



PROTECT AND DETECT:

AN ERGODYNE FOD/FME WHITE PAPER

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Whether a biblical reference to '*a fly in the ointment*', an industrial recognition of '*a spanner in the works*', or a muckraker's revelation of something disgusting found in a hotdog – we have unfortunately been familiar for many of decades with the concept of things that do not belong therefore causing a range of serious problems.

In a modern context, these “out-of-place” concerns remain. Foreign Object Debris (also known as Foreign Object Damage or FOD) and Foreign Material Exclusion (FME) are critically important concepts in a wide range of products and industries.

THE 4-1-1

Contamination of raw or processed food, beverage, pharmaceuticals, or many chemical products lead to wide scale product recalls, enormous and costly waste, expensive decontamination efforts, and long lasting damage to brands and reputations. The US Food and Drug Administration (FDA) advocates a Hazard Analysis and Critical Control Point (HACCP) process as, "*an effective and rational means of assuring food safety from harvest to consumption... The HACCP system for food safety management is designed to identify health hazards and to establish strategies to prevent, eliminate, or reduce their occurrence.*"

These engineered control points include the use of metal detectors, magnets, sifters, filters, and screens to identify and catch unintended materials including glass, metal, stones, bone fragments, etc. - which may contaminate finished food products.

In industries like aviation, aerospace, mechanical assembly, high voltage electrical systems, and nuclear power, foreign material can lead to anything from critical product and process breakdowns to catastrophic failures costing tens of millions of dollars per event. These exposures can occur during facility construction, product manufacturing, repairs and maintenance activities, or even during tours by outside visitors.

WHAT TO DO?

For certain critical products or components, manufacturing or assembly in a clean room is the only option. These highly controlled environments are designed to exclude even biological hazards (bacteria, viruses, etc.) or particulates (dust, etc.) and are very expensive to operate requiring special clothing, extensive worker training, and restrictions on many common items including pencils, note pads, food, and more.

For larger scale operations, “Object Management” is a mission critical approach. Object management focuses on the tracking and accounting of tools, parts, containers, and waste within the production system to ensure that none of these foreign materials get left behind. As with other leading edge programs, object management requires a high-level understanding of the processes performed, training for all employees involved, establishment of 'high risk zones' and 'buffer zones', procedures for purchasing, tracking, and accounting for all parts, tools, and equipment and methods for detecting anything left behind.

PREVENTION

Prevention begins with eliminating any unnecessary objects from the production or maintenance area. Work permits, Job Safety Analyses (JSA), standard work methods, or other documents specify essential tools, parts, and allowed equipment. However, other items including personal cell phones, watches, jewelry, and pens may be prohibited based

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on the hazards they pose. Some companies require work clothing, lab coats, or coveralls to be free from any external pockets where potential debris might inadvertently be carried. Housekeeping and vigilance are critical.

Formal accounting sheets or software may be required in some situations to document everything that goes in and comes out. Completion of these documents ensures compliance and most importantly, helps to reinforce the importance of accounting for foreign objects. All required items are tracked and accounted for, like the surgical nurse who counts each sponge in the operating room at the beginning and end of each surgery.

When it comes to approved objects and materials, the use of tethers, lanyards, and clips help to prevent tools from unintentionally slipping or dropping, whether or not they are noticed by the workers. The selection of approved tools for each process may include an evaluation of their ability to be tethered.

Preparation and pre-assembly of components can eliminate some foreign material like stripping insulation off wires or cutting components to length before entry into high-risk zones. Magnetic trays can be used to control and capture metal fasteners while pouches with closures help to securely carry parts as well as remove and capture any packaging, waste, debris, and components from high risk zones.

DETECTION

Detection is a quality assurance step that begins before the process by identifying items that might be dropped or left behind and selecting methods for exposing them. As with food processes, nets, screens, and filters can be used to catch or remove certain larger items while metal detectors, magnets, and even x-rays can alert the presence of certain tools, metal filings, broken parts and other foreign objects.

Some tools or job aids may be specially selected or modified to increase the likelihood of detection in critical situations. For example, pens or pencils made mostly of plastic or wood may be prohibited while models with a metal case may be allowed. Common, non-metallic items including earplugs or adhesive bandages can have small, trace pieces of metal embedded to trip detectors if dropped, left behind, or broken. Work gloves and similar items can have metal grommets installed to make them easy to clip into a retainer when not worn and be detectable if dropped.

Specialty products can also be designed with trace quantities of metal powder impregnated throughout the material. These items may have the appearance of molded plastic but retain most of the desirable properties of the base material and alert a metal detector even if the item is broken up into smaller pieces – an advantage over embedded metal traceability.

A list of approved items for FOD workzones should also include bright and contrasting colors that clearly stand out against the work background, other items that float on top of vats or liquid processes, and non-reactive materials which are soft enough to pass through a mechanical system without causing damage.

BOTTOM LINE

Controlling foreign material requires a commitment from management, purchasing, engineering, supervisory, and line employees to maintain a comprehensive and effective approach. Limiting the presence of undesirable items in FOD/FME critical areas is a first

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step. Selection and specification of allowed tools, personal protective equipment (PPE), and supplies is next. Along with strategies for tethering and controlling potentially loose items and detecting any which might get away, careful accounting of what goes in and what comes out provides a clear and documented way of preventing unpleasant and expensive surprises.

REFERENCES

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http://en.wikipedia.org/wiki/Foreign_object_damage

HACCP: Hazard Analysis and Critical Control Point

A systematic approach to the identification, evaluation, and control of food safety hazards.

<http://www.fda.gov/Food/GuidanceRegulation/HACCP/>

CGMP: Current Good Manufacturing Practices

CGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities

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