ioMosaic®

Minimizing risk. Maximizing potential.®

Technology Transfer Planning for Reactive Systems

An ioMosaic White Paper

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The Need for a Quality Technology Transfer Plan

To reduce time to market, the industry is putting out new products at a faster rate and outsourcing more activities than ever before. Time is of the essence. Therefore, technology transfer during product development, whether within and between companies, needs to work perfectly the first time, exceed expectations, and meet regulatory compliance. A quality technology transfer is just as important now (if not more so).

A critical component of success is demonstrating regulatory compliance. Accidents in chemical plants due to chemical labeling problems, lack of understanding of chemicals, or both, are more common than you might believe. Chemical, physical, and hazardous properties of a product must be well documented via proper labeling, documentation, packaging, provision of safe practices, and emergency response procedures.

For the granting organization to transfer production to a receiving organization with only a secrecy agreement or sales agreement and the manufacturing procedure is not acceptable. Technology transfer plans involve much more than that to ensure that the receiving organization can carry out a chemical process safely, on time, and within budget.

Reduce Risks & Increase Efficiency

ioMosaic professionals have decades of experience mitigating hazards for the chemical and pharmaceutical industries, which means you will have unrivaled efficiency and expertise to improve validation, increase efficiency, and lower costs. ioMosaic transfers data, analytical methods, and manufacturing processes. Our experts are well known for developing safety and risk management systems, guidelines and standards, and audit protocols around the globe. We can help you understand the requirements and comply with global industry standards such as Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Occupational Health and Safety Act (OHSA), OSHA's PSM Standard, CCPS, ACC, API and other RAGAGEPs, and the EPA's Risk Management Program (RMP) Rule.

Learn from History

Chemical Reaction, Hydrogen Release, Explosion, and Fire

On May 3, 2019, a chemical manufacturer in Waukegan, IL discovered the dangers of inadequate reactive chemical hazard recognition and evaluation. Read the Incident Report

Reactive Chemical Explosion

On December 19, 2007, a powerful explosion occurred at a chemical manufacturer during the production of a gasoline additive injuring 32 and killing 4 employees. Read the Incident Report

Thermal Hazards Assessment

Thermal hazards must be fully characterized by the receiving organization. The granting organization may provide data from calorimetric evaluations, but ultimately the receiving organization must verify if the intended equipment is capable of carrying out the normal process and be able to relieve a worst-case scenario. The following evaluations must be completed before the first run of the product at the new facility.

- Screening Tests
- Adiabatic Calorimetry
- Heat-Flow Calorimetry
- Vent-Sizing Calculations
- Heat-Transfer Capabilities

Laboratory Testing

ioMosaic works in concert with the professionals at ioKinetic Laboratory to not only provide you with timely, reliable, and reproducible data but also only recommend the services that are 'right' for your company's safety efforts. They'll work with you to determine the level of analysis required for your needs, assist in reducing hazards that you may otherwise not be aware of, and help you comply with today's regulatory standards with these testing services and more.

Screening Tests

An insight into the hazards of a material can be gained by running experiments with instruments such as Differential Scanning Calorimetry (DSC), Differential Thermal Analysis (DTA), and Thermogravimetric Analysis (TGA). They enable more targeted calorimetric experiments by estimating the temperatures at which reactivity and instability begin.

Adiabatic Calorimetry

If a worst-case scenario develops, such as loss of temperature control, it is necessary to know whether the hazard could be properly handled. For this purpose, tests are done in an adiabatic calorimeter in the laboratory to determine how pressure and temperature would evolve in case of control loss. The adiabatic testing must search not only for the intended reaction but also for secondary reactions that may produce decomposition gases. It is important to realize that this testing should be done for exothermic and endothermic reactions. Indeed, endothermic reactions may generate gases at elevated temperatures, creating hazardous pressurization. Adiabatic calorimetry is also used to characterize the hazards of substances that may exhibit chemical reactivity in storage or transportation, such as the Self-Accelerating Decomposition Temperature (SADT), a subcase of the Self-Accelerating Reaction Temperature (SART).

Heat-Flow Calorimetry

This testing measures the reaction heat of the normal process. The laboratory test is carried out in accordance with the manufacturing procedure and measures the heat generation or consumption as the reaction progresses.

Vent-Sizing Calculations

Mechanical Integrity must approve the industrial equipment and it must be capable of venting a worst-case scenario as specified in a Process Hazard Analysis (PHA) study. The output of adiabatic calorimetry is combined with equipment data to perform vent-sizing calculations, either through analytical methods or better yet, through dynamic simulations using software that can also be used to calculate the forces on the equipment associated with pressure relief.

Process Safety Office® SuperChems™ software offers a variety of well-validated models for single- and/or multi-phase reacting flow, dispersion analysis, droplet dynamics, and fire and explosion dynamics. This is the only platform that integrates consequence and risk analysis, chemical reactivity management, and relief and flare systems evaluation and design, and is the preferred software for AIChE/DIERS members.

Heat-Transfer Capabilities

Heat-flow calorimetry establishes how much heat per unit time must be removed or supplied to the system to maintain temperature control. The receiving organization's manufacturing equipment must be capable of meeting the heating and cooling requirements of the process. Calculations or tests with a surrogate fluid in the process vessel can be used to determine heat-transfer capacities.

Hazard Identification and Risk Assessment (HIRA)

The granting organization may provide the receiving organization with its risk assessment, but the receiving organization must perform its own studies. The receiving organization must conduct its hazard evaluation using at least one teamwork approach, such as Process Hazard Analysis (PHA), Layers of Protection Analysis (LOPA), Fault Tree Analysis (FTA), Fishbone Diagram, and so on. Although hazards cannot be completely eliminated, these studies aim to determine how to reduce the likelihood of their occurrence to acceptable levels. Some scenarios identified in these studies may require adiabatic and heat-flow calorimetry testing, followed by vent sizing and the determination of heat-transfer capabilities. PHAs in their various forms, such as Checklist, Hazard and Operability (HAZOP), and What-If, as well as LOPA, can be performed through software, such as PHAGlobal®.

Process Hazard Analysis (PHA) Studies

PHA studies are careful reviews of what could go wrong and what safeguards must be implemented to prevent the release of hazardous chemicals. A PHA is best performed by a team with expertise in engineering and process operations, and the team should include at least one associate from the granting organization who has experience with and knowledge of the process being evaluated. Also, one member of the team must be knowledgeable in the specific analysis methods being used to help explain reactive hazards to the other team members. Rely on ioMosaic professionals to provide high-quality PHA services for your organization. They are trained and proven PHA leaders who can prepare, organize and lead PHAs with your internal technical and operations staff and have extensive expertise with industry-recognized techniques. Their attention to detail and completeness assure the study complies with OSHA 29 CFR 1910.119.

Process Safety Office® PHAGlobal® simplifies the recording of findings and tracking follow-up from PHAs and LOPAs. It eliminates the need for any special application software when working with the results. It documents all findings and recommendations. As each recommendation is resolved, these are documented and your team is notified. This software is extremely easy to use and a timesaver.

Quantitative Risk Analysis or Facility Siting

These studies detect and document potential toxicity, fire, and explosion hazards at a manufacturing facility that might harm populated areas, both on-site and off-site. After a hazard characterization is performed with software such as SuperChems™, it is essential to evaluate them systematically with a Hazard Identification and Risk Assessment (HIRA) to find solutions for minimizing the risk and consequences of a hazardous chemical to employees, the public at large, and the environment.

Risk characterization and assessment are key to meeting regulations such as REACH and OHSA. Local fire, police, and emergency response personnel also must be informed of any hazards that may arise from the new process so they can prepare for and respond to chemical emergencies in their community.

ioMosaic professionals can help you make risk-based decisions with confidence. Our quality Quantitative Risk Assessments (QRAs) consist of six main steps:

1. Hazard Identification — the identification of all Loss of Containment scenarios (LOCs) with the potential to lead to an explosion, fire, or toxic hazards in a processing facility;
2. Frequency Analysis — estimates the likelihood of occurrence of all LOCs via analysis of historical data, specific plant data (if available), worldwide references with generic process equipment failure rates, and/or dedicated fault and event trees; i.e., bow-tie analysis;
3. Consequence Analysis — quantifies the effects and impacts of all potential outcomes that could occur from a given LOC, based on damage criteria for fires, explosions, and toxic hazards for personnel, structures, and process equipment;
4. Risk Analysis — quantifies the risk level as a function of the likelihood of occurrence (i.e., frequency analysis) of possible undesired events (LOCs) and the magnitude of their associated impacts (i.e., consequence analysis), and it can be divided into two (2) categories: individual risk and societal risk;
5. Risk Tolerability Criteria — consists of comparing the estimated risks to a worldwide recognized risk tolerability criteria to determine if the risk levels are deemed to be tolerable or not; and
6. Risk Reduction — consists of implementing risk reduction measures such as inherent safer process design, prevention, and/or mitigation to decrease the individual and/or societal risks to at least a tolerable level according to ALARP (As Low as Reasonably Practicable).

ioMosaic professionals also have extensive experience in conducting facility siting studies, assessing plant facilities, and providing recommendations to manage risk. The results of our process safety and risk management studies have been used by proactive companies to effectively manage the risks of highly hazardous operations. We are particularly proud that so many of our clients return to us for facility siting studies and guidance regarding expansions, modifications, and new facilities; and that they continue to rely on us for integrity, insight, and value. Our recommendations are practical and based on sound engineering practices while keeping operability and cost-effectiveness in mind.

Manufacturing Procedure

A well-written manufacturing procedure can make a difference in the safe execution of a process at the receiving organization. The granting organization must issue a well-written manufacturing procedure, but the receiving organization must ensure that the procedure is in the best possible format before it is handed to operations and that it is properly programmed in the Basic Process Control System (BPCS). A good Standard Operating Procedure (SOP) will include at least the following elements:

- A summary of the process
- The name of the author of the latest version, so that the individual can be contacted as needed
- Controlled revisions
- Removal of all outdated versions when a newer version is issued
- Applicable regulations
- Clear definition of who does what and when
- Required equipment
- Raw materials and their specifications
- The amounts of raw materials to be charged
- Text with active voice instead of passive voice with writing consistency throughout the document
- One specific action per manufacturing step. This means being clear, short, and to the point, for example, breaking down “heat from A to B and hold at temperature B” into smaller, more manageable steps such as one step for “heat from A to B” and one step for “hold the temperature at B.”
- Troubleshooting instructions, emergency procedures, and warnings for steps in which hazards exist
- Quality control during the process
- Documentation, including quality control results, temperature and pressure profiles during the run, and others specific to a process
- The maximum temperature at which the completed material can be removed from the manufacturing equipment. Reacted products should not be discharged at temperatures above which they might continue to react.

It is highly beneficial to have someone from the originating organization witness at least the first run at the receiving organization.

Raw Material Sourcing

The sourcing of raw materials may have safety consequences. The granting organization must inform the receiving organization about the sources of raw materials, levels of purity, and what contaminants should be avoided. Raw materials are quite pure in general, but they may have remnants of their manufacturing process, such as residual solvents, catalysts, etc.

Industrial accidents have occurred in which raw materials have been replaced by alternatives with the best of intentions. In one case, the original raw material contained a weak acid as the residual impurity. This raw material was replaced by another with a higher level of purity, but which contained a strong acid as the contaminant. The weak acid did not affect the process, but the strong acid catalyzed the chemical reaction, making it much faster and resulting in a runaway condition. It is essential to work with raw materials having the same specifications as in the originating process. If any modification is made, the process should be characterized in the laboratory for possible changes in chemical reactivity.

Process Safety Training

All affected personnel in the receiving organization are required to undergo safety training on the incoming process, including supervisors, engineers, chemists, operators, laboratory personnel, and contractors. Documentation of training needs to include the identity of the employee, the date of training, and how the employer verified that the employee understood the training. A training package should be provided by the granting organization, which the receiving organization should subsequently modify to better reflect its manufacturing conditions, including its equipment. Regulations requiring training include, among others:

- Process Safety Information (PSI) that identifies the hazards in the new process
- Reports on incidents involving this process at the originating organization
- Review of the manufacturing procedure
- Emergency actions focused on prevention
- Chemistry fundamentals
- Laboratory testing information
- Key HIRA findings and consequences of process deviations
- What to do in case of an emergency (see Evacuation Plan below)

Training Services

ioMosaic professionals deliver process safety training for clients in the chemical, petrochemical, pharmaceutical and other process industries. Our primary goal is to provide practical training and learning that can be used immediately. Our in-person, virtual, or online courses are prepared and led by senior staff and invited industry experts, well known for the depth of their experience and their strong academic and operating backgrounds. As an International Accreditors for Continuing Education and Training (IACET)-accredited provider, we have ensured that our policies and processes have been thoroughly benchmarked against the American National Standards Institute (ANSI)/IACET Standard for Continuing Education and Training. Course participants receive Continuing Education Units (CEU) and Professional Development Hours (PDH) continuing education credits following successful completion of a course.

Pre-Startup Safety Review

A Pre-Startup Safety Review (PSSR) is a detailed check of a process before initiating a potentially hazardous process. It enhances process safety and helps prevent accidents, employee injuries, equipment damage, and process downtime. Before making the first run at the receiving organization, a PSSR must be carried out with the appropriate form and completed. It is beneficial to have a representative from the granting organization on the PSSR team with experience in the process.

Evacuation Plan

An evacuation plan must be activated by the Incident Command System if it becomes clear that a hazardous condition has developed with the transferred process and that it cannot otherwise be prevented by available means. A warning of the emergency must be announced. The warning must include all employees and contractors on-site. The warning may also include the public at large, depending on the results of the QRA/Facility Siting analysis and the follow-up HIRA. A map with evacuation routes should be posted in every on-site location. Those with hearing impairment must be helped by a designated colleague.

Special precautions must be taken if the released material is toxic. It is important to listen to any announcement about wind direction and where to assemble. Depending on the conditions, employees should be directed indoors and air circulation be stopped to prevent the breathing of hazardous materials. If the new process introduces changes to the evacuation plan, a site-wide drill is required.

Emergency Management

Preparing before an emergency incident plays a vital role in ensuring that employers and workers have the necessary equipment, know where to go, and know how to keep themselves safe when an emergency occurs. If, despite the best planning, an incident occurs, it is essential that emergency pre-planning and training make employees aware of, and able to execute proper actions. For this reason, the granting organization must issue detailed information on the hazards of the process and the receiving organization must ensure that the emergency action plan is current and complete. Below are the five response stages in emergency management:

1. Prevention — the preferred action plan because it stops the cause before a hazard develops. For example, adding a short-stopper to an incipient runaway reaction.
2. Mitigation — refers to measures that reduce the consequences of an emergency. For example, pressure relief through an emergency vent directs the mass being relieved to a location that causes no harm to people, the environment, and assets.
3. Preparedness — involves planning, training, organizing, evaluating the hazards, and taking corrective actions to the plan before a possible incident occurs.
4. Response — activated by the Incident Command System as a result of an emergency. The goals include avoiding on-site and off-site injuries, damage to the environment, and reducing economic losses.
5. Recovery — includes activities beyond the emergency response to restore critical operating conditions for the facility.

Terminology Used

Granting Organization — an organization that requests the receiving organization to make a finished product or an intermediate under a contract.

Receiving Organization — the organization assigned to make the product or intermediate for the granting organization.

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