be revalidated following building or engineering work, changes to equipment or introduction of new product types.
32.5	1&2	Chemicals shall be suitably identified and controlled to prevent the risk of product contamination. They must be clearly labelled and no chemicals shall be decanted unless into properly labelled and identified containers. Adequate storage facilities shall be provided and sited so as not to compromise the safety, legality and quality of the product
32.6	1	Documented cleaning procedures shall be in place and maintained for the building, utilities, plant and equipment. Cleaning procedures shall include the following information as a minimum carried out in house or outsourced. • responsibility for cleaning • item/area to be cleaned • frequency of cleaning • method of cleaning • cleaning materials to be used • cleaning records and responsibility for verification
32.7	1	Cleaning and housekeeping shall be carried out by trained personnel in accordance with documented procedures and records shall be maintained
32.8	1	The effectiveness of cleaning and sanitation shall be verified and documented. Corrective actions shall be documented

33 Protective Clothing

Clause	Product Group	Requirements
33.1	1	Where a need for protective clothing has been identified by the risk assessment, this shall not pose a contamination risk to the product..
33.2	All	The company standard for PPE shall be adopted by all personnel, including contractors and visitors.
33.3	1&2	Protective clothing, where provided, shall be effectively laundered at an appropriate frequency.

33.4	1	Disposable protective clothing, if used, shall be subject to adequate control to avoid product contamination.

34 Hygiene Practices

Clause	Product Group	Requirements
34.1	1	All cuts and grazes on exposed skin shall be covered by a contrasting coloured plaster that is company issued and monitored.
34.2	1	The company shall have a policy to control the wearing of jewellery so that it poses no risk to product contamination.
34.3	1	Hand cleaning shall be performed at a suitable frequency to maintain hygienic conditions.
34.4	1&2	No eating, drinking or smoking shall be permitted within production or packaging areas. Drinking Water may be permissible in designated areas.
34.5	1	All head and facial hair shall be fully contained to prevent product contamination.
34.6	1	The company shall be vigilant concerning employees, including temporary employees, visitors and contractors when they may be suffering or have been in contact with any relevant infectious disease or condition.
34.7	1	Fingernails shall be kept short, clean and unvarnished. False fingernails are not permitted.

35A Health, Safety & Environment – Processes and Training

Clause	Product Group	Requirements
35.1	All	Responsibilities shall be defined along with deputising arrangements
35.2	All	Any enforcement notices or improvement actions required by government bodies shall have been adequately dealt with.
35.3	All	There shall be adequate controls in place to safeguard staff in the event of an emergency. These shall include, but are not limited to: - Appropriate fire exits - Appropriate fire extinguishers - Site map, in an appropriate place, clearly showing the above & other relevant information - Training for emergencies, e.g. handling of fire extinguishers, site evacuations, etc, with clearly defined frequency for refresher training
35.4	All	There shall be adequate First Aid training (which must comply with the local law) with clearly defined frequency for refresher training Medical facilities shall be adequate, including First Aid boxes with a defined process to check stock for quantity and date.
35.5	All	All machinery will have appropriate safety guards with adequate controls to ensure that the machines can not be operated without the controls.
35.6	All	All electrical test areas will have adequate signage and equipment to prevent the risk of an electric shock or damage to the product.

35B Health, Safety & Environment – Observations

Clause	Product Group	Requirements
35.7	All	There shall be no hindrances to emergency processes, which shall include: - Easy access to Fire extinguishers, fire hoses, etc - No blockages to fire exits - No locked fire exits, unless there is a permanent and easy way the lock can be opened
35.8	All	First Aid boxes shall contain adequate in date stock and there shall be adequate stock to replenish to the First Aid box There shall be clear signage, or an alternative means, to show who is a trained First Aid person
35.9	All	There shall be no signs of abuse of the machine safety guards
35.10	All	There shall be defined areas for HV electrical testing with visual indication of any testing in progress.
35.11	All	Electrostatic discharge (ESD) areas are provided when working with electronic components.

36 Product Risk Assessment

Clause	Product Group	Requirements
36.1	1	The company shall ensure that a documented product hazard and risk assessment carried out by competent staff is available and clearly identifies • the hazards, the risk level for each hazard and whether the risk is acceptable • The person responsible for the assessment • The date performed and the evidence (for example sample, drawings, computer graphics) from which the assessment was derived If the product requires modification, a new risk assessment shall be completed on the modified design.
36.2	1	The risk assessment shall be regularly to ensure that the assessment remains up to date, takes account of complaints or incidents with the product or similar products and reflects any changes in legislation
36.3	1	The risk assessment shall be carried out before production begins and completion shall be verified by a designated responsible person.

37 Environmental Controls

Clause	Product Group	Requirements
37.1	All	The company shall be accredited to ISO14001 or have adequate systems and controls in place to ensure that the environment is not negatively impacted

37.2	All	Waste shall be categorised according to legislative requirements based on the intended means of disposal, segregated if necessary and collected in suitably designated waste containers. Where legally necessary, it shall be removed by identified, licensed contractors and records of disposal shall be maintained by the company

38 Customer-Supplied Property

Clause	Product Group	Requirements
38.1	All	The company shall identify, verify, protect and safeguard customer property including software, intellectual property and products. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained.
38.2	1&2	Where tooling is owned by RI the following shall be demonstrated: - tool storage to provide protection from contamination - adequate tool monitoring and maintenance - clearly defined process for all tool movements All of the above must be included within the annual Internal audit schedule
38.3	1&2	Where tooling is owned by RI those handling the tools shall understand not just how to handle tools, but also the potential impacts of not carrying out the tasks correctly

39 Contingency & Crisis Planning

Clause	Product Group	Requirements
39.1	All	The company shall develop contingency planning for business continuity in the event of major incidents such as • Disruption to key services –e.g. water, energy, staff availability • Events such as flood, fire and natural disaster • Malicious contamination or sabotage • Total IT crash • Cyber security
39.2	All	Where a part of the production process is unique, and there is no obvious contingency, then it is expected that a Risk Assessment will have been carried out to review the risks of a catastrophic failure and to take appropriate actions to reduce such risks.
39.3	All	The crisis procedures shall include as a minimum • Identification of key staff constituting the incident management team and their key responsibilities • An up to date list of key contacts • Details of agencies providing advice and support
39.4	All	Crisis and Contingency procedures and documents need to be reviewed on a regular basis

40 Training and Competency

Clause	Product Group	Requirements
40.1	All	The company shall ensure that all employees are able to demonstrate competence with regards to their activity. The company shall: • identify the need for training • document training procedures and records to demonstrate that training is effective and regularly reviewed • ensure that training includes both general information on the company and specific job training
40.2	1	Employees having a direct effect on the safety, quality or legality of products shall be trained to ensure understanding of risk assessment procedures or outcomes as necessary for their activity. Those conducting or participating in risk assessments shall be adequately trained in risk assessment methods
40.3	All	Training shall be traceable to an individual employee.