Validation, Verification and Monitoring
For Product Inspection Equipment

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1 Introduction

This white paper is primarily aimed at Quality Managers and Production Managers in food manufacturing organizations, although manufacturers in other industries may also find it relevant. It gives guidance on the essential processes of validation, verification, and routine performance monitoring for in-line product inspection equipment. These terms are often used interchangeably, creating confusion within organizations and across industries because people interpret and use these terms in different ways. In fact, each term is a distinct process that has a clear purpose and role to play at different points within the equipment lifecycle. It is important to understand the purpose of each process to make sure that validation, verification and routine performance monitoring tests are performed to comply with regulatory requirements; particularly where the equipment is designated as a Critical Control Point (CCP).

A definition of each term is provided, followed by a brief overview of each process and what it involves. Recent changes in standards, regulations and legislation have put the responsibility for food safety with retailers and manufacturers. However, equipment manufacturers can offer significant support in meeting compliance obligations. A final section on recommended reading has been included for readers wanting more in-depth information on the topics highlighted within this white paper.

2 Definitions of Key Terminology

2.1 Validation

Validation is the initial qualification of a product or process against the stated design specification. The International Featured Standards (IFS) organization defines validation as "confirmation through the provision of objective evidences, that the requirements for the specific intended use or application have been fulfilled" [1]. In 2008, the Codex Alimentarius Commission defined validation as "Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome," [2].

Validation aims to answer the question "will this piece of equipment meet the specified objectives?"

Validation belongs at the start of the equipment lifecycle when the equipment is first installed (see Figure 1). However, re-validation may also be required if substantial modifications to the equipment, or the products being inspected (size, packaging material, etc) are made at any point after installation.
2.2 Verification

Verification is the periodic qualification that the equipment continues to be effective. The IFS defines verification as “Confirmation through the provision of objective evidences that specified requirements have been fulfilled,” [3]. Verification activities need to begin after validation is completed.

In 2008, the Codex Alimentarius Commission defined verification as “The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended,” [4].

Therefore, verification uses standard, formal processes to answer the question “Is the specified equipment under control and operating as expected?”

As Figure 1 highlights, verification is a periodic assessment that happens at regular intervals throughout the life of the equipment. Formal performance verification is typically an annual process to support audit requirements.

2.3 Routine Performance Monitoring

Routine performance monitoring (or “monitoring” for short) - differs from the processes of validation and verification in that it is a series of performance verification checks completed at frequent, regular intervals (see Section 6.0). These checks are designed to determine if processes are under control. IFS Version 6 defines monitoring as, “The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control,” [5].

Routine performance monitoring seeks to confirm whether the specified piece of equipment continues to perform as expected. Using objective evidence, employees can determine if the equipment is operating within the limits set, or whether a critical limit has been exceeded and corrective action is necessary.

In Figure 1, performance monitoring tests are shown as a continuous process throughout the equipment lifecycle, but the actual intervals between tests vary between manufacturers and industries. The frequency with which routine performance monitoring tests are performed is often dictated by retailer codes of practice or industry regulations and relates to the quarantine period for the applicable products. The frequency of routine performance monitoring testing during a production run will ultimately depend upon the probability and consequences of a failed test.

Figure 2: Documented records of validation procedures, performance verification processes and routine performance monitoring checks should be accessible to support audit requirements.
2.4 Validation, Verification and Monitoring in Practice

Table 1 gives a generic overview of the processes of validation, verification and routine performance monitoring to show the differences between each process, and the relationship between them.

<table>
<thead>
<tr>
<th>Process</th>
<th>Description</th>
<th>Who Performs it</th>
<th>Frequency</th>
<th>Expected Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validation</td>
<td>Initial qualification against design specification, of a product or process</td>
<td>• Supplier • Industry body</td>
<td>• Pre-installation or at the point of installation • When a piece of equipment has undergone significant modification (re-validation)</td>
<td>• Confirmation that the equipment supplied meets the specified design • Confirmation that the correct type of equipment has been selected to achieve the desired results</td>
</tr>
<tr>
<td>Verification</td>
<td>Periodic qualification of a product or process, to confirm the equipment is performing as inspected</td>
<td>• External party (such as an auditor or the equipment supplier) • Internal party</td>
<td>• Annually, as a minimum</td>
<td>• Confirmation that the equipment is performing as it is intended • Confirmation of any necessary improvement or action</td>
</tr>
<tr>
<td>Routine Performance Monitoring</td>
<td>Routine tests performed to confirm the equipment is under control</td>
<td>• Internal (for example by the line operator or Quality Manager)</td>
<td>• Regularly (such as every 2 hours) – frequency may be dictated by industry standards or retailer codes of practice</td>
<td>• Confirmation that the equipment continues to perform as expected</td>
</tr>
</tbody>
</table>

Table 1: Validation, verification and monitoring processes at a glance

3 Compliance Requirements

Validation, verification and routine performance monitoring are critical components of product safety and quality management programs throughout the food industry. The terms are applicable industry-wide, but the requirements for each step may vary across sectors. This section looks at some of the key compliance requirements affecting the food industry, and the most common types of product inspection equipment that can be integrated into a production line to meet these.

3.1 Food Safety Standards

Development of food safety programs is heavily influenced by the Global Food Safety Initiative (GFSI) or one of many GFSI-approved standards, including but not limited to:
- British Retail Consortium (BRC)
- International Featured Standard for Food (IFS)
- Safe Quality Food (SQF)
- Food Safety System Certification (FSSC) 22000

Validation, verification and routine performance monitoring procedures are central to each of these standards.

For example, the BRC Global Food Safety Standards Issue 7 states: "Reference measuring equipment shall be calibrated […] and records maintained" [6] and that "the site shall establish and implement documented procedures for the operation and testing of the metal detection or x-ray equipment." [7] The BRC documentation also specifies there is a requirement for "the location of the equipment or any other factors influencing the sensitivity of the equipment to be validated and justified," [8].

Similarly, guidance from the IFS v6 guidance document states, "All measuring devices shall be checked, adjusted and calibrated, under a monitoring system, at specified intervals and in accordance with defined recognized standard/methods," [9].
3.2 Hazard Analysis Critical Control Points (HACCP)

In food production, most manufacturers use a HACCP-based system as a framework to identify where hazards might occur. The HACCP structure is then used to put procedures into place which monitor and control each manufacturing step, mitigating the risk of the hazard occurring in the first place.

HACCP is based on seven core principles:
1. Conduct a food safety hazard analysis
2. Identify the CCPs - the point at which a hazard is optimally controlled
3. Establish critical limits for each CCP
4. Establish CCP monitoring requirements
5. Establish corrective actions when monitoring indicates that a particular CCP is not under control
6. Establish procedures to verify system is working as intended
7. Establish documented record keeping procedures

These seven core principles are fundamental to industry food safety standards and regulations. For example, they continue to underpin the latest requirements from the BRC, as documented in the BRC Global Standards Issue 7 publication. Clause 4.10.1.1 in Issue 7 states "a documented assessment in association with the HACCP study shall be carried out on each production process to identify the potential use of equipment to detect or remove foreign-body contamination," [10]. This can help food manufacturers select the most appropriate in-line product inspection systems and place them where they will be most effective as designated CCPs.

A knowledgeable manufacturer of in-line product inspection equipment should be able to provide guidance in implementing a HACCP-based program. When selecting the right in-line product inspection equipment, the decision-making process should take into account the equipment's ability to support monitoring requirements (such as reminders when performance monitoring tests are due or overdue) and available software to facilitate record-keeping procedures.

3.3 Food Safety Regulations

In addition to industry standards, food manufacturers must also obey local regulations. In the USA, the FDA's Food Safety Modernization Act (FSMA) is an example of recent legislation which places heavy emphasis on preventive controls in ensuring food safety. The FSMA 'Preventive Controls for Human Food' rule is now final; compliance dates for some businesses began in September 2016 [11].

The central principle of FSMA is Hazard Analysis Risk-Based Preventive Controls (HARPC). It applies to almost all food processing facilities, and requires that companies have written plans that:
- Identify hazards
- List the steps needed to minimize or prevent those hazards
- Identify monitoring procedures and how records will be recorded
- Specify what actions will be taken to correct problems should they arise

Part 507, Section C of FSMA states "Covered facilities must establish a food safety system that includes an analysis of hazards and risk-based preventive controls. The rule sets requirements for a written food safety plan and includes hazard analysis, preventive controls, and oversight and management of preventive controls including monitoring, corrective actions and corrections and verification," [12]. It is clear that under FSMA, validation, verification and routine performance monitoring processes are mandatory.

Depending on the equipment in place, manufacturers must also comply with additional regulations. For example, metrological regulations and guidelines govern checkweigher set-up, system design and choice of load cell technology. In most countries, there are regulations covering weights, measures, packaging requirements, net content, and maximum permitted variation value for a package being produced.
3.4 How Product Inspection Equipment Supports Compliance

Product inspection equipment fulfils an essential role in ensuring compliance with industry standards, legislation and regulations, in addition to increasing process efficiency. Unlike manual processes that are prone to human error, automated product inspection equipment ensures 100 percent of products are inspected.

- Checkweighers inspect each individual package for weight, to ensure compliance with Net Contents laws and can be used to maintain control of process prior to final packaging.
- Metal detectors can be integrated at any point along a production line to detect and reject metal contamination - whether it is in free-flowing material prior to packaging, or finished goods.
- X-ray inspection systems can be used to inspect for a wide variety of foreign body contaminants including calcified bone, glass, metal and other dense physical contaminants, but can also be used to perform a number of quality checks.
- Vision inspection systems can be used to inspect all packages for labeling compliance – content identification, registration, legibility, and the relevant production batch codes.

In addition to supporting compliance requirements, an additional benefit of in-line product inspection equipment is the ability to deliver improved product quality which helps safeguard the welfare of consumers and the manufacturers' reputations.

4 Validation Procedures

Validation procedures usually involve both internal and external parties, and may involve processes conducted at the equipment supplier's manufacturing site, at the end customer's site, or both. Table 2 provides an overview of some common validation processes, and the parties involved in executing them.

<table>
<thead>
<tr>
<th>Parties Involved</th>
<th>At the Supplier (Equipment Manufacturer)</th>
<th>At the End User Site (Food Manufacturer)</th>
</tr>
</thead>
</table>
| External         | • General - By an Nationally Recognized Testing Lab (NRTL) notified body in the EU, as a proof of product compliance with a standard (e.g., UL review of design and first allowance for UL-listing)  
 • Hygienic Design – USDA or 3A design qualification  
 • Weighing performance - (e.g., MID, NTEP), or on an application  
 • Hazardous locations - ATEX or FM initial qualification  
 • Quality process - ISO 9001 initial qualification  
 | • USDA inspection of a machine or assembly of machinery, prior to first use  
 • Pre-Start, Health and Safety Review by NRTL for Canadian installations, prior to start, or on modification of the line  
 • ATEX qualification at the site (EU)  
 • MID qualification by the supplier at the site  
 • Installation Qualifications – by the supplier |
| Internal         | • FAT protocol, or IFT protocol, using supplier methods, or using the criteria supplied by the customer - conducted by supplier’s personnel  
 • Supplier initial Safety Audits of manufacturers  
 • Declaration of Conformity for the machine, or Incorporation for a partly completed machine  
 • Safety Circuit Qualification for a product, or first-use on a custom machine  
 • Equipment Safety – Design-based Risk Assessment, Safety Circuit Qualification and Induced Failure Testing, for a model, or a custom application  
 | • Declaration of Conformity for the Assembly of Machinery (required by the Machinery Directive)  
 • Hazardous Location - Site installation for by the user's Professional Engineer  
 • Safety Qualification of a machine or line by the corporate Safety Officer; Task-based Risk Assessment and Safety Circuit IFT.  
 • Functional and Performance Testing for accuracy, rejector cycling |

Table 2: Common food industry validation processes and the parties involved
A well-executed and carefully carried out installation phase is the foundation of worry-free and efficient use of your in-line product inspection equipment throughout its working life. Therefore, equipment manufacturers are in a strong position to support their customers throughout the installation/start-up process by making sure that the equipment:

- Is capable of detecting the relevant foreign body contaminant types which may occur in the products being produced (the food manufacturer must ensure the correct product inspection equipment has been chosen for the application).
- Complies with relevant industry standards and regulations.
- Complies with quality management system audits and relevant legislation applicable to the country in which the equipment is installed.
- Supports proof of due diligence.
- Operates as intended when at factory default settings aligned to the customer’s product.
- Is adjusted properly so that the equipment operates as intended, and to the specification set.
- Is installed correctly with reference to system peripheral devices and reject systems.
- Can be used properly and effectively by operators, so that they can enjoy maximum benefit from the features that the in-line product inspection system offers.

As highlighted earlier in this white paper, if substantial modifications subsequently occur to the installed equipment, the equipment must be re-validated at that point.

## 5 Verification Procedures

Performance of equipment may drift away from the standards established during initial installation. Therefore, any in-line product inspection equipment, such as a checkweigher, metal detector, vision or x-ray inspection system, must be periodically verified (typically at 6 or 12 month intervals). Table 3 highlights some common activities related to performance verification processes.

<table>
<thead>
<tr>
<th>Parties Involved</th>
<th>At the Supplier (Equipment Manufacturer)</th>
<th>At the User Site (Food Manufacturer)</th>
</tr>
</thead>
</table>
| **External**     | • Quarterly review of electrical documents and construction to retain UL-listings, or other third-party approvals  
                     • ISO 9001 annual audits | • Annual or semi-annual qualifications by weights and measures notified bodies  
                     • USDA visits to ensure continued compliance  
                     • OSHA inspection |
| **Internal**     | • High-Potential and Ground Testing for HV circuits  
                     • Safety Circuit semi-annual qualification for models  
                     • Supplier annual Safety Audits | • Safety Circuit Checks  
                     • Accuracy tests  
                     • Rejector challenge tests with known faults |

Table 3: Common food industry verification processes and the parties involved

Verification makes sure that:

- The in-line product inspection equipment continues to operate in accordance with the specified standard (sensitivity, weight tolerances, etc) and continues to reject non-conforming product (such as under-weight or over-weight products, contaminated products, or mislabeled products).
- All additional warning and signaling devices are effective (such as alarm conditions).
- Installed fail safe systems are functioning correctly (such as reject confirmation, ‘bin full’ warning, and low air-pressure sensor, etc).
- All current safety standards are being complied with.
- Due diligence can be demonstrated in the event of a product recall or customer complaint.

Verification procedures must make sure that the relevant standards and product inspection policies are being complied with. The latest industry standards require that all in-line product inspection equipment must be independently verified, at minimum, on an annual basis. However, all the points above must also be taken into account during routine performance monitoring processes, as these are a form of verification activity.
The annual performance verification process involves more than simply repeating the scheduled routine performance monitoring tests that are performed by the individual sites. These verification checks must be in line with general industry requirements (such as HACCP or HARPC), fully documented and should include as a minimum the following:

- The product inspection system manufacturer's initial build parameters – not accessible to the user
- Electrical and mechanical installation checks
- System functionality checks including adherence to the specified critical limits
- Product related information checks
- Failsafe functionality checks
- Customer's test piece verification checks
- Verification that line personnel are trained and knowledgeable in undertaking the Standard Operating Procedures (SOPs) related to the local verification and monitoring tests

A summary of the verification tests performed must be completed. An indication of the performance since the last test and any potential degradation in the previous year and the following year should also be documented. Table 4 summarizes considerations for verification of different types of in-line product inspection equipment.

<table>
<thead>
<tr>
<th>Type of In-line Product Inspection Equipment</th>
<th>Verification Checks – Test For:</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checkweighers</td>
<td>• The presence of accurate weighing&lt;br&gt;• The correct rejection of products with deviating weights</td>
<td>• Compliance with Weights &amp; Measures legislation&lt;br&gt;• Cost control</td>
</tr>
<tr>
<td>Metal detection systems</td>
<td>• The accurate detection of specific types of metal contaminants&lt;br&gt;• The correct rejection of contaminated products</td>
<td>• Product safety and quality&lt;br&gt;• Brand protection&lt;br&gt;• Cost control</td>
</tr>
<tr>
<td>Vision inspection systems</td>
<td>• Verification that all packaging quality control and integrity checks are completed correctly</td>
<td>• Product quality&lt;br&gt;• Brand protection&lt;br&gt;• Compliance with industry labeling regulations</td>
</tr>
<tr>
<td>X-ray inspection systems</td>
<td>• Correct and reliable detection and rejection of contaminated products&lt;br&gt;• Correct and reliable detection and rejection of defective products (such as missing products, underfill or overfill and mass)</td>
<td>• Product safety and quality&lt;br&gt;• Brand protection&lt;br&gt;• Cost control</td>
</tr>
</tbody>
</table>

Table 4: Considerations for verification of different in-line product inspection equipment

The examples in Table 4 are types of external verification checks. Some standards bodies may also accept an internal risk assessment and completed associated activities as an alternative to external verification activities completed by a paid contractor.

In addition to the above, the test engineer must also verify how the system is being monitored by auditing a member of the production personnel (at random) with respect to performing the regular performance monitoring tests as detailed in the manufacturing site's SOPs for monitoring CCPs. Performance verification and audit procedures must be documented and communicated to all relevant staff, especially those responsible for performing necessary verification procedures and audits.

The performance verification procedure should be undertaken by a technically qualified party. This can be an external resource such as the equipment manufacturer, an agent acting on the manufacturer's behalf, or an independent company who can demonstrate evidence of their competency. In some cases, an internal resource may also be acceptable.
6 Routine Performance Monitoring Procedures

In making sure that the in-line product inspection system continues to detect and reject in accordance with the documented standard, the purpose of the routine performance monitoring test is to confirm or verify there has been no significant change in the in-line product inspection system’s performance level since the last successful test. These changes could occur as a result of alterations to:

- Machine settings
- Product characteristics
- The product inspection system’s functionality

Documented procedures should clearly state when routine performance monitoring testing should be performed within the manufacturing cycle (Table 5). Consideration should be given to implementing routine monitoring testing at the following stages:

- At the start and finish of daily production/shift
- At regular intervals during the production run, as necessary
- At changes in production batches
- At changes in machine settings
- After downtime for repairs

<table>
<thead>
<tr>
<th>Point in Time</th>
<th>Objective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start and finish of the daily production/shift</td>
<td>To confirm the in-line product inspection system detects and rejects in accordance with the standards that have been set, and make sure any additional warning systems are functioning correctly.</td>
</tr>
<tr>
<td>Regular intervals during a production run</td>
<td>To make sure any product that has passed through the in-line product inspection equipment since the last successful test can be quarantined if the system fails a performance check. It can therefore be easily identified and isolated pending further action.</td>
</tr>
<tr>
<td>Production batch changeover</td>
<td>To confirm the device continues to detect and reject in accordance with the standards that have been set. This is most important when the change of product type requires a selection of a different product memory setting within the equipment.</td>
</tr>
<tr>
<td>Setting Changes</td>
<td>To confirm detection and rejection in accordance with the sensitivity standard.</td>
</tr>
<tr>
<td>After downtime for repair</td>
<td>To make sure the in-line product inspection system and reject mechanism are operating in accordance with the standards that have been set.</td>
</tr>
</tbody>
</table>

Table 5: Points at which routine performance monitoring tests should be performed and the reasons why

6.1 Built-in Performance Monitoring Routines

An in-line product inspection system that has built-in performance monitoring software can aid the discipline and record-generation of routine performance monitoring testing procedures. Such routines can automatically request a test at an agreed pre-set time interval. The approved test operative should access the system feature that enables the test to be completed with the correct test samples. Failure to test the equipment at the agreed time interval could cause a range of different outcomes. Hard-copy documentation (which proves that testing has been carried out) can be provided through a local printer; alternatively, it can be downloaded to a central PC, using a detector with network connectivity capabilities, or data can be downloaded directly from the equipment using a USB port.

6.2 Condition Monitoring

A more robust approach to determining that an in-line product inspection system is continuing to detect and reject in accordance with the specified standard is to undertake continuous checks for changes in key operating parameters of the relevant in-line product inspection equipment. In certain applications, routine performance monitoring can have a negative impact on Overall Equipment Effectiveness (OEE), where the line has to be stopped to conduct the tests. In these scenarios, additional software may be available which monitors equipment performance, enabling the user to reduce the frequency of these tests.
This software-based approach means key operating parameters can be continually monitored for stability, therefore providing scope for reducing the frequency of performance monitoring testing. This offers the attractive benefit of increasing the user's OEE. Some commercially available in-line product inspection systems offer continuous monitoring features. However, when considering their use, it is important to ensure that the system will automatically alert users when there has been an unexpected change in the monitored parameter. This should prompt a verification test and a stop alarm if there is an unacceptable change. However, if the system remains in specification until the auto alert is activated, the benefits can be considerable to the user.

6.3 Automatic Collection of Test Results

Specific software may be available from the product equipment supplier that enables users to automatically record and store the results of routine performance monitoring tests in a single, online location. This type of software can improve operator efficiency, and provide records to prove due diligence has been exercised.

7 Supplier Support

Your in-line product inspection equipment supplier can be a valuable resource throughout the equipment lifecycle to assist you in meeting your compliance requirements. The supplier can facilitate initial equipment qualification and performance verification and can provide documentation to support the record-keeping requirements of standards, legislation, regulations and retailer codes of practice. The supplier should also be able to share their expertise to help you develop and implement routine performance monitoring tests that accurately and consistently assess the performance of your in-line product inspection equipment. In-depth training may also be available from the equipment manufacturer to give line operators additional guidance on operating the equipment and performing required testing correctly. Rather than view your relationship with your in-line product inspection equipment manufacturer as a transactional one that ends once the equipment has been delivered, consider engaging with them to maximize the after-sales service support they offer to help you more easily comply with the relevant standards, legislation, regulations and retailer codes of practice.

8 Summary

This white paper began by defining validation, verification and routine performance monitoring, before examining the differences between each of these distinct processes and the relationships between them. Each can be viewed in the context of where it sits on the equipment lifecycle continuum. 'Validation' procedures occur during the installation phase. They examine whether the correct piece of equipment has been selected, and whether that equipment is capable of performing the task it has been specified to do. 'Verification' procedures use objective evidence to confirm whether a piece of equipment is functioning properly, and occur at periodic intervals. Performance verification is a formal and in-depth process which typically occurs at annual intervals. Routine performance monitoring is a scheduled and planned verification activity that assesses whether a piece of equipment is under control, and takes place on a regular basis, often dictated by the quarantine window.

Having the right start builds a strong foundation for maximum compliance with standards and regulations, as well as supporting operational efficiencies. Initial validation at the point of installation ensures that your in-line product inspection equipment works as intended. Periodic performance verification throughout the lifecycle of your in-line product inspection equipment ensures it continues to perform as expected, and complies with the relevant standards and regulations. Routine performance monitoring tests must be conducted regularly to confirm equipment is under control to maintain product quality and protect against damage to your reputation.

It is important to understand the differences between the terms and how the processes relate to one another. Each is critical for compliance with industry standards and regulations. New in-line product inspection equipment installations should be validated by the manufacturer and have the verification and monitoring process in place before production starts. Records must be kept and the normal verification and monitoring frequency must be followed to achieve maximum compliance.
A competent in-line product inspection equipment supplier can be a valuable partner. Engaging with such suppliers can bring several benefits. Equipment suppliers can share expertise in meeting compliance requirements and provide support at both the point of installation (validation) and during the operational phase (verification and monitoring).

9 Recommended Reading

The following documents provide a more detailed overview of the validation, verification and routine performance monitoring processes for specific in-line product inspection technologies:


10 References

About Mettler-Toledo Product Inspection:

The Product Inspection Division of METTLER TOLEDO is a leader in the field of automated inspection technology. Our solutions increase process efficiency for manufacturers while supporting compliance with industry standards and regulations. Our systems also deliver improved product quality which helps to protect the welfare of consumers and reputation of manufacturers.

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