sesotec

Guide

Guide for validation of product inspection systems

Freefall Metal Detector RAPID 5000

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I. General information

1.1 Introduction

A reliable and documented system for foreign body management is an important part of any certification according to food safety standards and regulations. These systems or programs must be developed, implemented, documented and maintained. An important component of a foreign body management program is a phased process of demonstrating that the system is effective and functions as intended. This kind of proof is required in food safety standards under the terms of validation and verification.

Unfortunately, there is no uniform understanding of these terms in the food industry and as a result, very different interpretations of the associated measures exist. This results frequently in unpleasant deviations in audits.

This guide is intended to help quality managers and production managers in food processing companies to generate a common understanding regarding validation and verification processes in their own organization and to implement appropriate procedures.

The texts, illustrations and explanations in this guide are only intended to explain the validation and verification of Sesotec product inspection systems.

II. Standard for evaluation of quality and safety of food products

2.1 Basic information

Today, compliance with standards and regulations for assessing the quality and safety of food products is a great challenge, but at the same time a high responsibility for food companies. Some of the most important standards are briefly presented below using extracts.

2.1.1 DIN EN ISO 22000

„ISO 22000 is the only cross-level, globally designed and certifiable standard for food safety management systems. The starting point for the development of ISO 22000 was the call for standardization in the food sector. Multiple certifications are very common in the industry. HACCP, BRC and IFS, to name just a few, only cover certain sub-aspects. The standards recognized by the GFSI (Global Food Safety Initiative, an organization of global retail) (e.g. IFS, BRC) are recognized by retailers in different regions. For companies that do not deliver to the food retail (e.g. manufacturers of semi-finished products, equipment manufacturers, catering), there has been no comprehensive, generally recognized certification standard for food safety.“ [1]

2.1.2 FSSC 22000

„FSSC 22000 is based on ISO standards, is recognized by the Global Food Safety Initiative (GFSI) and enjoys a high level of acceptance in international retail and in the processing industry. The FSSC 22000 standard is owned by a nonprofit organization – the FSSC 22000 Foundation based in the Netherlands. Well-known food companies were and are significantly involved in the development of the standard. FSSC 22000 is a certification scheme for food safety and feed safety management systems in accordance with the requirements of ISO 22000 „Management systems for food safety“, sector-specific preventive programs of the ISO / TS 22002-X series and additional requirements of FSSC 22000.“ [2]

2.1.3 IFS

„As part of the audit according to the IFS Food Standard, the auditor checks whether the various components of the company‘s quality management and food safety system are documented, implemented, complied with and continuously improved.“ [3]

Target:
„The ever-increasing demands on the side of consumers, the increasing risk of claims for damages for retailers and restaurants, the growing number of legal requirements and the globalization of the flow of goods required the development of a uniform standard for quality assurance and food safety. We were looking for a solution to reduce the time required by the large number of different audits for everyone involved.“ [3]

2.1.4 BRC

„The standard has always been aimed at helping production sites and their customers to meet the legal requirements for food safety. Food safety legislation differs globally in detail, but generally obliges food companies to:

- *adopt an HACCP or risk-based approach to food safety management*
- *to provide a processing environment that ensures that the risks of product contamination are minimized*
- *The existence of a detailed specification that is legal and in accordance with the compositional and safety-related standards and good manufacturing practice*

– *To ensure that companies are convinced that their suppliers are able to manufacture the specified product, meet the legal requirements and operate suitable systems for process control*
– *Make visits, from time to time and when appropriate, to verify the competence of your suppliers or to obtain the result of other audits of the supplier's systems for this purpose.*
– *Establish and operate a risk assessment program for product testing, testing and analysis*
– *Track customer complaints and respond to them.*

The global food safety standard was developed to help companies meet these requirements." [4]

2.2 Conceptual explanations

The aim of this section is to explain and define the terms validation and verification based on food safety standards and to explain the context.

2.2.1 Validation

„Confirmation by providing objective evidence that the requirements for the specific intended use or application are met.

Validation provides proof that the control measure selected for a specific hazard or risk or a combination of control measures is able to control this particular hazard. The specific use or application is therefore taken into account here. A validation serves as proof that the selected system can be used to control the specific hazard." [3]

Regarding metal detectors, validation provides proof that the defined test specimen can be detected with the selected metal detector.

The aim of the validation is therefore to answer the following questions:

- **Do I have the right system regarding the foreign bodies which can be expected?**
- **Is the system, if correctly installed and set up, capable of controlling the hazard in the expected production environment?**

A validation is therefore carried out after the device has been installed. It must be carried out under production conditions and must take into account expected circumstances (extreme situations) that could affect the control of the hazard.

The results of the validation are then used to set the limits for subsequent verification activities.

A validation must be carried out again if changes are made to the production line or the products which are inspected (e.g. new packaging).

In order to increase the certainty of concluding a validation positively, food processors often define a **pre-validation** within the scope of or shortly after commissioning. In general, this is a validation with a smaller number of products, possibly not under full production conditions. This is particularly relevant if not all other production factors are available at the time of commissioning, which could affect a successful validation.

2.2.2 Verification

„Confirmation based on an investigation and by providing objective evidence that specified requirements have been met.

In quality and food safety management, the definition of verification measures to confirm the effectiveness of the HACCP system is mandatory. This must be done at least once a year. The standard sees, among other things, internal audits, analysis, sampling, evaluations and complaints from authorities and customers. The results of the verification are incorporated into the HACCP system.

For verification, it is important to have specific criteria for each verification topic (CCPs, CPs, flowcharts, hazard analyzes, preventive programs)." *[3]*

Concerning metal detectors, verification activities provide evidence that the equipment has been effective to control the hazard.

The aim of verification is therefore to answer the question:

Does the respective system function correctly?

Verification activities must therefore take place repeatedly in a defined frequency. It is recommended to have a graded sequence of verification intervals in order to have enough data available for a sub-sequent six-monthly or annual verification.

The frequented sequence of these routine tests is also called monitoring. On the one hand, monitoring activities provide the data for objective proof during verification. On the other hand, however, these tests enable a very quick reaction if a routine test fails.

In addition to the analysis of the results of regular monitoring tests, other factors should also be considered in an annual or six-monthly verification, such as the number of internal and external product alerts, compliance with the defined processes (especially if internal tests failed) or if the definitions of foreign bodies are up to date.

2.2.3 Process validation and control

„If technical systems such as magnets, metal detectors or x-ray inspection systems are being used for the detection and elimination of foreign bodies, an internal (initial) test must be carried out. ***Tests must be carried out to confirm that the intended detection with subsequent ejection and elimination is reliable.***

In order to check the effectiveness, a regular inspection and reassessment of the specified processes must be carried out. This is particularly necessary when process parameters have been changed or due to other new findings (e.g. new foreign body risks, complaints and alerts.“ [3]

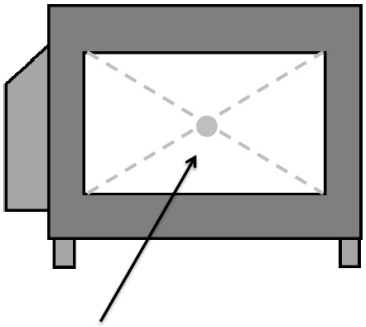
III. Requirements to metal detection systems

3.1 Influencing factors and requirements

3.1.1 Tunnel size

„Since the detection sensitivity is lowest in the middle of the passage opening (crosshairs), the test samples should pass through the metal detector together with the product in this position.“ [5]

Regardless of the coil design (rectangular or round), the center of the detection coil is the position at which the detection accuracy is the lowest.



The most unfavourable position is always the centre of the detection coil!

Illustration 1: Detection sensitivity [6]

The correct ratio of product dimensions to passage opening is important. [5]

„If specified transport speeds are exceeded or not reached, the detection accuracy can no longer be guaranteed (note the manufacturer‘s instructions). At discontinuous transport speeds (e.g. start-stop operation) there is a risk that the detection accuracy will decrease when the critical transport speed is undershot. Products that are in the tunnel of the detector at this time should therefore be checked again. The proper function of the rejection process should be checked in connection with the selected transport speed.“ [5]

3.1.2 Sensitivity

„The optimum verification method should be determined for each application and test samples should be selected according to the product, as well as to requirements according to customer specification. [5]

The following procedure can be used to determine the sensitivity to be tested.

From the risk analysis carried out according to the HACCP principle, the types of potential foreign bodies and their probability of occurrence should be listed. Depending on the process step, the size of a foreign body can also be determined.

Accordingly, procedures need to be developed to test also worst-case scenarios.

Possible procedures include:

- the types of foreign bodies that are most difficult to detect
- the detection position with the lowest sensitivity for each specified foreign body within the product and the detection point of the device with the lowest sensitivity

– the ability of the reject device, including conditions where multiple foreign objects could occur successively.[7]

„The level of performance should be based on a risk assessment and is a decision of the company using the inspection device.“ [7]

3.1.3 Test samples

„For reasons of traceability, test samples should be certified and permanently marked with the ball size, the material and the batch number. The manufacturer of the test samples should certify the specification with a certificate that shows at least the ball diameter, material and batch number and manufacturing standard. When using non-magnetic stainless steel samples, hardened test samples should be used for continuous detectability. [7]

„In general, the test samples should be chosen to be as small as possible in order to detect as many metallic foreign bodies as possible. Customer specifications must be taken into account. It must be ensured that the test samples are intact and do not themselves become a foreign object in any form. If there is any doubt as to the integrity of the test sample, it should be replaced.“ [5]

Manufacturers of inspection systems already offer systems that automatically convey test samples through a system at definable time intervals in order to verify the functionality of the search coil. However, this does not relieve you from the verification, in which the defined test samples must be tested together with the reject mechanism.

Test samples can be used on their own (without a product) to verify the functioning of a test system. For actual verification during production, test samples must be placed in the product or securely attached to the packaged product that is representative of the typical product. [7]

The recommended position of the test samples is the position with the lowest chance of it being detected. The exact position is difficult to determine because it can vary for each application. The positioning of the test samples within the product stream must be clearly defined in the company‘s documented standards. [7]

3.1.4 Test methodology

In addition to ensuring that the devices work according to the required sensitivity standard, the function of the reject unit should be checked. For the test to be successful, all test packs and test samples should be detected and properly rejected from the product flow. If the verification fails, the products that have been manufactured since the last successful test should be isolated and reinspected. [7]

The test samples should be placed in the product independently of one another. When sorting out, it should be checked that the test samples are appropriately removed or recovered. It is important to check that the specified test samples can be recovered again in the event of a non-detection or malfunction of the separation device. If this is the case, the specified test sample can be introduced into the product flow. If the device was specified with an access opening for the test sample and safety catch grid after the reject unit, the specified sample can be introduced into the product flow at that point. If there is no test opening, an access point must be identified above the metal detector in order to introduce the test sample. This point should be as close as possible to the point at which the test samples assumed the same speed as the product. In addition, a method must be defined as to how the test sample can be recovered if it has not been sorted out. [7]

3.1.5 Test interval

Food manufacturers should define a procedure for when and in what frequency verification checks should be carried out.

Possible times for the verification checks can be:

– at the beginning and end of the daily production / shift
– at regular intervals during the production process (time or quantity based)
– when changing products
– when changing batches
– in the event of changes to the machine or product settings
– after downtimes for repairs
– yearly and six-monthly verification

It is recommended that fail-safe system functions are being verified at the beginning of each shift. If a safety function fails, it should be corrected before the start of production. [7]

In case of a failed test, all products since the last successful test shall be secured and re-inspected.

The determination of the in-house test intervals is therefore based on the respective customer and industry requirements and the production quantity between the respective test intervals.

3.1.6 Fail-safe system planning

The consequences of a malfunction should be assessed during system planning, e.g. in the event of failure of the reject mechanism. Fail-safe systems should be considered during planning. Depending on the application, a distinction must be made as to how the product is being inspected, e.g. in conveyor applications with conveyor belt, pumped or in free fall.

Fail-safe systems should provide information about changes in the state of the test system at an early stage. As a minimum, a fail-safe system should fulfill some requirements:

- an automatic reject device to efficiently eject detected foreign bodies
- a locked reject container, to which only authorized, trained personnel have access
- warning device that indicates that the reject container is full of products
- complete coverage between the detector and the sorting container
- an acoustic and visual display of the system status, e.g. when product has been rejected
- a photocell to detect every package that has been rejected (to facilitate the correct timing of the reject mechanism)
- an automatic fail-safe stop system in response to the following events:
  - reject bin full
  - air pressure low
  - error with the reject confirmation system
  - error of the metal detector or x-ray device [7]

If metal detectors have been specified as a fail-safe system, the functionality of corresponding components must also bet regularly. If metal detectors have been specified as a fail-safe system, the functionality of corresponding components must also be verified regularly.

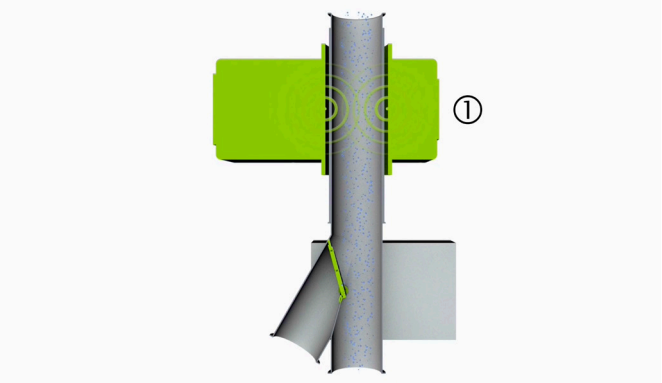


Illustration 2: Functional overview of a free-fall system [6]

The search coil at pos. 1 inspects the product flow for metallic foreign bodies. On detection, the reject system switches the reject flap to pos. 2.

If a test sample is detected, the reject flap switches to the „reject position“ and the test object or foreign body is being rejected into the reject outlet.

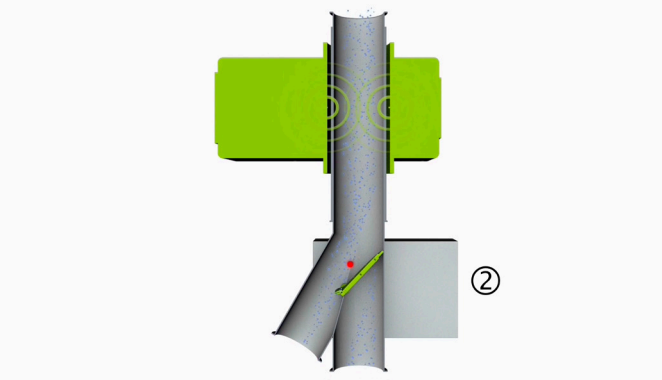


Illustration 3: Functional overview reject unit [6]

3.1.7 Actions for non-detection

If the inspection system fails to identify or reject a test sample during the verification test, production should be stopped. The reason for the failure should be found out and corrected.

If the malfunction can be attributed to manipulation or to a change in production conditions, procedures should be in place to prevent recurrence. If the failure has occurred due to a system fault, it should be repaired before production is re-started.

In both cases, the inspection system should be verified before production begins. Products manufactured since the last successful test should be considered as suspect and should be re-inspected with a working inspection system. The replacement inspection system should meet the sensitivity standard of the original system used on the line. [7]

IV. Validation and verification in practice

4.1 Requirements

4.1.1 Overview on validation and verification procedures

The determination and planning of validation and verification measures and procedures is the responsibility of the company using a product inspection system. It must be carried out in such a way that throughout the life cycle of the system, it provides evidence or confirmation on the capability to control a hazard resulting from the risk analysis.

It is recommended to collaborate closely with the manufacturer of the product inspection system. He already makes an important contribution to the validation and verification activities of the customer during the device qualification.

The manufacturer can also assist in determining suitable test procedures, regarding scheduling and by providing documentation templates for complete documentation. Manufacturers often also offer dedicated services for on-site support during commissioning, validation, periodic verification and for support before or during audits.

4.1.2 Test intervals

The test intervals of validation and verification measures must be coordinated and planned in such a way that a comprehensive and complete documentation of all audit-relevant information and inspection results is achieved.

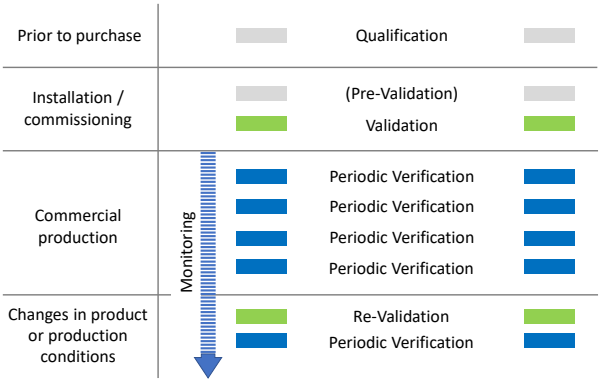


Illustration 5: Possible sequence of relevant checks

4.2 Documentation

For a successful audit, it is recommended that all validation and verification activities and the corresponding test results are documented in a reliable and comprehensive way. The documentation is ideally done with the help of ready-made forms. The device manufacturer can support with this.

	Qualification	Pre-Validation	Validation	Monitoring	Verification
When	Prior to purchase	At or right after installation and commissioning	1. Before commercial production 2. After changes in application → Completion of teach-in process	Frequent inspections daily, hourly, per shift, at product change, etc.	Daily verification Periodic verification min. annually
Where	Manufacturer of the detection system	Place of installation	In actual production environment	In actual production environment	In actual production environment
Target	Ensuring that the correct equipment is selected for acceptable detection of foreign objects or hazards from HACCP analysis	Determination of the detection accuracy for all available foreign body types	Confirmation of detection accuracy for all available foreign body types	Continuous monitoring of the system and data collection for periodic verification	Confirmation that the chosen system is working as intended and that the hazard is under control
Test, check and analysis	Check the detection accuracy with the intended products and foreign object types	e.g. 10/10 passes per foreign body type and per product (test with product)	e.g. 10/10 passes per foreign body type and per product (test with product)	Test at least 1x detection / rejection run per test piece (test with product)	- Daily inspection of number of rejections - Periodic inspection of the entire system and compliance of established procedures
Pay attention to	System settings with minimized false rejection rate	System settings with minimized false rejection rate	System settings and environmental conditions as in actual production	Current system settings and production environment	Completeness of records and verification of all relevant information during the period under consideration

Illustration 4: Overview and objectives

Manufacturers of product inspection systems also offer software solutions for the documentation and storage of frequent tests (monitoring). These automatically collect all test results and store them in a central storage location. In addition to the advantage that all results are automatically documented to prove due diligence, these kinds of software solutions have the advantage that the effort required for frequent tests can be reduced.

V. Summary

This guideline serves as a basis for the validation and verification of product inspection systems and is based on common guidelines of the food industry. With the help of this guide, the procedure of validation as well as its context shall be clarified and simplified.

In case of changes to regulations, standards and legislation, these need to be taken into account. Technical specifications are subject to change without notice.

The implementation of appropriate measures for validation and verification in operational practice is an important component of a reliable foreign body management program, which is being checked and certified in an audit on its consistency and compliance. Unfortunately, there is still no uniform understanding of these terms and their application in the food industry. As a manufacturer of product inspection systems, Sesotec is an important contact for its customers to jointly develop and implement suitable procedures.

Sesotec offers support for this – please contact us:

- Support in risk analysis – which foreign bodies can occur?
- Support in finding solutions on site – advice on advantages and disadvantages with regard to task, cost and benefits
- Support with preliminary tests / qualification – product tests in advance
- Support before or during an audit – on site support for audits by Sesotec
- Seminars / workshops – training of QM staff on site or at Sesotec

Schönberg, 06.04.2020

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VI. Disclaimer of liability and operator obligations

The information in this guide is intended to explain the terms validation and verification, as well as their application in operational practice. Sesotec does not guarantee the accuracy and applicability of the information in this document and therefore excludes liability for consequences and damages resulting from the use of this document.

Based on the informationin this document, Sesotec GmbH does not assume any liability for direct or consequential damages resulting from the use or misuse of these machines (devices). Any modification to a machine (device) without prior consultation with the manufacturer will void the warranty.

Operator obligations
The legal basis for this document is Regulation (EC) No 178/2002.
Sesotec is the manufacturer of the inspection system. This does not release the operator from his obligations according to (EC) No. 178/2002.

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VII. Literature

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