

WHITE PAPER

Hygienic Design and Containment During Construction

Guide for ensuring product and worker safety when performing construction in an operating food processing plant



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INTRODUCTION

The primary audience of this white paper is food processing plant managers and capital project execution teams considering plant additions or modifications. This paper defines the specialized protocols and measures for successfully and hygienically executing a construction project in a continuously operating food processing plant to prevent food product contamination. We consider how proper containment and other measures such as comprehensive training, the use of sign-off checklists, and monitoring the integrity of protective enclosures align with FSMA food safety plan requirements, Current Good Manufacturing Practices (cGMP), and other directives and requirements for ensuring facility safety. Additionally, this white paper offers guidance on selecting an engineering/construction team that is the best fit for managing your complex construction project.

Maintaining a clean and contaminate-free food processing plant is challenging, even under optimal conditions. One way to understand the stringency of the standards for cleanliness required in a food processing plant is to compare them with those in a hospital operating room (OR). In the OR, a failure of process standards to prevent contamination could lead to severe complications for the patient or death. But in a food processing plant, the failure could result in widespread illness and multiple fatalities. It's an order of magnitude more serious than in the OR. And unlike in the OR, a food processing plant failure can ruin the reputation of a business by quickly becoming headline news that leads to product recalls, lawsuits, FDA or USDA citations, and significant financial losses.

Given the degree of risk present under normal plant operating conditions, imagine how much more challenging operating a plant becomes during facility construction. The risks are akin to the dangers of constructing an expansion to the OR while the doctors continue to operate on patients. While this scenario is not conceivable in a hospital, it is the reality in most food processing plants. Due to their business requirements, food processing plants must seek out alternatives to avoid halting production.

Completing a construction project at an operating food processing plant is complicated, involving tasks above and beyond those normally associated with construction projects at non-food industrial plants. Both the plant operator and the selected engineer/constructor must understand and implement cGMP, hazard analysis, and risk-based preventive controls for human food (21 CFR Part 117). This white paper explores the essential steps a food processor and their engineering/construction partner must take to ensure the safety and continuity of their food processing operation during construction.

Engineering/Construction of Facility Additions or Modifications and Lessons Learned

As with any industrial construction project at an operating food processing plant, the engineering for a facility addition or modification starts with a conceptual design and continues with the following tasks:

- Development of a physical layout for the mechanical and electrical systems
- Equipment selection and sizing
- Structure and foundation design
- Creation of construction drawings
- Construction activities planning to prevent the disruption of plant operations
- Safety planning for the new design as it relates to personnel

The food industry is unique in that there is an additional set of activities, beyond those listed above, that plant stakeholders must undertake. These are dictated by the food process itself and go far beyond customary OSHA and journeyman training. They involve the preparation and implementation of food safety training, safety checklists, and specialized construction and audit procedures to ensure ongoing construction does not contaminate the food product.

1. Training

Ideally, plant managers and operators should select contractors and maintenance personnel who have prior food industry experience for their projects. These individuals should preferably be Food Safety Preventive Controls Alliance (FSPCA) qualified and have Safe Quality Food Institute (SQFI) training or an equivalent certification and training. However, this is not always possible. Therefore, workers new to the food industry must be given general food industry orientation training. Both experienced and new workers must receive training that is site-specific, because no two food processing plants, even those within the same industry working with the same product, are identical. If the plant has their own written contractor work rules, these should also be included in the site-specific training.

Food processing plants must develop a Hazard Analysis and Risk-Based Preventive Controls (HARPC) program compliant with 21 CFR 117, Subpart C for each project site. The stakeholders must validate the HARPC plan, train all project personnel in HARPC, and develop a plan for implementation at the site. Training should be conducted by personnel from the food plant or the engineering firm who are FSPCA Preventive Controls Qualified Individuals (PCQI) or SQF-certified practitioners. Managers should provide written training materials to all trainees. Documented competency testing should be administered, and project stakeholders should consider employing a FSPCA- or SQFI-certified third-party training body for these tasks. The training should not be a one-time effort but instead reinforced with weekly toolbox talks and food safety refreshers. Disciplinary methods must also be implemented to handle any deliberate violation of safety rules.

cGMP is fundamental to all food safety plans as laid out in 21 CFR 117 and other prerequisite programs and include hygienic zoning, product specifications, and other plant-specific protocols. While these programs are intended primarily for food processing plant operators, cGMP principles apply to construction activities in operating plants as well.



Contractors should be trained in the sections of 21 CFR 117 that pertain to food contamination from the following sources:

Physical Sources

- Grinding/welding debris
- Foot traffic
- General construction debris

Chemical Sources

- Painting/odors
- Solvents
- Cutting oils

Microbiological Sources

- Debris shaken loose from construction activities
- Drain backups
- Cross contamination from tools and equipment used at multiple facilities

2. Safety Checklists

Even with the best intentions, construction workers will not remember all of the steps required to work safely in an operating food processing plant no more than the pilot of a 747 can remember all of the steps required to take-off or land safely. The pilot uses a checklist – not because he’s incompetent – but rather to guarantee his passengers’ safety. Likewise, construction crews in an operating food processing plant use checklists to ensure the safety of food produced in the plant. Listed below are a few of these checklists:

- Pre-Construction Walk-Through Checklist
- Audit Checklist During Construction
- Start Up Safety Checklist/Walk-Through

3. Pre-Planning of Work

In a typical non-food industrial plant, pre-planning work for a facility modification or addition involves ensuring that construction activities do not interfere with plant operations. Materials and equipment are brought into the facility and stored until needed. The pre-planning phase in a food processing plant involves the same process, however, due to the high sanitation standards in food processing, the following additional food safety measures must also be implemented:

- Development of a food safety plan with a HARPC program
- Development of safe plans of action to avoid food contamination
- Use of lessons learned from previous work experience to plan new work

4. Protection Level Identification by Plant Area

Each area of an operating food processing plant in which construction is planned has unique protection requirements. These must be identified in the construction plan and included as critical control points in the food safety plan.

The first step in the development of a construction plan is for plant management to identify plant areas by activity and level of protection required. They may perform this step themselves or with the engineer/construction manager. The plan must address the following areas:

- Raw Goods and Ingredients – Grains
- Raw Goods and Ingredients – Meats
- Raw Goods and Ingredients – Fats, Oils, and Other Liquids
- Wet Processing
- Dry Processing
- Cooking/Drying
- Coating
- Packaging
- Warehouse
- Utilities
- Building Exterior and Grounds

Within each of the food processing areas, the following sub-areas or zones also need to be identified. Here is an example of how these zones might be designated in an operating food processing plant:

- Zone I – Food Contact Surfaces
- Zone II – Within 3 ft. of Food Contact Surfaces
- Zone III – Outside 3 ft. of Food Contact Surfaces

Once these steps are complete, a set of mutually agreed-upon codes should be used to uniquely identify each area and zone, and a plan should be developed for the plant that identifies the level of protection needed by personnel, equipment, and machinery within those locations.



5. Enclosures and Hygienic Segregation

An enclosure serves as a protective barrier that prevents the entrance or exit of materials, objects, or substances within a confined space. Enclosures keep construction contamination out of food processing areas and most food processing materials out of construction areas. They keep the contractors, materials, and equipment within the construction area and control the movement of traffic between the processing and construction areas.

The following types of enclosures may be used depending on the area and level of protection required:

- Tarps
- Stud walls with plastic sheeting on one side
- Stud walls with plastic sheeting on both sides
- Stud walls with masonite sheeting & plastic
- Sloped roofs (if required) in the containment area to allow water, food debris, and dust particles to run off the containment

The construction area must be maintained at a negative air pressure to ensure the containment of potential construction area contaminants. The specific amount of negative air pressure required is dependent on the area's classification. It is best to evaluate the existing HVAC system to ensure the enclosures are functioning as intended and hygienic separation is maintained. Use temporary exhaust systems to ensure the control of the differential pressure. Existing HVAC supply/return openings in the area should be sealed and associated equipment turned off. The exhaust systems should also be sized for both the air exchange rates and face velocity at the transition boundaries.

In areas classified as normal, the capture velocity may be about 100 feet per minute. In high-hazard or dusty areas, the capture velocity may be as high as 150 to 200 feet per minute. Six air changes per hour should be considered the minimum ventilation required inside a containment area, but this may be as high as 10 to 15 changes per hour in high-hazard areas.

It is also important to pay special attention to the location of the HVAC system exhaust. If air cannot be exhausted to a safe location outside the facility, then properly sized HEPA filters may be employed as an alternate solution. Exhaust systems that discharge outdoors should be located at least 10 feet above and 25 feet away from air intakes. Exhaust fans need to be located so that only the vacuum side of the fan is inside the enclosure. Ideally, the exhaust should be directed straight up to allow the plume to be carried away from the facility. Control of the condensation inside and outside the containment walls and worker comfort must also be taken into consideration in the temporary HVAC system design.

Anybody and anything that enters and leaves the construction zone must be sanitized to reduce the risk of contamination. Therefore, stakeholders should establish critical control points to control the movement of personnel, equipment, and materials into and out of protected areas. Transition zones, such as airlocks, may need to be established to isolate the area between the construction areas and the protected areas. Within these zones, personnel check in, gown, sanitize, and undergo swabbing and testing prior to transitioning to other areas of the facility.

Demolition activities typically produce waste materials. Therefore, provisions must also be in place for handling these materials and for removing them from the protected areas. All waste should be considered contaminated and be double wrapped and sanitized prior to removal from the construction zone. The integrity of the enclosure/containment must be monitored daily at the very least. Any damage or breach should be repaired immediately, documented, and reported both to plant supervision and to the engineer or construction manager. The cause of the damage or breach needs to be established and eliminated where

possible. Occasionally, operations and maintenance personnel become curious about the progress of a construction project. In hopes of reducing foot traffic, many construction companies use temporary barriers with clear plastic windows that allow onlookers to safely view the ongoing construction.

Notably, there are situations where a plant operator may need to enter the segregation area on a daily basis to perform work such as to operate the equipment or valves. In that case, the enclosure/segregation should be modified to prevent a breach. A checklist that includes approvals (signatures) from the plant owner/operator and engineer/contractor should be used for documenting the integrity of the inspections.

6. Sanitizing Personnel, Equipment, and Materials

When workers enter or pass through a food-protected area to access a construction area, they must take the following precautions:

- Only bring in the tools needed for the job (no toolboxes)
- Sanitize tools and other personal equipment prior to entrance into or exit from the work area - use tool wash sinks, sanitizing wipes, and captive tool programs
- Document tool cleaning
- Swab and test tools as needed
- Sanitize heavy equipment, carts, dollies, or rolling stock



7. Fumes and Odors from Traffic, Tools, and Materials

Vehicles, tools, and materials used in construction can produce fumes and odors. The following measures must be taken to prevent these fumes and odors from contaminating food product or causing worker illness.

- Ventilate to the outdoors (away from any plant air intakes) for vehicles going to/from construction areas
- Consider using only propane-fired or electric vehicles inside the facility
- When vehicles are used inside the containment area, be sure to continuously monitor carbon monoxide levels to prevent occupant illness
- Adequately ventilate for paints, caulks, solvents, epoxies, and other coatings that generate vapors and that can overwhelm workers and taint food on nearby production lines

- Adequately ventilate welding fumes that produce vapors and particulates that can overwhelm workers and taint food – electrostatic precipitators can help filter particulates and carbon filters can help remove odors
- Ensure the HVAC system is designed to prevent pockets of fumes or gases from collecting in confined spaces
- Control exhaust and any vaporized operating oils from air tools that can carry contaminants

8. Flow of Materials

Critical control points should be established along the designated materials path. During construction, materials and equipment constantly move into and out of the plant. In order to prevent contamination, a designated route must be developed from the plant entry point to the construction area. This route should be reviewed and approved by the plant operations team and maintained and sanitized by plant staff or other tradesworkers. Open food streams along the route must be protected and may require additional hand/foot/equipment/material sanitizing requirements and sanitizing locations.

Should soil need to be transported through the facility, buggies or other vehicles used to transport the soil should be kept covered. The wheels of these vehicles must also be sanitized after leaving the construction area. Material spotters can help guide the loads through the plant and ensure safety procedures are followed.

The designated route for transporting materials must be assessed on an ongoing basis because conditions in the plant may change. The plan for the flow of materials should be documented and posted in all contractor work areas. Assessments of the plan should also be documented. Finally, the route for the flow of materials should be marked throughout the facility and updated according to the results of the ongoing plant assessments.

Fabrication materials and equipment used during construction need to be stored prior to use. To minimize on-site storage requirements, Just-in-Time (JIT) inventory methods should be employed when possible. Materials may be stored outside or inside depending on the nature and size of the items. Outside storage of fabrication materials should be limited to large items and cleaned of any debris.

9. Fabrication & Laydown Procedures

Smaller fabrication items should be stored indoors unless there is no laydown area available. In that situation, they can be stored in a tractor-trailer. The following are guidelines for ensuring the safety of inside storage areas. These areas should be:

- Tarpred or designated w/ temporary barricades
- Monitored for accumulation of food dust/debris
- Cleaned and sanitized, as necessary
- Scheduled for inspection by facility sanitation teams
- Lit by temporary lighting as required
- Provided with plastic cribbing to store items for sanitation purposes

Plant stakeholders should introduce accountability for ensuring the continuing safety of the facility by defining the personnel who will conduct the safety inspections and cleaning tasks. In the fabrication area, the following procedures should be followed:

- Areas should be tarped to contain debris generated by the fabrication activities
- Areas should be monitored for the accumulation of food dust/debris
- Areas should be cleaned and sanitized as necessary
- Areas should be scheduled for inspection by the sanitation team
- Temporary lighting should be installed as required
- Items should be staged on plastic cribbing for sanitation purposes
- Plant stakeholders should implement welding barricades/shades where possible
- Temporary ventilation and/or electrostatic precipitators should be employed as required to eliminate fumes from welding or painting
- Equipment arriving at the project site should be inspected for possible infestation
- New equipment entering the plant should be sanitized
- A plan should be developed for an equipment sanitizing and drying area
- Removal of all wood cribbing, spacers, and chocks prior to bringing new equipment into the plant
- Document sanitizing
- Obtain swabbing results



10. Clean-up Procedures

When a construction project is complete, the engineering/construction team's job is not yet finished. There is still much to be done to render the construction area fit for food processing. The post-construction project cleaning requirements in a food processing plant go far beyond typical industrial cleaning procedures. In a food processing environment, clean-up of the construction area is conducted using a broom, brush, and mop. Any equipment that was worked on during the construction project is

tagged and documented.

The tagged equipment is then sanitized, swabbed, tested and, if necessary, re-sanitized prior to use. The segregation enclosure walls are also sanitized prior to their removal. The plant stakeholders will need to decide whether enclosure components such as metal studs and other non-porous materials can be re-used.

Special sanitizing methods must be used for non-washdown equipment such as electrical devices and switchgear. While alcohol-based sanitary wipes are sufficient for cleaning electrical equipment, superheated steam or dry ice may be needed to properly sanitize other types of equipment.

11. Testing in Production Areas

After the clean-up process is complete, the production areas are tested to ensure they are ready for production. A 3D grid for the production area should be established and testing locations specified. Swab locations should include all traffic paths and main entrances into and exits out of the construction areas. The number of swabs that need to be taken from an area should be defined prior to the start of the project. Food and air samples must also be taken and non-food contact surfaces tested.

If an area is judged to be contaminated during the testing process and is re-sanitized, it must also be re-tested. It is critical that the number of tests required before an area is deemed suitable for production be established by the plant's food safety department.

12. What to Seek in an Engineering/Construction Team for Facility Construction and/or Modification Projects

While there are a variety of factors to consider when selecting an engineering/construction team for a food processing facility construction and/or modification project, previous industry experience is the most critical. Always select a partner that understands the requirements of your facility. Other selection criteria that food processors should consider when hiring include the following:

- Number of principals or top management in the company with food industry backgrounds
- Number of long-term clients in the food industry
- Testimonials from satisfied clients
- Whether the company has an integrated team comprised of engineers and constructors under the same management to minimize handoffs and communication problems
- Number of team members with food industry backgrounds
- Percentage of team that are HACCP certified
- Number of SQF practitioners or PCQI on staff
- How the engineering/construction team works with the plant – Do they have an “us and them” type relationship or a “we” type of relationship?
- Experience with monitoring food safety regulatory (FDA or USDA) requirements to ensure compliance
- Experience with training contractors in cGMP for human food requirements

Conclusion

When a food processing plant undertakes a facility expansion or modification while remaining operational, management must prioritize food safety to mitigate the risk of contamination. They must implement comprehensive risk prevention measures that include training contractors in food-safe practices, pre-planning work procedures, defining protection levels for different plant areas, implementing segregation enclosures, and ensuring their facility is properly sanitized and ventilated. Contamination prevention requires ongoing diligence and vigilance. With the right processes in place, construction projects can be successfully completed without compromising food production output or food safety. Choosing a competent engineering/construction team as a dedicated partner is essential for ensuring the success of a construction project.

EAD: Experts in Construction Management, Construction Safety, and Hygienic Design for Food Processing Plants

Expertise You Can Trust – Completing a construction project in a continuously operating food processing plant is a complex endeavor. Preventing shutdowns and contamination requires the specialized knowledge of industry professionals. EAD leverages our years of experience providing hygienic construction management, design, and consulting services to ensure projects are completed on time and within budget.

A Teaming Approach – When planning your food processing plant construction project, you need more than a contractor—you need a partner. EAD understands the nuances of performing construction in a food processing plant including how to advance the project while maintaining operational momentum. Our team knows what needs to be done, how to accomplish it, and, crucially, how to communicate effectively with facility owners.

Comprehensive Communication – While we've outlined nine essential steps for ensuring the safe operation of a food processing plant during construction, our approach goes far beyond these basics. We prioritize clear, thorough communication to keep you informed at every project stage. Contact us if you're planning to expand or update your facility. We'll gladly share our extensive experience in the food industry and demonstrate how we can support the success of your project.

Reach out to us today to discuss your needs and learn how EAD can help you achieve your goals.

As we reflect on the last 20+ years of service, we find ourselves humbled. Working together behind the scenes as an extension of our clients, we've made a lasting impact. We have built our reputation as an expert, a support system and as a part of our clients' families.

With multiple locations across the US and projects on 5 continents, we are actively engaged in the advancement and expansion of Fortune 500 companies around the world. Leveraging the relationships we've built and the lessons we've learned, we hope to engineer a lasting, brighter future for many years to come.



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