White Paper

Enhanced User Safety in Weighing

Although not obvious to many, weighing, especially of hazardous substances, poses a significantly health risk to the operator. In fact, weighing has been identified as the largest risk of exposure to airborne and other contaminants, due to the close proximity between substance and analyst.

This white paper gives an overview of the different safety risks of weighing and provides solutions for a safer lab life.

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METTLER TOLEDO

Introduction

1. Overview

Chemical advances enabled by modern manufacturing techniques are creating new safety challenges for the chemical industry. As never before, the industry must systematically protect its analysts from the hazards of handling toxic or reactive substances. Protecting consumers from Out Of Specification (OOS) or contaminated final products is also of paramount importance.

Toxic and reactive compounds can have mutagenic, carcinogenic, developmental or reproductive toxicity or side effects at low doses. They may be easily absorbed through breathing or touch. They can show poor or no warning properties when ingested (delayed effect). Difficulties inherent in handling finely-milled substances also create heightened risks to operators coming in contact with them.

As toxic and reactive substances continue to be developed, the risk of over-exposure will continue to rise, requiring even greater levels of processing precision to protect consumers and limit analyst ingestion of these potentially toxic substances. Precision dosing and weighing procedures can help protect operators, avoid contamination to ease end users' mind, and shield manufacturers from industry fines and reputation-damaging lawsuits.

2. Defining safety/security risks

2a. Analyst exposure

From a manufacturing standpoint, exposure to toxic substances for those who work with them is a primary concern. The highly potent nature of hazardous substances, as well as their increased physical activity, has meant a tightening of workplace exposure limits. The first step in defining acceptable exposure is defining process risk, which includes determining:

- Amounts of a substance being handled;
- The standard weighing process (handling) duration;
- Whether the substance is isolated or diluted; and
- Whether the measured substance is solid, liquid or gaseous.

Any risk analysis must take into account when and where employee exposure occurs, and if it is possible to establish appropriate protective measures based on the lab's typical weighing procedures. Unfortunately, some of the basic strategies historically used to protect operators create risks of their own. Personal protective equipment (PPE) can be cumbersome, often requiring adjustment – yet an inadvertent tug can risk sample on gloves coming into contact with mucous membranes or exposed skin.

Containment systems, on the other hand, are designed around the process, not the person. Available solutions include fume hoods, BioSafety cabinets, enclosures, glove boxes, and isolators. However, containment systems using safety gloves can restrict motion and increase the risk of spills, adding processing and cleanup time to an already lengthy sample preparation process. Atmospheric conditions are continually monitored, however, creating enhanced contamination awareness.

At the most basic level, technical measures such as PPE and enclosures are only as good as the people who are trained to use them – and only if those individuals are willing to observe safety guidelines that mandate their use. It is for these reasons that there has been a move in recent years to create processing tools up to and including completely automated handling systems that provide better surety.

2b. Airborne particle limits

Because inhalation is the most effective route for absorption of hazardous substances into the blood stream special care has to be taken to avoid inhalation. Particles of 1-5 microns size present particular hazards because they can penetrate deep into the lung. Even particle sizes in the 50-100 micron range can be inhaled. They can also be seen, making inhalation risk more apparent to the analyst. Small substance particle sizes, e.g. achieved by milling down to few microns, readily become airborne during processing. The milling process itself can also create static effects, increasing the likelihood that substances will react energetically when sample containers are opened. As particles undetectable to the naked eye become airborne, they are destined to be inhaled by operators without effective containment precautions.

Air contamination has two measurements: one related to personnel exposure, and the other measured by fixed-point sampling. Personnel-related measurements reveal employees' direct exposure. Fixed measurements give data regarding substance distribution in a room, allowing conclusions to be drawn about the effectiveness of containment systems. Requirements for determining exposure depend on sampling time and the analysis pattern's elution volume.

Current airborne exposure limits for toxic substances are quite low. For non-hazardous dusts, exposure is limited to 10mg/m^3. For highly toxic substances this drops to between 10 and 1000 ng/m^3 – a staggering factor of 1,000-1,000,000 times less allowable exposure. Thus, production facilities handling highly toxic substances must have better effective containment by a corresponding factor, and masks and gloves are simply not enough. Fortunately, newer systematic containment strategies and dosing procedures can help keep airborne exposure limits at or below required levels.

2c. Surface particles/touch contamination

Surface contaminants must also be monitored as part of any robust containment plan. Slightly larger particle sizes – typically >30 µm, and still difficult to see – can settle, creating a risk for touch contamination and dermal absorption. An analyst can easily touch a contaminated surface, and then touch mucous membranes in the eye or nose for immediate absorption into the bloodstream. Contact with open skin while cleaning with solvents can also allow these substances to be absorbed directly through the skin via any small tear in gloves or other protective gear as well.

2d. Data integrity/OOS results

When considering safety in handling hazardous substances, traceability and data integrity is also critical. Complex manual sample preparation can have dozens of steps, including determining container tare, recording weights/amounts and transferring powders between storage containers and volumetric flasks or other measuring devices. How much of a substance has been dosed, and how much is still in storage? Any misrepresentation of data throughout this process can mean incorrect dosages and thus, OOS results.

Development of precision dosing and weighing procedures that help prevent OOS results can ease consumers' minds and help protect manufacturers from industry fines and reputation-damaging lawsuits. Robust and fully-traceable automated dosing equipment and other smart lab devices can help ensure data integrity, providing enhanced safety for lab operators, the company, and end users of chemicals.

2e. Explosions

In the chemical Industry, where solvents and other inflammable substances are utilized, there is an immanent risk of explosions. Areas, where explosive substances are handled, are termed as hazardous locations. They are defined as locations where concentrations of flammable dusts, vapors or gases occur. This risk implies stringent requirements for any electrical equipment used in hazardous areas. For instance, instruments have to be designed as not to initiate an explosion. For instruments in normal environments, it does not matter much if contacts of instruments are arcing (This is for example the small visible spark that occurs when instruments, e.g. lights are switched on) or if instruments develop high surface temperatures. Electrical equipment intended for use in a chemical factory or refinery is designed either to contain any explosion within the device, or is designed not to produce sparks with sufficient energy to trigger an explosion.

In an industrial plant such as a refinery or chemical process plant, handling of large quantities of flammable liquids and gases creates a risk of leaks. In some cases the gas, ignitable vapor or dust is present all the time or for long periods. Other areas would have a dangerous concentration of flammable substances only during process upsets, equipment deterioration, or during an incident. Refineries and chemical plants are divided into areas of risk known as divisions or zones.

For gases, vapors and mists the zone classifications are:

- Zone 0: A place in which an explosive atmosphere consisting of a mixture with air of dangerous substances in the form of gas, vapor or mist is likely to occur in normal for more than 1000hrs per year.
- Zone 1: A place in which an explosive atmosphere consisting of a mixture with air of dangerous substances in the form of gas, vapor or mist is likely to occur in normal operation between 10-1000hrs per year.
- Zone 2: A place in which an explosive atmosphere consisting of a mixture with air of dangerous substances in the form of gas, vapor or mist is not likely to occur in normal operation but, if it does occur, will persist for less than 10hrs per year.

Explosion danger symbol

Hazardous areas extend to laboratories and production areas and are a big safety concern for those working in the designated areas. Of course, this also has major effects on the instrument selection and also concerns weighing processes, where there is a high risk of evaporation, for instance during dosing processes.

3. Manual Weighing Challenges

3a. Weighing as a safety concern

Because sample preparation is typically multi-step, sample weighing has been identified as one of the most obvious points where protracted exposure to highly toxic substances occurs. Primarily, the risk is for airborne contaminants, due to the way the operator interacts with the sample and balance when transferring substances from containers to tare weighing plates or paper.

Manually handling hazardous substances with care – especially when they have the potential to go airborne – takes time. Complying with PPE requirements can also add extra time to already complex manual processes, which increases length of exposure and can negatively impact productivity in the fast-paced chemical world where there is crushing pressure to immediately deliver to the markets.

Containment systems such as glove boxes and PPE can also be uncomfortable and restrictive. Small samples can be particularly difficult to weigh under excessive gear restraint. Any spill necessitates the kind of cleanup that creates added processing time and dermal absorption risk. In short, for small amounts of hazardous substances, weighing can be made one of the most difficult parts of sample preparation due to its duration coupled with difficulties inherent in many PPE regimens and containment equipment.

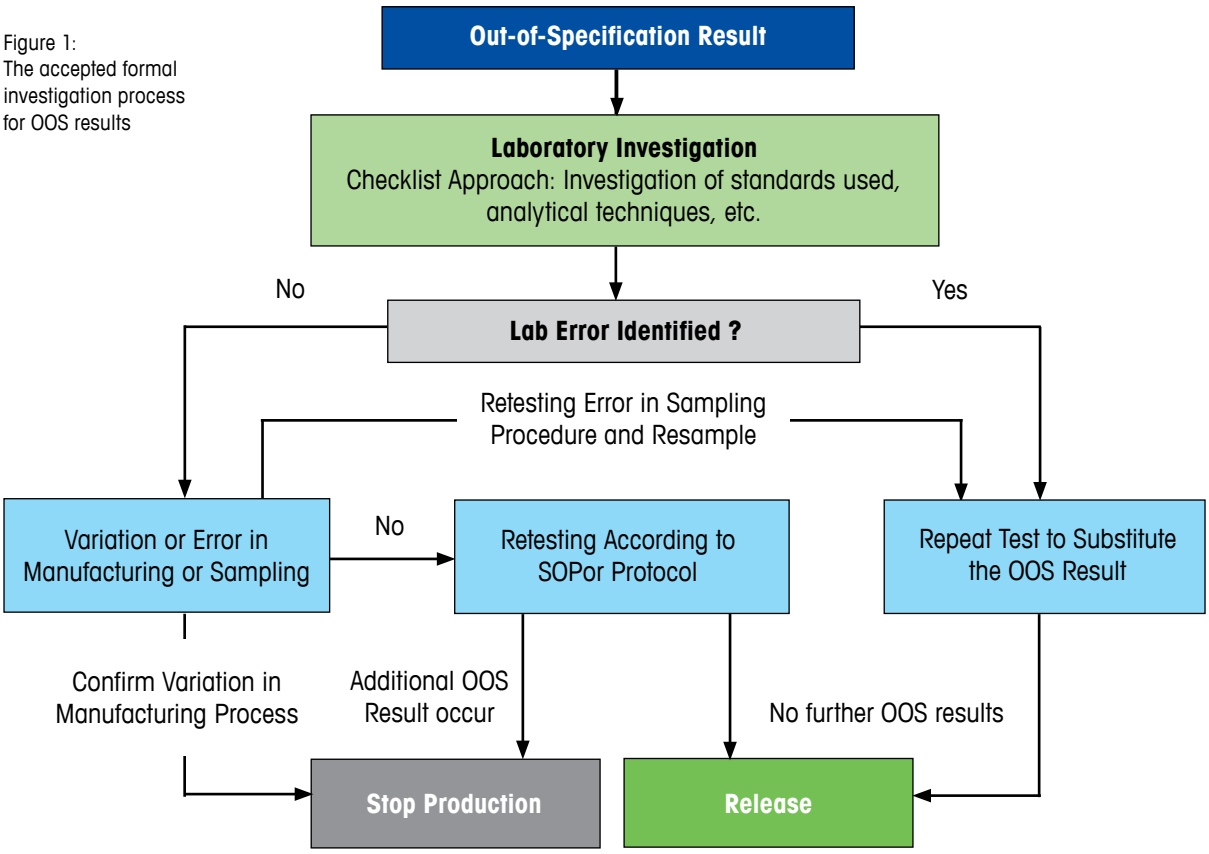
3b. OOS sources and impacts

Not only does the handling of these active substances pose a safety risk to the operators who handle them. Because of the inherent difficulties in the weighing process itself – particularly under the restraint of necessary exposure risk-reduction gear – OOS results are much more likely to occur and also carry risk to process safety and company resources.

OOS results have had a significant impact on the industry for years, not only in chemical industry, but also in the pharmaceutical industry, particularly since 1993 when courts decided in a U.S. court case involving Barr Labs that an OOS result did not necessarily constitute a simple (and relatively easily written-off) batch failure. Further, they determined these results should be investigated to see if there was fault on the part of lab personnel or other systematic production error that could be changed to help make sure similar results did not occur in the future. As a consequence, for example the U.S. Food and Drug Administration (FDA) updated their investigation guidelines as recently as 2006 (Figure 1). Since then, the FDA has issues a significant number of observations concerning poor investigations, noting that "frequent errors suggest a problem that might be due to inadequate training of analysts, poorly maintained improperly calibrated equipment, or careless work."

Prior research also supports the idea that the two largest sources of OOS results are sample processing followed by human error, and that sample processing – which almost without fail always includes weighing – is by far the most time-consuming task, particularly when performed manually. In fact, because of improvements in instrumentation and data processing, the amount of time spent manually preparing samples as a percentage of an operator's workday is very likely to have increased since the accompanying figures were created (Figure 2).

Figure 1:
The accepted formal investigation process for OOS results



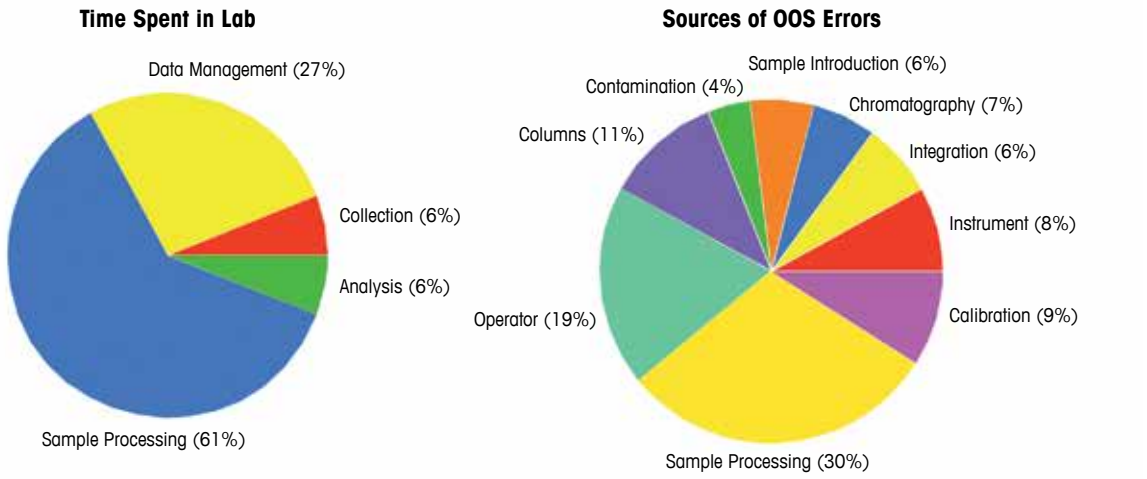


Figure 2: Sources of OOS results and time spent in laboratory

The great deal of effort expended researching and tracking down the cause of OOS results erodes valuable production time and analyst energy. While some cases take as little as three days to resolve, up to a month or more may be required to satisfy FDA or other regulatory bodies investigation requirements, with costs running into tens of thousands of dollars very easily. Lost production time can push costs to the company far above the costs of running the investigation itself.

One other impact OOS results and attendant investigations is mounting Corrective and Preventive Actions (CAPAs) that seem to multiply, complicating and in some cases even subverting safety procedures. Over time, they have the potential to become unmanageable, and in fact produce more procedural issues that create risks and productivity drains of their own.

Finally, given the impact that OOS results can have on a company's productivity and profits, every effort should be made to avoid them in the first place through smart procedures and even smarter equipment, when appropriate.

3c. Potential sample preparation errors

Data variability can be created by poorly implemented PPE and containment strategies and promote OOS results. Variability in weighing data comes in two types: determinate and indeterminate. A determinate error has definite direction, magnitude, and an assignable cause that can be eliminated with system adjustments. Indeterminate errors, on the other hand, are considered random. These can be minimized through smart system design or adjustment.

The largest cause of indeterminate errors in sample preparation is the human element during process points such as adding material to the weighing container, closing draft doors, allowing the balance to settle, and adding material when required. The balance itself and other equipment account for most determinate errors.

One of the most critical yet preventable determinate errors is minimum weight drift over time, which occurs due to changing environmental conditions that affect instrument performance such as vibrations, draft or temperature. The operator can even add indeterminate issues to what essentially is a determinate problem as people may weigh differently or have different levels of training using a particular weighing device.

3d. Appropriate safety factors

To ensure sample weights are always above the minimum weight in the face of both determinate and indeterminate errors, experts recommend periodic calibration of weighing instruments. Maintenance requirements can be quite stringent; though for companies that operate in or export to the U.S., daily balance testing will be eliminated as of December 1, 2013. (Calibration and weighing procedures are also clarified by the changes.)

To work well within any weighing standard, experts recommend adding a safety factor to all weighing processes. This ensures adherence to accuracy requirements and any applicable legal limits. A safety factor of 2 is commonly used for manual weighing, provided environmental influences are relatively stable and operators have been well-trained. For critical operations or an unstable environment, the safety factor can be even higher (Figure 3).

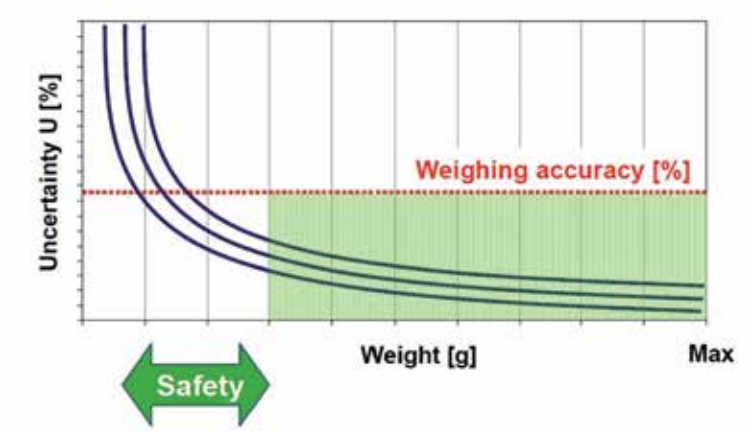


Figure 3: Weighing in the green area guarantees adherence to weighing accuracy requirements (safety factor)

Automated dosing systems may be able to ensure less waste by helping to ensure that expensive substances are not lost to process errors that lead to environmental contamination. Making smart investments in technology can help save a chemical company the hassle and cost of internal investigations and reduce risk of OOS product reaching consumers' hands where it can cause even greater damage to individual health and company reputation.

4. Product solutions

4a. SmartPrep funnel & spatula

Suitable procedures and equipment specifically designed for the task of handling hazardous chemical substances help provide a safe working environment for activities such as manual weighing. One of the simplest changes a lab can make to help reduce the risk of OOS weighing – as well as reduce risk of airborne and spilled contaminants – is to eliminate the use of weighing paper.

With weighing paper, a certain and often nearly undetectable amount of sample is nearly always left behind. This can become critical when weighing very small amounts of hazardous substances. SmartPrep, a new single-use funnel from METTLER TOLEDO, allows the simple and secure weigh-in of powders prior to volumetric sample preparation. The form, design and function of the new SmartPrep funnel helps speed up daily weighing activities and eliminates the sample loss inherent with weighing paper.
SmartPrep funnels are made from anti-static material, which helps to keep small particles from becoming airborne and eliminate exposure risk. This feature also reduces cross-contamination risk by reducing risk of spills when transferring weighed substances. Its shape allows both easy removal of excess sample for less waste – as well as complete rinsing to further eliminate risk of material loss – for savings in materials and cost, particularly when working with expensive or rare substances.

The funnel is designed to fit any common flask size. The funnel design ensures it remains in a stable position on the balance during weighing. Add the specially designed, static-free weighing spatula contained in the SmartPrep kit, and this relatively low-cost solution becomes a smart way to reduce exposure risk and eliminate several causes of both determinate and indeterminate weighing errors during chemical sample preparation.

4b. ErgoClips

ErgoClips provide another relatively simple way to upgrade weighing procedures and further eliminate the need for weighing paper. ErgoClips enable one-step dosing directly into a tare container, eliminating transfer errors and spill potential and ensuring complete sample transfer. They can be installed directly onto a grid weighing pan of METTLER TOLEDO Excellence balances.

ErgoClips provide secure fastening of various tare containers to the balance that are angled for ease and to provide a more ergonomic weighing procedure. As such, daily weighing routines are sped up and simplified. One-step dosing into the container reduces sample loss and minimizes the risk of cross-contamination. Faster, more precise dosing significantly enhances lab productivity.

Figure: ErgoClip Flask of Excellence balances

4c. Excellence Balances

METTLER TOLEDO Excellence Balances themselves have been designed with the kind of accuracy that minimizes OOS results, protecting consumers and brand. They also offer a host of innovative safety features that ensure users are kept safe during sample preparation and weighing procedures.

Excellence Accuracy and Security

METTLER TOLEDO Excellence analytical balances have earned their reputation for accuracy. New innovations continually increase weighing performance accuracy and set new standards in terms of personnel, sample, and data security. State-of-the-art draft shields and hygienic design ensure operators are not exposed to substances caught between plates, weighing pans, and shield walls. Operator rights and permissions ensure only authorized users can access SOPs and results, while premium connectivity options further ensure data security and integrity – essential features for compliance with today's industry regulations.

Easy Cleaning

METTLER TOLEDO Excellence Balances are also simple to disassemble and easy to clean, which can be of particular benefit in labs where multiple operators use the same balance. The complete weighing chamber of Excellence Analytical Balances – including all parts of the draft shield and the easily-removed SmartGrid weighing pan – can be disassembled within seconds for easy access.

Figure: Simply remove the base plate for easy cleaning

SmartGrid's innovative hanging weighing pan design has no gaps or holes where contaminants can be trapped, risking both operator safety and cross-contamination: any spilled substances fall through grid slats for easy wipe-away. For more robust applications, covered weighing pans are also designed hygienically with no gaps or shoulders where contaminants can be trapped for easy cleaning as well. All parts are dishwasher safe.

Static Discharge

Electrostatic charging is a common phenomenon which has adverse effects on weighing. Many tare vessels, especially plastic containers, are prone to electrostatic charging. Powdery samples tend to scatter or stick to the charged tare container, creating an unstable weighing environment, unreliable weighings and cross-contamination. Electrostatic charging of powdery samples can also be dangerous to the operator, because of increased risk of charged powder becoming airborne.

Excellence's built-in anti-static solutions, such as the point electrode, remove charges from samples and tare vessels in seconds, helping to eliminate exposure and cross-contamination risk. Flexible alternatives to built-in solutions are also available, making it possible to gain the benefit of static discharge on a wide range of balances and working place setups.

A side benefit to the easy discharge of static electricity is faster settling times. The addition of SmartPrep anti-static funnels and spatulas can further improve settling times and reduce buildup of static charge when handling powdery samples.

Decreased Sample Contact

METTLER TOLEDO's SmartSens technology allows hands-free operation of draft shield and balances. With a wave of the hand, draft shield doors open and close. Simple directional hand waves also start tare, weigh, and print operations, leaving operators free to concentrate on the sample being weighed. Valuable and potentially toxic materials can be weighed safely with reduced spill risk.

External and internal draft shield opening and closing mechanisms on XP microbalances can be configured separately to allow easier access to the weighing pan while reducing air turbulence to a minimum, further reducing risk of toxic powder samples becoming airborne. Programmable hands-free operation of draft shield doors enable faster stabilization and enhanced repeatability.

Figure: U-Electrode for static-free weighing and Excellence balance with kit for filter weighing

4d. A complete protection strategy: Quantos

For the most robust protection when handling powdery substances combined with significantly reduced processing time, an automated weighing system should be considered. Self-contained automated solutions, such as those that comprise METTLER TOLEDO's Quantos line, have typically been designed benefits such as:

- Ease of sample loading,
- Minimization of static production/static discharge,
- Pristine hygiene/easy cleaning, and
- The highest level of environmental containment and operator safety.

Quantos products include an automated powder dosing system and process-specific safety enclosure to enhance sample preparation accuracy while reducing the risk of repeated exposure to a potentially hazardous substance. Limiting exposure and enhancing productivity starts with the dosing head design.

Limiting Exposure

Initially, the Quantos dosing head is loaded with the hazardous substance, after which repeated sample dispensing can begin without reopening the dosing head. An RFID chip embedded in the dosing head stores important information such as the substance ID, amount dosed, and the date of dosing. After charging, the vial or bottle is stored with the dosing head attached, eliminating the need to reopen and risk exposure during the life of the dosing head. After a maximum of 500 doses, the head can be safely disposed of, avoiding unnecessary and time-consuming cleaning (as well as further exposure risk).

Eliminating OOS Results

Another significant benefit of the automated system is the controlled and reproducible nature of the dosing technology. Quantos dispenses accurately down to 1 mg (10 mg following USP requirements) into vials with openings as small as 6 mm diameter without spillage, virtually eliminating waste, as well as OOS results.

Figure: Quantos QB-1 Dosing system

Saving Time
Significant time savings are also achieved for enhanced productivity. An analyst manually weighing 100 mg inside a safety enclosure typically requires 2-3 minutes per weight. Quantos significantly speeds up this process, with the ability to dose 1 - 250 mg manually in 30-60 seconds, increasing overall throughput while reducing the amount of time that airborne contamination and exposure can occur. With an optional autosampler, up to 30 doses of a single substance can be made automatically without operator intervention.

Added Safety
The system can be operated inside a process-specific glove box. METTLER TOLEDO worked with Safetech to develop the QSE1, a process-specific safety enclosure designed for Quantos systems. It is ideally suited to the process of weighing powders and specifically created to mitigating typical ergonomic concerns that arise from working inside an enclosure, especially with PPE. Decreased spill risk and airborne contamination virtually eliminates contamination risk, while smart design of both containment and dosing system speeds up processing – a win-win for labs seeking to enhance throughput and operator safety.

When taken together, these benefits make Quantos an effective solution for companies seeking to reduce production timelines while simultaneously enhancing consumer and operator safety.

4e. Hazardous Area (Ex) Weighing

METTLER TOLEDO offers a wide selection of intrinsically safe weighing systems including balances, indicators and accessories, weighing modules, and weighing platforms of several sizes, shapes and capacities. These guarantee for complete safety with globally approved equipment for explosive environments classified as Zone 1 and 21, or Division 1 and Zone 2 and 22, or Division 2.

For the laboratory XS Ex balances are the right choice, whenever it comes to weighing and dosing processes in hazardous areas. These are fast, robust and precise balances for Ex Zone 2 environments. Different models span a weighing range of 210 g - 64 kg, and readability of 0.1 mg - 1 g. There are software solutions that permit automatic data handling for these balances: LabX software supports hands-free weighing applications in hazardous zones. Automatic weight detection and automatic data handling ensure results are secure, perfectly stored and easily sent to a printer. The balance's Bluetooth option allows communication with a printer up to 10 m away outside the hazardous zone.

5. Summary

Ingesting hazardous compounds by mouth or nose is an obvious and avoidable ingestion risk. But small sized particles – which offer benefits such as greater solubility or surface area – increase risk for inhalation and touch contamination/dermal absorption.

Fine milling also creates inherent weighing difficulties. Out Of Specification, or OOS, and contamination risks increase, posing threats to chemical companies in the form of bad publicity, governmental investigations, and fines while posing consumer risk. Containment strategies for hazardous substances must be robust, particularly at the smallest particle sizes.

Risk assessment for developing appropriate containment strategies includes how much substance is being handled, processing duration, and substance state. Some protective measures such as Personal Protective Equipment (PPE) such as glasses and masks or enclosures such as glove boxes may create their own risk by being cumbersome or restrictive. Risk can increase for both spills/exposure and OOS results.

Weighing is one of the most crucial parts of sample preparation because of opportunity for error and substance contact. As such, costs to a chemical company in terms of fines, lost productivity and lost revenue can be great. Weighing errors that can contribute to OOS results should be avoided with smart investment in appropriate technology.

METTLER TOLEDO offers a range of equipment solutions to help companies reduce operator exposure and consumer risk. Simple fixes such as adding SmartPrep funnels or ErgoClips to existing weighing equipment set-ups can create ease and reduce exposure risk. Excellence Balances, with their well-designed shields and fast settling can further reduce exposure risk, increase accuracy and enhance productivity.

Fully-automated dosing solutions such as those in the METTLER TOLEDO Quantos line offer easy loading and pristine, repeatable dosing at even the smallest increments. Traceability improves; exposure potential is strictly limited; and risk for OOS results is virtually eliminated.

When it comes to weighing in hazardous areas, METTLER TOLEDO provides a range of balances that fulfill Ex Zone 2 requirements for safe weighing.

For more on these and other METTLER TOLEDO processing solutions, visit www.mt.com.

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White Paper

Good Weighing Practice™

GWP® helps you to assure consistent product quality and to avoid out-of-spec results or bad production batches. With Good Weighing Practice™ you comply with all regulations applicable to your weighing process – at an optimal investment of time and money.

GWP® helps you to make the right decisions when it really matters, covering all important stages of the weighing process

1. Evaluation
Understanding your weighing process: The GWP® standard helps you in evaluating your weighing requirements in a simple and objective way.

2. Selection
Optimal match for perfect quality: You select the right balance or scale meeting your weighing requirements – not more, not less.

3. Installation
Proper installation and configuration: Professional installation, and qualification of the weighing system along with in-depth user training ensure trouble free weighing right from the start.

4. Calibration
Confidence in having the relevant documentation: Document the measurement uncertainty and minimum weight of your weighing equipment to assess its performance on site.

5. Routine Operation
Optimized testing minimizes risks and costs: A risk-based test scheme allows you to invest resources where it really matters.

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