

IFS Split Audit Protocol



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IFS SPLIT AUDIT PROTOCOL

0 Introduction and Objective

The purpose of this document is to ensure that the following new requirements on the split audit will be consistently applied during the audit process in accordance with the IFS Standards.

At IFS, the split option is a voluntary option, which needs to be agreed on in advance by the certification body and the company subject to an IFS Audit. It is developed as option to support situations, where a complete regular on-site IFS Audit at the physical site is hardly possible to realise (e.g. restrictions and limitations due to the pandemic situation, natural disasters, political or economic turbulence, etc.). The reason why the option of the IFS Split Audit is chosen, shall be clearly mentioned in the IFS Audit report.

Information and Communication Technologies (ICT) have made remote assessing more feasible. Referring to the document IAF MD4:2023, ICT is the use of technology for gathering, storing, retrieving, processing, analysing and transmitting information. It includes software and hardware such as smartphones, handheld devices, laptop computers, desktop computers, drones, video cameras, wearable technology, artificial intelligence, and others. The use of ICT may be appropriate for remotely assessing parts of the IFS Audit.

This document is applicable to all IFS Standards (except IFS Broker, which has a separate specific protocol).

This protocol shall be used in combination with the colour coded checklist from Part 2 of the relevant Standard (see Annex as example). This indicates whether a requirement needs to be checked on-site, remotely, or both and including a cross-check.

The on-site part is mandatory for all IFS Standards that include GMP and/or GDP (Good Distribution Practice). The IFS Split Audit includes an on-site (at the physical site) and a remote part. The remote part shall be performed after the on-site part.

Note: In the case of companies where the head-office/central management has no production activities, the audit of the head-office/central management can be performed fully remotely before the site part.

1 Scope

If not otherwise defined in this document, all requirements from the respective IFS Standard are applicable.

The use of ICT during parts of the certification and audit process is only possible for renewal (recertification) audit by following the rules described in this document. It can be applied for announced as well as for unannounced audit, whereas the remote part will be announced always.

The certification body shall develop a procedure that complies with the requirements of IAF MD4:2023 and the requirements described in this document. All activities using ICT during any part of the certification and audit process, shall meet the specified requirements.

There will be a new section of the IFS Audit Software where certification bodies are able to select or tick a check-box to indicate that ICT has been used during the audit. This box has to be used in case parts of the audit have been performed following the IFS Split Audit Protocol.

Note 1: An IFS Audit using ICT is always site specific (COID).

Note 2: An IFS Audit using ICT should preferably be conducted by the same auditor who did the last initial/renewal (recertification) audit.

2 Audit Planning and Performance

General

The audited company should clarify in advance with its customers whether they accept a certificate based on the IFS Split Audit Protocol. It is important to plan and determine which requirements should be audited in the on-site part and which in the remote part. The use of ICT during the audit process shall only be permitted with the written agreement of both parties involved. The certification body/auditor as well as the audited site shall have appropriate information technology (IT) infrastructure and environment (e.g. internet access) in place. The audited company shall have all relevant documents and records available online, or shall have a scanner or similar, to enable the digitalisation of documents or records, if necessary.

Risk Assessment

When there is an agreement to undertake an audit in part remotely, the certification body shall conduct an initial risk assessment prior to the audit to ensure that the realisation of such is feasible. The certification body shall evaluate and determine whether part of the IFS requirement objectives can be achieved with remote activities. ANNEX I of this protocol shows a coded example with explanations as to which requirements shall be assessed on-site or remotely for the relevant IFS Standard.

The assessment of risks that may impact the audit effectiveness shall include but is not limited to:

- The capability and availability of the certification body's staff/auditor to conduct a remote audit using remote ICT on the audited site,
- An agreed appropriate selected remote ICT and IT system, to which the certification body and the audited site have access,
- Possible security and confidentiality breaches of electronic or electronically-transmitted information when using remote ICT for the audit,
- The site's willingness to share information and documentation remotely,
- Consideration of the risk of possible ICT technology failure (e.g. loss of internet connection),
- Continuity of the audited site being certified under the same certification body,
- Number of employees at the company (on-site and/or mobile/home office) and participants necessary for conducting the audit,
- Results and nature of raised deviations and/or non-conformities from the last audit, including certification status,
- Number and kind of recalls/withdrawals/other incidents (e.g. food fraud) during the ongoing/last certification cycle,
- Activities needed to verify implementation of systems, i.e. audit, inspection, product testing etc..

In addition, the risk assessment shall document the ICT to be applied as well as the language, which will be used during the remote part.

It is the responsibility of the certification body to ensure data security, data protection and confidentiality in addition to deciding on the ICT to be used accordingly.

It is expected that all identified risks are addressed and mitigation measures are defined, as necessary. As per IAF MD4:2023, clause 4.2.1, where the application of remote technologies and methodologies are not a feasible possibility, the alternative of an on-site audit shall be proposed to the company.

If the risk assessment results in a positive outcome, its findings shall be addressed in the audit preparation, planning and duration. The risk assessment shall be available upon request.

Audit Time

The audit time has to be determined in accordance with the rules defined in the respective IFS Standard. At least two (2) hours of audit time have to be added to the calculated audit time to cover the time needed for the split audit approach.

The audit plan shall identify how and to which extent remote ICT will be applied. This shall include the time schedule, which clearly indicates the dates and time ICT will be used to evaluate standard requirements.

Note: The certification body shall consider that in certain cases more time is needed to present documents when using ICT (e.g. switching of pages, returning to previous documents for cross checks, internet connection, scanning of documents etc.) or during the on-site part in the case of critical situations.

Time for the initial risk assessment and the check of ICT at the beginning of the remote part shall not be considered in the audit duration.

Audit Trail

The on-site part has to be performed first, either announced or unannounced. The remote part shall be performed by an IFS Auditor who has been involved in the on-site part of the audit. In general, both parts of the audit have to be conducted by the same lead auditor. Only in the exceptional situation where the auditor of the remote part is different to the one conducting the on-site part, the auditor conducting the remote part shall be nominated as the lead auditor, and the auditor doing the on-site audit shall be nominated as co-auditor.

Following this protocol, at least 50 % of the total IFS Audit duration shall be allocated to the on-site audit of the physical site to allow the auditor sufficient time to comprehensively audit and inspect the product and the processes directly. For further information, see the IFS Doctrine and IFS Standards.

The on-site part at the physical site as component of this protocol shall include (but may not be limited to) the following areas:

- Production processes/logistical activities,
- Receipt, storage and dispatch areas, receipt including loading/off-loading, checking the condition (including temperature check if necessary) of transport units,
- Good Manufacturing Practices (GMP), including maintenance activities /equipment and repair, infrastructure, equipment, hygiene, pest control and cleaning activities,
- Product development with the following remark: If a company is using pilot plant/equipment for product development on-site, these shall be audited at the physical site. If there are no such areas, the area can be audited remotely,
- On-site laboratory/testing with the following remark: If there are no such areas, the requirements can be audited remotely,
- Maintenance facilities with the following remark: If there are no such areas, the requirements can be audited remotely,

- Monitoring devices (e.g. scales, thermometers),
- Staff and sanitary facilities,
- External areas including waste disposal,
- Verification that the Product Safety and Quality Management System (including HACCP/ Risk Assessment) addresses all applicable parts of the operation of the audited company,
- Investigation of findings from the last audit and the implementation of corrective actions if connected to the on-site part.

Whilst following and observing the running production lines, the IFS Auditor shall collect information on key process parameters, such as critical control points (CCPs) and CPs/control measures as well as their monitoring in order to cross-check them with the HACCP plan information. The IFS Auditor shall also observe and interview employees, inspect product and technology characteristics, take further samples for cross-checking, review recipes used during the manufacturing process, observe actual finished product dispatch and raw material delivery and audit the implemented product safety and risk management system in practice.

To ensure a regular and uninterrupted audit process, the site shall provide the following documents to the auditor at the beginning of the audit performed at the physical site:

- Information on the organisational structure (organisational chart) and deputy regulations,
- Site plan with information on routes for personnel, raw materials, semi-finished and finished goods,
- Current production/handling plan of the day/week,
- Flow chart of the processes with identification of the CCPs,
- An overview of CPs/control measures and CCPs including monitoring overview and limit values,
- Pest monitoring documentation,
- Overview of allergens present in the company,
- At least all hazard analyses required by the IFS requirements.

The audit part performed at the physical site is followed by a comprehensive remote part using ICT for documentation and record review, including cross-checking of related documents. This remote part of the audit shall always be announced. This part of the audit aims at verifying the information collected from the on-site part and the audit of further requirements.

Note: The samples collected in the on-site part will be revealed to the company at the time of the remote part in order to maintain the audit character and to avoid preparation by the company between both audit parts.

Before starting the remote part of the IFS Audit (i.e. opening meeting), it needs to be ensured that the ICT platform and necessary features function properly and that all relevant audit participants have accessed the platform successfully.

The auditor shall explain the remote part during the opening meeting and explain how ICT is applied for the purpose of collecting objective evidence.

In case of connection problems, it is possible to repeat the remote part once more on a different day within the 14 day timeframe. This decision has to be documented by the certification body. Measures to ensure confidentiality and security shall be confirmed by the auditor during the opening meeting.

The remote part will be conducted using a combination of features such as documentation and record review via screen-sharing, taking screenshots or sending documents including remote interviews. Interviews include appropriately sampled representatives of management and operational personnel involved in the processes.

Only records and documents presented to the auditor

- during the on-site part and
- during the ongoing remote part

can be considered as audit evidence.

The auditor shall delete and remove access to any documented information and records not required as objective evidence from its system after completing the audit.

The certification body has the flexibility to audit requirements marked as "remote" on-site as well. An adjustment of the minimum on-site time might be necessary.

The maximum period of time between the beginning and the end of all audit activities, including the remote part, shall be kept as short as possible and shall not exceed 14 days. All audit activities (on-site and remote) have to be completed within the general audit time window otherwise the certification cycle will be interrupted.

In cases where the auditor identifies during the remote part that the audit cannot be finalised using ICT, the auditor has to visit the site again within the original 14 day timeframe to finalise the audit. If not, the IFS Audit is deemed as failed and a certificate cannot be granted.

3 Scoring and Non-compliance

The scoring of the checklist requirements will be made in accordance with the requirements of the respective IFS Standard.

In case of potential non-compliance identified on-site, according to the IFS rules, the additional document evaluation shall also be carried out on-site so that the facts can be conclusively audited. This may lead to an adjustment of the on-site duration.

In accordance with the existing procedures for suspension, the certification body has to ensure that the current IFS Certificate will be suspended in the IFS Database as soon as possible and within a maximum of two (2) working days after the identification of the non-conformity, even if the full audit has not yet been finalised.

4 Reporting and Certificate

In addition to the report of the respective IFS Standard, the requirements partly or fully evaluated using ICT have to be marked with "ICT" in the explanation field.

As compulsory information, the certificate and the company profile in the report have to be amended with the following information: "Part of the audit has been performed using ICT – Split Audit". When preparing the report in the IFS Audit software the tick (from the moment it is available) has to be set, that the audit has been performed by using the IFS Split Audit Protocol. The reason behind the choice for the IFS Split Audit option shall be indicated in the report.

Justification for the IFS Split Audit and the ICT Tool chosen to conduct the remote part of the audit shall be provided in the company profile.

Note: Additional hand written notes shall be taken by the auditor and be available on request and according to the relevant IFS standard.

5 Corrections and Corrective Actions

The implementation of corrections and corrective actions identified during the on-site part and the part using ICT shall follow the rules of the respective IFS Standard.

Note: Corrections and corrective actions implemented and solved during the timeframe between the on-site part and remote part shall have no influence on the final audit result.

Corrections or corrective actions to deviations identified during the on-site part cannot be approved during the remote part of the audit. Only after the remote part is completed the auditor can check/approve the implementation of corrections and corrective actions.

6 Certification Cycle

The date for the renewal (recertification) audit shall be calculated from the last day of the original initial audit (or in case of a new certification cycle from the date of completion of the IFS Audit). If the audit is not performed in due time, the business partners will be notified via the IFS Database.

7 Auditor Competency

The procedure to be developed by the certification body shall include requirements for certification body staff and auditors involved in the process covering competence and training in accordance with IAF MD4:2023.

The basic rules for IFS Auditor qualification are described as required per IFS Standard. For both parts of the audit, it shall be ensured that the auditor performing the activities is covering all required product and/or technology scopes. This applies equally to auditor teams.

It is the responsibility of the certification bodies to train the IFS Auditors in a way that they are able to conduct the remote part in line with IFS principles, to provide a high professional standard. Auditors are required to attend a min. 90 minutes training for remote audit prior to conducting his/her first IFS Audit according to this protocol. This training shall be conducted by the certification body internally by the IFS TTT based on the material provided by IFS. Training records have to be part of the auditor competency documentation. This training can be performed online. After the successful completion of the training, the certification body is responsible to mark it as performed in the IFS Database. If this is not included, the IFS Integrity program will receive a notification, that the Audit was performed with an IFS Auditor not having the mandatory training.

The auditor shall be aware of the risks, their mitigation measures and necessary corrective actions, of possible malfunctions of the information and communication technologies used and the impact that they may have on the validity and objectivity of the information gathered.

8 Technical Guidance for performing the Remote Part

The certification body performing the IFS Split Audit including the remote part shall be able to ensure compliance with the following essential requirements:

- The security and confidentiality of electronic or electronically-transmitted information is ensured when using ICT for this check. The certification body/auditor conducting the remote part shall ensure compliance with the essential requirements below:
 - No unauthorised voice or video recording is allowed.
 - No unauthorised screenshots of documents as audit evidence are allowed. Any screenshots of documents or records or other kind of evidence shall be previously authorised by the audited organisation.
 - All reviewed information will only be used as evidence to support audit findings and conclusions.

- The use of ICT shall be mutually agreed between the certification body and the auditee in accordance with information security and data protection measures and (local) regulations before ICT is used. This shall be confirmed during the opening meeting of the remote part of the IFS Split Audit.
- The certification body is responsible for sufficient IT infrastructure at the certification body's office. Furthermore, the certification body is obliged to review the IT infrastructure at the audited site to ensure that the remote part can be successfully conducted. This also includes the company's capability to provide documents, records and personnel for interview by using ICT defined by the certification body.
A trial meeting, using the same technology/media platforms agreed upon should be conducted to ensure the scheduled audit can be performed as planned and without interruptions.
- The certification body shall ensure that the ICT used allows the recording of the session as objective evidence. The identification of participants by name needs to be clearly stated/understood and recorded as part of the session.
- The certification body is obliged to record these sessions and store the data according to the IFS Standard rules

Note: Clarifications regarding "recording": IFS considers recording a screenshot at the start/end of a session, where the participants and the duration of the session can be identified as sufficient. Furthermore, the log-file of the ICT used shall be stored and available on request.

Reference/other applicable documents:

- [1] IAF MD4:2023: for the use of information and communication technology (ICT) for auditing purpose
- [2] Relevant IFS Standard
- [3] Relevant Doctrine
- [4] Marked checklist (Part 2) of relevant Standard

ANNEX 1:

Example of colour coded checklist from IFS Food version 8

The following colour code is used:



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 audited 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.

The table shows few examples taken from the IFS Food v8

1	Senior Management Responsibility	
1.1	Corporate Policy/Corporate Principles	
1.1.1	<p>The senior management shall draw up and implement a corporate policy. This shall consider as a minimum:</p> <ul style="list-style-type: none"> • customer focus • environmental responsibility • sustainability • ethics and personnel responsibility • product requirements (includes: product safety, quality, legality, process and specification). <p>The corporate policy shall be communicated to all employees.</p>	remote
2.2	Food Safety Management	
2.2.1	HACCP System	
2.2.1.2	The HACCP system shall cover all raw materials, products or product groups as well as every process from goods into dispatch, including product development and product packaging.	on-site
3	Resource Management	
3.1	Human Resources Management	
3.1.1	All personnel performing work that affects product safety, legality and quality shall have the required competence by education, work experience and/or training, commensurate with their role, based on hazard analysis and assessment of associated risks.	on-site/remote
4	Planning and Production Process	
4.15	Transport	
4.15.4	Where goods must be transported at certain temperatures, maintaining the adequate range of temperatures during transport shall be ensured and documented.	on-site and remote "cross-check"

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