IFS Global Markets HPC version 1

Checklist for IFS Split Assessment Protocol

FEBRUARY 2021

ENGLISH

PREFACE

This checklist was structured as aditional assessment tool based on IFS Split Assessment Protocol, document and respective IFS Global Markets HPC version 1 Program and Guideline. Assessments shall be performed according to refered documents.

Considerations and explanations to each requirement assessment technique:

on-site:
Those requirements shall be evaluated fully on-site. This includes physical and documentation check.

remote:
Can be completely remote, (but it could be assessed physically too depending on the situation)

on-site and remote:
Part of the check of the requirement is carried out on-site, the associated document review can be done remotely

”cross-check”:
The auditor collects on-site information for random samples that are to be cross-checked in the remote part at the latest.

Additional notes:

1) IFS Split Assessment Protocol for IFS Global Markets HPC version 1 applies for Intermediate Level requirements, which at least 50 % of the assessment duration shall be allocated on-site.
2) On-site assessment has to be performed first and assessor is required to have the general on-site overview and its elements to assess requirements addressed with the **“remote”** technique.

Basic Level Requirement

Intermediate Level Requirement

Level	No.	IFS Global Markets HPC version 1 Requirements	Assessment technique
	1	**Senior Management responsibility** The senior management shall be committed to the production of the safety and quality goods and shall provide to the employees the necessary resources to make it possible. Communication between senior management and the department responsible for quality and product safety management shall be assured.	
	1.1	**Corporate structure**	
Basic	1.1.1	The senior management shall provide sufficient and relevant resources to meet the product requirements.	**on-site/remote**
Intermediate	1.1.2	An organization chart shall be available showing the structure of the company.	**remote**
Intermediate	1.1.3	The senior management shall ensure that employees are aware of their responsibilities relating to product safety and quality. Senior management shall also ensure that mechanisms are in place to monitor the effectiveness of the operation of the employees. Such mechanisms shall be clearly identified and documented.	**on-site/remote**
Intermediate	1.1.4	The department responsible for quality and product safety management shall have a direct reporting relationship to the senior management.	**remote**
	1.2	**Customer focus**	
Intermediate	1.2.1	A documented process shall be in place to identify fundamental needs and expectations of customers.	**remote**
	1.3	**Management review**	
Intermediate	1.3.1	Senior management shall ensure that the quality and product safety management systems are reviewed at least annually, or more regularly, if changes occur. Such reviews shall contain at least: • results of audits, • customer feedback, • process compliance and product conformity, • status of preventive and corrective actions, • follow up actions from previous management reviews, • changes that could affect the product safety and quality management system, • complaints from Authorities, • recommendations for improvement.	**on-site/remote (cross-check)**

Level	No.	IFS Global Markets HPC version 1 Requirements	Assessment technique
	2	**Quality and product safety management** The risk management system shall be based on scientific principles and it will be revised every time when any modification is made in the product, process or any change that could affect product requirements.	
	2.1	**Quality management**	
	2.1.1	**Documentation requirements**	
Basic	2.1.1.1	The quality and product safety management system shall be documented and implemented, and shall be retained in one location (it can be an electronic documented system).	on-site/remote (cross-check)
	2.1.2	**Record keeping**	
Basic	2.1.2.1	All relevant records necessary for the product requirements shall be completed, detailed and securely maintained (e.g. with backup system) and shall be available on request.	on-site/remote (cross-check)
Basic	2.1.2.2	All records, including records showing the effective control of process, product safety and quality shall be kept in accordance with legal requirements and customer specifications. These records shall be kept for a minimum of one year after the end of shelf life period and/or in line with customer´s requirements.	on-site/remote (cross-check)
	2.2	**Product safety management system**	
	2.2.1	**Risk management system (hazard analysis and risk assessment)** An effective implementation of good manufacturing practices is essential to establish a sound foundation, prior to application of risk assessment.	
Basic	2.2.1.1	Before developing a risk management system, the company shall have implemented all necessary Good Manufacturing Practices (GMP's) which are commonly used in its scope of activity.	on-site
Basic	2.2.1.2	The basis of the company's product safety control system shall be a fully implemented, systematic and comprehensive risk management system. It shall take into account any legal requirements of the production and destination countries which may go beyond such principles. The risk management system shall be implemented at each production-site. The risk management system shall cover all raw material groups, products or product groups, as well as every process (included outsourced process) from goods receipt to product dispatch, including product development and product packaging.	on-site/remote
Intermediate	2.2.1.3	The risk management system shall be reviewed and necessary changes shall be made when any modification is made in the product, process or any change that could affect product requirements.	on-site/remote (cross-check)
	2.2.2	**Risk Management team**	
Basic	2.2.2.1	The risk management team shall be multidisciplinary and include operational staff. Personnel appointed as risk management team members shall have specific knowledge of hazards and risks associated to products and processes. Where competent knowledge is not available, external expert advice shall be obtained.	remote

Level	No.	IFS Global Markets HPC version 1 Requirements	Assessment technique
Basic	2.2.2.2	The risk management team shall have senior management support and shall be well known and established within the company.	on-site/remote
	2.2.3	**Hazard analysis and risk assessment** **For all products, the following shall be included:** Describe the product and product category (including raw materials, packaging, finished product) and the required conditions for storage and distribution. Describe the intended use of the product and identify the target consumer. Describe all of the steps taken to produce the product in a process flow diagram. Compare the process flow diagram with the production process to ensure it is accurate.	
Basic	2.2.3.1	**Describe the product:** Describe the product and product category (including raw materials, packaging, finished product) including composition, chemical parameters, conditions for storage, packaging, labeling, etc.	remote
Basic	2.2.3.2	**Identify intended use:** Expected use taking into account vulnerable groups of consumers.	remote
Basic	2.2.3.3	**Construct flow diagram:** Describe all of the steps taken to produce the product in a process flow diagram taking into account products, product categories, raw materials etc. In the event of changes the flow diagram shall be revised.	remote
Basic	2.2.3.4	**On-site confirmation of the flow diagram:** Compare the process flow diagram with the production process to ensure it is accurate.	remote
		The production site shall perform a hazard analysis of its manufacturing process as a minimum step in order to determine if there are any hazards associated with the production of its products. The production site could choose any tool industry recognized to accomplish this assessment. If hazards are identified within the manufacturing process, it is expected that the production site shall take appropriate actions necessary to avoid risks for the consumers.	
Basic	2.2.3.5	**Conduct a hazard analysis and risk assessment for each step:** A hazard analysis shall be available for all physicall, chemical and biological hazards that may be reasonably expected. It shall be conducted for each step from raw materials to the finished product including development and packaging material validation. The assessment shall demonstrate the actions required if a hazard is a risk and the likelihood to harm consumers and severity of the damage. The chosen methodology shall be documented.	on-site/remote (cross-check)
Basic	2.2.3.6	**Determine critical control points:** Based on level of acceptability of risk, critical control points shall be identified and documented.	remote
Basic	2.2.3.7	**Establish critical limits for each critical control point:** For each critical control point identified, the appropriate critical limits shall be defined and validated in order to clearly identify when a process is out of control.	on-site/remote

Level	No.	IFS Global Markets HPC version 1 Requirements	Assessment technique
Basic	2.2.3.8	**Establish a monitoring system for each critical control point:** Specific monitoring procedures shall be established for each critical control point to detect any loss of control. Records of monitoring shall be maintained for a relevant period. Each defined critical control point shall be under control at all times. Monitoring and control of each critical control point shall be demonstrated by records. The records shall specify the person responsible, as well as the date and result of the monitoring activities.	on-site/remote
Basic	2.2.3.9	**Establish corrective actions:** For each critical control point, corrective actions shall be established. In case the monitoring indicates that a particular critical control point is not under control, adequate corrective actions shall be taken and documented. Such corrective actions shall also take into account any non-conforming products.	on-site/remote
Basic	2.2.3.10	**Establish verification procedures:** Procedures of verification shall be established to confirm that the risk management system is effective. Verification of the risk management system shall be performed at least once a year. Examples of verification activities include: • internal audits, • analyses, • sampling, • evaluations, • complaints by authorities and customers. The results of this verification shall be incorporated into the risk management system.	remote
	3	**Resource Management** The company shall provide all necessary resources (like hygiene policies, training, staff facilities etc.) to all personnel in order to meet hygiene criteria and to provide education to the workers.	
	3.1	**Personnel hygiene management**	
	3.1.1	**Personnel hygiene**	
Basic	3.1.1.1	There shall be documented requirements relating to personnel hygiene. These include, as a minimum the following criteria: • protective clothing, • hand washing and disinfection, • eating and drinking, • smoking, • actions to be taken in case of cuts or skin abrasions, • fingernails, jewelry and personal belongings, • hair and beards. The requirements shall be based on hazard analysis and assessment of associated risk in relation to product and process.	on-site
Basic	3.1.1.2	The requirements for personnel hygiene shall be in place and applied by all relevant personnel, contractors and visitors. Compliance with the requirements shall be checked regularly.	on-site

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Basic	3.1.1.3	Visible jewelry (incl. piercing) and watches shall not be worn. Any exceptions shall have been comprehensively evaluated based on hazard analysis and assessment of associated risk.	**on-site**
Basic	3.1.1.4	Cuts and skin abrasions shall be covered by a colored plaster/ bandage (different from the product color). Any exceptions shall have been comprehensively evaluated based on on hazard analysis and assessment of associated risk.	**on-site**
	3.1.2	Protective clothing for personnel, contractors and visitors	
Basic	3.1.2.1	Company procedures shall exist to ensure that all personnel, contractors and visitors are aware of the rules regarding the management of wearing and changing protective clothing in specified areas in accordance with product requirements.	**on-site**
Basic	3.1.2.2	In work areas where wearing headgear and/or beard snood (covering) is required, the hair shall be covered completely, so that product contamination is prevented.	**on-site**
Basic	3.1.2.3	Clearly defined usage rules shall exist for work areas/ activities where it is required to wear gloves (colored differently from the product color). Compliance with these rules shall be checked on a regular basis.	**on-site**
Intermediate	3.1.2.4	Suitable protective clothing and devices to ensure personnel safety shall be available in sufficient quantity for each employee, when required.	**on-site**
	3.1.3	**Procedures applicable to infectious diseases**	
Basic	3.1.3.1	There shall be written and communicated measures for personnel, contractors and visitors in case of any infectious disease which may have an impact on product safety. In case of declaration of infectious disease, actions shall be taken in order to minimize risk of contamination of products.	**on-site**
	3.2	**Training and instruction**	
Basic	3.2.1	The company shall implement documented training and/or instruction programs with respect to the product requirements and the training needs of the employees based on their job which shall include: • training contents, • training frequency, • employee's task, • languages, • qualified trainer/tutor, • evaluation methodology.	**remote**
Basic	3.2.2	The documented training and/or instruction programs shall apply to all personnel, including temporary workers and employees from external companies, employed in the respective work area. Upon employment, and before commencing work, they shall be trained in accordance with the documented training /instruction programs.	**on-site/remote (cross-check)**
Intermediate	3.2.3	The contents of training and/or instruction shall be reviewed and updated regularly and take into account company's specific issues, product safety, product related legal requirements and product/process modifications.	**remote**

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	3.3	**Staff facilities, sanitary facilities and equipment for personnel hygiene**	
Basic	3.3.1	There shall be in place rules and facilities to ensure the correct management for personnel belongings and food and other materials brought to work by personnel and shall include, food from dining room and from vending machines. The food and other materials shall only be stored and/or consumed in designated areas.	**on-site**
Basic	3.3.2	Toilets shall not have direct access to an area where products are handled. The sanitary facilities shall be equipped with adequate hand washing facilities. Sanitary facilities shall have adequate natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area shall be avoided.	**on-site**
Basic	3.3.3	Hand washing facilities shall provide as a minimum: • water, • liquid soap, • appropriate equipment for hand drying.	**on-site**
Intermediate	3.3.4	Changing rooms shall be separated from production area and shall be sited so that they allow direct access to the areas where products are handled. Based on hazard analysis and assessment of associated risk, exceptions shall be justified and managed.	**on-site**
	4	**Planning and production process** Finished product specifications are the basis for product composition, any change or modification shall be agreed with the customer. Written contracts shall be established with contract partners.	
	4.1	**Contract agreement**	
Basic	4.1.1	The requirements which are defined in the contract with the customer shall be established, agreed upon and reviewed concerning their acceptability before a supply agreement is concluded. All clauses related to quality and product safety shall be known and communicated to each relevant department.	**remote**
Basic	4.1.2	Changes of existing contractual agreements shall be documented, communicated and updated between the contract partners.	**remote**
	4.2	**Specifications and formulas**	
	4.2.1	**Raw materials (including packaging materials), semi-finished products and rework specifications**	
Basic	4.2.1.1	Specifications shall be available and in place for all raw materials (raw materials/ingredients, additives, packaging materials, rework) and where relevant, for semi-finished product. The specifications shall be up to date, unambiguous, available and always in conformance with legal requirements.	**on-site/remote**
Basic	4.2.1.2	Where relevant, raw material specifications identifying allergens requiring declaration shall be available. The company shall maintain a continuously up to date listing of all raw materials containing allergens used at its premises, which also identifies all blends and formulas to which such raw materials containing allergens are added.	**remote**
Basic	4.2.1.3	When raw materials including packaging materials are repacked, the new label shall contain the relevant information as on the original label.	**on-site/remote**

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Basic	4.2.1.4	A reevaluation of the suitability of raw materials shall be in place, in cases where raw materials are close to the best before date, or when they are returned to storage or other relevant parameters given by the supplier.	**remote**
Basic	4.2.1.5	Identification of raw materials including packaging materials shall contain the following information: • name of the product, • unique identification code, • date or number of receipt (if relevant) • supplier´s name, • expiry date, if existing, • batch reference given by the supplier and the one given at receipt, if different.	**on-site/remote**
	4.2.2	**Finished product specifications**	
Basic	4.2.2.1	Specifications shall be available for all final products and shall be agreed upon in writing with customers. The specifications shall be up to date, traceable, unambiguous, available to relevant personnel and always in conformance with legal and customer requirements.	**remote**
Basic	4.2.2.2	Current and approved finished product specifications shall be the basis for the composition of products. They shall also be the basis for the control of the production process and to monitor the finished products' compliance.	**on-site/remote**
	4.3	**Legislative framework**	
Basic	4.3.1	The company shall comply with the current applicable legislation and shall be able to demonstrate its own role in the supply chain	**remote**
Basic	4.3.2	For all relevant raw materials, safety data sheets shall be available in the format required by the destination country and kept up to date.	**on-site/remote**
Basic	4.3.3	The conformity of the product with its labeling shall be reviewed each time before a new label is issued for use. Such review shall take into account the product requirements and particular relevant legislation in the destination countries.	**on-site/remote**
Basic	4.3.4	Where relevant, the safety data sheet and/or composition for final products shall be provided and communicated to the appropriate organizations (e.g. national safety centers, public website, etc.), taking into consideration the current legislation of the destination country.	**remote**
	4.4	**Purchasing (including outsourcing if applicable)**	
Basic	4.4.1	The company shall control purchasing processes to ensure that all externally sourced materials (raw materials, including packaging materials) and services, which have an impact on product safety and quality, comply with requirements. Where a company chooses to outsource any production process that may have an impact on product safety and quality those processes shall be identified, risk assessed and documented withing the product safety and quality management system	**remote**
Basic	4.4.2	A contract shall exist between the company and its subcontractor.	**remote**
Basic	4.4.3	There shall be a procedure for approval and monitoring of suppliers (internal and external), outsourced production and sub-processes. In case of any kind of outsourced production, the customer shall always be informed.	**remote**

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Intermediate	4.4.4	The approval and monitoring procedure shall contain clear assessment criteria such as: audits, certificates of analysis, supplier reliability and complaints, as well as required performance standards based on hazard analysis and assessment of associated risk.	remote
Intermediate	4.4.5	Based on hazard analysis and assessment of associated risk, the company shall regularly check the subcontractor in the event of outsourcing, by using an audit checklist covering IFS HPC requirements (e.g. relevant documented risk management system, control plan, traceability system, crisis management, etc.). Documents of such checks shall be available.	remote
Intermediate	4.4.6	The checks performed at the subcontractor shall be performed by a qualified auditor/inspector.	remote
	4.5	**Factory location**	
	4.5.1	**Site security**	
Intermediate	4.5.1.1	The production and storage areas of the site shall be secured effectively by controlled access in order to prevent unauthorized entry.	on-site
	4.5.2	**Factory exterior**	
Intermediate	4.5.2.1	The factory exterior shall be sustainable maintained, clean and tidy. The external condition of the premises shall be considered within the internal audit process.	on-site
Intermediate	4.5.2.2	All grounds within the site shall be in good condition. Where natural drainage is inadequate, a suitable drainage equipment shall be installed.	on-site
	4.5.3	**Plan layout and process flow**	
Basic	4.5.3.1	The process flow, from receipt of goods to dispatch, shall be organized so that a contamination of raw materials including packaging materials, semi-processed, rework and finished products is avoided. The risk of cross-contamination shall be minimized through effective measures.	on-site
Intermediate	4.5.3.2	Where relevant, products shall not be produced, stored and filled on the same equipment as products with another intended use, unless evidence is available that there is no negative effect on the products.	on-site
	4.5.4	**Buildings and facilities**	
	4.5.4.1	**Buildings and internal structures**	
Basic	4.5.4.1.1	All buildings used in the manufacture or storage of products shall be designed and constructed in order to allow unobstructed installation, ease of maintenance, efficient pest control and easy cleaning of the equipment, as well as compliance with all relevant legislation.	on-site
Intermediate	4.5.4.1.2	Drainage equipment shall be designed to facilitate cleaning and to minimize the risk of product contamination (e.g. adverse impact, ingress of pests, environment impact etc.). The hygienic disposal of waste water shall be ensured.	on-site

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Intermediate	4.5.4.1.3	Where relevant, for laboratories: • location of laboratories at the factory shall not affect product safety • microbiological laboratory shall be physically separated from chemical laboratory • suitable equipment and environment shall be available for all tests performed.	**on-site**
	4.5.4.2	**Lighting, air conditioning/ventilation**	
Basic	4.5.4.2.1	All working areas shall have adequate lighting.	**on-site**
Basic	4.5.4.2.2	Adequate natural and/or artificial ventilation shall exist in all areas.	**on-site**
	4.5.4.3	**Water quality**	
Basic	4.5.4.3.1	All process waters (including water used as an ingredient) shall be tested regularly for compliance with chemical, physical and microbiological specifications. Special attention shall be paid after periods of no water consumption (e.g. after a weekend or holiday period). The risk assessment shall address this topic. The company shall demonstrate the effectiveness of its water treatment and usage.	**on-site**
Intermediate	4.5.4.3.2	Recycled water which is used in the process shall not pose a contamination risk. The water shall comply with applicable legal requirements for potable water; records of compliance testing shall be available.	**on-site**
	4.6	**Cleaning and disinfection**	
Basic	4.6.1	Based on hazard analysis and assessment of associated risk, cleaning and disinfection schedules shall be available and implemented. These shall specify: • objectives, • responsibilities, • the products used and their instructions for use, • the areas to be cleaned and/or disinfected, • cleaning frequency, • documentation requirements, • hazard symbols (if necessary). These schedules shall be documented.	**on-site/remote**
Basic	4.6.2	Cleaning utensils and chemicals shall be clearly identified, used and stored appropriately, to avoid contamination or unintended use.	**on-site**
Intermediate	4.6.3	Where relevant, only qualified personnel shall be allowed to undertake cleaning and disinfection. The personnel shall be trained and retrained to carry out the cleaning schedules.	**on-site/remote**
Intermediate	4.6.4	Current safety data sheets (SDS) and instructions for use shall be always available on-site for chemicals and cleaning agents. Personnel responsible for cleaning shall be able to demonstrate their knowledge of such instructions.	**on-site**
	4.7	**Waste disposal**	
Basic	4.7.1	All current legal requirements for waste disposal shall be met.	**on-site**

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Intermediate	4.7.2	Waste collection containers and, where existing, compactors shall be clearly marked, suitably designed, in good state of repair, easy to clean, and disinfected where necessary.	on-site
	4.8	**Risk of foreign materials**	
Basic	4.8.1	Based on hazard analysis and assessment of associated risk, procedures shall be in place to avoid contamination with foreign material.	on-site
Basic	4.8.2	Potentially contaminated products shall be isolated.	on-site
Intermediate	4.8.3	Access and actions for further handling or checking for these isolated products shall be carried out only by authorized personnel according to defined procedures. If product's contamination is confirmed, those shall be treated as non-conforming products.	on-site
Intermediate	4.8.4	A glass and brittle material management shall be implemented, taking into account preventive and corrective measures; the system shall include reference to procedures in the event of glass or brittle material breakage. Where a risk assessment has identified a potential for product contamination, the presence of brittle material (including glass) shall be excluded or, if this is not possible, the risk shall be managed.	on-site/remote
Intermediate	4.8.5	Based on risk assessment metal and/or other foreign material detectors shall be installed to ensure efficiency of detection, in order to avoid subsequent contamination	on-site
	4.9	**Pest monitoring/pest control**	
Basic	4.9.1	The company shall have a pest control system in place which is in compliance with local legal requirements, and as a minimum shall cover the following criteria: • the factory environment (potential pests), • site plan with area for application (bait map), • identification of the baits on-site, • responsibilities (in-house/external), • used products/agents and their instructions for use and safety, • the frequency of inspections. The pest control system shall be based on hazard analysis and assessment of associated risk.	on-site/remote
Intermediate	4.9.2	The company shall have qualified and trained in-house staff and/ or employ the services of a qualified external provider. Where an external provider is used, the activities required on-site shall be specified in a written contract.	on-site/remote
Intermediate	4.9.3	Incoming deliveries shall be checked on receipt for the presence of pests. Any infestation shall be documented and control measures taken.	on-site/remote
	4.10	**Receipt of goods and storage**	
Basic	4.10.1	All incoming goods, including packaging materials, shall be identified and checked for conformity against specifications/other legally required documentation and to a determined control plan. The control plan shall be risk based. Test results shall be documented.	on-site

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Basic	4.10.2	Products shall be clearly identified on receipt and when stored. Use of products shall be undertaken in accordance with the principles of First In/First Out and/or First Expired/First Out, in accordance with relevant industry best practices.	on-site
Basic	4.10.3	Outdoor storage shall be kept to a minimum. Where goods are stored outside, hazard analysis and assessment of associated risk shall be undertaken in order to ensure that there is no risk of contamination or adverse effect on quality and product safety.	on-site
Intermediate	4.10.4	Periodic inventory shall be performed to ensure stock reliability. Any significant discrepancy shall be investigated and corrective action taken.	on-site
Basic	4.10.5	The storage conditions and locations of raw materials including packaging materials, semi-processed and finished products as well as working materials shall in each case correspond to product requirements, shall not be detrimental to other products and shall minimize cross contamination.	on-site
	4.11	**Transport**	
Basic	4.11.1	Before loading transport vehicles, their condition (e.g. absence of strange smells, high dust load, adverse humidity, absence of contamination, pests, mold) shall be checked and actions taken, if necessary. At the raw materials and packaging materials receipt, checks shall be made in order to assess that transportation has taken place under in good conditions.	on-site
Basic	4.11.2	In case of transport of dangerous goods, the company shall ensure that all the relevant legislative requirements are fulfilled.	on-site/remote
Intermediate	4.11.3	Security of transport vehicles shall be appropriately maintained.	on-site/remote
	4.12	**Maintenance and repair**	
Basic	4.12.1	An adequate system of maintenance shall be in place. This system shall be maintained and documented, covering all critical equipment (incl. transport) for compliance with product requirements. This applies both for internal and external maintenance activities.	on-site/remote
Intermediate	4.12.2	Product requirements and prevention of contamination shall be ensured during and after maintenance and repair work. Records of maintenance and repair work and of corrective actions taken shall be kept.	on-site/remote
Intermediate	4.12.3	All materials used for maintenance and repair shall be fit for the intended use.	on-site/remote
Intermediate	4.12.4	Failures of plant and equipment (incl. transport) covered by the maintenance system shall be documented and reviewed so as to adapt the maintenance system accordingly.	on-site/remote
	4.13	**Equipment**	
Basic	4.13.1	Equipment shall be suitably designed and specified for the intended use. Before commissioning, it shall be verified that the product requirements are complied with. Consumables used for equipment should not affect the quality of the product.	on-site
Intermediate	4.13.2	Equipment shall be designed and locationed so that cleaning and maintenance operations can be effectively performed.	on-site

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	4.14	**Traceability**	
Basic	4.14.1	A traceability system shall be in place which enables the identification of product lots and their relation to batches of raw materials, packaging in direct contact with product and packaging intended or expected to be in direct contact with the product. The traceability system shall incorporate all relevant processing and distribution records. Traceability shall be assured and documented until delivery to the customer.	on-site/remote
Intermediate	4.14.2	The traceability system shall be tested on a periodic basis at least annually, and each time the traceability system changes. The test shall verify downstream and upstream traceability (from raw materials to delivered products and vice versa), including quantity checking. Test results shall be recorded.	remote
Intermediate	4.14.3	Where relevant, it shall be possible to identify at all times all major equipment used for the production of finished product (containers of raw materials and of semi-finished products, mixers, filling lines, etc.).	on-site/remote
	5	**Measurements, analyses, corrective actions and management of incidents**	
	5.1	**Internal audits**	
Intermediate	5.1.1	Effective internal audits shall be conducted according to a defined agreed audit program and shall cover at least all requirements of the IFS HPC Standard. Scope and frequency of internal audits shall be determined by risk assessment. This is also applicable for off-site storage locations owned or rented by the company.	on-site/remote (cross-check)
Intermediate	5.1.2	Internal audits shall be carried out at least once a year in all departments	remote
Intermediate	5.1.3	Audit results shall be communicated to the senior management and to responsible persons of concerned department. Necessary corrective actions and a schedule for implementation shall be determined, documented and communicated to every relevant person.	remote
	5.2	**Factory inspections**	
Basic	5.2.1	Regular factory inspections shall be planned and carried out to assess criteria such as product control, hygiene, foreign material hazards, personal hygiene, and housekeeping. Any deviation and the associated corrective actions shall be documented.	on-site/remote (cross-check)
	5.3	**Manufacturing process validation and control**	
Basic	5.3.1	The criteria for process validation and control shall be clearly defined. All processes critical to product safety and product compliance shall be validated.	on-site/remote (cross-check)
Basic	5.3.2	Processing operations shall be carried out in accordance with processing control documentation, and shall include: • suitable equipment, • composition of the product, • list of all raw materials identified according to relevant documents indicating batch numbers and quantities, • detailed processing operations for each stage, such as addition of raw materials, temperatures, mixing times, sampling and semi-finished product transfer. Where applicable, a batch number shall be assigned.	on-site/remote

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Basic	5.3.3	The company shall ensure that in the event of changes to processing methods, equipment and product formulation (including rework and packaging material), process characteristics are reviewed in order to assure that product requirements are complied with. If relevant, customers shall be informed accordingly.	on-site/remote (cross-check)
Intermediate	5.3.4	In circumstances where the control of process and working environment parameters (temperature, time, pressure, chemical properties etc.) is essential to ensure the product requirements are met, such parameters shall be monitored and recorded continuously and/or at appropriate intervals.	on-site/remote
Intermediate	5.3.5	There shall be appropriate procedures for prompt notification, recording and monitoring of equipment malfunction and process deviations.	on-site/remote
	5.4	**Calibration, adjustment and checking of measuring and monitoring devices**	
Basic	5.4.1	The company shall identify the measuring and monitoring devices required to ensure compliance with product requirements. These devices shall be listed and clearly identified.	on-site/remote
Intermediate	5.4.2	All measuring devices shall be checked, adjusted and calibrated, under a monitoring system, at specified intervals and in accordance with defined recognized standard/methods. The results of these checks, adjustments and calibrations shall be documented. Where necessary, corrective actions on devices and on processes and products shall be carried out.	on-site/remote
	5.5	**Quantity checking (quantity control/filling quantities)**	
Basic	5.5.1	The frequency and methodology of quantity checking shall be determined so that the legal requirements and customer specifications, or if relevant, guidelines for nominal quantity are met.	on-site/remote
Intermediate	5.5.2	A procedure shall exist to define compliance criteria for lot quantity checking.	on-site/remote
	5.6	**Product analysis (including quality checks)**	
Basic	5.6.1	There shall be procedures ensuring that all specified product requirements are met, including legal requirements, performance and specifications. Results of microbiological, physical and chemical analysis required for that purpose shall be available.	on-site/remote
Basic	5.6.2	Analyses, which are relevant for product safety and legality, shall preferably be performed by laboratories having appropriate accredited programs/methods (ISO 17025). If the analyses are performed by a factory internal or a laboratory not having appropriate accredited programs/methods, the company shall be able to demonstrate that the results are reliable.	remote
Basic	5.6.3	Where internal analysis is undertaken, qualified and trained personnel shall be in place, as well as appropriate equipment and premises.	on-site/remote
Intermediate	5.6.4	Results of checks on finished products including rework material shall be reviewed by authorized personnel in order to verify the conformity of the finished and semi-finished products with the acceptance criteria.	on-site/remote

Level	No.	IFS Global Markets HPC version 1 Requirements	Assessment technique
	5.7	**Product quarantine (blocking /hold) and product release**	
Basic	5.7.1	A procedure shall be in place for the quarantine and release of all raw materials including packaging materials, semi-processed and finished products, and processing equipment. The procedure shall ensure that only products and materials conforming to product requirements are processed and dispatched.	**on-site/remote**
	5.8	**Management of complaints from authorities and customers**	
Intermediate	5.8.1	A system shall be in place for the management of product complaints and, when relevant, shall take into account specific procedures (e.g. undesirable effects).	**remote**
Intermediate	5.8.2	Complaints shall be analyzed with a view to implementing preventive and corrective actions which avoid the recurrence of the non-conformity.	**remote**
	5.9	**Management of incidents, product withdrawal and product recall**	
Intermediate	5.9.1	A documented procedure shall be defined for management of incidents and of potential emergency situations that impact product safety, legality and quality. This procedure shall be implemented and maintained. This includes as a minimum: the nomination and training of a crisis team, an alert contact list, sources of legal advice (if necessary), contacts availability, customer information, and a communication plan, including information to consumers.	**remote**
Intermediate	5.9.2	There shall be an effective procedure for the withdrawal and recall of all products, which ensures that involved customers are informed, as soon as possible. This procedure shall include a clear assignment of responsibilities.	**remote**
	5.10	**Management of non-conformities and non-conforming products**	
Basic	5.10.1	A procedure shall exist for the management of all non-conforming raw materials including packaging materials, semi-finished and finished products and processing equipment. This procedure shall include always the following criteria, but may include other requirements: • isolation/ quarantine procedures, • risk assessment, • identification (e.g. labeling), • decision about the further use (e.g. release, destruction, rework/post-treatment, blocking, customer information, rejection/ disposal).	**on-site/remote**
Basic	5.10.2	Where non-conformities are present, immediate corrections shall be taken to ensure that product requirements are complied with.	**on-site/remote**
Basic	5.10.3	Out of specification finished goods or finished goods that do not meet other legal and/ or customer requirements are not allowed to be placed on the market. In case of private labels, exceptions shall be agreed in writing with the contract partners.	**on-site/remote**
	5.11	**Corrective actions**	
Basic	5.11.1	Corrective actions shall be clearly formulated, documented and undertaken, as soon as possible to avoid further occurrence of non-conformity. The responsibilities and the timescales for corrective actions shall be clearly defined. The documentation shall be securely stored and easily accessible.	**on-site/remote**
Intermediate	5.11.2	The effectiveness of the implemented corrective actions shall be documented and shall be validated.	**on-site/remote**

IFS Management GmbH
Am Weidendamm 1 A | DE 10117 Berlin
Phone: +49 (0)30 726 10 53 74
E-mail: info@ifs-certification.com

www.ifs-certification.com