Food Regulatory Guide

Food Safety & Compliance with

High Performance Weighing & Inspection

METTLER TOLEDO

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Prepare to Improve Safety
Ensure High-Quality Food

Consumers deserve high-quality and safe food. However, maintaining an effective food-quality control system that fulfills all food-safety requirements and standards is challenging. This guide offers know-how in 16 different areas, where weighing and foreign-body control helps to ensure your products are compliant while achieving the level of safety and quality your customers demand.

Food producers are under constant pressure to deliver high quality food and to comply with national laws and global food safety and quality standards.

In addition to existing quality standards such as ISO9001, GMP or FDA's Food Modernization Act (FSMA) it is becoming increasingly important for a food manufacturer or retailer to be certified according to a food-specific, GFSI-accepted standard.

The Global Food Safety Initiative (GFSI) benchmarks existing food standards against food safety criteria with a goal of standardizing certifications and eliminating multiple audits.

In 2016 the following GFSI-accepted standards rank as the most-often used worldwide.

- BRC Global Standard
- FSSC 22000
- IFS International Featured Standard
- SQF Code

This expanded and updated second edition of the Food Safety Guide offers guidance to fulfill global food safety and quality standards without harming production efficiency.

There are 16 areas where weighing equipment, foreign body detection, or quality control solutions can be critical for achieving compliance and efficiency.

This guide helps to ensure your products reach your customers exactly as they should – no more, no less, correct, complete, and safe, inside and out.

Select Your Focus Topics

Consider your area of interest and see to which regulatory standard chapter they correspond.

Topic / Chapter		BRC	FSSC 22000	IFS	SQF	Page
Standards	Food Safety & Quality Standards	BRC Global Standard (Version 7)	FSSC 22000 (Version 3)	International Food Standard (Version 6)	SQF Code, Edition 7, Module 2	6
Traceability	Traceability / Product Identification	• 3.9 Traceability • 3.11 Management of incidents, product withdrawal and product recall	• 7.9 Traceability system	• 4.18 Traceability • 4.2 Specifications and formulas	• 2.6 Product identification, trace, withdrawal and recall	14
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Food Safety & Quality

The Trend Towards Certification

Consumers, retailers and food manufacturers today are increasingly focused on food safety and quality. In fact, an annually-repeated industry survey conducted by the Consumer Goods Forum found that food and product safety remain among the top concerns of manufacturers and retailers.

The only thing on retailers' and manufacturers' minds more than safety? The economy and consumer demand, which translates to profitability. In a competitive world market made even tougher by recent legislation in major markets such as the U.S. and China to reassure consumers, producers at every point in the supply chain are carefully watching margins while seeking new strategies to protect market share.

In addition to general food safety, other industry issues such as healthy or organic/biologically-grown foods – as well as animal welfare – are also gaining importance. Addressing these issues in addition to food safety & quality basics via certification by a globally-accepted food standard – which helps ensure consumers get what they pay for – is one way manufacturers have begun to carve out niches for themselves in the global food arena. Specialization aside, with the broader adoption of global food standards, retailers and manufacturers are now able to favor purchasing from certified suppliers and sub-suppliers.

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For this reason, work to gain conformity among standards – and help manufacturers decide which one is best for their purposes – is underway, mainly driven by the Global Food Safety Initiative (GFSI), a retailer/manufacturer non-profit foundation. This paper highlights four of the most-used standards. It also offers a short comparison of each, providing points producers may want to consider when deciding which standard to adopt. Finally, it gives an outlook on trends – such as the need for manufacturers and suppliers to take a more active role in certification to ensure future profitability – in food safety & quality discussions worldwide.

1 Certification: Oversight, Responsibilities & Benefits

At its most basic, certification can be defined as a procedure by which an accredited certification body gives written assurance that a product or a process is in conformity with the respective standard. Standards can be set up by the public sector (governmental institution) or by the private sector (retailer/industry association).

Benefits of certification

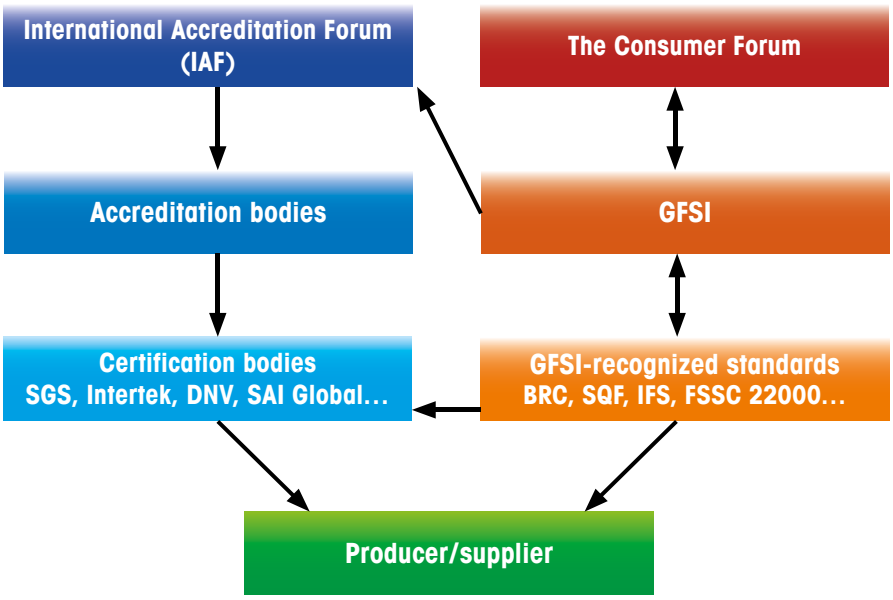
In addition to existing quality standards such as ISO9001, GMP or HACCP, it is becoming increasingly important for food manufacturers and retailers to be certified according to a food-specific, GFSI-accepted standard. Benefits include:

- Improved customer confidence
- Enhanced brand protection
- A standard process/quality measure
- Minimized costs through not having to "clean up" after distribution of nonconforming products

The Global Food Safety Initiative (GFSI)

The GFSI is run by the Consumer Goods Forum, which brings together CEOs and senior management from 650 retailers, manufacturers, service providers and other stakeholders across the food industry. The initiative was set up in 2000 against the backdrop of various food safety crises, including BSE, with the intention of ensuring worldwide consumer confidence in food safety.

GFSI benchmarks existing food standards against food safety criteria with a goal of standardizing certifications and eliminating multiple audits. Preferred implementation places the GFSI just above Third Parties/Accreditation Bodies, as referenced in the following graphic. Key elements and further requirements are summarized in the GFSI Benchmarking Requirements/Guidance Document (found via the links at the end of this paper).



2 Choosing a Standard

As a result of their ongoing work to ensure each certification method is sound, GFSI promotes the equal acceptance of all approved standards: "Once certified, accepted everywhere." Actual practice proves, however, that retailers, manufacturers and even entire segments may have strong certification preferences.

Before deciding on a standard or a set of standards, check with customers to determine which standard they accept – and which ones they prefer. Understanding these preferences, some certifying bodies offer combi-audits (for example, BRC & FSSC 22000) in a single, integrated audit process.

3 GFSI-Accepted Standards

Mid-2016, the following standards are GFSI-recognized manufacturing schemes. Schemes in bold currently rank as the most-often used and accepted worldwide.

- **BRC Global Standard**
- **FSSC 22000**
- Global Aquaculture Alliance (Seafood)
- Global Red Meat Standard
- **IFS International Featured Standard**
- **SQF Code**
- PrimusGFS Standard

The most commonly-used, GFSI-accepted food safety and quality standards are overviewed below, ranked in order of prevalence in today's market.

BRC (British Retail Consortium)

Originally developed in response to the needs of UK members of the British Retail Consortium, BRC Standards have gained use worldwide and are specified as acceptable by growing numbers of retailers and branded manufacturers in the EU, North America and further afield. BRC covers the supply chain with four related standards: BRC Global Food Standard, BRC Storage and Distribution, BRC IOP for Food Packaging and BRC Consumer Products.

BRC Global Standard for Food Safety was first introduced in 1998 and now has almost 23,000 certificated suppliers in over 125 countries. It was developed to specify safety, quality and operational criteria required for food manufacturers to comply with regulations and protect consumers, it was the first standard accepted by GFSI in 2000.

The International Featured Standard (IFS)

Founded in 2002 by a German retailer association, in 2011 the IFS represents more than 190 dealers including 16,800 IFS-certified suppliers in 90 countries. The standard provides a range of integrated checks on safety and quality in food processing companies and offers certification across the whole range of food processing with the exception of agricultural primary production.

The IFS comprises six related standards: IFS Food, IFS Broker, IFS Logistics, IFS Cash & Carry/Wholesale, IFS HPC and IFS Global Markets.

Safe Quality Food (SQF) Code

SQFI has combined the SQF 1000 Code, for primary producers, and the SQF 2000 Code, for manufacturers, distributors and brokers, to create one standard for food safety from farm to fork. Developed in Western Australia but now owned by the Food Marketing Institute (FMI) in the USA, the scheme aims to meet the needs of buyers and suppliers worldwide. The standard certifies that a supplier's food safety and quality management system complies with international and domestic food safety regulations.

The only international food certification body headquartered outside Europe, SQFI counts more than 8,900 companies among adopters of its certification.

FSSC 22000

FSSC 22000 is a food safety certification scheme based on the existing internationally recognized standard ISO 22000 and complemented by technical standards ISO/TS 22002-1, ISO/TS 22002-4 or PAS222 which cover the prerequisites.

It was accepted by GFSI in 2010 and lists over 11,000 FSSC 22000 certified organizations from 149 countries. This includes public and private companies that manufacture perishable animal or vegetable products, products with a long shelf life, food ingredients, and/or food additives.

Manufacturers who are already ISO 22000-certified only need to be reviewed against the ISO/TS 22002-1, ISO/TS 22002-4 or PAS222 and any additional requirements to ensure they receive this GFSI-approved certification. This may be the easiest certification route for companies who are already ISO 22000-compliant.

Other standards are largely industry specific (red meat, aquaculture). However, the food safety specifics of these industries are also covered to a great extent by one or more of the major certification schemes.

4 Comparing the Standards

All GFSI-accepted standards, whether for primary or secondary production, must meet three main areas of certification requirements:

- Companies must demonstrate they have a food safety management system
- Companies must demonstrate Good Manufacturing Practices (GMP), good distribution practices and/or good agricultural practices
- Companies must demonstrate they have conducted Hazard Analysis and identified the Critical Control Points where warranted in line with HACCP principles

Each scheme varies in scope and structure. The following chart analyzes basic differences among the most widely-used standards.

Subject	BRC	IFS	SQF	FSSC 22000
System requirements	Quality and food safety	Quality and food safety	Level 2 - HACCP based food safety plans Level 3 - Comprehensive food safety and quality management system	Food Safety
System establishment and implementation	Prescriptive requirements	Prescriptive requirements	Prescriptive requirements	Provide frame-work requirements for the company to demonstrate how to comply and demonstrate their food safety system
Report/ data management	By Certification body and Standard owner	By Certification body and Standard owner	Registration, audit documents, reports and certificate all managed in the SQFI database by certification body and SQFI	By Certification body and Standard owner
Certification process	No stage 1; Company goes directly to an on-site certification audit	No stage 1; Company can easily go direct to on-site certification audit	Document review on-site or off-site; Facility certification audit on-site	Stage 1 on-site; Stage 2 on-site
Certificate validity	Certificate valid for 1 year; Grade C-Recertification within 6 months	Certificate valid for 1 year	Certificate valid for 1 year if 'E' or 'G' rating 6 months Surveillance if 'C' rating	Certificate valid for 3 years
Integrated audit	Recertification depends on audit result (grade C needs to be 6 months so interval or integrated condition will be changed depending on result)	Does not allow integration with ISO management system standard, allows integration with product certification schemes	Different management system structure but possible for integrated audit	Same management system structure as ISO standard so it is easy to integrate with other management system standards
Recertification/ maintenance visit	Same audit time as certification visit	Same audit time as certification visit	Same audit time as Certification audit	Less audit time than stage 2 on-site
Certification mark	Not allow to be displayed on the product	Not allow to be displayed on the product	Level 3 certification can use SQF shield on product	Not allow to be displayed on the product

Source: COMPARING GLOBAL FOOD SAFETY INITIATIVE GFSI RECOGNISED STANDARDS, SGS, 2016

Factors producers may want to consider before applying for consideration include:

- Product characteristics
- Company's position on the supply chain
- Current management systems
- Company's historic compliance with existing regulations
- Customer/industry preferences

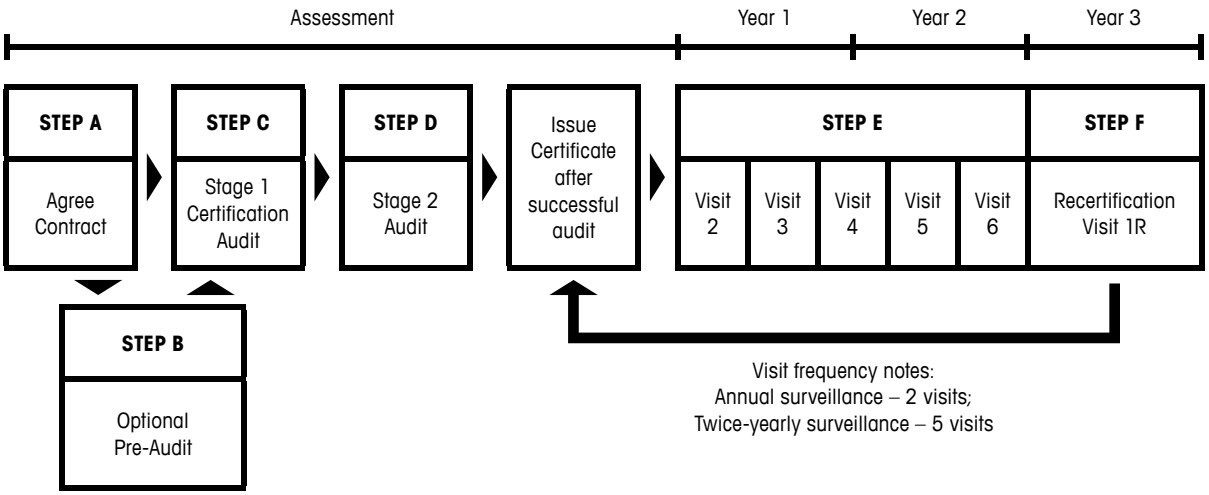
As noted previously, one standard may be easiest to apply – yet not offer certification's benefits because it is not considered acceptable among a particular company's customers.

5 Sample Audit Procedure

The following flow chart illustrates the standard procedure for obtaining FSSC 22000 certification. Other procedures may vary slightly; however, this is an excellent basic representation of a certification audit.

The process can be arduous; however, experts within the certifying body and industry are available to provide necessary guidance to ensure systems are compliant and safe.

FSSC 2200 & ISO 2200 certification processes



6 Outlook

The trend towards more stringent food safety & quality regulation continues. New challenges concerning food safety & quality aspects are created through developments such as GMOs (Genetically Modified Organisms), nanotechnology and the increase in international sourcing/trade of food/feed, and actions such as these are expected to propel this trend forward even more strongly.

The following food safety issues are expected to gain importance in the coming years:

- Organizations taking even more ownership for food safety to protect their brands
- Even tighter controls established to safeguard the food supply chain
- Traceability and integrated management programs becoming an essential – and perhaps involuntary – part of food production

With these trends, and corresponding changes in international and national laws, standards and certification processes will be subject to regular revision. Examples of recent legislation impacting certification processes include:

China Food Safety Law

The China Food Safety Law launched in 2009 was adopted by the country's top legislative body, The Standing Committee of China's National People's Congress (NPC), and became effective on Oct 1, 2015.
With 154 articles, 50 more than were found in the original law, the revamped Food Safety Law adds new articles and provisions on penalties, baby formula and online shopping.

Stiffer penalties

Consumers can demand reparation of three times any loss they suffer from substandard food. Bigger fines for offenders are also on the menu. Manufacturers who add inedible substances to food could find themselves behind bars for up to 15 days. Producers may face fines of up to 30 times the value of their products, up from 10 times.

Baby formula

Producers are required to register powdered baby milk formula with the food and drug regulator, and have to test every batch of their product, conduct regular internal inspections and submit reports to regulators.

Online shopping

The amendment adds new articles on online shopping, clarifying the liabilities of shopping platforms. They are required to register the real identity of vendors and check their certificates.

U.S. Food Safety Modernization Act (FSMA)

The FDA Food Safety Modernization Act (FSMA), signed into law by President Obama on Jan. 4, 2011 enables the FDA to focus more on preventing food safety problems rather than primarily reacting to problems after they occur. FSMA shifts from a HACCP (Hazard Analysis Critical Control Point) principle to HARPC (Hazard Analysis Risked Based Preventive Control). The FSMA impacts facilities globally as exports to the US must meet the requirements.

FSMA requires a written Food Safety Preventive Controls plan developed by a Preventive Controls Qualified Individual (PCQI) for each food manufacturer and storage facility. This plan must identify certain food safety risks associated with their foods and processes and to implement preventive controls that minimize these risks.

The law also provides the FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems

when they do occur. The law also gives the FDA important new tools to hold imported foods to the same standards as domestic foods and directs the FDA to build an integrated national food safety system in partnership with state and local authorities.

With these more stringent requirements in mind, and knowing that global oversight bodies are working to ensure that certification standards are comprehensive and widely-accepted, more and more manufacturers and suppliers will find themselves seeking certification to stay ahead of legislative changes and ensure profitability well into the future.

7 Summary

Consumers – and governments worldwide – are becoming increasingly concerned about unsafe food. Recent contamination cases are published and distributed widely via electronic media, which clearly leads to reduced income for involved suppliers – and even perhaps the industry segment as a whole.

Being certified according to a GFSI accepted standard such as IFS, BRC, FSSC 22000 or SQF demonstrate the company's engagement in meeting the demand that they focus on safety.

While all certifications deal with similar food safety related concerns, choosing the right certification based on the company's industry, needs, and customer preference remains important, even as GFSI continues to work to create harmony among the approved scheme owners and provide a "once certified, accepted everywhere" approach.

Knowing and implementing requirements according to one of these standards provides a framework for continually improving production quality processes. This helps to protect and enhance brand reputation and ensure future profitability in a competitive global market.

8 Additional Resources

- METTLER TOLEDO, Meet Global Food Safety Standards and Increase Productivity and Profitability **www.mt.com/food-regulations**
- SGS – This chapter "Food Safety and the Trend Towards Certification" contains an extract from the paper "COMPARING GLOBAL FOOD SAFETY INITIATIVE (GFSI) RECOGNISED STANDARDS" and remains the copyright of the SGS. This white paper can be downloaded from the SGS homepage www.sgs.com/gfsiwhitepaper
- International Featured Standards (IFS) www.ifs-certification.com
- British Retail Consortium (BRC) www.brcglobalstandards.com
- Safe Quality Food (SQF) Institute www.SQFI.com
- Global Food Safety Initiative (GFSI) www.mygfsi.com
- The Consumer Goods Forum www.theconsumergoodsforum.com
- Food Safety System Certification 22000; FSSC 22000 www.fssc22000.com
- FDA Food Safety Modernization Act, FSMA http://www.fda.gov/fsma

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Traceability for Standard Compliance and Process Improvement

Reoccurring incidents such as e-coli in spinach and dioxin in pork emphasize the rising importance of efficient traceability. Tracking & tracing food, feed, and food-producing animals through production and distribution stages is proving vital to consumer safety and company reputations.

Food Safety regulations such as EU178/2002 or US Bioterrorism Act, as well as retail-driven standards, require food suppliers to assure traceability on a one-up/one-down principle but do not dictate methods. Some companies comply using paper-based systems; others may require full networked computer and bar code systems to effectively meet requirements.

This paper focuses on in-plant traceability and discusses how good traceability not only helps a manufacturer comply with legal and regulatory requirements; it also shows how the right systems and equipment can contribute to production efficiency through better stock management and minimized waste.

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1 The Importance of Traceability

Traceability is a legal requirement for food, feed and related products. In addition, it is a basic element in safety and quality management schemes such as the GFSI accepted standards (BRC, IFS, SQF, and FSSC 22000) or in national industry and product specific regulations (e.g. EU beef labeling regulations).

Traceability requirements are linked to legislative demands that any product placed on the market shall be fit for purpose and not injurious to health. As a risk management tool, traceability allows businesses and authorities to withdraw products identified as unsafe. It also:

- Minimizes costs incurred by making recall more effective
- Allows targeted action to prevent recurrence
- Assists in problem diagnosis, passing on liability where relevant
- Promotes customer confidence and brand protection
- Optimizes production efficiency and quality control (stock control, material usage, and origin/characteristics of products).

What is traceability?

Traceability is defined as:
'Ability to … follow raw materials and components intended to be, or expected to be, incorporated into a product, through all stages of receipt, production, processing and distribution.'

Traceability can also ensure that product safety and quality attributes have been checked (country of origin, species of animal, whether all components are quality-checked and released for production or that products are free of foreign bodies).

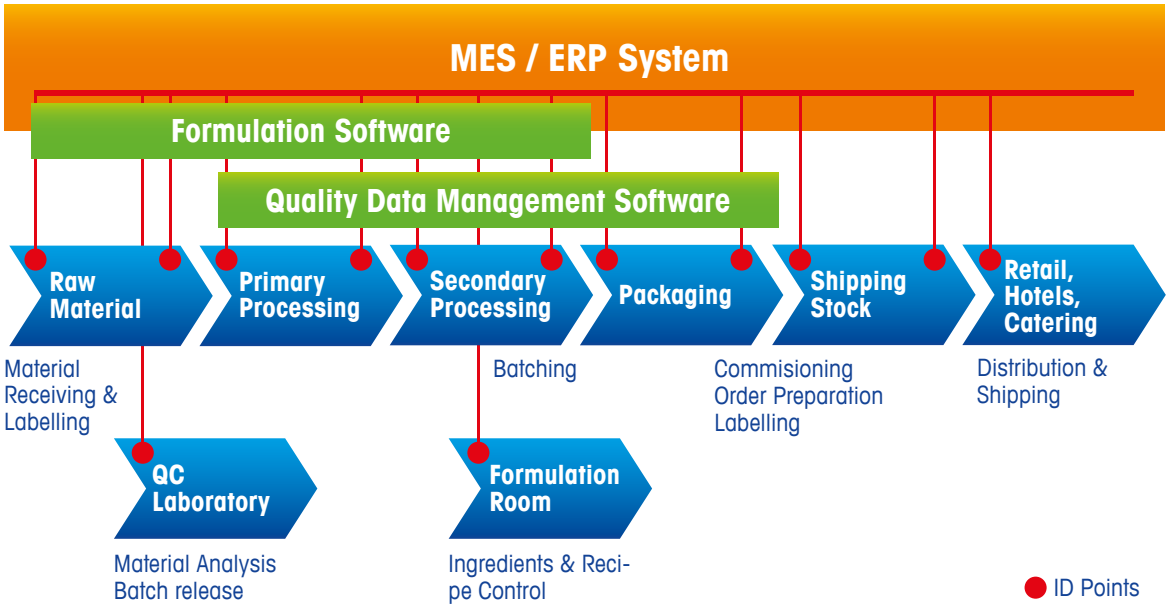

Figure 1: Software solutions for ID Points, Formulation Recipe Weighing and Quality Data Management

2 Designing a Traceability System

Legislation generally requires a 'one up'/'one down' approach to traceability. Integration of internal and external systems improves efficiency. Therefore, it is worth considering systems operated by raw material or component suppliers as well as customers to understand a company's interaction within the supply chain.

General principles

Some general principles to consider when designing or challenging an existing traceability system include making sure that it:

- Covers all stages of production, processing and distribution
- Identifies raw materials suppliers
- Identifies which components have been used in which product
- Identifies supplied customers
- Identifies which products and intermediates have been disposed of (verification of destruction may be required)
- Ensures products supplied to customers are adequately labeled or identified to facilitate traceability
- Provides details to authorities on-demand in a timely manner.

An ideal system fits into a company's normal work practice and enables quick and easy collection of relevant information.

Risk assessment

Relevant variables such as the nature of products and raw materials must be considered through adequate risk assessment. Design will depend on on elements such as:

- Number/nature of raw materials and components
- Criticality and risk of components used
- Batch/lot sizes and uniformity
- Production processes
- Number of component combinations & lot splits

Consider where batches merge/diverge and traceability may be reduced or lost; establish what information is going to be recorded and how.

The system should include documentation of intermediate/semi-processed materials, those that are part-used, rework, and any rejected materials or those 'on hold' pending investigation.

Figure 2: Weighing Station with METTLER TOLEDO Indicator IND890 as ID Point

Batches

Unique identity codes such as: delivery date, production or run time, batch size, and expiry date should be used. This may consist of an internal system for assigning a sequential number, or use the supplier's batch code or GTIN (Global Trade Identification Number).

Codes should include enough detail to ensure traceability back to the production batch.

Labeling

Consider labeling suitability. Traceability is often confused if 'old' labels are not removed from containers. When implementing a system, investigate alternative systems of marking, such as:

- Permanent marking pens
- Labels aimed at minimizing contamination risk (for example, metal-detectable labels, RFID)
- Reusable, visually-distinct tags.

Quantity check

In order to account for all materials, quantity details should be included. The amount of incoming raw material must be checked against the amount used in the resulting finished products, taking process waste and rework into account. Thus:

A + B + C	=	processing	=	X, Y, Z
(raw materials)		(yields/waste/rework)		(finished products)

It is unlikely that the mass balance check will account for all materials to 100% accuracy; however, any discrepancies should be justified (such as ingredient dehydration). A company must demonstrate that it understands the variance to ensure traceability system effectiveness. Mass balance is a key measure that can also highlight areas for improvement.

Timing

The traceability system must allow actions such as isolation of an unsafe batch or recall from a depot to be taken within an appropriate time frame. This time frame will relate to product characteristics such as shelf life, production process/supply chain complexity, and consumer risk.

3 Verifying Product Safety and Quality Attribute Checks

A traceability system can be used to confirm that safety and quality checks have been performed and sufficient records have been retained for verification. This is particularly significant when investigating customer complaints and legal compliance. Any test results, such as microbiological testing, must also link back to original batches.

An growing number of consumer products must be supported by an electronic file containing documentation that demonstrates the product meets safety standards. This file becomes part of the traceability system. It is good practice to use technical files even when it is not a specific legal requirement.

4 Documentation

Meaningful documentation provides evidence of production history such as:

- Incoming goods records and raw material quality checks
- Intermediate component records or mix recipes
- Warehousing and storage records
- Delivery orders to the final customer
- Records of any subcontracted work

Additionally, if traceability is used for confirming that safety/quality checks have been performed, then the following documentation would also be required:

- HACCP or hazard analysis documentation
- Process records for manufacturing the finished product
- Operator instructions for the recording of batch codes for all raw materials, work in progress and finished products
- Personnel training records

Legislation dictates traceability record retention timeframes related to product characteristics. For example, foods with a shelf life of less than three months would need to be kept at least six months. Otherwise, general rules dictate a 5-year retention minimum.

5 Traceability Testing

The company should determine the method and frequency for traceability system checks depending on production process complexity and product criticality. Regular testing will demonstrate effectiveness and allow system improvements. The company must prove how quickly information can be collated and corrective action – such as quarantine – can be taken.

6 Traceability Technologies

Regulations and certifications require traceability, but none are prescriptive. A system may be paper- or computer based. The best system fits into the company's normal working practice and enables easy information access. Weighing scales are often important material identification points in a traceability system (Figure 1).

Paper-based systems

A paper system may be cost-effective for processes with limited number of materials/components and little lot combination/split situations. But documentation practice and form design will need to be reviewed to reduce human error risk.

Barcode labeling

Bar code systems can be more accurate where large amounts of data need to be tracked. Internationally recognized GS1 Standards can ensure integration of information throughout the supply chain matching information flow with physical flow. Because of its ability to provide globally unique identification of trade items, assets, logistic units, parties and locations, the GS1 System is particularly well suited to be used for traceability purposes. RFID systems provide efficient, interactive data management as well but are typically more expensive.Intelligent weighing terminals connected to barcode printers and scanners can clearly mark and identify raw materials received, semi-finished and final products. For areas with multiple formulation processes such as vitamin premixes or spice kitchen, PC-based recipe weighing can provide seamless documentation of how much of what component was weighed when, where and by whom. Benefits include material flow transparency, better stock management and human error reduction. Improved production follow-through may be guaranteed for some industry segments.

Integrated systems

Integrated solutions that include scales, scanners and printers from goods-in to shipment provide the highest level of traceability. All data can be linked and processed in real-time, providing clear identification of raw materials/intermediate components and warehousing/storage records. Genealogy trees allow immediate upstream tracing and downstream tracking of potentially faulty components and batches. General efficiency improvement through functions such as yield analysis, line performance comparison and stock optimization help improve productivity.

7 Summary

Recent worldwide recall episodes have heightened the profile of traceability. Implementing state-of-the-art traceability offers:

- The ability to perform fast, precise product recalls
- Minimized number and scope/impact of recalls
- Enhanced consumer protection and confidence
- Improved brand building & protection
- Increased production efficiency and quality control

Integrated technology can help eliminate manual record-keeping, save time and eliminate error potential. It also improves quality control and supports data integration into existing MES or ERP systems. Ultimately, a well-designed traceability system will provide easier fulfillment of legislative principles and a wealth of data that can help with internal process improvement.

8 Additional Resources

- Directive 2001/95/EC on General Product Safety (2001) – This European directive requires companies to have traceability systems to effect recall of dangerous or illegal products from the market.
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:011:0004:0017:en:PDF

- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 This European regulation lays down the general principles and requirements of food law, establishing the European Food Safety Authority and procedures in matters of food safety.
  www.food.gov.uk/multimedia/pdfs/1782002ecregulation.pdf

- GS1 – Global organisation for design of systems including traceability standards.
  www.gs1.org/productssolutions/traceability/gts/

- BRC Global Standards – This chapter "Traceability for Standard Compliance and Process Improvement" contains an extract from the BRC Global Standard Best Practice Guideline Traceability and remains the copyright of the BRC. If you wish to purchase a copy please visit the BRC Bookshop
  www.brcbookshop.com

- RASFF – The Rapid Alert System for Food and Feed (RASFF) enables the rapid exchange of information whenever a risk to food or feed safety is identified.
  http://ec.europa.eu/food/safety_en

- METTLER TOLEDO Formulation / Recipe Weighing Solution
  www.mt.com/formulation

- METTLER TOLEDO Quality Data Management Solution
  www.mt.com/freeweigh

- METTLER TOLEDO Traceability Solutions
  www.mt.com/traceability

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Improved Production Yield through Process Oriented Recipe Management

Food manufacturing companies are under increased pressure to improve plant productivity, product quality and consumer safety. For all three, ingredient traceability and process tracking play central roles.

International standards designed to ensure product safety (EC 178/2002, US Bioterrorism Act, FDA, GMP, BRC, IFS, ISO 22000) are cropping up. A prerequisite to the traceability required is documentation of all relevant formulation and weighing process activities.

A computer-guided and networked, rather than paper-based, production system provides easily accessible production data. The resulting documentation and analysis can improve quality, reduce waste and protect both consumers and brand reputation, providing significant bottom-line improvement.

This paper will address the benefits of investing in such a system as well as considerations that help ensure the system enhances manufacturing processes.

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1 Increasing Regulatory Pressure Requires Traceability

From bird flu to bioterrorism threats, modern reality has forced both governments and food processors to impose new rules for food and allied product manufacturing.
The IFS (International Food Standard) – for example – requires producers to guarantee traceability of goods flow, as stated in IFS Version 5, paragraph 4.16.1: Similar requirements are stipulated in BRC (British Retail Consortium) Issue 4, paragraph 2.13 and ISO 22000, paragraph 7.9.
Aside from regulations, unpredictable supply-chain or customer events may require investigation into production steps. If defective batches appear, the root cause of the problem must be identified and measures taken to ensure future product quality and safety.

Essentially, food producers must document all processes – without gaps. This includes recipe development, quality lab, production planning, monitoring, dispensing and packaging / distribution. A computerized and intelligently networked formulation / weighing system is key.

A traceability system shall be in place which enables the identification of product lots and their relation to batches in direct contact with food, packaging intended or expected to be in direct contact with food.

The traceability system shall incorporate all relevant processing and distribution records.

2 True Traceable Formulation/Weighing Is Computer-Based

Truly gapless traceability requires that all involved parties feed recipe – relevant data – ingredients, structures, work instructions, batch and production order information – into a centralized system. A computer-based system's advantages over a paper-based system include data consistency, speed of data analysis and improved recall management.

An electronic system can also document processes, generate weighing and manufacturing reports, and print labels to identify goods-in-process. This brings users one important step closer to compliance with EU 178 / 2002; BRC; and Controls Used for Manufacturing, Processing, Packing, or Holding Dietary Supplements for FDA 21 CFR Part 111 CGMP Regulations.
This type of system is also vital for transparent manufacturing processes and providing a proper decision base for streamlining processes.

End-to-end documentation

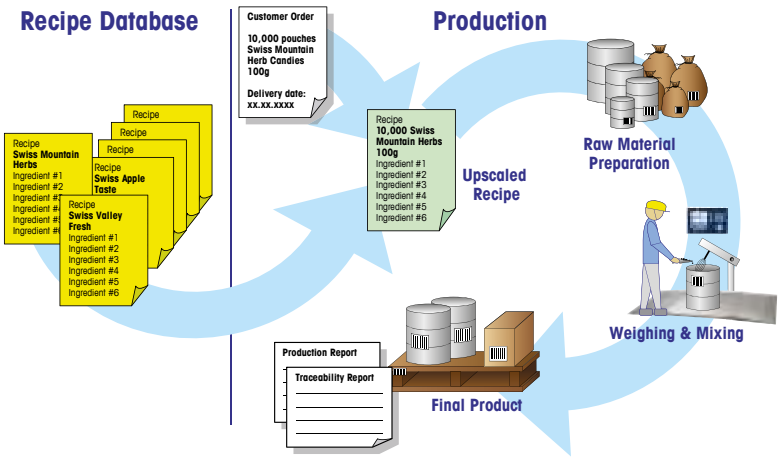
Tracking and tracing demands documentation of all production actions from goods receiving to end-product shipment. To be effective, manufacturers must ensure systems provide relevant data quickly. Some governments request access even within few hours.

For example, in a recall, a manufacturer must identify:
- Who delivered the spices used in batch XY of meat pie Z?
- What quantity was used?
- Who released the recipe?

If end-product taste deviates from recipe expectations:
- What area of processing needs to be adjusted?

Most critically:
- How quickly can a manufacturer's current documentation process answer these questions?

In an effective and fully networked system, this information is immediately available when the system offers features such as:



Clearly identified materials via labeling/barcoding. At each stage a label indicating material and status is affixed. Corresponding entries are made in the database.

Online monitoring. Monitoring functions offer information about exceptional factory situations.

Industry-standard networking. System components communicate with a centralized database via Ethernet LAN. Clients such as dispensing stations and control devices such as balances, scales and other peripherals exchange production data with the server. Windows-compliant applications use standard resources such as network printers for reporting.

Expandability and connectivity. System expansions are possible without disturbing other components unless software is updated. A dedicated ERP Gateway can offer a configurable interface between the solutions and an ERP system such as SAP.

Benefit in terms of ROI

Virtually any company blending different materials in a well-defined recipe can benefit from a computer based formulation system to streamline procedures. More expensive or higher risk materials will produce the fastest return on investment; however, nearly any processor should be able to prove ROI on an appropriately scaled system in 12 months or less through:

- Reduced consumer risk
- Enhanced regulatory compliance
- Less product waste
- Lower disposal / rework / recycling costs

all leading to substantial bottom-line enhancements.

3 System Components/Configuration

A standardized configurable system that has been tuned to manage critical weighing process parameters has many advantages over client-specific systems with custom programming.

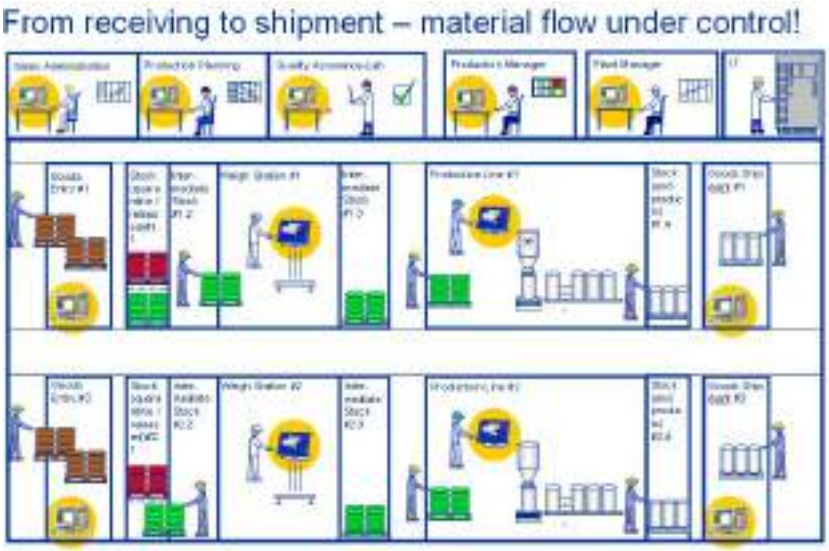
Standard interfaces allow a high degree of customization while offering expert system maintenance and support over the life of equipment and software. The initial investment better maintains its value and can secure optimal production performance well into the future.

Master data management

In a networked system, a master station allows overall data management and maintenance. This can include tracking of:

- Materials
- Instructions
- Recipes
- Orders
- Preparation batches
- Warehouse status
- Containers
- Operators
- Consumption data
- Exceptions
- Production activities
- Password activities
- User connections
- Database activity log
- Weighing / calibration
- Audit trail
- Electronic and hardcopy reporting on the above

Reliability and security are critical. While processes can be controlled at individual process weigh stations, all process data is gathered at the master station.



User-friendly screens simplify weighing and minimize potential operator errors

Specialized weigh stations

For required formulation activities, the following weigh stations are available:

- **Dispensing** – batch components are pre-weighed and ready for execution
- **Production** – components are verified before mixing according to recipe sequence
- **Dispensing & production** – combines both actions, used primarily at smaller companies where pre-weighing is performed in the production area

Screens must be designed for optimum readability for fast information recognition and analysis. Clearly visible instructions and color-coded weigh process results can help ensure a straightforward and efficient process that increases accurate throughput.

Security plays a role here, too: Only trained and authorized users are be able to manage materials via user rights configured to their processor status. Additionally, if an ingredient entry scanned and checked against the recipe does not match, the system can reject it and produce an error message, reducing human-error risk. Steps become immediately traceable. Hazardous materials precautions can also be clearly indicated when necessary.

Ease-of-use considerations reduce time spent in training. Standard log-in/lock-out procedures also reduce unproductive downtime between operator shifts and enhance security.

Seamless data exchange with ERP/MES systems

As noted previously, ERP interfaces permit integration of an appropriately configured and effectively networked weighing system with many ERP and MES systems. Seamless data exchange avoids redundant data maintenance:

- **ERP system data** becomes available in the weighing process.
- **Production data** is sent back without manual intervention.

All consumption data are available in the ERP/MES system without manual interaction. Based on this data exchange stock levels are automatically adjusted. Seamless exchange supports batch release in the MES/ERP system, simplifies data handling and avoids manual input errors.

After successful log-in, planned production orders are presented to the operator

Barcodes guarantee simple, fast verification with the connected reader

4 Integrated Traceability

In every production step from goods entry to shipment, database entries correspond to in-process materials. In a computerized system, barcode-reader enabled labels assist with component identification and overall traceability during processing.

A newly printed weighing label helps guarantee component identification

Printers connected to weighing workstations can print labels at the point of identification that enable fast materials recognition. Label types include:

- **Stock labels.** These ensure stock is known upon arrival and becomes traceable. Descriptions, lot numbers, quantity, delivery date, expiry and status is entered. The material enters the database and is available for processing.
- **Weighing labels.** Dispensed materials for an order are marked. Order, batch and lot number help guarantee processors do not mistake components.
- **Pallet labels.** These identify a pallet and its contents, particularly when materials are placed on a pallet before they are moved into production.

Scans help avoid confusion as materials are brought into production and ensure that the right material is added to a mixture at the right moment. Recorded results help manage stock, FEFO (first expired, first out), overall inventory and enhance process transparency.

Company logo and safety / danger symbols, as well as important status information

5 Summary

In an era of modern threat to food safety as well as increased regulatory scrutiny, a well-designed, computer-guided formulation and weighing process results in straightforward, efficient and fully traceable food production.

With easily integrated, standardized weigh stations, label printers and barcode scanners, materials mix-ups and wrong quantities become history. The resulting active stock management makes sure that components flow into the production process timely and that available materials are fully exploited. The results are less waste, less rework, less recycling, and lowered production costs. Productivity is significantly improved at the same time compliance with international regulations regarding materials traceability is assured.

Enhanced output and higher yield from available raw materials should result in ROI on initial system investment in 12 or fewer months.

6 Additional Resources

- 21 CFR Part 111
  Controls Used for Manufacturing, Processing, Packing, or Holding Dietary Supplements for FDA 21 CFR Part 111 CGMP Regulations – www.mastercontrol.com/regulations/21_cfr_part_111.html

- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002
  This European regulation lays down the general principles and requirements of food law, establishing the European Food Safety Authority and procedures in matters of food safety – www.food.gov.uk/multimedia/pdfs/1782002ecregulation.pdf

- **www.mt.com/formulation**

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www.mt.com/ind-food-guides
For more information

Food Safety

Fresh Products in Grocery Retail

Existing legislation, such as the FDA Food Safety Modernization Act (FSMA) and EU Regulation 1169/2011 on the provision of food information to consumers, is increasingly placing responsibility for food safety on retailers' shoulders. Such regulations stipulate extensive declarations, seamless traceability and effective measures for avoiding product recalls.

Food safety is both a duty and an opportunity. For consumers, it is very important to have access to detailed additional information about a product. Dietary plans, allergies and risk awareness all play a part in purchasing decisions. Retailers who credibly exemplify their food safety with effective measures are rewarded with loyal customers who trust their brand.

Existing traceability frameworks form a basis for further potential improvements to food safety. In cases of serious food risk, a well-documented product distribution is required and enables product recalls to be executed quickly and consumers to be alerted precisely, if necessary on a regional level. An unsafe food product can be identified and removed at every stage along the process chain. Parameters can include internal samples of product quality, dates such as the use-by date or external events such as alerts by the RASFF in the European Union or by the FDA and USDA in the US. Traceability is therefore a very valuable and effective control instrument for food safety. Food retailers benefit from being able to identify critical or repeatedly problematic process steps and suppliers.

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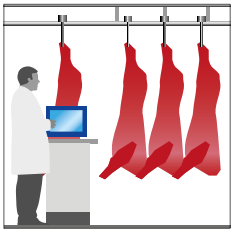
1 Monitoring Food Safety

When it comes to ensuring the safety of food products, traceability is an important instrument. Food retailers rely on documentation about internal and external processes in order to preclude risks. Traceability offers retailers better food safety, reinforces their brands and strengthens customer loyalty. New opportunities and optional measures for improving food safety emerge along the process chain.

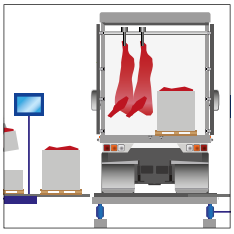


Farming and meat processing industry

- Ensure receipt of comprehensive information from suppliers and transfer it into the ERP system

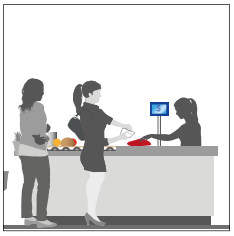
Pre-packed goods

- Use the data from the ERP system to print a declaration on the label or packaging in accordance with the relevant regulations
- Label or packaging displays the batch number to ensure unambiguous traceability



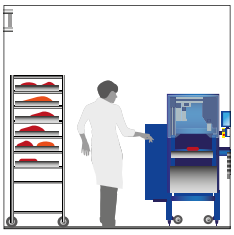
Supermarket Back goods received

- Compare information from suppliers against risk alerts
- Allocate internal batch number and barcode
- Sample analysis such as pH test as part of quality assurance



Checkout

- System control to check the shelf life when scanning the item
- System control after any risk alerts
- Additional information will be available online for customers

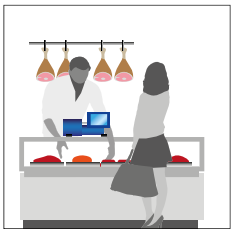


Storage and backroom

- Document further processing steps and responsibilities
- Collate product information such as nutritional values and input into ERP system
- Check use-by date, carry out quality controls

Administration

- Centralized administration and storage of all data regarding traceability and labeling
- System control after any risk alerts
- Set-up of secure infrastructure for uniform and up-to-date maintenance of all connected devices



Service counter

- Register batch number of each service counter produce
- Ensure all the product information is accessible at batch level through the counter scales
- System comparison to check the shelf life, for example by entering the PLU
- Visual check of the product's condition
- Print receipt containing product information and instructions for use

2 Food Labeling in the EU

EU Regulation 1169/2011 on the provision of food information extended the scope of what must be declared for many products. Consumers receive more information to help them assess the quality of a food product. In the case of fresh products such as meat and fish, additional data such as nutritional values are also mandatory. The information must be provided not only for pre-packed products but also, with some modifications, for loose products. This also applies to products which are further processed on retail premises.

It is mandatory to indicate substances which can cause allergies or intolerances even in loose food products such as those sold at the meat counter. The way in which these must be listed is determined by the individual EU Member States at national level. It may suffice to print details of the substances on the receipt or display the information digitally at the point of sale, for instance. It is therefore advisable to provide employees with online access to all labeling data at the point of sale.

Allergens: Substances which can cause allergies or intolerances must be emphasized on the packaging or label. This can be done by using bold letters (recommendation of the BRC). However, an emphasized indication will not be required if the name of the food clearly refers to the substance concerned (-> Art. 21).

Country of Origin: Indication of the country of origin is mandatory for beef, pork, lamb, goat and poultry. For all other types of food, indicating the country of origin is voluntary. If the primary ingredient comes from a different country than that named for the foodstuff, this too must be indicated (-> Art. 26).

Name of the food: The name of the food should contain extra descriptive information if it concerns imitation foodstuffs such as analog cheese or reconstituted meat or fish products. This also applies to frozen foods. In the case of minced meat, the fat content and collagen/meat protein ratio must be indicated (-> Art. 17).

Date of freezing: The date of freezing must be indicated for both frozen meat and meat-based products and for frozen, unprocessed fish (-> Art. 24).

Nutrition declaration: The amounts of fat, saturates, carbohydrates, sugars, protein, salt and the energy value must be presented in the prescribed tabular format. The prescribed reference value is 100 grams or milliliters. Additional information per portion is permitted. The figures are average values (-> Art. 29).

Formal requirements: Mandatory information must be clearly legible and printed in characters using a font size where the x-height is equal to or greater than 1.2 millimeters (-> Art. 13).

For pre-packed products, the label must include:

	Meat	Minced meat	Fish	Prepared food	Cheese	Bakery products
Name of the food	●	●	●	●	●	●
Country of origin or place of provenance		●	●**	●**	●**	●**
Use-by date	●	●	●	●		
Best-before date					●	●***
Information on traceability of beef according to regulation EU 1760/2000*	●			●		
Freezing date**	●	●	●	●	●	●
Percentage of fat and collagen/meat protein ratio		●				
Special storage conditions and/or conditions of use	●					
Preparation information if required for safe consumption of the food	●					
Instruction for storage and instrutions for use in so far as required for safe consumption of the food		●	●	●	●	●
Net quantity or number of pieces	●	●	●	●	●	●
Price*	●	●	●	●	●	●
Name and address of the food business operator which is marketing the product	●	●	●	●	●	●
Barcode*	●	●	●	●	●	●
List of ingredients in the case of more than one ingredient or if it is not obvious from the name of the product	●	●	●	●	●	
List of ingredients						●
Nutrition information		●	●	●	●	●
Allergens	●	●				
Alcohol content – if more than 1.2 percent by volume						●

* Not required by regulation 1169/2011: please check other regulations
** Mandatory information, depending on the type of product
*** can be omitted for bakery products, which by their nature should be consumed within 24 hours of purchase

3 Food Labeling in the US

Food labeling is controlled by both federal and state law. From a corporate governance perspective, labeling at a minimum, is essential for foods which are manufactured by a grocery chain for the following reasons:

- to avoid an unsuspecting consumer from eating a food product which contains an unidentified allergen;
- for ease of use when grocery chains produce labels on food manufactured at the grocery location which identify ingredients and
- to ensure that procedures for product traceability are met.

General guidelines for nutrition labeling at the meat counter

Effective since March 1, 2012, nutrition information must be provided at retail for raw major cuts of single-ingredient, meat and poultry and for raw ground product on the label or at point-of-purchase. All ground or chopped products are covered by the FSIS final rule – e.g. ground beef, ground pork and ground turkey.

Muscle cuts: Nutrition information is only required to be provided for the major cuts and the ground product. Major cuts are determined by regulation, they not necessary reflect what consumers are purchasing. Information for muscle cuts may be provided at the point-of-purchase.

Signs, posters and pamphlets are all acceptable means of providing nutrition information for muscle cuts. Grocery retailers can use the UDSA poster based on the Federal Nutrient Database for Standard Reference to comply with FSIS final rule. The regulation requires the poster to be placed in close proximity to the products, but doesn't mandate a size for the poster.

Ground product: Ground product must be labeled on the package. The label does not have to be on the principal display panel. The requirements for labeling ground products are the same as for other packaged foods, which means they are subject to USDA regulations for packaged foods. The simplified format will apply in many cases.

Nutrition facts panel: The nutrition facts panel may be on the principle display panel or on the information panel, which often is the back panel or the bottom of the package. The panel may either be part of the overall printed label or applied as a separate sticker.

The nutrition facts panel format is regulated. Meat and poultry products qualify to use the simplified format. If the total square inches of labeling space for the entire package is less than 40 square inches, the tabular format may be used. A side-by-side format may be appropriate if the regular Nutrition Facts label does not fit. But in most circumstances, since grocery retailers can label on the back, they have to go with the vertical format.

At a glance: labeling for grocery retailers

- A ratio like "85/15" is not a correct statement of the lean and fat percentage. It must read "85 percent lean" and "15 percent fat" or "% lean" and "% fat". FSIS rule does not cover advertising. So "85/15" can be used for flyers and other promotional items, but signs right in front of the meat have to say "85% lean/15% fat". The statement of fat percentage must be contiguous to, in lettering of the same color, size, and type as, and on the same color background as, the statement of lean percentage.
- The minimum nutritional elements that have to be shown on the label are: serving size, servings per container, calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium and iron.
- Total carbohydrate is a core nutrient and must be listed on labels or point-of-purchase materials. For meat or poultry, total carbohydrates will generally be declared as "0".
- Nutrient values are not out of compliance, unless they are more than 20% above the labeled value. That rule applies to the labeled values for vitamins, minerals, protein, total carbohydrates, dietary fiber, other carbohydrates, polyunsaturated or monounsaturated fat or potassium. For calories, sugars, total fat, saturated fat, cholesterol and sodium, retailers cannot exceed 20 percent of value declared. Otherwise the product can be considered misbranded.
- Burgers made in the retail store with diced cheese and chopped onions are exempt from nutrition labeling because they are multi-ingredient products processed at a retail store, not multi-ingredient ground or chopped meat products.
- If a full service meat counter where none of the meat is packaged until a customer selects a product, sells the major cuts of single-ingredient, raw meat and poultry products listed in the nutrition labeling final rule, it will need to provide point-of-purchase materials for the "major cuts" it sells.
- A "servings per container" statement is required on the labels of ground or chopped products. The service per container may be listed as "varied", because ground or chopped products are often random weight products.
- A "servings per container" statement is not required on the major cuts of single-ingredient, raw meat and poultry products.

4 Hygiene: Reducing Health Risks

When preparing or selling fresh food items, the top priority is to provide customers with perfectly safe, untainted products. Defining and maintaining good hygienic practices guarantees that customers receive safe food products. Hygiene measures reduce the exchange and spread of microorganisms such as bacteria to a non-hazardous level. Grocery retailers are required to define processes and set up control mechanisms which ensure adherence to the hygiene measures. These are founded on the basic principles of HACCP for targeted recognition and prevention of hazards.

Good hygiene practices

Front-of-store and backroom employees are crucial to the effectiveness of good hygiene practices. Clear work instructions and responsibilities as well as regular controls ensure long-term success. The main focus is on direct contact with the fresh, unpacked goods:

- Handle meat, cheese and cooked meats using clean forks or tongs whenever possible
- When removing items for weighing, always place them immediately on suitable paper or film
- Do not use staples – they present a hazard around food. Instead, seal bags using labels
- Wash hands and disinfect regularly, e.g. after handling a transaction or before switching to a different task such as food preparation
- Regularly check the cleanliness of the counter and temperature in the display cabinets
- Implement cleaning and disinfection plans for critical control points

Cleaning and disinfection

It is essential to ensure that HACCP rules for cleaning and disinfection are followed. Important: cleaning does not mean disinfection. A proper disinfection needs specific products and should be done after each cleaning in order to ensure a high hygienic standard. For cleaning and disinfection of the counter, equipment and backroom, it is highly recommended to only use food safe products. Standard non food safe products can contain flavor and colorant agents which may contaminate the food with allergic components.

Using spray for cleaning or disinfection should be avoided, as the mist could accidentally spread to areas where food is stored, which could lead to contamination. Additionally, spraying cleaning products can also be dangerous for employees if they breathe in the mist. The hygienic condition of work surfaces, utensils and other equipment used in the preparation and sale of fresh food products needs to be critically monitored continually. Regular cleaning and maintenance is an essential part of good hygiene practices.

5 Additional Ressources

- Regulation (EU) 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF
- Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:139:0001:0054:en:PDF
- FDA Food Safety Modernization Act
  http://www.fda.gov/Food/GuidanceRegulation/FSMA/
- METTLER TOLEDO White Paper: Food Safety Regulations
  http://us.mt.com/us/en/home/supportive_content/White_Papers/product-organizations/retail/USfoodsafety.html
- METTLER TOLEDO Webinar: Key Issues in Labeling and Packaging
  http://us.mt.com/us/en/home/events/webinar/ondemand/RET_Labeling_Packaging.html

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Package Quality Control

Net Content Control

Billions of packages of all kinds are filled around the world every day. "Package" can mean bottle, jar, tube, box or can – any container filled with product. All prepackaged goods by law display net weight or volume and number of pieces. Today, the value of a product includes more than its assignment. Saleable elements include safety and image as well. Even simple products include these elements and can influence their perceived compliance with regulatory requirements and enhance consumer acceptance.

Thorough product inspection includes ensuring packages contain labeled amounts. Statistical Quality Control (SQC) can help. A quality assurance system based on SQC provides, among other attributes the following core quality data:

- Production (period) mean value
- Number of violations of the legally defined tolerance limits T1- and T2-
- Mean standard deviation of the production (period)
- Other quality or safety relevant attributes (CCPs)*

A suitable control system must be fast, simple to operate, reliable and objective and requires an up-front investment. However, the right system can increase productivity and provide a return on investment within 12 months through:

- Minimized product giveaway caused by excessive and continuous overfilling
- Prevention of government obstacles to product distribution
- Better end-user product acceptance
- Streamlined QA procedures/personnel
- Prevent legal conflicts

This paper addresses the aspects and benefits of implementing robust quality data management solutions and systems, such as METTLER TOLEDO's FreeWeigh.Net®, to ensure overall product quality and safety improvement.

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1 Cost Control through Optimized Filling

Filling is subject to a large number of influences that can cause fluctuations in packaged goods weight. However, weight fluctuations must not cause the net weight of even a single package to fall appreciably below stated net weight. Government regulations gen-erally specify permissible underfill amounts.

Some manufacturers systematically overfill to eliminate risk of consumer and legal complaints. But such general overfills can be costly and lower the revenue considerably. Even with the modest output rate of smaller companies, corresponding product give-away costs are striking.

Accurate monitoring and quality data management provides better results. Giving the process closely controlled limits can help reduce expensive product give-away.

2 Available Methods – Random Sampling and 100% Inspection

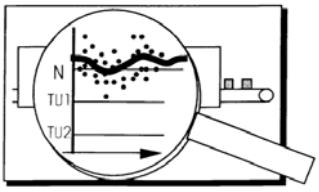
In many countries static scales must be used to verify compliance with net content legislation and produce package tare weight verification reports. Product specific parameters and processes, in combination with financial and economic factors, usually dictate which method is beneficial on a production line.

In-depth understanding of filling machine scatter and package parameters are essential to select the right sampling method, random sampling on static scales or 100% checks of all packages using dynamic Checkweighers.

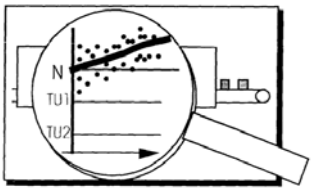
Random sampling control with static scales	**100% inspection control with dynamic checkweighers**
• Random sampling, • Rapid product change (size, weight) • Low space requirements • Low system costs • Tare weights, component weighing and filling head control • Optimum regulation to the nominal fill quantity • Allows collecting and analyzing additional quality and safety attributes • Higher accuracy and repeatability	• All packages are checked (100%) • Tolerance infringements are automatically sorted out • Use in filling processes in which access to the product is difficult • Less control personnel • Operator errors less probable • Slightly higher deviations

Process and economic factors to consider when choosing static or dynamic checkweighers include:

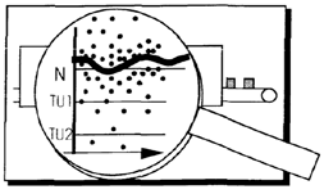
- weight fluctuation potential, filling machine repeatability/scatter
- product characteristics (package weight, package size, shape, …)
- production line throughput
- trade off between sampling speed and measurement precision
- initial investment budget
- running costs of ownership
- manual efficiency and personnel costs



SQC delivers good results



SQC or 100% depending on speed and product

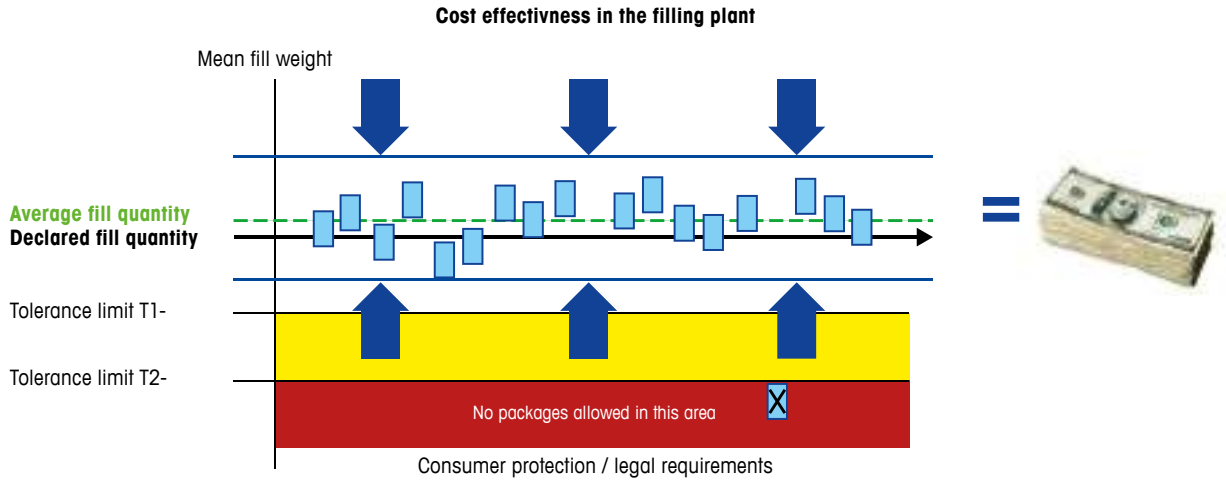


100% checks allow to sort out defects

How SQC helps

To truly quantify and control product fill, an understanding of Statistical Quality Control (SQC) is required. SQC takes random sample data and creates comprehensive quality control information.
This information helps ensuring that a batch meets legal requirements.

The question of the optimum or lowest, possible fill quantity can be answered irrespective of the control system used. The goal of the filling process is to attain optimum mean filling quantity while fulfilling net content legislation requirements.



SQC spot-checks determine batch acceptability

3 System Considerations

Ideally, a solution should address any needs for quality data acquisition throughout the factory and test labs. It should be highly configurable and expandable to ensure an enhanced degree of control with no need for software engineering during implementation or daily routine. System design considerations include:

System usability

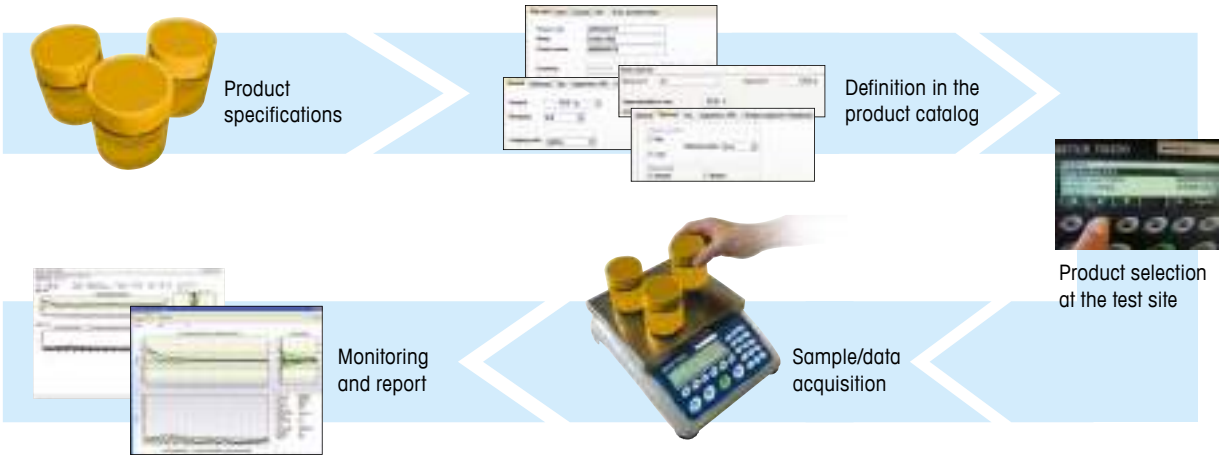
Intuitive user interfaces allow increased setup flexibility, ease of operation and more precise control during filling and packaging.

Data connectivity

Industry standard data communication interfaces such as Ethernet with TCP/IP protocol, help keeping infrastructure costs low when adding and networking instrumentation such as balances and scales, checkweighers, metal detectors, terminals and sensors to a comprehensive quality-control system, as well as other existing devices to protect given infrastructure and limit investments.

Easy and fast data access

Easy and fast access to production parameters is crucial. A key parameter in most cases is fill quantity. However, increasingly other parameters such as foreign body detection, ingredient analysis data (e.g. pH, moisture…), results from visual inspection or any results from other critical control points.



Gaining quality information can be broken down to five easy steps with a well-designed solution.

Step 1: Product specification
Define declared net content, applicable tolerances, tare management and other quality attributes

Step 2: Catalog definition
Adding product data and test item information to define the quality process

Step 3: Product selection
Product is selected on the test scale or terminal in direct dialog with the system

Step 4: Sampling / data acquisition
Samples are taken, guided by the system according to test plan and quality process

Step 5: Monitoring and reporting
Results are automatically analyzed by the system and process deviations lead to immediate, alarm messages to operators and supervisors.
Printed reports in addition to electronic records can be produced based on documentation requirements

Enhanced compliance

If the process begins deviating from the target, the chosen solution should ensure that appropriate corrective measures can be taken for enhanced compliance as well as optimized production. For compliance tracking, traceability of all quality and safety relevant data is critical over the entire life of ingredients as well as final products.

Increasing regulatory requirements require food industries such as infant formula or nutraceuticals to adapt the longer the more to Pharma like practices such as 'audit trail' or electronic record keeping.

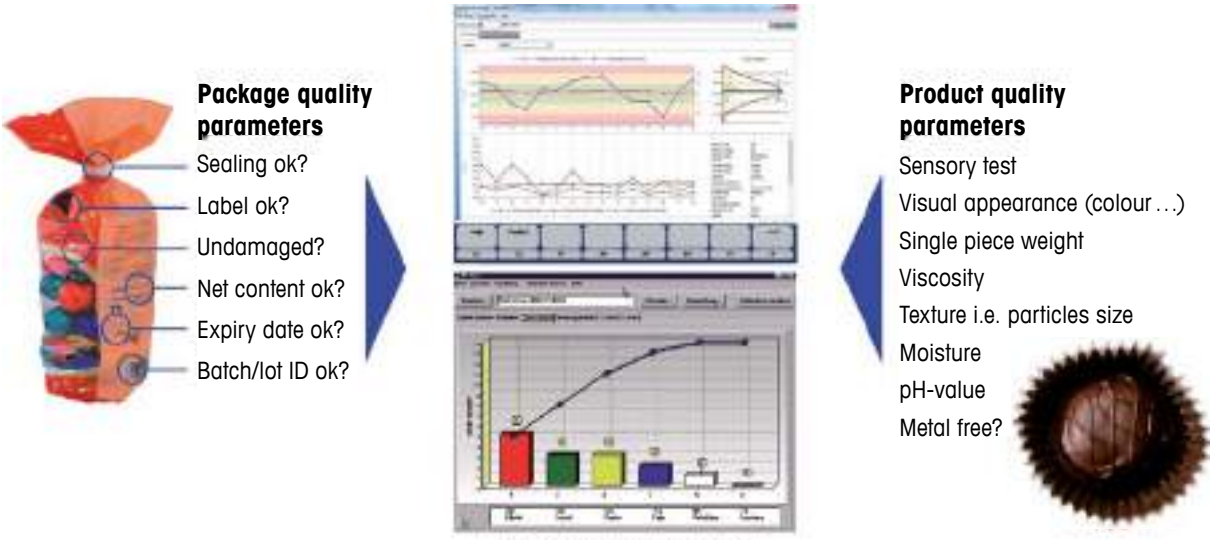
The US FDA has implemented 21 CFR Part 11 in such a way that electronic audit documents become the original, while paper printouts are non-binding copies. Companies wishing to comply with 21 CFR Part 11 must therefore implement systems that support it.

Overall, a well-implemented quality data management solution or system reduces user error and subsequent loss of product information. The resulting improved product quality helps a manufacturer reach important operating targets.

4 Summary

Overfill cost is directly related to raw material costs. But safe-margin overfills are an effective way to ensure compliance with net content legislation. Overfills are costly, even with the modest output rate of small companies. Calculated, minimized overfilling can be very effective at controlling giveaway and its resulting expense without increasing personnel costs.

Various solutions are available, such as static scales for offline random sampling, as stand-alone or network solutions of net content data or inline checkweighers for 100 % data checks.



Typical FreeWeigh.Net® screens

Product quality – a function of countless individual variables and attributes can be processed with FreeWeigh.Net®

A state of the art quality data management system, such as METTLER TOLEDO's FreeWeigh.Net® offers multiple benefits to food manufacturers. It allows data collection for important quality attributes from static scales, in-line Checkweighers, Foreign Body Detectors, pH meters, sensory test panels. It alerts operators to required adjustments almost immediately, thus helps preventing failed production batches. Further, centralized test planning and decentralized data acquisition at individual workstations can account for unique company structure and expansion. It also integrates easily with MES or ERP systems.

An integrated quality data management system is an excellent way to achieve better quality control and real cost-savings. METTLER TOLEDO offers solutions and systems that pay for themselves and provide a full ROI within 12 months or less.

5 Additional Resources

- WELMEC (European Cooperation in Legal Metrology)
  www.welmec.org

Additional information on METTLER TOLEDO solutions can be found under the following links:

- General SQC information
  www.mt.com/sqc

- SQC Application Overview
  www.mt.com/sqc-application

- Quality data management solution FreeWeigh.Net®
  www.mt.com/freeweighnet

- Request your free copy of the comprehensive SQC guide
  www.mt.com/sqc-guide

- Asses your potential savings through reduction of overfilling – ROI Calculator
  www.mt.com/sqc-calculator

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In-line Checkweighing

In-line Checkweighing

Aspects of a Key Technology

A checkweigher is usually part of a typical quality control system, ensuring that every product leaving a production line is the right weight and corresponds to packaging requirements. Selling products with incorrect weights causes problems for manufacturers: underweight products can result in companies being fined, whilst overweight products generate expensive product giveaway.

Checkweighers systematically weigh 100 per cent of production line items and provide a complete overview of data such as:

- Product counts
- Batch tracking
- Total weights
- Good weights
- Rejected weights

In an increasingly competitive marketplace, checkweighers are essential in fulfilling ever-changing customer needs and in complying with local Weights & Measures standards, as well as global standards.

Different checkweighing approaches and implementation considerations are discussed in this paper.

Contents

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1 Benefits of Checkweighing

As part of overall quality control, checkweighing protects both manufacturer and consumer. Manufacturers are assured that they use raw materials effectively and offer compliant products. Their brand and reputation is protected. Consumers receive a high quality product that includes the correct net content or parts.

Today's technology makes checkweighers more reliable and accurate than ever before. The information that a quality team would have previously collected manually can now be collected in a fraction of the time by a checkweigher, resulting in the following benefits.

Improved resource use

An accurate checkweigher makes the most of existing resources though tighter production tolerances. More items can be created using the same amount of raw materials. Figure 1 shows a simple calculation to underline the savings which can be made by reducing overfill by just 1 gram.

Package and production information	Savings (1 gram overfill reduction)
Labelled package weight = 450 grams	0.1 ct savings per package
Material cost = 0.1 ct per gram	20 ct savings per minute
Line rate = 200ppm	€12 savings per hour
Line utilization = 65%	€124 savings per day
Shift = 8 hours	€28,704 savings per year
Shifts per day = 2	
Production days per year = 230	

The reduction of 1 gram overfill as shown in this example would free enough raw materials to produce an additional 60,000 products

Figure1: Example Showing the Impact of Reducing Overfill by 1 gram

Enhanced product consistency

A line with a throughput of 100 packages per minute where 15 packages are manually sampled every hour means only 0.25 percent of total packages are sampled. A checkweigher however automatically weighs 100 percent of all packages on the line. Operators can react immediately if a problem is detected to ensure results are more uniform.

Increased overall equipment effectiveness (OEE)

Checkweighers provide real-time monitoring of production processes, including yield statistics and SPC trending all of which can be used for process improvements and operating efficiencies (Figure 2). This can result in increased OEE.

Filler monitoring

Active monitoring of filler performance minimizes over and underfills by keeping filler heads properly adjusted. Checkweighers communicate directly with the filler control/network and existing factory automation for seamless feedback control.

Figure 2: Real-Time Monitoring of Production Processes

Better net content

Net content laws and regulations differ from country to country. However, an effective checkweigher program can minimize risk of non-conformance and eliminate potential lawsuits and customer complaints.

Fewer false rejects, less rework and reduced scrap

An accurate, well-maintained checkweigher improves processes while reducing scrap and reworks. False rejects are also minimized. Accuracy becomes more precise as zone settings are refined.

Brand/legal protection

Branding frequently drives repeat purchases and justifies premium product pricing for manufacturers and retailers. If a company is investigated after consumer complaints, checkweigher documentation will provide invaluable evidence of appropriate quality control.

2 Checkweigher Application/Statistical Application

Checkweighers perform a critical range of quality control functions based on weight.

Manufacturers use checkweighers to:

- Check for under and overweight
- Check volume or density (bread, yogurt)
- Ensure net content for pre-packaged goods
- Measure raw/unwrapped food prior to packaging
- check for missing components (labels, instructions, lids, leaflets)
- Verify counts for warehouse or delivery
- Check mixes for solid-to-liquid ratio
- Reduce giveaway through filler adjustments
- Classify products for grading or portioning ensure customer or agency (USDA, FDA, OIML, FPVO) standards are met
- Report production line data to drive process improvement

Statistical uses include:

- Monitoring speed efficiency (packages per minute)
- Monitoring standard deviation for out of tolerance conditions or trends
- Keeping and management of regulatory records
- Analyzing filler head performance
- Accumulating totals for a day, shift, hour, batch or run
- Providing Statistical Process Control (SPC) charts for manual process adjustments
- Weight zone or classification analysis
- Monitoring efficiency through total count and total weight

Figure 3: Monitoring production data

- Providing SPC for closed loop control and automatic process adjustments
- Interfacing with business systems, Programmable Logic Controllers (PLC) and SCADA systems that link the checkweigher to the production process, including checkweigher remote control

All of these uses add up to increased quality control and its resultant production line and compliance improvements. It may even lead to reductions in quality control personnel.

3 Production Phases where Checkweighers Are Used

Figure 4 shows four distinct areas where checkweighers are typically used in a manufacturing operation. These include:

- **Prior to packaging** – such as handling raw dough prior to freezing. The checkweigher could also send a signal to the divider/former to maintain consistency and reduce giveaway.
- **Primary packaging** – to checkweigh tubes of frosting prior to cartoning to keep fillers tuned and prevent non-conforming product from reaching

the next process stage. This eliminates rework and costly waste in the secondary production phase.

- **Secondary packaging** – ensure all components have been included in the final package.
- **After case packing** – specialized checkweighers called caseweighers ensure short cases are not shipped. They may also transmit case weight data to a manifesting system for shipping. This checkweigher is also used for large bulk product bags such as 25kg bags of dry dog food or flour for net weight control.

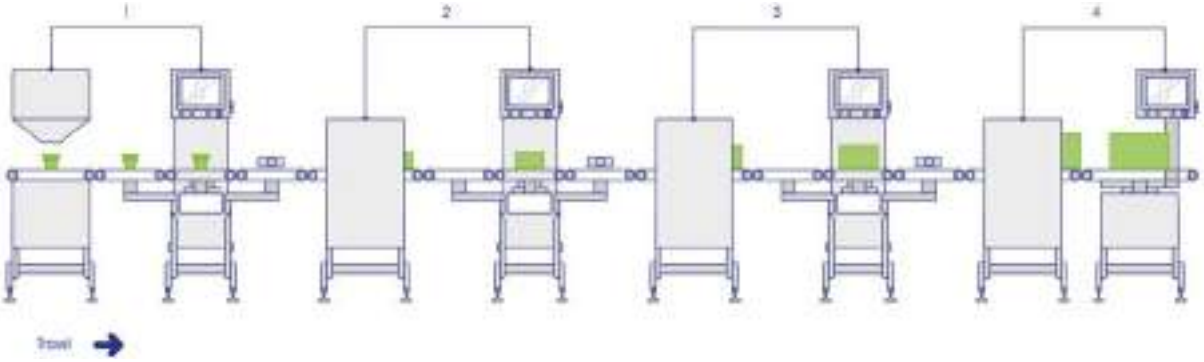

Figure 4: Checkweigher usage in manufacturing operations

4 Static and Dynamic Checkweighers

In many countries static scales must be used to sample product for completion of net contents and package tare weight verification reports. Processes, in combination with financial and economic factors, usually dictate which system is used on a production line.

A comparison of static and dynamic checkweighers follows.

Static checkweigher	Dynamic checkweigher
• Weighs stationary objects • Requires manual intervention • Sample spot-checking • Target weights/sample tests • Higher accuracy/repeatability	• All packages are checked (100%) • Tolerance infringements are aretomatically sorted out • Use in filling processes in which access to the product is difficult •100% process control • Slightly higher deviations

Process and economic factors to consider when choosing static or dynamic checkweighers include:

- Initial investment budget
- Weight fluctuation potential, filling machine repeatability/scatter
- Product characteristics (package weight, package size, shape, ...)
- Production line throughput
- Trade off between sampling speed and measurement precision
- Initial investment budget
- Running costs
- Manual efficiency and personnel costs
- Governance of sample rates

5 Integrated or Combination Systems

Integration of other inspection devices such as metal detectors, X-ray devices, cameras, scanners, marking systems or sensors makes the checkweigher part of a high performance product inspection solution.

Integrated systems make it easy to check for a wider variety of quality control items, such as:

- Open flaps, missing caps
- Package orientation and skew detection
- Printed information such as batch number, expiration date
- Bar code labels and RFID tags
- Contaminants such as metal, stone or glass

Primary benefits of combining devices include:

- Consolidation of user interfaces
- Reduced for set-up and line changeover time
- Less opportunity for operator error; shorter training
- Reduction in maintenance and cleaning costs
- Smaller equipment footprint; maximized production space

Using a combination system, rejected products can be quarantined at once for effective management of non-conforming products.

Integrated systems are easier to install and usually less expensive than separate systems.

Checkweigher combination systems with x-ray or metal detector

6 Summary

Today's technology makes checkweighers more reliable and accurate. Information previously collected manually can now be collected in a fraction of the time, resulting in:

- Improved quality control
- Better raw materials use rates
- Less product giveaway
- Enhanced consistency and operational effectiveness
- Better net content
- Reduced scrap
- Brand/consumer protection

Checkweighers are used to:

- Check under- and overweight, volume and density
- Ensure net content
- Check for missing components
- Verify counts
- Classify products for grading or portioning
- Ensure customer or agency standards are met
- Report production line data to drive process improvement

Both static and dynamic checkweighers have places on production lines. Decisions about how to implement each must be made based on application and budget.

Integration of other devices such as cameras, scanners, metal detectors and X-ray systems add up to a high performance inspection solution, providing benefits such as a smaller warehouse footprint and reduced maintenance costs.

7 Additional Resources

- METTLER TOLEDO Garvens Principles of Checkweighing Guide serves as a definitive checkweighing reference work with helpful information on everything from basic principles to comprehensive program implementation. Request your free copy at
  www.mt.com/cwguide

- White Paper – Overall Equipment Effectiveness (OEE)
  Increasing the productivity of a production line is not just a matter of buying faster equipment. Using the OEE (Overall Equipment Effectiveness) calculation, companies can become more efficient and utilize their processes more effectively. This white paper describes OEE in detail and shows, using the simple calculation, how you can improve productivity whilst also reducing costs.
  www.mt.com/Garvens-OEE

- METTLER TOLEDO On-demand webinars allow 24/7 self-paced learning on a wide range of important process integration topics
  www.mt.com/pi-ondemand

- OIML – International Organization of Legal Metrology OIML R87 Quantity of product in prepackages
  www.oiml.org/publications/R/R087-e04.pdf

- NIST – US National Institute of Standards and Technology, Handbook 133, Fourth Edition
  http://ts.nist.gov/WeightsAndMeasures/upload/Complete-HB133-05-Z-2.doc

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Vision Inspection

Driving Quality and Process Security

Vision inspection provides highly specialized and effective quality control. It brings together cameras, lights and image processing software in a unified system which inspects high speed manufactured packaging and labels.

Vision systems help to prevent distribution of defective products and significantly enhance a manufacturer's quality assurance. This reduces the risk of a product recall and its associated costs by preventing the distribution of mislabeled or poor-quality packaging to consumers. They can even lower personnel costs because fewer employees are required for quality control.

Unlike a human inspector, vision systems never blink. This ensures that every product on the line is inspected for defects.

This paper seeks to support vision inspection implementation by exploring uses, benefits and system design considerations that assure optimum function at high line speeds.

Contents

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1 Why Vision Inspection?

Vision inspection helps to prevent defective product from being distributed – a very valuable function for manufacturing, assembly and packaging operations.

Research shows that 65 percent of consumers refer to packaging when buying products. If a package's label is missing, incorrect or damaged, a customer may be exposed to an allergen or harmful ingredient unknowingly. This exposes the manufacturer to a potential lawsuit on top of the cost of a product recall and potential lost business. The Canadian Supplier "PackagingWorld.com" confirms that 55 percent of food industry recalls arise from improper labeling.

In an effort to reduce these label-based product recalls, manufacturers are turning to vision systems. With the ability to inspect every product on the line, vision ensures defective products never reach customers.

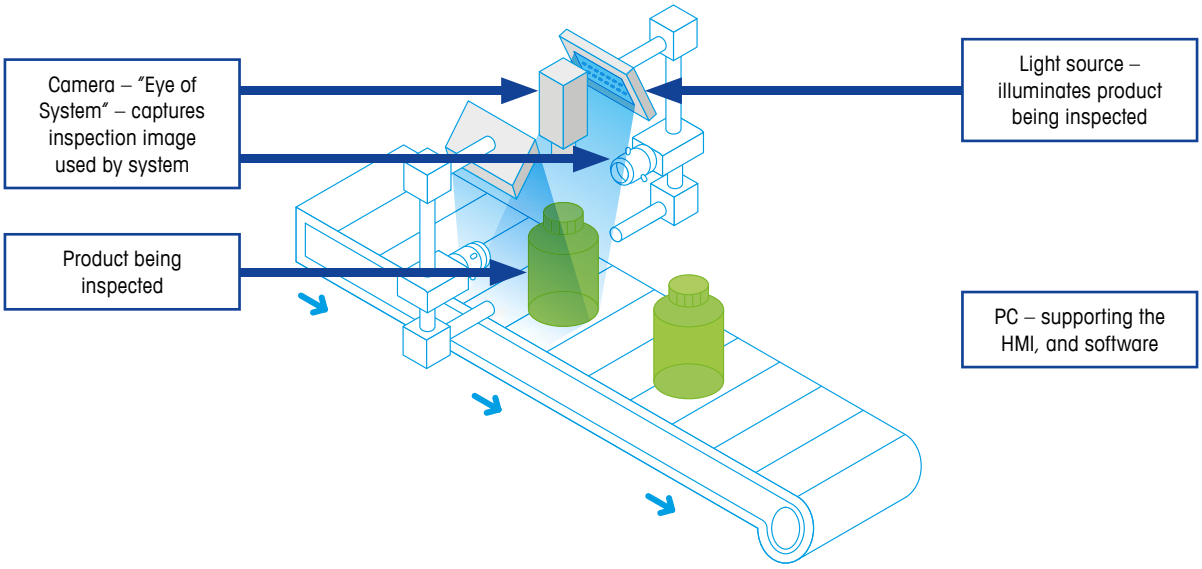
2 Introduction to Machine Vision Systems

Machine vision brings together cameras, lighting and image processing software to create a system that "sees" objects, accurately inspecting them for flaws at high speeds. The vision software is the brain of the system, processing the camera images and comparing them to stored images of how products should look.

Machine vision has become more sophisticated and user-friendly since its introduction in the 1980s. Initially, optical character recognition (OCR) systems were used in industrial applications to read and verify letters, symbols, and numbers. Today's higher-level image capturing devices feature the latest in frame-grabbers, software, and sensor technology.

Machine vision systems cost-effectively:

- Conduct item inspections
- Verify accuracy of work-in-process assembly
- Maintain "e-pedigree" records tracking a product through the production and packaging life. This helps demonstrate due diligence as well as maintain package quality.



3 Uses of Vision Inspection

By inspecting products and packages at production line speeds, a machine vision system can instantly identify:

- Damaged or malformed products and packages
- Misapplied elements such as crooked caps or incorrect labeling
- Missing parts or kit components

Such a system can simultaneously check a bottled liquid product for a misapplied cap, proper neck shape, foreign material, fill level, and the presence or positioning of the label. The right system will also track rejects so management can use the information to further improve processes.

A vision system can easily:

- **Reject defective items** – some systems even separate defective packaging to be recycled from contaminated packaging to be scrapped
- **Identify products/pallets** – alpha/numeric & bar codes are verified; item placement is ensured and pallets are identified as correct before shipment
- **Confirm parts** – coding verification helps ensure proper assembly
- **Update inventory & maintenance data** – communicating with an enterprise system to update production, inventory and maintenance data; if defects exceed threshold, the line can be shut down for adjustments
- **Facilitate automatic changeovers** – automatically adjusting camera position and conveyor speed after viewing a new package or programmed puck.

Of course, the level of automation depends on customer needs and budget. Competing systems offer various feature combinations. METTLER TOLEDO CI-Vision, for example, can include all of the features described above and more.

4 Reasons to Establish a Vision Inspection Program

It is important to identify why the program is being considered. ROI for a well-designed vision inspection program is achieved through:

- Minimized quality defects
- Enhanced customer/consumer protection
- Protection of company brand and reputation
- Easier adherence to best practice guidelines and industry standards
- Minimized risk and of product recalls and returns
- Staff reductions
- Lowered costs resulting from the above

When a vision inspection program has been optimized for a manufacturer's desired inspection capabilities, benefits and cost savings continue year after year. Changes to a product's packaging shape or design can render a less-flexible system design obsolete, which can have a negative impact on ROI. This makes selecting a vision system with flexibility in its design a better long-term investment.

Quality assurance

Quality problems can cause output loss – particularly on high-volume automated lines. Such costs can be easily overshadowed when customers or consumers discover defective product, which can result in product recall, damage to the brand, adverse publicity, and potential legal action.

A thorough vision inspection program reduces internal waste, improves output, and all but eliminates customer complaints. This inevitably yields a better return than money lost to additional raw materials, line downtime, consumer response tactics, and lawsuits. Higher profitability is the result.

Customer/consumer protection

Modern manufacturing techniques are constantly improving to eliminate quality defects, although there is always a risk that the processes or procedures can break down. Manufacturers have an obligation to minimize these instances and ensure consistent quality and end-user safety. Vision inspection can protect retailer relations and future business opportunities.

Brand/reputation protection

Strong product branding gives retailers and consumers assurance of safety and quality, drives repeat purchases and justifies premium product pricing. For this reason, a manufacturer must protect the brand and company reputation. Documentation provided via a vision inspection system can provide evidence of a sufficient protection program.

Adherence to best practices/ industry standards

Vision inspection systems frequently become the focus of audits, especially if they are used as a CCP in a HACCP program. They provide evidence of a factory-wide quality program and can help with:

- Internal food safety and management system audits
- Retailer audits
- Quality management system audits e.g. ISO9001:2000
- HACCP audits, including BRC, IFS, SQF 2000, and ISO 22000

While no legal requirement for vision systems exists, the records and statistics produced by a vision system can provide evidence of due diligence in the event of a product recall or lawsuit. Additionally, recent legislation in the United States has placed an even greater emphasis on the product labeling process, making vision inspection a more attractive proposition.

Minimizing risk of product recalls/returns

The consequences of a defective product reaching the marketplace continue to increase. Consumers may take legal action or contact media. In order to protect themselves, retailers will often fine manufacturers who deliver defective products. This adds to the difficulty of getting fairly priced product on store shelves. The overall result can be devastating to a manufacturer's bottom line.

An effectively managed vision inspection program can help keep defective product from reaching retailers. It can inspect one hundred percent of products coming down a production line at real time, lowering risk of product recalls, returns, and fines.

5 Designing for Reliability

External factors influence reliability in predictable ways. Accommodations for these external factors must be considered to ensure:

- **statistical repeatability** – detecting the same defect on the same bottle sent through the system multiple times to consistently detect defects at production speed; and
- **measurement repeatability** – ensuring measurement differential on a single part measured multiple times is no greater than a small fraction of tolerance.

When comparing solutions, ensure that repeatability is being measured the same way. In-line simulations make sure that inspections are repeatable for the intended application and operating environment. Factors that influence repeatability and reliability include the following.

Mechanical design

As the camera's lenses, standoff distances and light sources are determined, mechanical setups including camera and light mounts must be considered. Devices must be protected against vibration or shock; isolation might be necessary.

Cameras and light positions should be adjustable independent of each other and include appropriate lock-down.

Environmental conditions

Plant vibration, dust, ambient lighting, humidity, and temperature changes can become acute when running multiple inspections at high speeds. Consider equipment in factory conditions to avoid undesirable line speed reductions in production.

Inspection speed

While conveyor speed is seldom a factor when discussing system reliability, the processing power of the vision system is often the critical factor which will determine how quickly inspections can happen. The more powerful the processor, the faster the inspection system can perform.

Lighting

Optimum set-up requires experimentation so inspected features present with maximum contrast. Good set-up increases performance and decreases software complexity. Possibilities include:

- Diffuse darkfield, axis, and backlight methods
- Fluorescence, infrared or ultraviolet light
- Spectrum verification for color
- Polarization to increase contrast between direct and diffuse reflection

Multiple illumination set-ups or camera stations might be required to avoid interference among inspections. Different colored lights in combination with colored camera filters may be another alternative.

Product handling

Product must display in a consistent manner. A well-designed solution can handle a certain amount of variation in product presentation through software or special optics.

6 Summary

Vision inspection can be a critical element in a system that prevents distribution of defective product and can significantly enhance quality assurance. Vision inspection systems never blink, detecting virtually 100 percent of the defects they are programmed to capture, helping to ensure defective and mislabeled products never reach consumers.

Machine vision cost-effectively identifies:

- Damaged or malformed products and packages
- Crooked caps or labeling
- Correct pallets/parts
- Inventory automatic line changeovers

ROI is achieved through:

- Enhanced customer/consumer/brand protection
- Best practice and industry standard adherence
- Fewer product recalls/returns
- Reduced personnel
- Lowered costs

Mechanical design, environmental conditions, inspection speed, lighting and product handling must be considered in the system design phase or when comparing different solutions. Thus, different solutions are best considered in their operating environment.

When a vision inspection program has been optimized for a manufacturer's desired inspection capabilities, benefits continue year after year.

7 Additional Resources

- METTLER TOLEDO CI-Vision "Building an Effective Vision Inspection Program" Guide serves as a definitive reference work and provides detailed insight into specifying and installing the right vision inspection solution. Request your free copy at **www.mt.com/ci-vision**
- METTLER TOLEDO On-demand webinars allow 24/7 self-paced learning on a wide range of important process integration topics **www.mt.com/pi-ondemand**

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www.mt.com/ind-food-guides
For more information

Foreign Body Detection

Metal

In order to make informed decisions about metal detection systems, it is important to gain an understanding of the main system components and principles of operation. This chapter aims to deliver a basic overview and develop an understanding of metal detection technology, equipment capabilities and performance.

A metal detection system can represent a significant capital investment. Equipment must be designed for the intended application and used in an effective manner to ensure ROI. A solid metal detection program can reduce incidents of broken machinery and resulting output loss when metal items are discovered before processing. Perhaps more importantly, a metal detection program can reduce litigation risk and monetary/brand image costs when metal contaminated products are discovered after delivery.

A well-designed metal detection program must focus on good manufacturing practices, correct equipment selection, proper installation and consideration of equipment in a broader foreign body/metal detection program.

This paper will seek to support implementation of an effective program by exploring:

- Reasoning for metal detection
- Metal contamination sources
- System components
- Often-overlooked system design considerations
- Additional resources on detection and governing standards

Contents

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1 The Case for Metal Detection

Reasons for implementing a professional metal detection program include the ability to:

- Minimize costs
- Increase manufacturing uptime
- Enhance consumer protection
- Maintain brand/company reputation
- Meet certification and compliance standards
- Demonstrate due diligence

A metal detection program based on effectively designed and installed technology is critical. It can help a manufacturer avoid costly contamination errors that damage machinery and cause loss of output in-process or result in a product recall, adverse publicity, and legal action after shipment.

No broad-based legal requirement for metal detection yet exists, though different global HACCP based food safety standards put the burden of establishing reliable product inspection programs on manufacturers to minimise the risk of foreign body contamination within the finished product. In legal proceedings, metal detection systems help manufacturers prove due diligence. Major retailers may also instate their own codes of practice. Increasingly, formal metal detection is expected before supplier approval is granted.

Metal detection has also become important in safety, customer, quality, and regulatory audits such as FSSC 22000 and SQF1000/2000 Code, as well as FDA, USDA, IFS and BRC national/international certification standards. Links to more on these standards can be found in this paper's **Additional resources**.

2 Metal Contamination Sources

Contamination sources include:

- **raw materials** – lead shot in meat, wire in wheat, tractor parts in vegetables, hooks in fish
- **personal effects** – buttons, pens, jewelry, coins, keys, hair/paper clips
- **mechanical maintenance** – screwdrivers, welding slag/copper wire/metal shavings following repairs
- **plant processing** – crusher, mixer, blender, slicer and transport system parts including screens, milling slivers and foil

Good working practices help keep these metal particles from entering production flow. However, correct metal detection equipment selection and integration maximizes product rejection once metal has entered the production stream.

3 Production Stages where Metal Detection Is Used

Metal detectors are primarily used at two production stages. These are:

Bulk "In-Process" Inspection, which eliminates metal before bulk items are broken down to protect machinery (grains/meat before milling/grinding) and reduce product/packaging waste by eliminating the need to reject finished product.

Finished Product Inspection, which eliminates consumer danger and ensures compliance with retailer and consumer brand quality standards.

A combination of inspection types often provides the best results.

4 System Components

A typical system consists of four main parts.

Detector coil/search head

The first type of metal detector utilizes a 'balanced coil' search head. Detectors of this design are capable of detecting all metal contaminant types, including ferrous, non-ferrous and stainless steels, in fresh and frozen products. The products being inspected can be either unwrapped or wrapped, and can include products wrapped in metallised films.

The second detector type utilises permanent magnets in a 'Ferrous-In-Foil' search head. These search heads are capable of detecting ferrous metals and magnetic stainless steels only within fresh or frozen products which are packed in an aluminium foil wrapping.

User interface/control panel

The front-end of the control system, the user interface is often mounted on the search head. It can also be remote and connected with cables if the search head is too small or installed in an inaccessible location.

Transport system

The transport system passes product through the aperture. Conveyors are common. Alternatives include plastic chutes mounted on an incline or non-metallic pipes mounted horizontally or vertically to inspect powders or liquids.

Automatic rejection system

An automatic reject device is often fitted to the transport system to remove contaminated product without manual intervention. Styles include air blast, push arm, or drop flap. Reject device type depends on the inspected product.

Other components

To enhance total system capacity and support due diligence extra fail safe and monitoring systems are now widely available and may include:

- A rejected product collector/container
- A cover between detector and reject device
- A failsafe alarm to signal faulty operation
- A sensor to confirm contaminated product is rejected
- A beacon and/or alarm to signal scheduled tests or full reject bins
- Reject container secure/locked monitor
- Air failure alarm
- Keyless reject container locking facility

5 Key Design Elements

Reliability is critical. It helps avoid difficult choices such as stopping production when the metal detection system is down or continuing to operate with contamination risk. Despite widespread metal detector use, few guidelines are available to help users evaluate detector reliability.

Factors that help ensure a system's success include ease of set-up, mitigation of drift/erratic detection, and elimination of false rejects without constant attention to maintain sensitivity standards. Ensuring actual, effective "production line" sensitivity means taking the following critical elements into account.

Overall detector design

Modern metal detectors benefit from advanced microprocessor technology, adding a range of appealing features. However, these "add-ons" will not necessarily contribute to detector effectiveness. A long feature checklist and an assumption that the brand with the longest list is the best choice can prove a costly error. "Which unit is more sensitive?" as a basis of comparison also does not provide a full picture, as this is only one of several important factors in a detector's function.

Factors that influence reliability include:

- Stability
- Electronic drift
- Repeatability
- Ease of set-up
- Radio frequency immunity (RFI)
- Modular electronics design
- Self-checking/condition monitoring
- Fail safe operation

Metal detector selection should also meet a product's hygiene requirements and operating environment. If the product is high-risk, such as meat or dairy, the metal detector should be constructed to withstand deep cleaning and sterilization to avoid expensive repairs resulting from water/steam ingress.

If a metal detection system is to be used in a potentially explosive environment such as a flour mill, system design should be certified and the manufacturer approved to sell such systems.

A more in-depth look at other performance considerations follows.

Balance stability/vibration immunity

The majority of metal detectors in use today are balanced coil, so mechanical stability affects performance. Very small movements, such as temperature expansion, mechanical shock, or external vibrations can cause false triggers or balance drift.

Systems that have to be manually balanced on a regular basis or that are prone to vibration are of little value on an automated production line. Good electronics design such as automatic balance control and good mechanical design such as enhanced potting techniques help minimize system failures.

Conveyor design

Metal detectors emit a high frequency signal that create tiny eddy currents. These currents have no effect if they remain constant. However, if the conveyor has intermittent jolts of variable resistance, currents change and create interference in the form of eddy current loops.

Metal-to-metal contact points are primary loop sources. These include:

- Bolted assembly supports
- Pulley shafts and bearings
- Chain drives and guards
- Reject supports
- Metal conduit clamps

Joint oxidation or changes in lubrication can cause eddy currents to worsen.

Good conveyor design can avoid loops that create static build up and interference. Fully welded structures with appropriate metal-free zones, isolated rollers, pulleys, cross structures and detector head mountings are essential. Belts should be metal-free and manufactured with contaminant-free joints. Anti-static materials should be avoided.

If these precautions are not taken, false rejects gradually increase. The easy solution is to downgrade equipment sensitivity. However, this can result in contravention of sensitivity standards and poor performance.

Non-conveyor design

Similar considerations should be given to metal detection systems that do not incorporate conveyors such as vertical pipelines for liquids and slurries. Poorly designed supports and reject devices reduce metal detection program effectiveness.

Reject mechanism design

Reject systems are probably the weakest part of most detection systems. As a result, contaminated products are not reliably rejected. A correctly specified system should reject all contaminated product under all circumstances independent of contamination frequency or where metal is found within the product.

Hygienics & safety

Metal detection systems must account for the operating environment and appropriate sterilization.
Good design:

- Eliminates cavities/bacterial traps
- Seals hollow sections
- Avoids ledges and horizontal surfaces
- Uses open-design, continuous-weld frames for easy access and cleaning
- Allows hygienic electrical cable, trunking and pneumatic service management

System design should also meet statutory regulations and standards in force at the time of sale. For example, CE markings in machinery standards minimize employee injury risk, which also reduces costly workers' compensation claims.

Failsafe system design

What happens if a reject device does not remove contaminated product or a fault occurs within the detector? Failsafe features mitigate malfunction risks.

Reject confirmation can show when contaminated product reached the reject bin; built-in condition monitoring can provide early warning of operational state changes.

6 Summary

A metal detection system that is capable of consistent, reliable detection without false rejection will win the confidence of line operators and management.

Effectively designed and installed technology is key. With it, a manufacturer can avoid costly contamination errors that damage machinery and cause reduced output during processing – or worse, loss of reputation, product recall, adverse publicity, and legal action after shipment.

Attention to design before purchase and during installation will ensure ROI. This includes a review of balance stability to avoid drift so a system can reliably detect potentially damaging objects such as metal shot, wire, machine parts, personal effects, slivers, shavings and foil. Attention to conveyor and reject system design also helps ensure effective operation by eliminating signal eddy loops that create interference, increase false rejects and decrease sensitivity.

No broad-based requirement for metal detection exists yet. Though to help minimize risk of contamination in the finished product, different global HACCP-based food safety standards such as IFS and BRC put the burden of establishing reliable product inspection program onto food manufacturers. Metal detection systems can help manufacturers prove due diligence and also become important in internal safety, customer, quality, and regulatory audits.

7 Additional Resources

- METTLER TOLEDO Safeline Metal Detection Guide serves as a definitive reference work on building a cost-effective metal detection program, improving overall production productivity and protecting your brand. Request your free copy at **www.mt.com/metaldetection**

- METTLER TOLEDO On-demand webinars allow 24/7 self-paced learning on a wide range of important process integration topics **www.mt.com/pi-ondemand**

Standards increasingly call for food/allied product inspection via metal detection. These resources also offer additional information on food inspection using metal detection equipment:

- British Retail Consortium (BRC)
  www.brcglobalstandards.com

- CIES – International Committee of Food Retail Chains
  www.ciesnet.com

- Codex Alimentarius
  www.codexalimentarius.net

- Food and Agriculture Organisation (FAO) of the United Nations
  www.fao.org

- International Food Standard (IFS)
  www.food-care.info

- ISO 22000:2005 – Food Safety Management System Standard
  www.lrqa.co.uk/certification/food/iso22000/

- Safe Quality Food (SQF) Institute
  www.SQFI.com

- United States Department of Agriculture (USDA)
  www.usda.gov/wps/portal/usdahome

- United States Food and Drug Administration (FDA)
  www.fda.gov

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Foreign Body Detection

X-ray Inspection

X-ray inspection technology is used in food, pharmaceutical and related industries, to ensure product safety and quality. Manufacturers use x-ray inspection systems to detect foreign bodies and perform in-line quality checks to avoid product recalls.

X-ray inspection technology not only offers exceptional ferrous, non-ferrous and stainless steel detection, it is also extremely good at detecting other foreign bodies such as glass, mineral stone, calcified bone, high density plastics, and rubber compounds. In addition, x-ray systems can be used to perform a wide range of in-line quality checks including:

- Measuring zoned and gross mass
- Counting components
- Identifying missing or broken products
- Monitoring fill levels
- Inspecting the integrity of a product seal or closure
- Checking for damaged product and packaging
- Detecting agglomerates such as flavour and powder lumps
- Measuring head space

Food manufacturers are under pressure to adopt the standards of the Global Food Safety Initiative (GFSI). Other directives and standards such as HACCP (Hazard Analysis Critical Control Points) and GMP (Good Manufacturing Practice) require food and pharmaceutical manufacturers to make their processes as safe and transparent as possible.

This chapter explores why x-ray inspection could be the solution, how x-ray inspection technology works and looks at effective x-ray inspection system design.

Contents

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1 The Case for X-ray Inspection

With increasing line speeds and growing consumer expectations, manufacturers are under pressure to adopt more reliable product inspection methods.

A well-designed x-ray inspection programme can help:

- Minimise contaminants such as metal, glass, stone, bone, high density plastics, and rubber compounds.
- Reduce costs caused by customer complaints, safety scares and product recalls.
- Protect consumers and brand reputation by ensuring consistent quality and product safety.

OEE (Operational Equipment Effectiveness) can be increased through x-ray inspection providing pack integrity and allowing manufacturers to manage quality control within their supply chain.

An x-ray inspection system helps manufacturers demonstrate their commitment to guidelines and standards such as HACCP and to effectively manage process risks.

2 How X-ray Inspection Systems Work

X-rays are an invisible form of electromagnetic radiation like radio waves. Their short wavelength allows them to pass through materials that are opaque to visible light. But they don't pass through all materials with the same ease. In general, the denser the material, the fewer x-rays that pass through. Hidden contaminants, like glass and metal, show up under x-ray inspection because they absorb more x-rays than the surrounding product.

An x-ray system is essentially a scanning device that captures a grey-scale image of the product which is compared to a predetermined standard (Figure 1).

On the basis of the comparison, the system accepts or rejects the image. If rejected, a rejection signal is sent, removing the product from the production line.

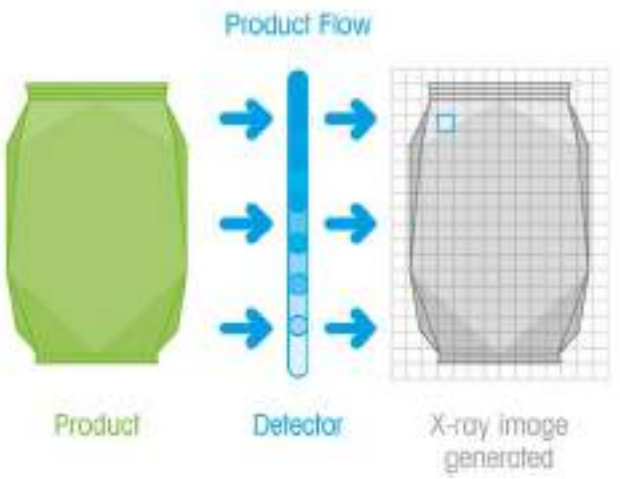

Figure 1

3 X-ray Inspection System Design

An x-ray inspection system consists of an x-ray generator, a detector and a control system encased in a stainless steel cabinet with a highly visible lamp stack that signals the system status.

Food and pharmaceutical x-ray inspection systems are built for tough environments, can be run at high line speeds, and detect very small contaminants. They should be easy to set up, clean and maintain to improve quality without reducing efficiency.

Despite widespread use of x-ray inspection, few guidelines exist to help manufacturers evaluate system features or compare machines. Knowing how system design affects day-to-day production can help identify the best system for a particular application.

Health and safety

X-ray inspection systems must be built to comply with safety standards to ensure all personnel and production staff are safe when operating the equipment. For example, x-ray inspection systems must meet ionising radiation regulations for the country where the machine is used.

Some x-ray manufacturers have safety barrier photocells across the machine's entry points. When the photocell is blocked for an extended period the belt stops. This protection method also may not be acceptable, for certain countries.

The requirement for a Category 3 (dual circuit) safety interlock design is driven by a risk assessment scoring system which is fully described in ISO 13849-1. Power isolators should be lockable and emergency stops must be fitted at every operator station. Emergency stops should be used as a back-up for safeguarding measures and not a substitute for them.

Cabinet design

X-ray inspection cabinets should be stainless steel sealed to minimum IP65 rating as standard or IP69 for harsh wash-down environments with greater ingress risk.

Systems should include air conditioning or heat exchangers to keep internal electronics safe in a sealed cabinet. A basic open fan is not enough as it reduces the cabinet's rating below IP65. Air conditioning eliminates water use. A built-in gauge should indicate overheating. A mains suppressor, filter and UPS (uninterruptable power supply) should be included to enable controlled shutdowns during power failures.

Conveyor design

The conveyor belt should be removable without tools and incorporate a quick-release tension roller. Tracking must also be simple to adjust. On wide-belt – typically over 800 mm – or very wet/greasy applications, automatic tracking should be considered. Misaligned belts can cause substantial downtime, due to premature wear.

For bulk-flow applications, troughed belts or side-skirted belts retain product, minimise spills and improve transport.

Hygienic design

Environment and cleaning regime must be considered before purchase. Design should:

- Eliminate cavities/bacterial traps
- Seal hollow sections
- Avoid ledges/horizontal surfaces,
- Use open, continuous-weld, easy-access frames
- Allow hygienic electrical cable, trunking and pneumatic service management

Drainage slots in catch trays and easy strip belts should be used whenever possible to ensure thorough cleaning in high-risk applications.

Pipeline systems should incorporate clean-in-place (CIP) procedures, allowing hot fluid flush with no need to disassemble the manifold or disconnect pipes. Aseptic manifolds with double O-ring seals for x-ray connections allow injected steam to kill microorganisms in sterile applications.

Good hygienic design helps HACCP compliance. 3-A, AMI, EHEDG and NSF machine design standards are also highly regarded and offer additional information on this topic. For more information please see the Additional Resources section at the end of this chapter.

X-ray tube

X-ray tubes should match the application. Glass-windowed tubes are common. Low-density/low-depth products are suited more to beryllium. The lower energy and softer rays improve detection of medium-density contaminants such as glass, mineral and bone and lend themselves to bulk-flow, small thin-pack and product-in-seal inspections.

X-ray detector

Various diode sizes are available to suit a diverse range of applications. Product depth, size and production line speed must all be considered during the selection process.

User-friendly interface

Full-colour touch-screen displays with intuitive software and different user access levels allow quick set-up and reduce errors. Added displays allow remote visibility. Multiple language options allow operators to select the most appropriate.

Variable speed

Advanced systems should match scanning speed and reject timing to line speed. Image proportions and sensitivity should be made for the speed range.

Adaptive filtering

For dense-edged containers e.g. glass jars, adaptive technology allows high-absorption areas to be filtered out. Fixed-width filters, by contrast, may let contaminants pass or cause false rejects.

Information storage

Many x-ray systems are PC based and record large amounts of useful information, so the Control Panel should be specified to provide sufficient processing at all times. Features such as USB and Ethernet ports allow immediate access to statistical data and the reject library. This access helps with reporting, traceability and HACCP compliance.

Diagnostics

Well-designed inspection systems will use self-monitoring software that continually checks machine operation to flag potential problems. It can flag up a potential problem in advance, so as to provide an early warning system, plus a field-based service engineer can also dial into the machine remotely via Ethernet to fix faults or prepare parts for a site visit.

Failsafe system

A highly visible lamp stack with a top beacon should be visible from 360 degrees around the machine (Figure 2). It indicates that x-rays are on/off, that x-rays are about to start up, that the system is in fault mode, and that power is on the machine and the system is healthy.

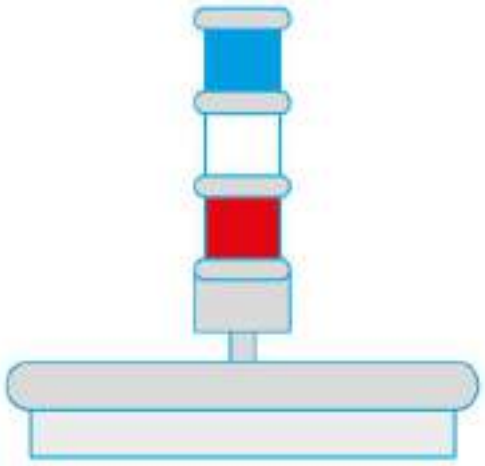

Figure 2

The lamp stack also alerts operators that a PVR (Performance Verification Routine) is required. It can also indicate activation of any of the failsafe features, namely reject confirmation, bin-full warning and low air pressure. An audible alarm is usually activated at the same time.

4 Summary

X-ray inspection systems involve significant capital investment. Equipment must be well-designed to ensure ROI (Return on Investment). Cost savings, regulatory compliance, consumer/brand protection, and enhanced sales can justify the initial expense. A well specified and reliable installation will also help to maximise OEE (Overall Equipment Effectiveness) on the line.

The short wavelength of x-rays allows them to pass through materials opaque to visible light. Because they do not pass through all densities with similar ease, they detect contaminants, which absorb more x-rays than surrounding product.

Food and pharmaceutical x-ray inspection systems should be easy to set up, clean and maintain to improve quality without reducing efficiency. They must offer durability and accuracy during high-speed operation. Safety, hygiene, cabinet/conveyor/x-ray tube design and data collection capabilities should be considered for optimised selection.

The capability of x-ray inspection systems to detect a range of contaminants can help manufacturers prove appropriate risk management. X-ray detection can also be considered the highest level of inspection in a diligent HACCP program.

5 Additional Resources

- METTLER TOLEDO Safeline X-ray Inspection Guide serves as a definitive reference work for development of an effective x-ray inspection program. Request your free copy at **www.mt.com/safeline-xray**

- METTLER TOLEDO On-demand webinars also allow 24/7 self-paced learning on a wide range of important process integration topics **www.mt.com/pi-ondemand**

Several regulatory bodies advocate x-ray inspection. For more on emerging standards and other helpful information, please visit the following:

- 3-A standards organization
  www.3-a.org

- European Hygienic Engineering & Design Group EHEDG
  www.ehedg.org

- National Sanitation Foundation NSF International
  www.nsf.org

- American Meat Institute AMI
  www.meatinstitute.org

- British Retail Consortium BRC
  www.brcglobalstandards.com

- International Food Standard IFS
  www.food-care.info

- ISO 22000:2005 – Food Safety Management System Standard
  www.lrqa.co.uk/certification/food/iso22000

- Safe Quality Food (SQF) Institute
  www.SQFI.com

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For more information

Hygienic Design

Hygienic Designed Food Scales

Less Contamination, Enhanced Profits

In today's global market, in an effort to ensure safety, weighing equipment construction must follow international guidelines based on EHEDG, NSF and 3-A standards. These standards encompass issues such as equipment surfaces, materials and design.

Contaminated food processing equipment has been responsible for a number of major food poisoning outbreaks.It also accounts for innumerable instances of product spoilage and quality defects.

In some cases, these events result from a failure to maintain, clean, or operate equipment hygienically; in others, the fault is found in the design of the equipment itself. Either way, the results can be catastrophic for consumers and food producers.

To ensure safe food, equipment used for food processing must be designed and installed according to sound sanitary design principles. Equipment must allow efficient cleaning and sanitizing, and surface materials must resist exposure to corrosive food products and cleaning chemicals.

This paper highlights several of the the most important food processing equipment aspects that are relevant to bench- or floor-scale design to ensure food safety, reduce spoilage, and enhance profits.

Contents

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1 Food Contact Surfaces

A food product contact surface is defined as a surface in "direct contact with food residue, or where food residue can drip, drain, diffuse, or be drawn" (FDA, 2004). Because contamination of these surfaces can result in food product contamination directly, rigid sanitary design criteria must be met.

Non-product contact surfaces include equipment parts such as feet, supports, and housings that do not contact food directly. However, contamination of these surfaces can cause indirect contamination. They must also be included when considering sanitary design. Risk analysis can help define areas with indirect or cross-contamination potential.

Generally, particularly if a structure is coated with metal alloy or non-metal (ceramic, plastic, or rubber) the final surface must be:

- Smooth
- Impervious
- Free of cracks and crevices
- Corrosion-resistant
- Durable and maintenance-free
- Nontoxic
- Nonporous
- Nonabsorbent
- Non-contaminant
- Cleanable
- Nonreactive

3A Standards also require that such coatings maintain corrosion resistance and be free of surface delaminating, pitting, flaking, chipping, blistering, and distortion during the equipment's intended use. Similarly, if any other modification or process is used in fabrication– such as welding, bonding, or soldering – it should be done using appropriate materials and in a manner that ensures the final surface meets the same sanitary design criteria.

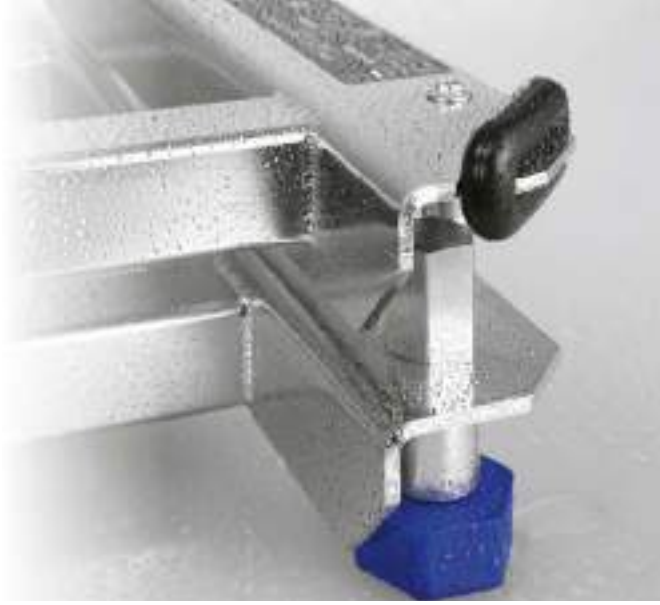
2 Materials

A variety of materials are used in the construction of food equipment. These materials vary in their properties with regard to workability, compatibility and sanitary design features. Depending upon the application, various metals as well as non-metals such as plastics and rubber are used.

Metals

Stainless steel is the preferred general-use metal for food contact surfaces because of its corrosion resistance and durability in most food applications. In general, the properties of the stainless steel alloy are related to its relative levels of chromium which offers corrosion resistance; and nickel which adds strength.

3A Standards also provide specifications regarding alloys and other coatings used in fabrication.



Hygienically designed portable bench scale feet: Example of non metal material in a scale, feet without open threads

ANSI, DIN/EN designations of stainless steels commonly used in the food industry:

ANSI	**DIN/EN**	**Typical analyses**					
		C%	Cr%	Ni%	Mo%	Ti%	N%
304L	e.g.: DIN 1.4307 (EN X2CrNi18-9)	< 0,03	18	9			
316L	e.g.: DIN 1.4435 (EN 2CrNiMo18-14-3)	< 0,03	18	14	3		
410	DIN 1.4006 (EN X12Cr13)	< 0,12	13	< 0,75			
409	DIN 1.4512 (EN X2CrTi12)	< 0,03	11,5			< 0,65	
329	DIN 1.4460 (EN X3CrNiMoN27-5-2)	< 0,05	27	5,5	1,7		< 0,20

Non-metals

A variety of non-metal materials find application in food contact surfaces such as probes, gaskets, and membranes. Non-metal materials used in food contact surfaces include:

- **Plastics, rubber, and rubber-like materials**
  These should be food-grade and meet requirements designated under 3A Sanitary Standards or EHEDG. Compliance with FDA regulations can be covered through Food Contact Notification (FCN) certificates.

- **Ceramics/glass**
  Ceramics are used primarily in membrane filtration systems; glass may be used as a food contact surface. These applications are limited due to breakage potential.

- **Paper**
  Has been used over the years as a gasket material in piping systems designed for daily disassembly. Paper is considered a single use material.

- **Wood**
  is highly porous and difficult to clean and should be avoided. More details on polymeric materials, elastomers, adhesives, lubricants, and other non-metallic materials can be found under Chapter 9 "Additional resources".

In general, non-metal surfaces may lack the corrosion resistance and durability of metal surfaces, so maintenance programs should include frequent examination for wear and deterioration and be replace as appropriate.

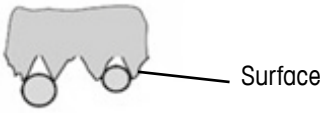
3 Surface Texture and/or Finish

If a surface is ground, polished, or textured in any way, the final result must be smooth, durable, free of cracks and crevices, and meet the sanitary design requirements described in the previous section.

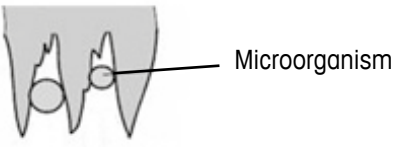
Large contact surface areas should have a finish roughness (Ra) of 0.8 µm or better. However, cleanability strongly depends on the applied finishing technology, which can affect surface topography.

A roughness of Ra >0.8 µm is acceptable if test results have shown that the required cleanability is achieved through other design features or procedures such as a high-flow cleaning agent rate. Specifically, in the case of polymeric surfaces, hydrophobicity, wettability and reactivity may enhance cleanability.

Hygienic design



Hygienic risk



Product contact surfaces should have finsih a roughness of Ra < 0.8µm

4 Functional Requirements

Food processing equipment should be easy to maintain. This ensures it will perform as expected and prevent microbiological problems.

Poorly designed equipment requires more severe cleaning and prolonged cleaning time. This can include aggressive chemicals and longer cleaning/decontamination cycles which results in higher costs, reduced production availability and shorter equipment life.

Easy-clean equipment, on the other hand, allows high-pressure washdown, reduces costs, and shortens cleaning time.

- Full stainless-steel construction
- Continuously welded and completely closed column, no disturbing cables
- Platter with smooth surface, brushed (ra < 0.8 mm)
- Ingress protection IP68/IP69k

5 Construction and Fabrication

Food equipment design and fabrication should avoid sharp corners and crevices. Mated surfaces must be continuous and substantially flush. Construction should allow for easy disassembly for cleaning and inspection.

Liftable floor scale with easy cleaning access

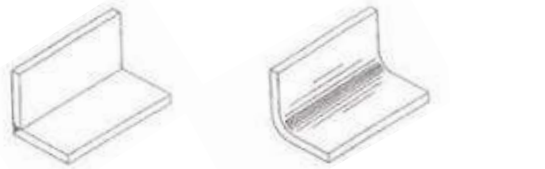
Floor scale with hinged load plate where contamination and corrosion have no chance due to high-quality material, hermetically seal-welded tubes and smooth surfaces

6 Internal Angles/Permanent Joints

Internal angles should be coved or rounded with defined radii as shown in the accompanying figure. Equipment standards state appropriate radii for specific equipment applications and components.

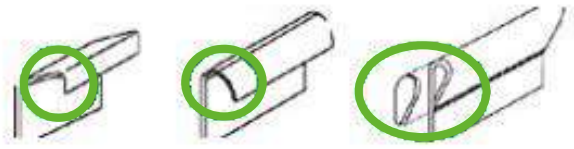
For example, radii requirements stated in the 3A Sanitary Standards indicate that "all internal angles 135 degrees or less should have a minimum radius of 1/4 inch (6.35 mm)". EHEDG defines it in a similar fashion: "Corners should preferably have a radius equal to or larger than 6 mm; the minimum radius is 3 mm. Sharp corners (≤90°) must be avoided."

Hygienic risk **Hygienic design**



Hygienic risk

Hygienic design



7 Testing

A series of EHEDG test methods for assessing the hygienic characteristics of equipment is available under Guideline EHEDG No. 2A (Additional resources).

8 Summary

The primary intent of international standards organizations such as 3-A, EHEDG and NSF, is the application of sanitary principles in food equipment manufacturing to ensure food safety. Even with subtle differences among a reputable equipment manufacturer such as METTLER TOLEDO will implement these principles when designing bench and floor scales.

Hygienic design and high-quality materials ensure that machines can be cleaned quickly and with less costs. This leads to fast shift changes, fewer cleaning agents and an overall reduced food contamination risk.

9 Additional Resources

The following resources provided additional information on hygienically designed equipment specifications.

- European Hygienic Equipment Design Group (EHEDG)
  www.ehedg.org

- HYGIENIC EQUIPMENT DESIGN CRITERIA, Second edition, April 2004
  www.food-info.net/uk/eng/docs/doc8.htm
  Guideline EHEDG No. 2A - Method for assessing in-place cleanability of food processing equipment
  Guideline EHEDG No. 8 - Hygienic equipment design criteria
  Guideline EHEDG No. 9 - Welding stainless steel to meet hygienic requirements
  Guideline EHEDG No. 13 - Hygienic design of equipment for open processing
  Guideline EHEDG No. 32 - Materials of construction for equipment in contact with food

- The National Sanitation Foundation (NSF)
  www.nsf.com

- 3A Sanitary Standards
  www.3-a.org

- Sanitary Design and Construction of Food Equipment, Ronald H. Schmidt und Daniel J. Erickson,
  http://edis.ifas.ufl.edu/fs119

- Meat and Poultry equipment: NSF/ANSI/3-A Standards 14159-1, -2 and -3.
  www.nsf.com/business/meat_and_poultry_equipment

- Food and Drug Administration
  www.fda.gov/Food/GuidanceComplianceRegulatoryInformation

- METTLER TOLEDO Hygienedesign
  www.mt.com/hygienic-design

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Cleaning Production

7 Considerations for Cleaning Production

Equipment in Hygienically Sensitive Environments

Scales, used in hygienically sensitive industries, such as the meat industry, are often in direct contact with the product. They are consequently a potential contamination risk. Independently, if they are used in a basic weighing application in the goods entrance or as a checkweighing solution in the packaging area, they are located in hygienically sensitive areas that follow strict sanitation procedures.

Such an equipment sanitation procedure has to ensure adequate cleaning of product-contact and product non-contact surfaces. A common sanitization standard for contamination reduction of food-contact surfaces is generally accepted as 99.999% achieved in 30 seconds. The sanitization standard for non-food contact surfaces is accepted as a reduction of 99.9% [1].

Disinfection, in contrast, must destroy or irreversibly inactivate all specified organisms within a certain time, usually 10 minutes [2].

To achieve those requirements, the equipment has to be hygienically designed and efficiently treated during the sanitation program. This white paper provides guidance on where to focus when cleaning equipment, such as scales and checkweighers, and provides a typical example of a sanitation plan.

Contents

METTLER TOLEDO

1 Choose a Hygienically Designed Scale

An effective and efficient cleaning starts with the right equipment. Available on the market are scales that have the European Hygienic Engineering and Design Group (EHEDG) and National Sanitation Foundation (NSF) approval for hygienic design.

But what construction elements are relevant if such an approval is missing? Consider the following points when selecting a scale for a hygienically sensitive environment [3].

Topic	Considerations
Cleanable to a microbiological level	
The equipment should be designed to prevent bacterial ingress, survival, growth and reproduction on both product and non-product contact surfaces of the equipment.	• All surfaces are accessible for mechanical cleaning and treatment to prevent biofilms formation
Made of compatible materials	
Construction materials must be completely compatible with the product and environment. Water collection points have to be avoided.	• All surfaces should be designed to eliminate water pooling and should be self- draining • Product contact surfaces must be made with materials which are corrosion resistant e.g. stainless steel • Hollow areas must be eliminated • Equipment parts should be free of niches nooks, such as pits or cracks • Check materials against FDA components list of food contact materials [8]
Accessible for inspection, maintenance, cleaning and sanitation	
All parts of the equipment shall be readily accessible for inspection, maintenance, cleaning and sanitation without the use of tools.	• Bench scale: Lift the platter for cleaning • Floor scale: Easy to lift platter or scale
Sanitary operational performance	
During normal operations, the equipment must perform so that it does not contribute to unsanitary conditions or the harborage and growth of bacteria.	• Buttons on control panels have to be cleaned and sanitized during operations (risk: microbial harborage)
Hygienic design of maintenance enclosures	
Maintenance enclosures and human machine interfaces, such as push buttons, switches and touchscreens, must be designed to ensure that product residue or water does not penetrate or accumulate in and on the enclosure or interface.	• Maintenance enclosures in direct wash-down areas must be able to be exposed to water • Securing with a plastic bag is not acceptable. Should be NEMA and IP rated, including high-pressure washing

(Scale design principles, adapted from 10 Principles of Sanitary Design, AMI Foundation)

2 Prepare a Surface for Sanitizing

Preliminary cleaning is an important operation and is aimed to achieve visual cleanliness of the equipment.

Prepare a surface for sanitizing

For a sanitizer to be effective, the surface being sanitized must be physically clean. One cannot sanitize a dirty surface – organic soils will consume the sanitizer. Detergent residues must be rinsed well – they will neutralize many sanitizers. Spraying a surface with a sanitizing solution without first cleaning the surface properly is a waste of time and money. [2]

Sanitation food-contact surfaces

Sanitizing of food-contact surfaces aims to minimize disease producing bacteria and viruses, substantially reduces the number of other undesirable organisms, and does not adversely affect the product or its safety for the consumer. Sanitizing does not affect bacterial spores – that is beyond the capability of the process.

Non-food contact surfaces

Non-food contact surfaces shall be free of unnecessary ledges, projections and crevices, and designed and constructed to allow easy cleaning and to facilitate maintenance. Although usually the regulations do not explicitly address potential indirect food-contact surfaces, such as terminals, these surfaces can be an important source of microbial contaminants.

Relevant non-food contact surfaces

Bench scale platforms

Remove the platter: The daily cleaning procedure should include all parts underneath the platter and the feet. [7]

Floor scales

Look underneath the platter: Choose floor scales that can easily be cleaned underneath the platter. Different types of floor scales offer the capability to only lift the platter or the complete scale. Another good alternative are mobile floor scales. [7]

Terminals

Buttons on control panels should be cleaned in order to avoid microbial harborage or biofilm.

Checkweighers

An open construction for cleaning and visual inspection is important, including a toolless removal of components and high ground clearance.

3 Cleaning with Detergents

After removing food debris and rinsing with water, the standard cleaning procedure with detergents includes the following procedures:

- **Cleaning with alkali detergents**
  Daily: Application of chlor-alcalic foam with low pressure
  Once a week: Application of acid foam
  Consider the instruction of the detergent supplier regarding concentration and temperature, because the effectiveness of the detergents depends on the temperature used and duration of application.
- Rinse with water after the predefined contact time.

Which detergent and sanitizer to apply?

This cleaning involves the use of a product with detergent action, approved for cleaning with food-contact surfaces. The choice of cleaning product depends on the principal type of soil present and the equipment used. Such products may be divided into the following broad categories:

- Alkalis (sodium, potassium, etc.) are active against organic soiling, as they saponify fats and dissolve proteins. Consequently, these products are frequently used in the meat and poultry industries.
- Acids are used mainly to eliminate calcium deposits (from hard water) and to restore stainless-steel surfaces.
- Organic (surface-active) products are often incorporated into the alkali and acid preparations mentioned above. Those products have the ability to reduce the surface tension of water, inhibiting the tendency for droplets to form on cleaned surfaces. [4]

4 Visual Controls

Check visually if all surfaces now look clean and correct if necessary.

5 Disinfection

The aim of disinfection is to eliminate the microorganisms still present on surfaces, adhering to anchorage points. Some bacteria become attached a few nanometers from the surface, while others produce substances that result in an adhesion that is difficult to break down (biofilm) [4].

It includes:

- **Daily:** Cleaning with disinfectants
  Contact time and pressure wash-down requirements depend on the product and are defined in the manuals of the suppliers.

6 Final Rinsing

This is a relevant step to remove all traces of soil, detergents and disinfection substances, which may get in contact with food.

Sanitation plan

A common sanitation plan for the meat industry is described below:

Sealed Air
Food Care

	SOP	Page 1 of 1
Version 1	**Production (8-10°C)**	Valuable from:
		04.06.2015
		Document issued by
		SealedAir

Cleaning plan

Machine / object		Interval					Product	Application			Remarks
		After each usage	Mo / Tues / Wed / Fri	Thursday	Weekly	Monthly		Conc. [%]	Temp. [°C]	Time [min.]	
Tables / walls / floor		x					Water				Remove debris, pre-rinse and rinse after foaming
			x				Enduro Chlor	3	40	15	Chlor-alcalic foam
				x			Aciclean VK39	3	40	15	Acid foam
		x					Suredis VT1	1	20	15	Disinfection
		x					Water				Rinse after each disinfection
Scales / equipment		x					Water				Remove debris, pre-rinse and rinse after foaming
			x				Enduro Chlor	3	40	15	Chlor-alcalic foam
				x			Aciclean VK39	3	40	15	Acid foam
		x					Suredis VT1	1	20	15	Disinfection
		x					Water				Rinse after each disinfection

Chlor-alcalic
Acid
Alcalic
Neutral

7 Verification of Procedures

Upon completion of sanitation, you need to verify that the procedures have been effective. The simplest approach is a visual assessment that no debris remains. Further protein residue or microbiological tests can be performed using contact plates or swaps. [6]

8 Summary

Production equipment, such as bench and floor scales, are often installed in hygienically sensitive environments in a production plant and should be cleaned according to strict sanitation plans. This paper highlights criteria to use when selecting a weighing scale for such an area and provides guidance on how to specifically treat food-contact and non-food contact surfaces. It shows most relevant cleaning steps and contains a detailed sanitation plan for a daily and weekly cleaning procedure in a meat factory.

Acknowledgement

[1] Official Detergent Sanitizer Test, AOAC International Official Methods of Analysis 2009 AOAC International, Gaithersburg, MD

[2] Alan Parker, Effective cleaning and Sanitation Procedure, University of Maryland and the JohnsonDiversey Corporation, 2007

[3] Sanitary Design Equipment Principle, 10 principles of sanitary design, AMI, 2014

[4] G. Salvat & P. Colin, Cleaning and disinfection practice in the meat industries of Europe, Rev.sci. tech. Off.int. Epiz., 1995, 14

[5] Pratical cleaning guidance for the meat industry, SealedAir, 2015 www.sealedair.com

[6] Developing a Cost-effective Sanitation Plan for Small-to-medium Processors, Keith Warriner, Ph.D. Food Safety Magazine, 2011

[7] Examples of hygienically designed bench and floor scales **www.mt.com/ind-bench-floor-hygienic**

[8] FDA, determining the Regulatory Status of Components of a Food Contact Material, www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/RegulatoryStatusFoodContactMaterial/default.htm

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Efficient Quality Management
in a Regulated Environment

Ensuring compliance with quality management and regulatory standards, such as ISO or GMP, requires an understanding of parameters influencing the accuracy of weighing processes. In highly regulated industries where consumer safety is at stake – such as food, cosmetics, pharmaceutical or automotive production – it can also mean being subjected to frequent audits.

Before acquiring weighing system and instrument verification, performing a thorough risk analysis between service visits can help put regulatory guidelines into effective practice, while reducing costs and increasing productivity and product safety. Helpful actions include:

- Determining required process tolerances
- Selecting appropriate technology
- Documenting compliance
- Setting adequate testing and calibration schedules
- Choosing appropriate performance measures

Instituting relatively simple weighing tests as part of standard operating procedures (SOPs) can help ensure top quality product and audit results. Good Weighing Practice™ (GWP®), the global weighing guideline developed by METTLER TOLEDO, can help, regardless of the manufacturer of a particular scale or balance.

Contents

METTLER TOLEDO

1 Putting Quality Management in Perspective

Weighing process quality was once primarily a question of accuracy. However, it has become increasingly concerned with risk evaluation and management and is the daily preoccupation of quality managers worldwide.

Quality assurance complexity often arises from the regulations themselves. They give only a vague framework on performance targets. No concrete implementation information is given based on the assumption that the user knows his or her process best – and can therefore choose the best solution to any issue.

Questions left to interpretation include:

- How should verification be made? At what interval? Using which standard?
- How should validity of results be assessed? Recorded?
- What action should be taken?

Putting the weighing process itself at the center of the quality management equation can help establish helpful, documentation-ready SOPs that pass audits and improve productivity and profitability. METTLER TOLEDO's GWP® offers a framework in nearly any regulatory scenario, regardless of a weighing system's manufacturer.

For example, take this weighing practices excerpt from ISO 9001:

ISO 9001: 7.6 Control of monitoring and measuring devices
Measuring devices shall be **calibrated** or **verified** at **specific intervals**, or **prior to use**, against **measurement standards** traceable to international or national measurement standards. The organization shall **assess** and **record** the validity of the previous measuring results when the equipment is found not to **conform to requirements**. The organization shall take **appropriate action** on the equipment and any product affected.

2 Establishing an Appropriate Weighing Practice

METTLER TOLEDO's GWP® offers a framework to establish a weighing practice that works. The five basic GWP® steps follow:

STEP 1: Good evaluation
Evaluate the process from a metrological perspective to establish parameters, such as smallest net weight and required process accuracy. These parameters set expectations for a given instrument.

Good Evaluation

STEP 2: Good selection
Select a scale that fulfills the preceding requirements, or matches the accuracy to the process needs. The minimum weight concept is used as a basis for selection.

Good Selection

STEP 3: Good installation
Document that appropriate installation – unpacking, set-up, configuration, calibration, adjustment and operator training – has taken place and that the equipment still fulfills selection requirements.

Good Installation

STEP 4: Good calibration
Calibrate a scale in its operating environment. Documenting scale performance and issuing applicable certificates at regular intervals is the qualified technician's task.

Good Calibration

STEP 5: Good operation
Establish SOPs and test schedules to help guarantee that weighing process criteria are fulfilled between service visits.

Good Operation

Each step involves assessment of process parameters to ensure equipment can meet tolerances and quality requirements.

3 Matching Instrument Accuracy to Required Process Tolerance

A weighing system's life starts with assessing process requirements from a metrological perspective. This means establishing process parameters such as:

- Weighing range
- Smallest net weight
- Process tolerance
- Applicable regulations
- Need for safety margin

Other important concerns include ruggedness of the construction, mechanical stress when loading the scale, hygiene, connectivity and environmental conditions, such as humidity, temperature, ingress protection, explosion/corrosion protection, hygiene and connectivity.

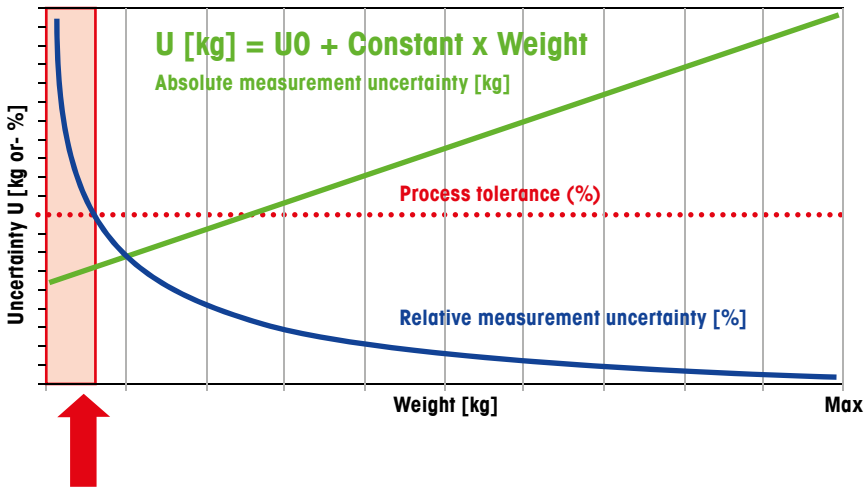
Quality will be assured if an instrument's measurement uncertainty is always better than the acceptable process tolerance. For example, measuring 1 kg with a tolerance of 1% is only possible with a scale providing a measurement uncertainty better than 1% (<1%) at the given net load of 1 kg.

The relative measurement uncertainty of any measuring instrument – particularly a scale – can be assured by considering the following characteristics.

Minimum weight

In the low range, there will be a limit under which any measurement will have an uncertainty greater than the acceptable tolerance. This is called the 'minimum weight' characteristic.

Relative uncertainty becomes bigger at smaller weights



For smaller weights, the **relative measurement uncertainty** can be so high that the weight cannot be trusted anymore!

Smallest net weight

The smallest net weight of the weighing process under consideration has to fulfill the required process tolerance requirement. As each scale will have its own absolute and relative measurement uncertainty curve (see figure 1 on next page), the only scales that are appropriate are those where the minimum weight characteristic is smaller than the smallest net weight of the respective process.

In the example (figure 1), it is obvious that Scale 3 is not appropriate, because its relative measurement uncertainty is greater than the required relative tolerance at the smallest net weight. Scale 2, taking into account only the minimum weight, could be a candidate. Upon further investigation, however, we see that Scale 1 is the proper selection.

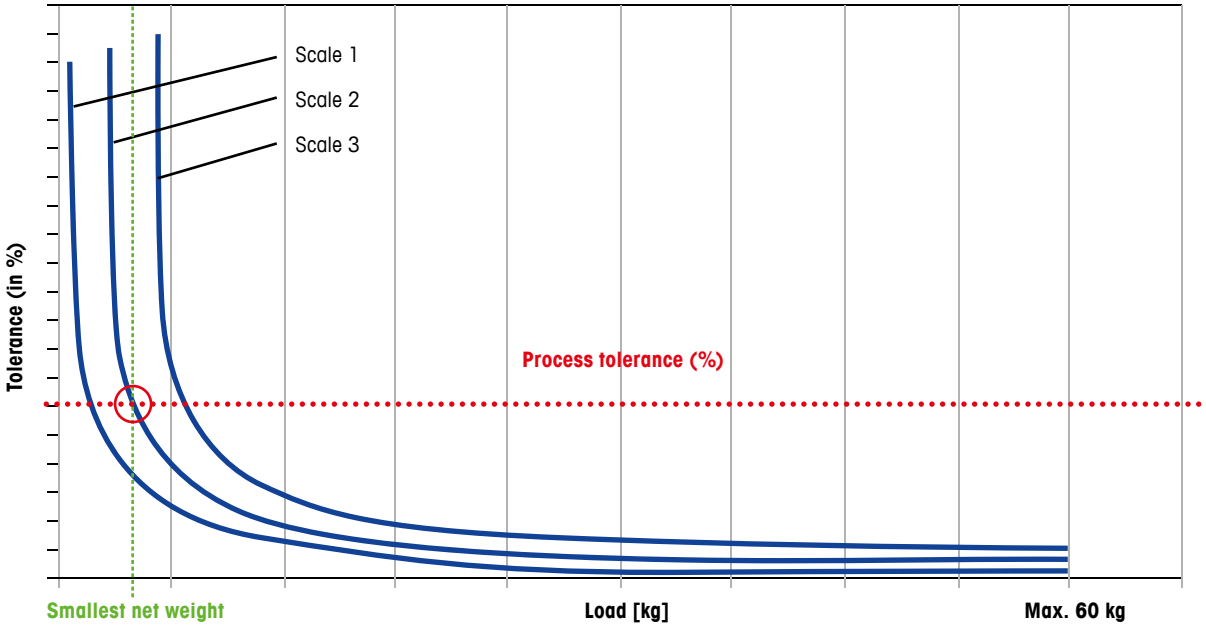


Figure 1 – Relative measurement uncertainty (%) of 3 scales of 60 kg

Process tolerance & safety margin

Instrument performance is strongly influenced by the environment. Certain environmental factors, such as air currents, temperature changes and vibrations, can lead to a reduction in instrument performance, resulting in less accurate weighing. Therefore, some safety margin must be anticipated in order to prevent external influences from throwing measurements out of tolerance.

A safety factor on the Minimum Weight must be applied. In other words, the Minimum Weight of a scale at a given tolerance should be at least half of the smallest net weight to be measured (safety factor >2). A safety factor >2 is recommended if risk analysis determines that accuracy is critical. Using these criteria, in this example, only Scale 1 can fulfill all process requirements.

4 Understanding Process Risks in a Regulatory Context

Industrial processes always carry risk. Errors may impact the company (increased costs, loss of image, loss of production time), consumers, the environment – or all of the above. Errors as a result of a weighing inaccuracy may result in over- or under filling, waste of production materials, overpaying for materials, quality issues and customer complaints, which may lead to financial losses for the company.

Mistakes across complex industrial processes may be difficult to detect. Identifying, describing and minimizing operational risks has become the focus of most current regulations and quality systems, such as ISO, GMP, IFS, and HACCP.

High risk and a narrow process tolerance may call for frequent instrument accuracy verification. Even under a more frequent testing schedule, regulators determine an instrument's uncertainty principle based on an assumption that proper installation and calibration actions have been performed. Therefore, proper installation and calibration are critical to comply with the standards.

How operator training impacts audits

Installation includes unpacking, set-up, configuration, calibration, adjustment, training – and documentation of all these actions. The manufacturer can install a system in good order and document that the equipment will perform the task for which it was selected. However, many users invest large sums in instrumentation but neglect end-user training. Since the user is often the biggest source of measurement uncertainty, this can be a costly error in terms of lost production and audit failures.

Establishing audit proof documentation

Calibrating a scale in its operating environment helps document performance under the influence of environmental factors. Documenting scale performance at regular intervals is the task of an authorized and trained technician. He or she will determine the value of the different contributions to the measurement uncertainty such as scale sensitivity, weighing repeatability, eccentricity deviation and non-linearity. The scale will also be serviced so that any deviation from original specifications is minimized or alleviated.

A calibration certificate establishes links to applicable standards and proves compliance. For critical instruments, documentation demonstrating measurement uncertainty under additional tolerance and safety factors may be valuable. For its clients, METTLER TOLEDO issues a Minimum Weight Certificate to establish bulletproof documentation that helps in passing audits.

5 Verifying Equipment Accuracy

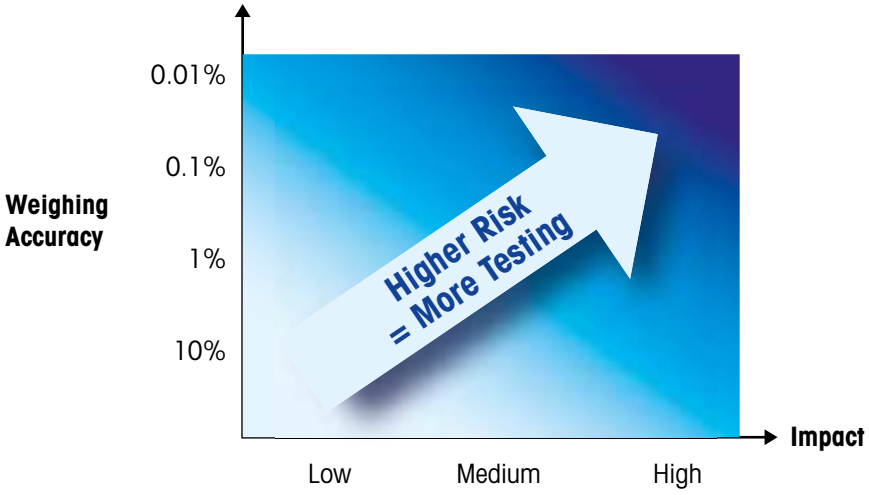
Inappropriate use, accidental damage, changes in environment conditions or water ingress can alter instrument accuracy. Since calibration is normally only carried out once or twice per year, users typically perform process-specific verifications between formal service visits themselves.

Users determine which tests to perform, taking into account process risks and tolerances. Ideally, this means establishing:

- A test list (sensitivity, repeatability, eccentricity)
- Testing frequency
- Weights used
- SOPs to be followed for the tests
- Test weight verification/recalibration frequency
- Verification of tolerance, control and warning limits

Regulations like ISO, GMP, and GFSI-based standards remain silent on determining these parameters. Here again, concepts developed under the GWP® guideline work.

Test frequency should be determined by risk level and process tolerance, as depicted in the following diagram.



If a measurement mistake has no impact on the process (low risk) and required tolerance is wide (>10%), there is almost no need for verification. Conversely, if a mistake would impact consumer health (high risk) and process accuracy has a narrow tolerance (<0.1%), a verification procedure with higher frequency is necessary. More risk plus stricter tolerance equals higher testing frequency.

Service technician calibration is the only method to establish national and international standards compliance and also determines measurement uncertainty so that it can be confirmed that process tolerances can be achieved. However, to determine if an instrument will satisfy process tolerance on a daily basis, an operator can:

- appeal to instrument functions and self-tests, or
- use weights to perform simplified routine testing.

Verification tests only work if an operator can obtain appropriate weights. METTLER TOLEDO has developed two-weight sets called CarePacs, which are sufficient to conduct all tests required to ensure scale accuracy called CarePacs and can also supply high-quality reference weights for testing any capacity scale. Because a larger and more expensive weight set is not required, the initial investment is reduced. Costs associated with maintenance and recalibration are lowered as well.

METTLER TOLEDO can assist with the appropriate combination of tests as well as the selection of test weights themselves.

6 Summary

Efficient quality management helps increase productivity and reduces costs. Choosing the right weighing system, establishing testing frequency based on risk and tolerance, and training internal personnel to spot-check accuracy can help a manufacturer pass required audits, assure quality and keep rejects – or worse, recalls – to a minimum.

Establishing characteristics such as weighing range, smallest net weight, process tolerance and safety margin helps guide weighing system selection. Other important concerns include ingress protection, explosion/corrosion protection, hygiene and connectivity.

Service technician calibration establishes national and international standards compliance. However, routine self-testing on an established schedule can help with regulatory compliance and improve day-to-day operations. If weighing mistakes are low-risk and tolerance is wide, verification needs are few. However, if issues such as company reputation or consumer health are at stake, higher testing frequency is required.

Testing costs and operator experience are integrated into METTLER TOLEDO's Good Weighing Practice™ (GWP®), a reality-based weighing practice model that can be applied in any scenario in which accurate weighing is crucial to product quality and safety.

7 Additional Resources

- For more information about Good Weighing Practice™, risk evaluation or effective scale operation, log onto **www.mt.com/gwp**
- For more information about CarePacs® and their role in establishing cost-effective, highly accurate scale testing practices, visit **www.mt.com/carepacs**

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For more information

Legal Metrology

Meeting Legal Metrology

Standards

Weight determination related to consumer protection – whether the concern is health, public safety, the environment, or fair taxation/trade – is subject to tight regulation. This strict application of weight standards is known as Legal Metrology. Global regulations – in combination with national or local laws – create performance control and reliability verification requirements for weighing instruments used in these legal applications.

For specific weighing applications as e.g. legal-for-trade, it is mandatory to use a verified scale. But the verified scale must also be used correctly. Improper use of a verified scale can lead to incorrect results as quickly as use of an unverified scale. Re-verification must then be performed, increasing production costs. Persistent inaccuracies can even result in fines. Increasingly demanding legal metrology requirements worldwide are not only challenging manufacturers but also entire industries. Within these tightening structures, questions such as the following become topics of heated debate:

- Where do we need a verified scales or balance?
- Can we adjust a verified instrument and what are the consequences?
- What do we have to do in case of a scale failure or equipment change?
- What legal actions can be taken by authorities in the case of non-compliance, and what consequences can we expect? And, finally,
- How costly could non-compliance be to us?

This paper highlights various aspects of legal metrology, as well as actions that can be taken to effectively implement legally compliant weighing activities – while at the same time ensuring efficient, cost-effective performance control/maintenance of compliant measuring devices.

Contents

METTLER TOLEDO

1 When are Verified Instruments Needed?

Legal metrology generally includes provisions related to:

- Units of measurement,
- Measurement results (e.g. prepackages)
- Measuring instruments

as well as the legal control performed by or on behalf of a government.

Determining mass

Legally verified instruments are required for determination of mass in (variations depending on national law):

- A commercial transaction
- The calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity or similar payment
- The application of law or regulations; expert opinion given in court proceedings
- Weighing medical patients for the purpose of monitoring, diagnosis and treatment
- Preparing prescriptions in a pharmacy or formulating medication in a pharmaceutical laboratory
- Calculating a price on the basis of mass for a direct public sale or the labeling of pre-packaged commodities

For definitions of 'Verification', 'Calibration' and 'Adjustment' see paragraph "6 Additional Resources"

When weight impacts cost

Regardless of whether the transaction is with another business or direct-to-consumer, it is wise to check if a verified instrument is needed in any situation where money is charged for weighed amounts – or whenever the weight of a product directly impacts a business deal.

2 Oversight and Requirements for Instrument Approval

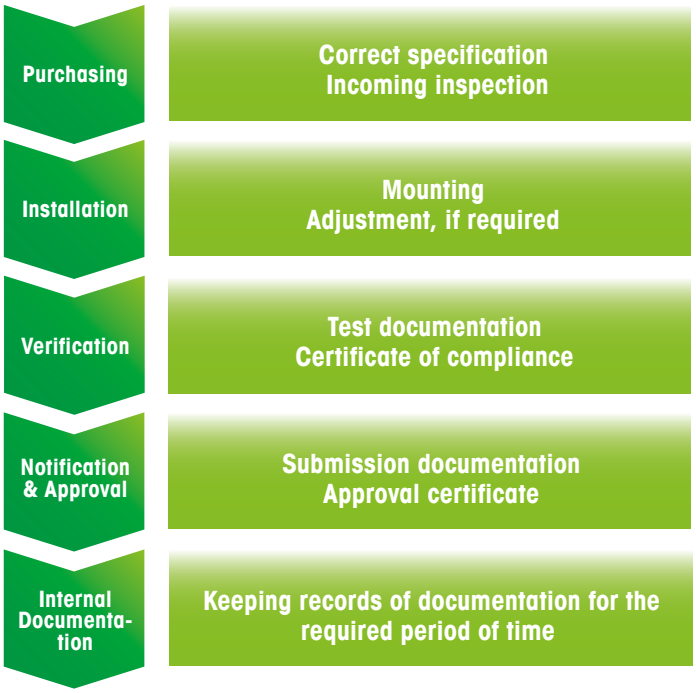
Legal metrology is subject to national legislation. However, these authorities or institutes are also organized on a global level.

Established in 1955, the International Organization of Legal Metrology (OIML) is an intergovernmental treaty organization. Their members cover 86 percent of the world's population and 96 percent of its economy. Each region of the world also has its own organizing body – such as WELMEC or NCWM – representing different national legal metrology authorities. A rough map of these regional bodies and the countries they serve follows.

Legal metrology organisations (worldwide)

Approval process

Though these organizations are separate, each has a similar approach to approving instruments used in legal applications. The following chart gives a basic idea of actions required.



Recognizing a Verified Instrument

Type approved Instruments have to be marked and verified for all uses subject to legal metrology.

Europe CE Mark Metrology mark	USA NTEP Certificate of Conformance	China Certificate ID: CMC
		

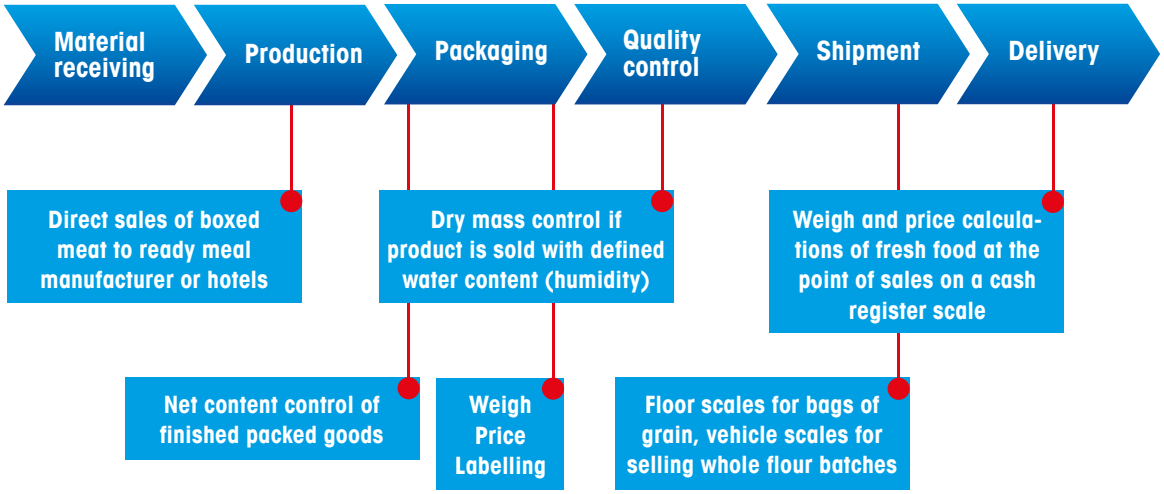
This paper and all given examples focus on non-automatic weighing instruments. Automatic weighing is described in the European Measuring Instrument Directive (2004/22/EC) and other national regulations.

3 Designing a Compliant System

A systematic analysis helps identify whether a specific weighing application requires a verified scale or not.

The following examples illustrate different applications or transaction conditions that require verified scales.

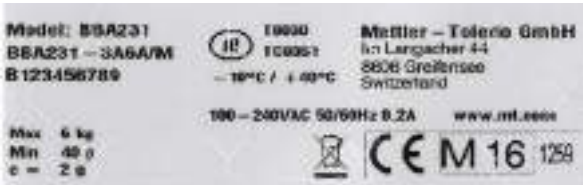
If there are questions as to whether or not a verified scale is needed, an ISO 17025-certified service provider such as METTLER TOLEDO can provide guidance for the decision-making process.



Specifying the right instrument

A selected instrument should meet the metrological requirements defined by the process, in which it will be used. Data that should be checked are:

- Weighing range(s) defined by value(s) for minimum and maximum capacity indicated by Min/Max
- Measuring accuracy required by the expected process. This sets requirements to the accuracy class of the instrument and verification scale interval "e"
- Environmental conditions such as temperature range

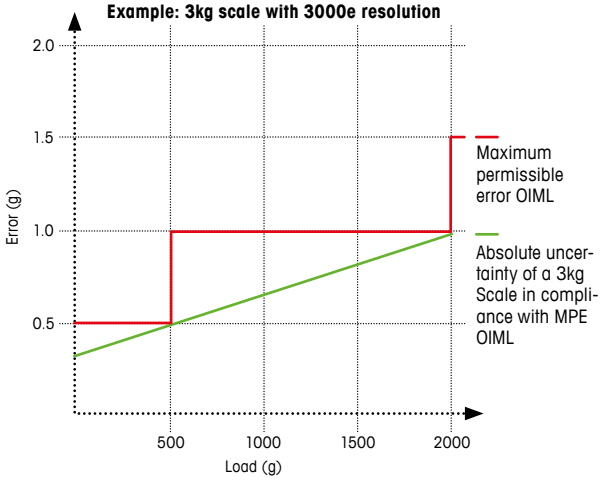


Weighing accuracy facts:

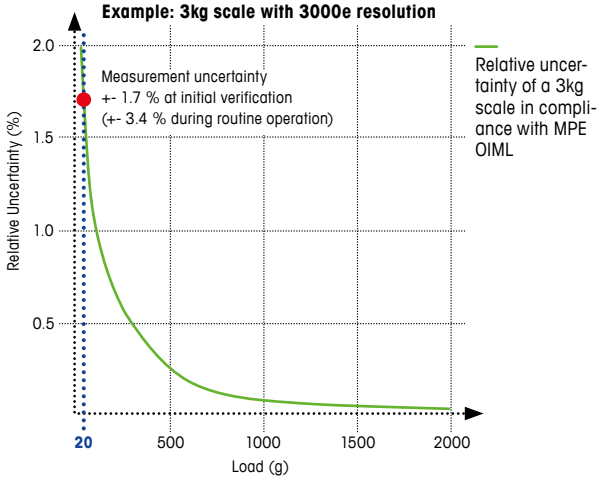
The accuracy classes for instruments including the maximum permissible error on verification/class is given in the table below (OIML R 76-1:2006).

Maximum permissible error (MPE)	**Load in verification scale intervals (e)**				
Max. permissible error on verification	Max. permissible error in routine operation	Class I Special accuracy	Class II High accuracy	Class III Medium accuracy	Class IIII Ordinary accuracy
0.5 e	1 e	0…50000	0…5000	0…500	0…50
1 e	2 e	50000…200000	5000…20000	500…2000	50…200
1.5 e	3 e	> 200000	20000…100000	2000…10000	200…1000

In case of a 3000e verified scale (class III) the minimum capacity is set at 20e (e.g. OIML). A maximum permissible error of +/- 0.5e is accepted for an initial verification and +/-1e during routine operation. In the following two diagrams we illustrate the measurement uncertainty profile of a scale that fulfills OIML requirements (initial verification). At all points, the scale's absolute measurement uncertainty is comprised within the limits set by OIML (graph 1).



Graph 1: MPE within tolerances for a 3 kg scale



Graph 2: Relative uncertainty of a 3 kg scale

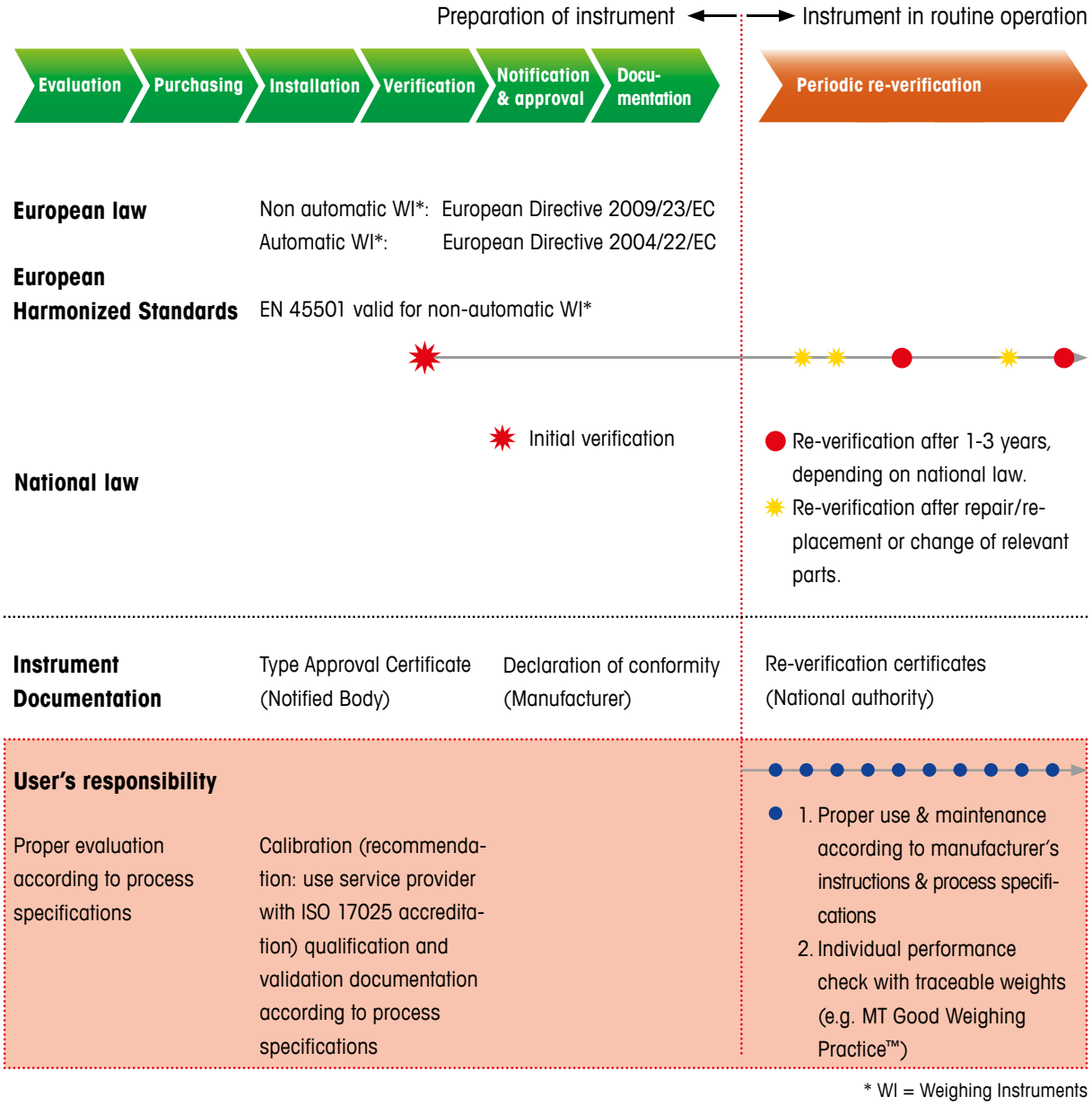
Looking at the relative measurement uncertainty of this instrument (graph 2), we can see that at 20e (min = minimum capacity according OIML) the measurement uncertainty of the instrument is of 1.7% for initial verification (and consequently 3.4% during routine operation).

In other words, a strict application of the OIML recommendations may lead to measurement uncertainty of maximal 3.4%. This is accepted from legal point of view for all legal applications listed above, but may probably be outside of the tolerance your process requires. It is therefore strongly recommended to define a second minimum weight corresponding to the effective process tolerance required and to adopt the largest of both minimum weights: The OIML minimum capacity or the process related minimum weight.

Helping tools to determine if your installed instruments meet process related standards are commonly available (see "6 Additional Resources: Good Weighing Pratice™").

4 Planning for and Maintaining a Compliant System

Any installation of weighing instruments that meet legal requirements should be planned carefully. As an example, based on current European regulations, the following graph summarizes the individual parties involved in setting up a compliant weighing process



* WI = Weighing Instruments

Ensuring traceability

Traceability of the weighing process is required for legal-use scales. Complete documentation of installation, maintenance and ongoing performance of a scale is mandatory.

The chart above can be used for ensuring that required documentation is available on every necessary step along the quality chain.

Maintaining compliance

Maintaining compliance over time requires a documented control system that accounts for:

- Maintenance
- Calibration
- Service
- Repair
- Modification

When establishing a performance verification schedule, process requirements should be considered in addition to specific regulatory requirements.

While the company operating the scales can carry out all of the required actions, it may be advisable to contract with an experienced service provider to ensure legal-use scales remain in good working order.

The application of industry benchmarks or a system such as METTLER TOLEDO's Good Weighing Practice™ (GWP®) Verification can help ensure a system meets expected process parameters all the time.

Re-verification

Legal metrology requires re-verification after any instrument manipulation that impacts metrological characteristics. Any sealing break by non-authorized personnel automatically causes accreditation loss. Re-verification is mandatory.

Standard re-verification (generally after 1-3 years) is usually performed by the respective national weights and measures inspectors. Any use of an instrument outside of its verification period or after unauthorized instrument manipulation may lead to an investigation and prosecution for operating a non-compliant scale.

5 Summary

Legal metrology regulations require correct handling and management of verified instruments as part of a company's overall quality management system. International and national law defined guidelines, as well as process steps and requirements, for how to install, handle, check and service verified instruments.

Weights and measures inspectors will check to see if instruments are being used according to the applicable regulations. They will also conduct the re-verification process after a certain time period.

It is up to the user to guarantee that verified instruments are maintained well and operate within legal tolerances. Systematic performance checks against the company's own process parameters can offer practical support to achieve product quality and safety within legal metrology tolerances.

Certified service providers offer systematic methods that support the user along the whole process chain-starting with determining where a verified instrument is needed through providing appropriate maintenance and calibration documentation for the next audit.

6 Additional Resources

Definitions (from Dictionary of Weighing Terms, A Guide to the Terminology of Weighing, R. Nater, A. Reichmuth, R. Schwartz, M. Borys, P. Zervos, Springer, 2009)

Verification
Procedure which includes the examination and marking and/or issuing of a verification certificate that ascertains and confirms that the measuring instrument complies with statutory requirements.

Calibration
Result of the action of calibrating an instrument. To calibrate means to determine the deviation between the measurement value and the true value of the measure under specific measurement conditions.

Adjustment
Adjusting is the action of setting a measuring instrument or standard so that the measured value is correct, or deviates as little as possible from the correct value, or the deviation remains within acceptable limits of error.

Principles of assurance of metrological control, CHAPTER II
THE METROLOGICAL CONTROL SYSTEM, INTERNATIONAL DOCUMENT, OIML D 16, Edition 1986
OIML
www.oiml.org/publications

National Institute of Standards and Technology (NIST)
http://ts.nist.gov

For more about Good Weighing Practice™, risk evaluation, or effective scale operation, log onto
www.mt.com/gwp

Professional factory service is offered by METTLER TOLEDO
www.mt.com/service

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Reaching Specified Food Attributes

with Compliant Analytical Instruments

Increasing consumer safety and public health awareness pose some demanding challenges on the food and beverage industry of today. At the same time, the pressure on margins is rising too. Hence, the food and beverage industry is walking on a narrow path between high process efficacy and low process risks. Despite the cost pressure, to compete in the market the food industry needs to produce safe and high quality food.

Analytical instruments play a key role in the biological, chemical and physical examination of raw materials, of finished food stuff but also of elements like the packaging material etc. By investing in the correct measuring and monitoring devices and by maintaining them regularly companies can reach compliance with internal and external standards more easily. By training the staff professionally the level of performance can be enhanced additionally.

The better the biological, chemical and physical analyses the greater are the control possibilities in production, and the closer are the properties of the finished product to the specifications. High precision measuring devices that undergo frequent performance verification assure the attributes that are desired. Also from a cost of ownership perspective, getting it right the first time costs considerably less than measuring and evaluating repeatedly.

Content

METTLER TOLEDO

1 The Quality Umbrella: Good Measuring Practices

Guided by considerations on process safety, METTLER TOLEDO has published a series of eight guidelines specific to various product lines under the umbrella of the Good Measuring Practices program. They were developed as a tangible means of translating the well-established and widely enforced, albeit rather generic working instructions, such as good laboratory practice (GLP) or good manufacturing practice (GMP), into specific sets of guiding principles for its own product portfolio, which are, however, also fully applicable for any other manufacturers' instruments.

Recognizing the paramount importance of standardized methods, various industrial guidelines were established between 2007 and 2016, covering technologies used for standard chemical and physical measurements and analysis such as weighing, titration or pipetting, conductivity or pH measurement, determining density or refractive indexes, or thermal analysis.

The guidelines address all critical interactions between the instrument, its location and environment and the operator, starting by evaluating the application-specific needs and then selecting the models best suited to comply with these requirements. Next, the program provides standard procedures for equipment installation and qualification and for extensive operator training, guaranteeing a smooth start – free of application errors and complications. Finally, the guidelines recommend appropriate routine operations, such as frequent verification testing by the operator and regularly scheduled maintenance services with subsequent calibration executed by the manufacturer's field service technicians. These measures are recommended to ensure optimized operating hours, to guarantee accuracy of the measuring processes and thus to minimize the risk of out-of-specification results.

While meeting these guidelines can sometimes be cumbersome, not meeting them can cause products to be ineffective. The Good Measuring Practices program provides continuous proactive support throughout the entire lifecycle of laboratory equipment, giving the user the confidence that he can run the instrument at any time within proper operational conditions and thus always fully rely on the results without any compromise on quality.

2 Risk-Based Management Approach

Ensuring that manufacturing processes critical to product quality generate results within predefined tolerance windows is fundamental. The potential risk for economic damage related to not meeting such quality requirements is specific to each process step and therefore needs to be thoroughly assessed together with the responsible manager. Appropriate quality assurance measures are then to be identified, implemented, documented and continuously monitored.

Ensuring that the final results are always within these very often rather narrow process tolerance ranges requires an in-depth knowledge of the applications, a thorough understanding of the underlying measuring principles, and – most importantly – a continuous control of the operational state of the equipment in use. Anything less means leaving results to chance.

All Good Measuring Practices guidelines involve a scientific process-specific risk check. The assessment of the risk associated with each measuring process provides the instrument operator with detailed recommendations on frequency and method for regular performance verifications, and proposes intervals for preventive maintenance visits. Only such a holistic view of the entire measuring process allows proper instrument performance day-in, day-out, all year around.

Implementing a systematic and scientific evaluation approach for optimal equipment selection, installation and maintenance is the only way to safeguard consistent adherence of critical manufacturing standards to process requirements across various production locations – and even throughout the industry. This ensures not only manufacturing accuracy but consistent product quality for enhanced safety industry-wide.

3 The Eight Guidelines

METTLER TOLEDO'S Good Measuring Practices program currently hosts eight different guidelines, each specific for a group of instruments, all of them providing application-driven, risk-based management advice for laboratory equipment. This includes

- **GWP® – Good Weighing Practice™**
  for laboratory balances, scales and moisture analyzers;
- **GTP® – Good Titration Practice™**
  for titrators;
- **GPP™ – Good Pipetting Practice™**
  for pipettes;
- **GDRP™ – Good Density and Refractometry Practice™**
  for density meters and refractometers;
- **GEP™ – Good Electrochemistry Practice™**
  for pH, redox, conductivity, ion and dissolved oxygen meters;
- **GTAP™ – Good Thermal Analysis Practice™**
  for thermal analysis instruments;
- **GMDP™ – Good Melting and Dropping Point Practice™**
  for melting and dropping point instruments;
- **GUVP™ – Good UV/VIS Spectroscopy Practice™**
  for ultraviolet and visible light spectrophotometers.

4 The Five Steps in Each Lifecycle

Each of the Good Measuring Practices guidelines introduced above and described in more detail in later chapters of this paper is structured in five steps that represent key moments in the lifecycle of an instrument. The guidelines present advisory support beginning already with pre-purchase considerations, going all the way to recommendations for testing, calibrating and maintenance interventions during the many years of daily operation.

For all these stages in an instrument's life, Good Measuring Practices consultants provide a process framework to maximize operational security. Each guideline can therefore be considered as an easy-to-follow sequence to identify appropriate quality assurance measures for handling laboratory instrumentation in any given quality management system.

Keeping an eye on risk and security equilibrates process hazards with testing efforts and operational efficacy in every one of the following five basic steps of an instrument's lifecycle:

- Evaluation of application, environment and instrument requirements – gaining a detailed understanding of all criteria to be taken into account for setting up an efficient workflow while achieving secure processes and high-quality results, and, last but not least, guaranteeing safe data handling;
- Selection of the instrument – identifying the best suited package of equipment plus service that meets the financial budget and best complies with process requirements over a long period of time;
- Instrument Installation / Operator Training – ensuring professional installation and setup of the instrument followed by an in-depth user familiarization on operational fundamentals by the manufacturer's experts;
- Initial Qualification / Regular Calibration – testing and releasing the instrument for dedicated routine operations, ensuring full compliance with internal quality standards as well as global and local industrial regulations and norms;
- Routine Operation – providing explicit guidance on optimal frequency and methods of process verification by the operator, and recommendations for scheduling preventive maintenance and re-calibration visits by the manufacturer's service team.

All Good Measuring Practices guidelines follow this lifecycle consultancy in five steps; however, depending on the very nature of the various instrument groups, the focus of steps 3 and 4 differs slightly between guidelines in order to give more emphasis to topics of superior importance to the instrument's risk-based lifecycle management.

5 How Can the Guidelines Assist?

Each step of the lifecycle of the Good Measuring Practices guidelines contains business-relevant deliverables for the responsible managers in various departments of any company such as the quality assurance manager, the department head, or the procurement officer, who typically focus on both product quality and process profitability. However, the guidelines also contribute significantly to trouble-free applications and are thus of interest to instrument operators, providing fundamental knowledge and practical tips and tricks for smooth and uninterrupted workflows. The guidelines may assist regarding the following topics:

- **Quality assurance:** The guidelines provide the scientific fundament for top quality, highly accurate measuring results, combining the operator's application expertise with the manufacturer's technological proficiency and the built-in test and reminder functionalities of the instruments.
- **Minimized risk:** The guidelines were established to assist with active management of process risks by defining and implementing operational methods that ensure procedural consistency while fulfilling quality assurance and regulatory requirements taking into account environmental influences.
- **Service optimization:** Each guideline issues recommendations for testing and service schemes that are costoptimized while providing safe margins with regard to process tolerances, following the paradigm "Test as much as needed but as little as possible".
- **Audit-worthy documentation:** The guidelines further provide information on METTLER TOLEDO's equipment qualification packages and calibration certificates, obtainable in audit-proof formats, fully compliant with industrial standards and norms under any regulatory regime, professionally documenting the measuring performance of instruments and its interpretation linked to pass/fail criteria.
- **Stability and sustainability:** Last but not least, following the guidelines leads you to increased process stability and lean workflows, thus contributing to ecological sustainability, supporting reduction of process waste due to excessive testing and/or poor product quality.

Each of these guidelines ensures high process quality, particularly when coupled with professional consultation, and thus helps prevent the kind of poor results that causes economic damage due to production delays, rework or recall, or monetary losses in terms of fines and even litigation.

6 Optimized Test Procedures Are Key

The systematic approach taken in the Good Measuring Practices program seeks to ensure that sufficient action is taken to guarantee accurate and reproducible results without onerous or burdensome over-testing. This helps achieve operational continuity while taking into account process requirements and a potentially negative impact on product quality, and hence consumer satisfaction and environment.

If operators must continually test their equipment and take it offline, the impact to already thin profit margins in the fast-paced industry may become business critical if not business threatening. The guidance given in the various Good Measuring Practices frameworks for balancing process risks and testing efforts seeks to ensure optimal uptime while providing greater confidence for smooth internal quality reviews and worry-free external audits.

7 Summary

Precision measurements and chemical analysis applying technologies, such as weighing, titration, or pipetting, are common methods of various departments, such as R&D, quality control or production.

In order to guarantee adherence to internal and external norms and regulations, to enhance data and product quality, and last but not least to minimize consumer risks, it is crucial to ensure that the instrumentation is selected according to a risk-based evaluation of the application process, professionally commissioned, installed, maintained and calibrated, as well as to make sure that the operators are adequately trained.

Under the umbrella of its Good Measuring Practices program, METTLER TOLEDO has developed eight scientific, risk-based management guidelines for various technologies relevant in most research, production and quality control laboratories.

Applying the holistic approach embedded in all of METTLER TOLEDO's Good Measuring Practices guidelines is the only way to secure long-term process consistency, performance reliability and overall data quality day-in, day-out. This approach addresses the basic quality needs for a food manufacturer at all workbenches of research, production and quality control departments.

Good Measuring Practices
www.mt.com/gp

8 Additional Resources

Guides and white papers
Scientific literature on current topics in the field of laboratory weighing, analytical instruments and liquid handling can be found here:
www.mt.com/lab-library

Webinars
METTLER TOLEDO provide web-based seminars (webinars) on different topics. Check out Good Weighing Practice™ - The Global Weighing Guideline, at:
www.mt.com/webinars

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www.mt.com/ind-food-guides
For more information

Moisture Analyzer

Routine Performance Testing

Moisture affects the processibility, shelf life, usability and quality of many food products. Errors when conducting moisture analysis may negatively impact quality results and influence product prices. This white paper offers guidance on how to optimize moisture content determination and instrument performance.

Most products and ingredients have optimum moisture content for obtaining the best possible processing results and therefore attaining maximum quality. Furthermore, moisture content impacts on price and there are statutory rules for some products governing the maximum permissible moisture content (e.g. as defined by national food regulations). This means that trade and industry need to determine moisture content levels.

To run measurement equipment and analytical instruments in a quality system, industry specific regulatory requirements often have to be followed. But regulatory guidance is commonly not very specific. They do not offer specific statements as to how the guidelines should be achieved in everyday practices. Questions such as "How often should I test my instrument?" are not answered.

This white paper describes the influences and sources of error which may be present when conducting moisture analyses. It discusses the routine tests which are necessary to ensure reliable determination of the moisture content and correct functioning of the instrument. The recommended tests and their frequencies are presented in the framework of a risk-based approach.

Contents

METTLER TOLEDO

1 Influences on Accuracy

The accuracy of moisture analyzer results may be influenced by several factors. The most important are variability of the heating temperature, of the weighing results and of the sample characteristics. In this white paper we elaborate on how these influences on the accuracy affect the final drying result and how these influences can be controlled by performing appropriate routine testing. It is important to know that there are two types of influences that can limit the performance of an instrument - permanent and temporary influences.

Permanent influences occur and persist. They limit the accuracy of the moisture analyzer and will be detected when the next performance test is carried out. They do not disappear until a corrective action has been taken. Temporary influences limit the accuracy of a moisture analyzer only for the duration of the influence. The limitation on the accuracy will disappear without any intervention or corrective action as soon as the influence has stopped.

Safety factor

Reproducibility of the moisture content as determined from a limited number of measurements will vary, even if the setup is left unaltered. Besides these statistical variations, environmental conditions, sample handling and different operators influence the performance of the moisture analyzer. It is therefore recommended to apply a safety factor to stay within the defined acceptance criteria. It is good practice to define two different acceptance criteria, the warning and the control limit. The control limit represents the limit value which has to be adhered to in order to satisfy the required accuracy. The warning limit is defined as the control limit divided by the safety factor and provides an early warning to indicate that the accuracy of the moisture determination might deteriorate. It is recommended to apply a safety factor of minimum 2 by default to compensate for the variations. The safety factor should be increased in accordance with the strength of the expected influences. I.e. in rough environments a higher safety factor should be applied.

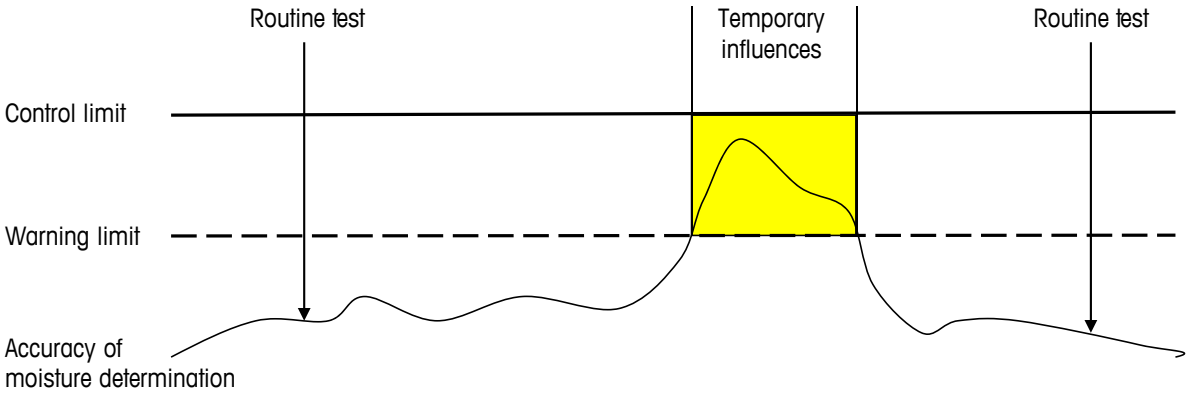

Figure 1: Temporary influences may affect the accuracy of a moisture analyzer without being detected by a routine test. The safety factor builds a margin between the warning and control limits to lower the probability that measurements exceed the control limit even if temporary external influences reduce the accuracy.

2 Accuracy of Moisture Analyzer Results

The following chapters focus on the main permanent influences that affect the determination of moisture content. To find out what the main influences are and what measures are meaningful in terms of quantifying the accuracy of a moisture analyzer, the questions below need to be answered.

- What causes variations of moisture content results [%MC] in a moisture analyzer?
- Where do these influences come from?
- How strong are the influences with regard to the accuracy of the moisture determination?
- What measures can be taken to control these influences?

Variability in moisture analyzer results is mainly influenced by three elements: the heating unit, the weighing unit and the sample itself.

Heating unit

Heating temperature variability

Possible reasons for variability of the heating temperature are:

- The heating unit is not adjusted correctly or has not been adjusted on site, under working conditions.
- The instrument location has changed since the last adjustment/calibration.
- The protective glass or reflector is contaminated.
- The temperature sensor is defective or contaminated.
- The temperature calibration kit is defective.
- The correction values of the temperature calibration kit were not applied correctly during temperature adjustment.

Impact of temperature variability on the moisture result

If the heating temperature is too low:

- Not all moisture is able to evaporate since lower layers of the sample are not heated enough.
- Only a certain part of the moisture evaporates (e.g. ethanol but not water).
- Only the surface water but not the crystal water evaporates.

If the heating temperature is too high:

- Components may oxidize, burn or combust.
- Properties of the substance change and not all moisture can evaporate (e.g. paint or glue forms a skin when the drying temperature is too high).

Temperature elasticity of the sample

It is important to know how susceptible the sample is to the variations in heating temperature. For some substances, the result of the moisture determination (%MC) barely changes even when the heating temperature changes considerably. Other substances show large differences in moisture content when the heating temperature varies only slightly. The degree to which the %MC result of a sample is affected by a temperature change in °C is called "temperature elasticity". Therefore, the amount of influence from an erroneous temperature change depends on the temperature elasticity of the sample.

- High temperature elasticity
  Substances with high temperature elasticity exhibit a big change in the moisture content result with just a small change in heating temperature (typically organic substances).
- Low temperature elasticity
  Substances with low temperature elasticity need a big change in the heating temperature until an influence on the moisture content result is visible (typically inorganic substances).

Weighing unit

There are several properties which limit the performance of the weighing unit. The most important are repeatability, eccentricity, nonlinearity and sensitivity.

Sensitivity
Sensitivity is the ratio between the weighing value (indicated on the balance) and the actual mass of the reference weight. A sensitivity of 1 (one) means that the displayed mass value equals the mass of the reference weight. The evaluation of the moisture content [%MC] is based on the difference between the wet sample weight and the dry sample weight. Determining the moisture content is based on relative weight measurements. Hence sensitivity has no impact on the moisture result.

Eccentricity
Eccentricity is the deviation in the measurement value caused by eccentric loading, in other words, asymmetrical placement of the load on the weighing pan. Generally, the eccentricity error has no considerable influence on the moisture content result: Firstly, the weight loss due to the drying process is usually small compared to the balance capacity, and secondly, the sample is not moved during drying.

Consequently, eccentricity is not a dominant contributor to the measurement uncertainty and routine eccentricity tests by the user are not recommended.

Nonlinearity
The ideal characteristic weighing curve of a balance is a straight line through the measurement points of no-load and full load (nominal weighing capacity). Nonlinearity is the deviation of the indicated weighing value from this straight line.

A nonlinearity error has no considerable influence on the moisture content result as the weight loss due to the drying process is generally small compared to the balance capacity.

Consequently, routine nonlinearity tests by the user are not recommended.

Repeatability
Repeatability is the ability of a weighing instrument to provide identical results when the same load is placed several times and in a practically identical way on the weighing pan under reasonably constant test conditions. Repeatability is the dominant error for small sample weights. It influences both readings (wet weight and dry weight). However, repeatability has a very small influence on the accuracy as compared to a possible temperature deviation between the programmed target temperature and the actual temperature.

Relevance of deviations of heating unit and weighing unit

In general, measurement errors due to deviations between the programmed target temperature and the actual temperature are more likely and have a higher impact on the accuracy of the %MC results than measurement errors due to the influence of repeatability of the weighing unit. Also the impact of a change in heating temperature is larger for samples with higher temperature elasticity.

Hence, tests that detect temperature deviations (SmartCal, temperature calibration) are more often required than weighing performance tests.

3 Routine Testing of Moisture Analyzers

Maintaining the accuracy of an instrument and reducing the risk of being out of specification requires testing by the service provider and the user.

Service
By calibrating all measurement components of the instrument using traceable standards and manufacturer SOPs, the service provider provides a comprehensive statement of the instrument's condition.

User
In between maintenance and calibration by the service provider, the user should perform routine tests to monitor the most important parameters influencing measurement accuracy.

Instrument
Many state-of-the-art instruments include built-in test and adjustment functionalities, as well as software

and hardware features (e.g. LevelControl) that help to avoid measurement errors.

Hierarchy of tests – temperature versus weighing

As described above, measurement errors due to deviations between the programmed target temperature and the actual temperature are more likely and have a higher impact on the accuracy of the %MC results than measurement errors due to the influence of repeatability of the weighing unit. Weighing is a more stable and controlled process than heating. Hence, the risk stemming from the weighing unit is rather low, as long as no defect occurs.

Therefore, the main reason to test the weighing unit is to check its proper functioning and/or detect defects. This can be done by performing periodic sensitivity tests. Periodic testing of eccentricity, nonlinearity and repeatability is not as important and can be done by the service technician within the framework of periodic maintenance when performing a calibration. Temperature deviations are more likely and have a bigger impact on the moisture result than variability in weighing. The impact depends on the temperature elasticity of the sample.

Conclusion

The frequency of tests that focus on temperature should be higher than tests that focus on the weighing accuracy. Moisture analyzers that are used to measure the moisture content of samples with higher temperature elasticity require more frequent testing than those used for samples with lower temperature elasticity.

Recommended tests

During the routine operation of a moisture analyzer only those tests are recommended which deliver a meaningful statement with regards to controlling the quality of the measurement result.

Calibration and adjustment of weighing and heating unit (by service engineer)

Calibration by a service engineer is an extensive test of all important parameters of a moisture analyzer. Preferably, a calibration is combined with preventative maintenance where all parts are cleaned and the functions of all components are tested before calibration.

The calibration of the weighing unit comprises the comprehensive tests of the weighing parameters. If deviations from manufacturer tolerances are detected, an adjustment is carried out. The calibration of the heating unit using the temperature calibration kit is performed against manufacturer tolerances. If deviations occur, an adjustment is performed. All calibration results are documented and handed out to the user.

SmartCal test (by user)

The SmartCal test substance is highly temperature elastic and contains a specific amount of moisture which makes it an ideal test substance for verifying the performance of moisture analyzers. Specific control limits for the SmartCal test are recommended by METTLER TOLEDO.

A defect or substantial inaccuracy will be detected with SmartCal by showing a result outside the SmartCal control limits.

Sensitivity test (by user)

Performing the sensitivity test delivers an indication of incorrect adjustment of the weighing unit as well as defects of the weighing cell that require more in depth diagnosis before further use of the moisture analyzer (e.g. defect due to improper transportation).

Temperature calibration (by user)

Temperature calibration is performed by using a temperature calibration kit as a reference. Performing a temperature calibration indicates the condition of the heating unit. Temperature deviations due to changes in the environment, will be detected.

Test or adjustment with built-in reference weight (by instrument)

Testing and adjustment mechanisms built into instruments consist of one or more reference weights, and a loading mechanism that is activated either manually or automatically. Such a mechanism allows convenient testing and/or adjustment of the sensitivity of the weighing instrument.

4 Summary

Deviations of a moisture analyzer are mainly influenced by the heating unit, the weighing unit and the sample.

Temperature deviations are more likely than weighing deviations and have a bigger impact on the moisture result.

The following tests are recommended for performance monitoring of a moisture analyzer:

By the user
- SmartCal test
- Sensitivity test (SmartCal test can be done instead)
- Temperature calibration (SmartCal test can be done instead)

By service engineer
- Calibration & adjustment

By instrument
- Test with built-in reference weight (FACT, by instrument)

The frequency of each routine test depends on the risk that is associated with the measurement process.

For more detailed information, read the full white paper 'Routine Testing Moisture Analyzer':

www.mt.com/moisture-routine-testing

5 Additional Resources

- Moisture analyzers, METTLER TOLEDO
  www.mt.com/moisture

- Method Collection: Find Your Moisture Method for Food, METTLER TOLEDO
  www.mt.com/moisture-food-methods

- White Paper: Drying Oven vs. Halogen Moisture Analyzer – A Practical Guide to Compare Methods, METTLER TOLEDO
  www.mt.com/moisture-or-oven

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Intrinsically Safe Solutions

Accurate Weighing in Hazardous Areas

Accidents in hazardous areas can have dramatic consequences for businesses in terms of both human life and profit. Intrinsically safe equipment is designed to ensure process safety and to comply with hazardous area standards and regulations.

Two primary considerations must be taken into account when choosing the right weighing equipment for hazardous areas. They must be approved for the defined hazardous area classification and they must feature an appropriate method of ignition protection. When it comes to weighing applications in hazardous areas, the two most common ignition protection types available are intrinsic safety and flameproof (or explosionproof).

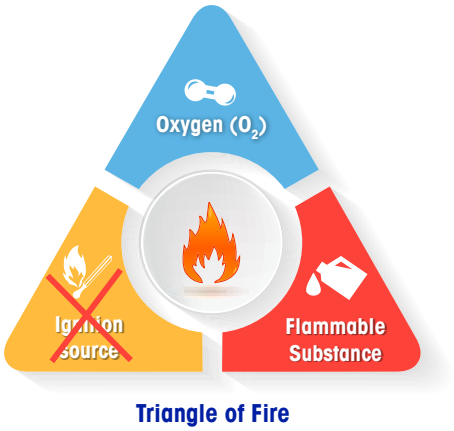
Intrinsic safety is one of the safest ignition protection types. It provides a range of benefits which sets it apart from other protection types. This white paper describes the principles of intrinsic safety and compares it to other protection methods, specifically flameproof/explosionproof. In addition, the white paper examines different weighing configurations in hazardous areas.

Contents

METTLER TOLEDO

1 Hazardous Areas and their Classifications

An explosion is the sudden exothermic chemical reaction of a flammable material with oxygen and the simultaneous release of high energy. To eliminate the risk of explosion, one of the three elements of the "Triangle of Fire" must be removed.



Picture 1. Triangle of Fire

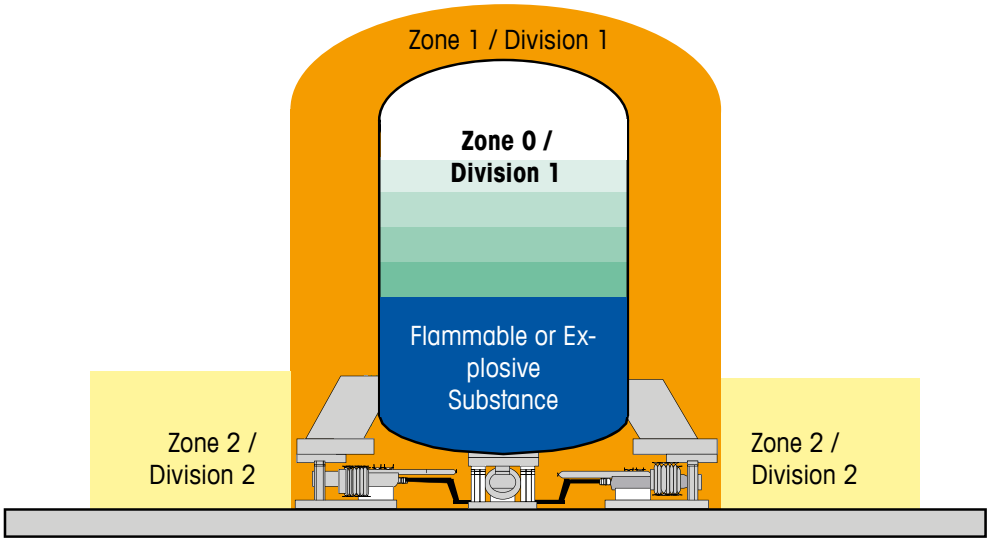
Flammable substances may be present in the form of gases, vapors, mists or dusts. Together with oxygen these substances can form an explosive atmosphere. It can be ignited by an ignition source such as flames, sparks, hot surfaces or electromagnetic fields.

One approach to prevent an explosion is to eliminate the ignition source by keeping the system's active ignition energy below the minimum ignition energy. The minimum ignition energy is the smallest amount of energy required to ignite a combustible vapor, gas or dust cloud. The minimum ignition energy is measured in joules.

For example, the explosive "hydrogen-air" mixture can ignite with very low energy input; its minimum ignition energy at atmospheric pressure is about 10-5 joules. The minimum ignition energy of dusts is in the range of several milijoules up to 100 milijoules.

Businesses conducting collection, transformation and production processes with inflammable substances are obliged to conduct hazardous risk analysis to identify the potentially hazardous areas where dangerous concentrations of explosive mixtures of flammable or explosive materials can occur. Such areas are called "hazardous areas."

When electrical equipment is used in a location classified as hazardous, it must be appropriately certified and provide the required level of protection. The selection of an appropriate protection method is based on the classification of the hazardous area. That is why it is important to understand area classifications and their differences. Picture 2 shows a weighing tank and the distribution and classification of hazardous areas.



Picture 2. Hazardous Area Definitions

Classification varies throughout the world, but generally, there are two types of classification. Europe has adopted the International Electro Technical Commission (IEC) philosophy referred to as "Zoning."

Information and specifications for zone classification are defined in the norm IEC EN60079-10 and in national standards. Furthermore, the installation and operation of electrical systems in hazardous locations and the zone classification within the European Community are defined in the ATEX 2014/34/EU Directive.

Table 1 shows an overview of the zones, divisions and the allocation of equipment for the relevant hazardous area classification.

According to the ATEX Directive, hazardous areas are divided into three zones for gases and three zones for dust substances. The classification is defined according to the probability of the presence of an explosive atmosphere. Each zone is corresponding to the particular equipment category.

In North America, areas are classified into classes. Classes are further categorized into Division 1 and Division 2, according to the probability of materials present in a potentially hazardous quantity. Class I (Gases) and Class II (Dust) hazardous areas are divided into subgroups based on the type of flammable gas, vapor or particles present. Class III (Fibers) is not divided into subgroups.

<table>
<tr><th rowspan="2">Substance</th><th rowspan="2">Hazardous area characteristics</th><th colspan="3">Hazardous area classification</th><th rowspan="2">Equipment category</th></tr>
<tr><th>USA NEC500</th><th>USA NEC505 / NEC506</th><th>ATEX 2014/34/EU</th></tr>
<tr><td rowspan="3">Gases / vapors</td><td>Explosive atmosphere is present continuously</td><td rowspan="2">Division 1</td><td rowspan="3">Class I (NEC505)</td><td>Zone 0</td><td>1G</td></tr>
<tr><td>Explosive atmosphere is likely to occur occasionally</td><td>Zone 1</td><td>2G (1G)</td></tr>
<tr><td>Explosive atmosphere is likely to occur infrequently or for short periods of time</td><td>Division 2</td><td>Zone 2</td><td>3G (1G and 2G)</td></tr>
<tr><td rowspan="3">Dusts</td><td>Explosive atmosphere is present continuously</td><td rowspan="2">Division 1</td><td rowspan="3">Class II (NEC506)</td><td>Zone 20</td><td>1D</td></tr>
<tr><td>Explosive atmosphere is likely to occur occasionally</td><td>Zone 21</td><td>2D (1D)</td></tr>
<tr><td>Explosive atmosphere is likely to occur infrequently or for short periods of time</td><td>Division 2</td><td>Zone 22</td><td>3D (1D and 2D)</td></tr>
</table>

Table 1 - Hazardous Area Classification according to EU and USA Standards.

2 Ignition Protection Methods

The basic safety concept is to eliminate the simultaneous existence of the possible ignition sources.
The method of protection will likely depend on the degree of safety needed for the defined hazardous area classification. In addition, other considerations must be made, such as the size of the equipment, its normal function, power requirements, installation costs and flexibility of the protection method for maintenance.

Tables 2 and 3 show an overview of the standardized types of protection for Zones and Class/Division. It describes the basic principle of each protection method as well as the applicable standard and the classified area.

While the protection methods are standardized, those standards may vary in different countries. However, the principles of protection are the same regardless of the country. When it comes to designing and developing weighing equipment for hazardous areas, the two methods, intrinsic safety and flameproof, are mainly applied. Intrinsic safety provides numerous technical and economical advantages, which makes it the preferred protection method for weighing equipment.

Protection types: zones

Protection type	Protection principle	Standard	Equipment marking	Zone
General regulation	Basis for protection type	IEC/EN: 60079-0 ANSI/ISA: 60079-0 CSA: C22.2 No. 60079-0	EU: Ex USA: AEx Canada: Ex	Gas/dust
Intrinsic safety 'I'	Limit energy; no sparks or hot surfaces that can cause an ignition	IEC/EN: 60079-11 ANSI/ISA: 60079-11 CSA: C22.2 No. 60079-11	ia ib ic	0/20 1/21 2/22
Flameproof enclosures 'd'	Enclosure can withstand an internal explosion without igniting external atmosphere	IEC/EN: 60079-1 ANSI/ISA: 60079-1 CSA: 22.2 No. 60079-1	db db	1 2
Protection by enclosure 't'	Special enclosure design (dust) to exclude explosive atmospheres	IEC/EN: 60079-31 ANSI/ISA: 60079-31 CSA: 22.2 No. 60079-31	ta tb tc	20 21 22
Increased safety 'e'	Dust and water tight enclosure. Prevent sparks or hot surfaces	IEC/EN: 60079 -7 ANSI/ISA: 60079-7 CSA: 22.2 No. 60079-7	eb ec	1 2
Non-sparking 'n'	Non-sparking equipment	IEC/EN: 60079-15 ANSI/ISA: 60079-15 CSA: 22.2 No. 60079-15	nA	2
	Sparking with protection		nC	2
Encapsulation 'm'	Keep explosive atmosphere away from ignition source	IEC/EN: 60079-18 ANSI/ISA: 60079-18 CSA: 22.2 No. 60079-18	ma mb mc	0/20 1/21 2/22
Pressurized enclosures 'p'	Prevent ingress of explosive gas atmosphere	IEC/EN: 60079-2 ANSI/ISA: 60079-2 CSA: 22.2 No. 60079-2	pxb/pyb pzc	1 2
	Prevent ingress of explosive dust atmosphere		pb pc	21 22
Oil immersion 'o'	Keep explosive atmosphere away from ignition source	IEC/EN: 60079-6 ANSI/ISA: 60079-6 CSA: 22.2 No. 60079-6	ob ob	1 2
Powder filled 'q'	Prevents ignition from spreading by snuffing in an inert powder	IEC/EN: 60079-5 ANSI/ISA: 60079-5 CSA: 22.2 No. 60079-5	qb qc	1 2

Table 2. Protection Methods and Related Electrical Standards for Zones

Protection types: class/division

Protection type	Protection principle	Standard	Class	Division
General	Basis for protection type	FM3600	I,II,III	1 and 2
Intrinsic safety	Limit energy; no sparks or hot surfaces that can cause an ignition	FM3600 UL913	I, II, III	1 and 2
Explosionproof enclosure	Enclosure can withstand an internal explosion without damage and without igniting external atmosphere	FM3615 UL1203	I	1 and 2
Non-incendive equipment	Equipment with circuits where any arc / heat released is incapable of igniting a flammable atmosphere	ISA 12.12.01 FM3611	I II III	2 2 1 and 2
Purged and pressurized	Purge enclosure with protective gas, prevent entrance of flammable compounds	NFPA 496	I, II, III	1 and 2
Dust ignition-proof	Enclosure does not allow entrance of dust, prevents ignition of exterior atmosphere	FM3616 UL1203	II, III	1 and 2
Dust-tight enclosure	Enclosure prevents entrance of dust	NEMA 250 UL50E	II III	2 1 and 2
Hermetically sealed	Equipment which is completely sealed by fusion to prevent contact with the external atmosphere	—	I II III	2 2 1 and 2
Oil immersion	Keep the explosive atmosphere away from the ignition source	—	I	2
Gas detection system	Power to system is shut off when presence of combustible gas is detected	ANSI/ISA 12.13.03 FM6320	I	1 and 2

Table 3. Protection Methods and Related Electrical Standards for Class/Division

3 Intrinsic Safety – Basic Principles

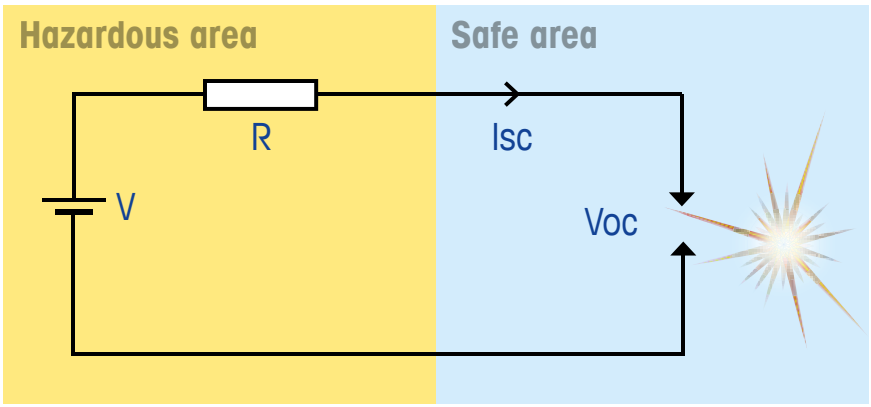
Since it was introduced in non-mining applications, intrinsic safety has evolved to become one of the most commonly used protection methods in process industries. Today, intrinsic safety is one of safest and most advanced methods of ignition protection. It has become the method of choice because, independent from the application, it keeps the entire system safe.

Intrinsically safe technology prevents explosions by ensuring that the energy transferred to a hazardous area is well below the energy required to initiate an explosion. As such, it is restricted to electrical apparatuses and circuits in which the output or consumption of energy is limited. Intrinsically safe systems enable equipment to be used without risk of igniting any flammable gas, dust or fibers that may present in hazardous areas.

Intrinsically safe circuit

An electrical circuit is intrinsically safe when it produces energy below the minimum ignition energy (MIE), which is defined by the appropriate standards. In Europe, IEC EN60079-11 specifies the construction and testing of intrinsically safe equipment; in the USA, FM3610 does this. Intrinsically safe electrical equipment is designed to limit the open circuit voltage (Voc) and the short circuit current (Isc) to keep the produced energy at the lowest possible level.

It also must be done in such a way that sparks produced when opening, closing or earthing the circuit or produced by any other hot part of the circuit itself would not cause ignition. Intrinsically safe electrical equipment and wiring can be used in hazardous areas classified as Zone 1/21 and Division 1 as long as they are approved for the location.



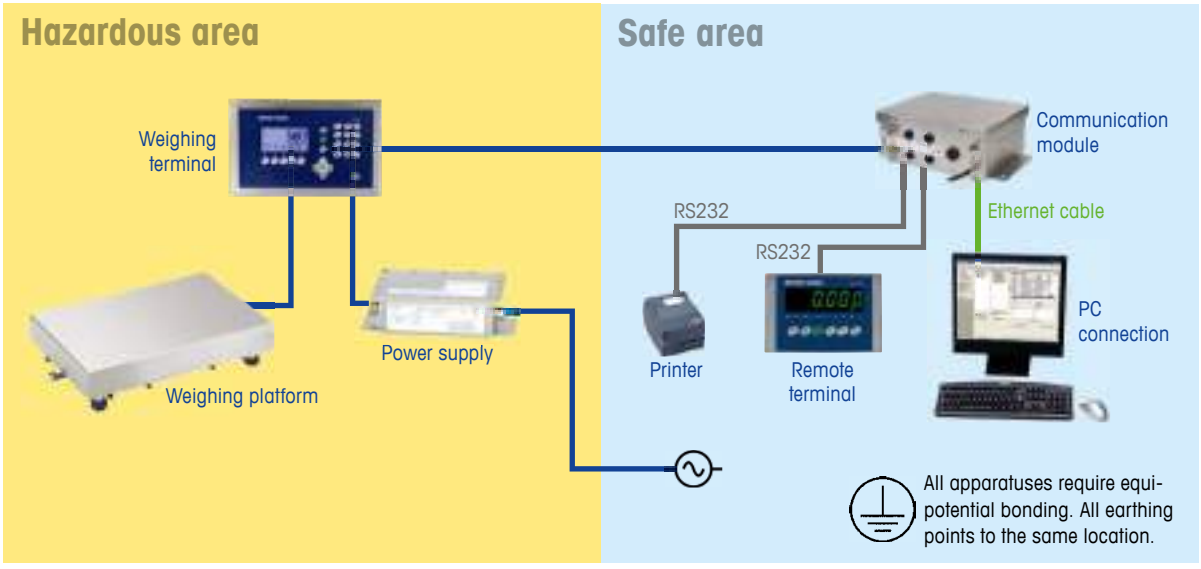
Picture 3 Intrinsically Safe Circuit.

Intrinsically safe system

An intrinsically safe system may combine intrinsically safe elements, associated elements and special approved wiring with standard equipment, which is installed in the safe area. All elements of the system must be compatible to form an intrinsically safe system.

Let's consider an example with an intrinsically safe weighing system (picture 4). In our example, the intrinsically safe apparatus consists of an analog weighing platform and the intrinsically safe weighing terminal IND560x. The intrinsically safe power supply APS768x serves as the power source for the weighing terminal and is defined as a simple apparatus. Communication to the standard peripherial instruments, such as PC, barcode reader or even remote control terminals, is possible through a special barrier. This is achieved via a communication interface ACM 500, which encompasses both intrinsically safe and non-intrinsically safe electrical circuits.

In an intrinsically safe system, physical barriers are used between the hazardous and safe areas to limit the energy that enters the hazardous area. Intrinsically safe barriers maintain approved levels of voltage and current via power limiting components. They ensure that even under fault conditions, no more than the approved voltage or current enters the hazardous area. This allows standard electrical devices installed in the safe area, such as printers, computers and PLC systems, to be directly linked into a hazardous area.



Picture 4. Intrinsically Safe Weighing System

Levels of classification and protection

Intrinsic safety offers three classification levels, "ia," "ib" or "ic," which are based on the safety level and number of faults possible. Each classification attempts to balance the probability of an explosive atmosphere being present against the probability of an ignition occurring. The level of protection "ia" is a prerequisite for Category 1 equipment and is suitable for use in Zone 0/20. The level of protection "ib" for Category 2 equipment is suitable for use in Zone 1/21 and Division 1. The level of protection "ic" for Category 3 is suitable for use in Zone 2/22 and Division 2.

The classifications ensure that the equipment is suitable for an appropriate hazardous application. For example, having equipment classified as "Ex ib" means that the equipment is designed containing an intrinsically safe circuit and can be installed in the certified hazardous areas Zone 1/21 and Division 1. Moreover, the "ib" classification indicates that one fault is possible.

Table 4 presents different protection levels, the numbers of faults possible and the appropriate hazardous area.

Protection level	ai	ib	ic
Hazardous area	Zone 0, 1, 2 / Division 1	Zone 1, 2 / Division 1	Zone 2 / Division 2
Faults possible	2	1	Normal operation

Table 4. Intrinsically safe protection levels

4 Intrinsic Safety Benefits

In Europe, intrinsically safe systems have become the standard solution for weighing in hazardous areas. In other regions such as Asia or North America intrinsically safe weighing systems are quickly gaining acceptance over the traditional flameproof or explosion-proof protection methods. This development can be attributed to the significant benefits intrinsic safety offers compared to other protection methods.

With intrinsically safe equipment, the ignition of an explosive atmosphere is not possible because the energy in the equipment is limited below the level required to generate sparks or hot surfaces that could cause an ignition. It is very unusual that errors will occur in an intrinsically safe device and in the rare occasion that an error occurs it will not cause an explosion.

Intrinsically safe equipment and components such as cables and cable glands are relatively inexpensive and installation is less complex than with flameproof/explosionproof equipment. An explosion proof system requires a sophisticated enclosure which is able to contain and vent an internal explosion without igniting the surrounding atmosphere. This also leads to higher efforts because heavy conduits and bolted enclosures need to be installed.

Maintenance of intrinsically safe equipment is easier and requires less time than with explosion proof enclosures. The reason is that opening and closing the heavy, bolted explosion proof enclosures is labor intensive. In addition, great care needs to be taken to ensure the integrity of the enclosure before restarting the system. However, also with intrinsically safe weighing systems it is important to make the area safe when conducting maintenance activities.

Explosion proof housings include safety provisions to contain and vent a possible explosion which makes them larger and heavier and which also leads to mechanical and structural complications. Intrinsic safety enables the design of compact and modular solutions that can be better tailored to the process requirements and easily integrated into existing structures.

International and local certification bodies such as IECEx, ATEX, NEC, NEPSI, TR-CU, KTL, and others accept the intrinsic safety protection method. Explosion proof (NEC) and Flameproof (IECEx/ATEX) protection methods on the other hand are subject to different standards, while other protection methods are only accepted by individual certification bodies. However, there are some differences within the national standards on how intrinsic safety is defined.

5 Summary

Weighing is an important component of many manufacturing processes, and it requires special attention when conducted in potentially explosive environments. The two most common methods for the implementation of hazardous area approved weighing solutions are intrinsic safety and flameproof/explosionproof. However, intrinsically safe weighing technology is seeing significant growth as it combines several benefits that help manufacturers ensure process safety while improving productivity.

Intrinsically safe weighing systems are less expensive and can be installed faster. The systems are less heavy and bulky and can be easily integrated into existing infrastructure. They provide the same weighing functionality as in the safe area which ensures accurate, reliable and efficient weighing processes.

A wide range of weighing platforms weigh modules and control terminals are available to implement hazardous area weighing applications from simple manual to highly automated weighing processes such as filling, dosing or checkweighing. Flexible data interfaces ensure seamless integration into the production data management systems.

Most importantly, intrinsic safety can be considered the safest and most advanced method of ignition protection. Intrinsically safe systems enable equipment to be used without risk of igniting any flammable gas, dust or fibers providing an extra level of confidence in the safety of the process.

6 Additional References

- IEC EN 60079-0: Explosive Atmospheres – Part 0: Equipment – General Requirements
- IEC EN 60079-10-1: Explosive Atmospheres – Part 10-1: Classification of Areas – Explosive Gas Atmosphere
- IEC EN 60079-11: Explosive Atmospheres – Part 11: Equipment protection by intrinsic safety "i", 5th Edition
- ATEX Directive 2014/34/EU: Guidlines on Application, European Comission, First Edition, 2016.
- National Electrical Code®, Article 500, NFPA 70, 2011, Delmar: Nacional Electric Code
- National Electrical Code, Article 505, NFPA 70, 2011, Delmar: Nacional Electric Code
- METTLER TOLEDO Hazardous On-Demand Webinar Standards and Regulations – **www.mt.com/ind-hazweb-standards**
- METTLER TOLEDO Hazardous On-Demand Webinar Protection Methods – **www.mt.com/ind-hazweb-protection**
- METTLER TOLEDO Hazardous Catalog – **www.mt.com/ind-hazcat**
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