

# Project Management

## Project Management Team

As team effort begins with the need for a containment application from a client, typically, a process engineer is involved to design a concept of the proposed equipment. He/She has the responsibility to determine interface, ergonomics and engineering from experience with past successful applications. This is an evolving process to come up with a practical, affordable and safe containment system.

### - Design Concept

The design will be a factor in the rooms, facilities access and the utilities required having a functional design when completed. The concept requires either drawings of equipment or dimensional information to accurately interface the isolator and locations of gloveports. It will factor in production, service and maintenance requirements if interfacing with equipment.

### - Proposal Prepared

Whether a URS or Functional Specification is created by a client, ICS will assist the client to create or recommend a competent A&E firm experienced with this equipment. A formal or budgetary proposal is now prepared mapping out a scope of supply, drawings and how operations will be conducted in the isolated environment. Additionally, this covers transfers, details of construction and support information on supplied equipment.

### - Order is placed

Once an order is placed, the ICS Team will have a kickoff meeting to go over project requirements, schedule and the proposal. This can be either in person or using electronic means, depending on the client's departmental availability. A project manager and engineer are officially assigned to the team. The process engineer stays involved with the project from start to successful installation and works closely with the plant. It is this commitment that guarantees a successful installation.

- Mockup to determine practicality of the design for isolators

A mockup is manufactured from plywood to simulate as much of the process and operator interface to perform these operations within the limits of an isolator. This can be manufactured and delivered in a short time after an order is placed. This is a very economical solution to resolve problems that might not be found otherwise. This is the best solution towards a successful installation.

- Follow-up changes based on the mockup

Any changes found during the mockup are now changed on the concept drawings and sent to the client. This is the final iteration prior to the Submittal Drawings.

- Approval Drawings Submitted

The clock with many projects is the approval of the Submittal Drawings. Materials are ordered to the client's requirements and shop drawings are prepared. In some situations, long lead equipment may be purchased prior to the approval by client approval to proceed. The schedule is amended if the approval time was exceeded or additional changes are required. Cut sheets for controls and equipment used in the construction of the isolation system is part of the Submittal process. P & IDs for the ventilation, wash system and electrical connection are also part of the process. The final 'As-Built' Drawings are given with the manual.

- Fabrication Schedule Produced after Approval of Drawings

A fabrication schedule is prepared with milestones to the plant and client's requirements. This is a detailed schedule that factors in all the logistics of the order. This schedule is circulated to all the parties involved for co-coordinating all facets leading to a successful installation.

- Materials Procured

Materials, used for the direct manufacture of the equipment, are procured. This includes client's requirements from a URS or Functional Specification. This includes C of Cs for materials and finishes. Quality accepts and receives these materials based on ICS and client's requirements. This assures the proper materials are used for a high quality installation.

- FAT (Factory Acceptance Testing) documentation submitted

This documentation consists of the testing performed at the factory to assure the equipment meets the requirements imposed by the URS or Functional Specification and the approval package. This documentation is submitted to the client for final review and any changes based on any clarification.

- FAT Protocol approved by client

The FAT Protocol is received and mutually agreed on by both ICS Team and Client. The document is now circulated to all parties involved in execution of the document.

- Production Phase

Production of the equipment requires the logistical co-ordination of the shop fabrication, materials, panel shop, integration and QC testing departments to flow in an orderly phase through the plant. This requirement is controlled with weekly production meetings with all groups involved. This co-ordination keeps communication with the client, client's installation personnel and all parties, to make an on time delivery so critical to today's industry.

- FAT executed at Plant with Project Manager

The project manager has the responsibility of schedule, logistics and customer communication. Although a member of the project team, they ultimately, make certain the project will meet the mutually agreed ship date.

- IQ & OQ Documents Submittal and Approval

An IQ & OQ is considered the validation blueprint for the equipment and will follow the equipment through its useful, productive life. It is a living document that will be maintained at the client's plant and at ICS. It is for these reasons the document has a review process and approval. This approval process allows input into the document for the client's own validation requirements and to assure the equipment can be later tested to the original testing criteria when it was received at the client's site.

- Execution of the IQ & OQ at clients site

This involves the testing equipment, the document final approval sign off and the individual trained to execute the

testing. This is witnessed generally by the client or client's designee. This is the as-built test of functionality of the equipment after all utilities are tied into the systems, all equipment reassembled and installed as designed and approved. A sign off is required for every item in the test.

- Manuals, electronic copy and binders provided

After the execution of the IQ & OQ a final As-built manual is supplied. This includes the operation, maintenance, spare parts recommendation, as-built drawings, cut sheets for purchased items, C of Cs for materials, schematics, and PLC Ladder logic diagrams (annotated) along with screens for all of the operations of the PLC. This manual will have an electronic back up for the PLC and RS Logics program in the event there is a module failure. Additionally, service recommendations and preventative maintenance are included to keep the equipment healthy over a long life.