

1. INTRODUCTION

Climate is what we expect, weather is what we get.

Mark Twain

Individual and collective human behavior displays traits that are, in certain ways, analogous to the natural appearance and impact of weather events. Normalization of deviation is this type of human behavioral trait.

To help make the connection to this analogy, let us accept the following premise. If humans are involved in any type of goal reaching behavior, that activity involves a process. If a process exists, however formal or informal it may be, there can be deviation from that process. Whether we use a simple example, a person preparing their evening meal, or a complex example, a group designing, building, operating, and maintaining a chemical processing plant, the trait of normalization of deviation will undoubtedly appear in some measure. The consequences of such behavior need to be addressed.

- We always hope the weather (that is, our situation) will be fine today. Sometimes we have advance notice of what to expect from a forecast for the weather. This is similar to the chemical plant's most recent audit report with action items. Sometimes an unexpected weather event affects us (as will the effects of our or others' behavioral deviance).
- Normalization of deviance, like the weather, will appear and it will influence our experience. It is inevitable and can affect our goals in a negative way—unless we monitor it and react to it.
- The analogy works in the following way.
- The weather is sometimes beautiful all day and night. We wish it were like this every day. The process is running normally. Normalized deviance appears to be non-existent. Procedures and standards are being followed. All is well.
- On other days that start out beautifully, normalized deviance may appear later with low impact, like a nice day with a few clouds or showers that roll through the area. Our process is experiencing some upsets that need to be watched or addressed. We do what we need to do to avoid the immediate effects and things might clear up for the rest of the day.

- On days when the skies turn threatening, normalization of deviation's impact can be like a sudden storm, unanticipated and harmful. It can appear quickly and demand immediate actions not previously part of the planned process. It is like a violent thunderstorm or tornado that appears during a large outdoor public event. A process safety incident or near miss that results from non-compliance with standards would be a processing related example.
- On yet other beautiful days, maybe even on the very day described in the first bulleted example in this list, deviations are being normalized somewhere just outside of our awareness (more likely, right under our noses) and its effects are not sensed at all—or they are ignored like small changes in the weather—until specific events line up at the right time to allow a perfect storm to occur. Then, like tornados or tsunamis, process safety incidents can develop quickly.

Luckily for the chemical processing industry, the analogy above fails in one critical way. Unlike natural weather events, in the case of normalized deviance we can forestall the worst effects of the gradual organizational acceptance of nonconformance when we apply the twenty process safety elements of Risk Based Process Safety (RBPS) [CCPS 2007]:

Process Safety Culture: The combination of group values and behaviors that determine the manner in which process safety is managed. A sound process safety culture refers to attitudes and behaviors that support the goal of safer process operations.

Compliance with Standards: Identify, develop, acquire, evaluate, disseminate and provide access to applicable standards, codes, regulations, and laws that affect a facility and/or the process safety standards of care that apply to a facility.

Process Safety Competency: Maintain, improve, and broaden knowledge and expertise.

Workforce Involvement: A series of activities that (1) solicit input from the entire workforce (including contractors), (2) foster a consultative relationship between management and works at all levels of the organization, and (3) help sustain a strong process safety culture.

Stakeholder Outreach: The efforts to (1) seek out and engage stakeholders in a dialogue about process safety; (2) establish a relationship with community organizations, other companies and professional groups, and local, state, and federal authorities; and (3) provide accurate information about company/facility operations, products, plans, hazards, and risks.

Process Safety Knowledge: The work activities to gather, organize, maintain, and provide information to other process safety elements. Process safety knowledge primarily consists of written documents such as hazard information, process technology information, and equipment-specific information.

Hazard Identification and Risk Analysis (HIRA): All activities involved in identifying hazards and evaluating risk at facilities, throughout their life cycle,

to make certain that risks to employees, the public, or the environment are consistently controlled within the organization's risk tolerance.

Operating Procedures: Written, step-by-step instructions and information necessary to operate equipment, compiled in one document including operating instructions, process descriptions, operating limits, chemical hazards, and safety equipment requirements.

Safe Work Practices (SWP) practice: An integrated set of policies, procedures, permits, and other systems that are designed to manage risks associated with non-routine activities such as performing hot work, opening process vessels or lines, or entering a confined space.

Asset Integrity and Reliability: A process safety management system for ensuring the integrity of assets throughout their life cycle.

Contractor Management: A system of controls to ensure that contracted services support (1) safe facility operations and (2) the company's process safety and personal safety performance goals. It includes the selection, acquisition, use, and monitoring of contracted services.

Training and Performance Assurance: Practical instruction in job and task requirements and methods, and the means by which workers demonstrate that they have understood the training and can apply it in practical situations. Training may be provided in a classroom or at the workplace, and its objective is to enable workers to meet some minimum initial performance standards, to maintain their proficiency, or to qualify them for promotion to a more demanding position.

Management of Change (MOC): A management system to identify, review, and approve all modifications to equipment, procedures, raw materials, and processing conditions, other than replacement in kind, prior to implementation to help ensure that changes to processes are properly analyzed (for example, for potential adverse impacts), documented, and communicated to employees affected.

Operational Readiness: The efforts to ensure that a process is ready for start-up/restart. This element applies to a variety of restart situations, ranging from restart after a brief maintenance outage to restart of a process that has been mothballed for several years.

Conduct of Operations: The embodiment of an organization's values and principles in management systems that are developed, implemented, and maintained to (1) structure operational tasks in a manner consistent with the organization's risk tolerance, (2) ensure that every task is performed deliberately and correctly, and (3) minimize variations in performance.

Emergency Management: The work activities performed to plan for and respond to emergencies. : A systematic approach for determining the causes of an incident and developing recommendations that address the causes to help prevent or mitigate future incidents.

Measurement and Metrics: Establishment of performance and efficiency indicators to monitor the near real-time effectiveness of the RBPS ,management system and its constituent elements and work activities.

Auditing: A systematic, independent review to verify conformance with the RBPS elements via a well-defined review process to ensure consistency and to allow the auditor to reach defensible conclusions.

Management Review and Continuous Improvement: The routine evaluation of whether management systems are performing as intended and producing the desired results as efficiently as possible.

By working to apply the concepts in this book thoroughly, you will find that occasionally a normalized deviation may reveal a positive thing. It occasionally reveals a process that needs to be revised to reflect reality. For example, many plants find that their operators are not using the operating procedures in the way desired by the company and expressed through rules. The reason is often that the documents are not current and the operators have been taking different actions to compensate. In addressing a discovery like this, it is essential that the organization evaluate these deviations on the part of the operators and assess how to best integrate them into various levels of the organization. These levels include management (technical and business), operations, maintenance, engineering, technical services, and quality. In this case, when an audit team finds the workers are not using the procedures, the team needs to dig deeper. The real deviation almost certainly stemmed from not managing change effectively. One good practice for this specific situation is to have provisions for the operators to recommend or make field changes to documents as they use them. When the field change process is planned and documented, it is a sub-routine of your management of change (MOC) system. The need for a field change is identified when a worker actually uses a procedure to do a task, but finds the plant configuration different from that described in the procedure. It is an unquestionable opportunity for organizational learning to advance.

This book addresses how to recognize and respond to the normalization of deviation that can occur in any ongoing process that involves humans. The primary focus is on reducing the incidence of normalization of deviation and the associated increased risk exposure due to its effects while operating a chemical manufacturing facility. This book attempts to make it clear that actively addressing normalization of deviation can assist manufacturers to succeed in improving performance in five main business-driven areas:

- Process safety performance
- Personnel safety performance
- Environmental responsibility
- Product quality performance
- Sustainable long-term profitability

1.1 THE DEFINITION OF NORMALIZATION OF DEVIANCE

This book focuses on how normalized deviance relates to catastrophic events, but the techniques it offers to address normalization of deviation can optimize any business process—also called work processes—whether the focus of the process is personnel safety, quality, environmental compliance, or business viability.

The following definition from the *Guidelines for Risk Based Process Safety* provides the basis of our discussion on how normalization of deviation affects our industry, especially in the area of process safety management [CCPS 2007]:

Normalization of Deviation - A gradual erosion of standards of performance as a result of increased tolerance of nonconformance.

Normalization of deviation is a long-term phenomenon in which individuals, work teams, and entire organizations sometimes gradually accept a different standard of performance until that becomes the norm. It is typically the result of conditions slowly changing and eroding over time. A human interaction based deviation has to have occurred repeatedly, over time, without causing an incident or a problem that noticeably affects the process in other ways, such as yield or product quality. To summarize, normalization of deviation requires these characteristics (Figure 1.1):

- It is a human based deviation.
- The deviation occurs repeatedly, over time.
- The deviation does not cause an immediate incident or a noticed process effect.

This does not necessarily mean the same work process deviation is occurring repeatedly, but the same types of deviations are occurring repeatedly; skipped steps, workarounds, and shortcuts. Nor does a deviation have to be practiced consistently. These types of deviations may be commonly practiced in the same way by one work crew “Hey, I found a new way to change that filter cartridge!”, but they may not be communicated between work crews. Some people will do it one way, some will do it another way.

Normalization of deviance can begin as a shortcut or poorly documented temporary change in a standard work practice, procedure, or business process. If there are no apparent negative consequences, or there is no recognition of the change as a deviation from the standard, the new practice becomes accepted and displaces the original practice. Over time, this process repeats. When the changes are small and seemingly insignificant, they are easy to miss. Normalization of deviance in critical process steps for hazardous chemical units may not always represent a breach of the management of change (MOC) system. It includes shortcuts related to management of subtle changes, even when an item may be considered a replacement-in-kind.

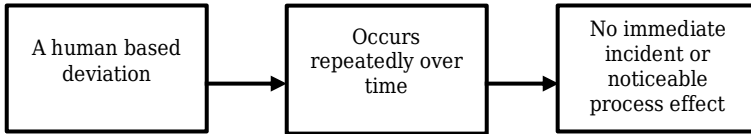


Figure 1.1. Three Characteristics of Normalized Deviation

The start can be a deviance within the acceptable operating range just on the low or high end and over time drift out of the acceptable range and become a safety issue. By that time the normalization of deviance is already established.

These types of deviations have been major contributors to many serious incidents. As an example, the Baker Panel Report found normalized deviance contributed to organizational dysfunction within BP [Baker 2007]. One example included a 2005 behavioral safety culture assessment that a consultant conducted described “the occurrence of at-risk behaviors and normalized deviations” at the BP Toledo refinery. The consultant further described a perception among workers that safety was not the highest priority among the refinery workforce. The consultant noted a belief that equipment was run to failure or near failure and problems were not fixed “until something bad happens.”

The BP Carson refinery appeared to have some issues related to operating discipline, risk identification, toleration of deviations from safe operating procedures, and apparent complacency toward serious process risks. A third-party behavioral safety culture assessment that BP commissioned indicated that the Carson refinery suffered to some extent from normalized deviations from safety practices, although the assessment found these deviations to be more common in personal safety procedures. It also found a number of factors driving at-risk behavior at Carson:

1. a culture that did not accept failure
2. the normalization of deviations from safety practices through repetition and the resulting failure to either recognize or report risk
3. positive reinforcement of unsafe behaviors as well as the lack of positive reinforcement of safe behaviors
4. the open-endedness of procedures that invited individual interpretation

1.1.1 Deviation Versus Deviance

Is there a difference between normalization of deviation and normalized deviance? The terms are used interchangeably in general discussion of the concept and in this book. Explicitly, deviation means departing from an established course or accepted standard (and in statistics, it means the amount

by which a single measurement differs from a fixed value such as the mean). Deviation implies a somewhat more quantitative departure (think standard deviation) than deviance does. It implies that something can be isolated and counted or individually examined. Usage examples are, *“A contributing factor to the incident was a deviation from the normal pressure range”*, or *“Three deviations from the approved procedure were observed.”*

Deviance, however, implies a more general quality. The definition is the state of departing from usual or normal behavior. A usage example would be, *“Our audit team found deviance in the management of change / pre-startup safety review elements of the administrative program.”* Deviance refers to the fact or state of departing from usual or accepted standards. Deviance can also be used to denote a systemic compounding of multiple or repeated deviations.

Regardless of which term or combination of terms is used in general discussion or throughout this book, the point remains that individual deviations to standardized work processes that go unrecognized or uncorrected will lead to deviance in those same work processes until eventually the deviations replace the standardized work processes.

1.2 THE MOTIVATION FOR WRITING THIS BOOK

While the CCPS team found several overarching normalization of deviation issues in the chemical processing industry that motivated this book's development, the ubiquity of normalized deviance within all organizations is, in itself, reason to address it. Other inherent issues include:

- Normalization of deviation can have a dramatic impact on production efficiency, product quality, process cycle times and other economic concerns.
- The unexpected appearance of normalized deviation promotes human error during operational and incident response efforts.
- The effects of normalized deviation can range from a quality issue to a catastrophic event.
- Incident investigations regularly identify both catastrophic and near miss process safety events where normalization of deviation was a contributing factor.
- Recognizing normalized deviance can be a significant improvement tool to help the chemical industry monitor every element of a process safety management system.
- Economic catastrophe after a process safety incident is a real possibility for some sectors of the chemical processing industry. Normalization of deviation can cause catastrophes.

1.3 OUR AUDIENCE AND HOW TO USE THIS BOOK

This book is intended for anyone interested in normalization of deviance as it relates to the chemical processing industry specifically or to manufacturing in general whenever there are critical process safety, personnel safety, quality, or environmental implications. The Center for Chemical Process Safety (CCPS) seeks to help both experienced process safety professionals and persons entering the field of process safety to better understand and manage normalization of deviation.

This book offers examples of techniques used by industry leaders to identify, respond to, and alleviate normalization of deviation. It can be used to check your practices and help reinforce or improve upon your current process safety management system.

The following list identifies positions within an organization that may benefit from this book:

- Managers of process safety and risk management programs and process safety management (PSM) coordinators at a manufacturing facility
- Corporate process safety management staff
- Project managers and project team members whose projects initiate the PSM life cycle for their design
- Engineers or other staff members performing management of change activities, particularly final approvers
- Incident investigation team leaders, team members, and trainers
- Industrial hygienists and safety department personnel
- Operations, maintenance, and other manufacturing personnel who may be part of a PSM element team
- Any employee participating in the PSM program
- Contractors at chemical processing facilities
- Executives and business leaders of any organization in the chemical process industry (CPI) and outside the CPI. Understanding the concept of normalized deviance is helpful in all business processes

1.4 HOW OUR WORLDVIEW AFFECTS US WHEN RECOGNIZING NORMALIZED DEVIANCE

Diane Vaughan is an American sociologist with wide-ranging academic interests. She developed the concept of normalization of deviance to describe a phenomenon she found through her work looking at the darker side of organizations. Her primary interest is in how things go wrong. *How did we make that huge mistake? How could that person have done such an unethical/illegal/incorrect thing? How did we let this disaster happen?* Her research points out that trouble comes not only from individual performance failures but also from endemic organizational failures.

Her work gained worldwide attention from the process safety community, incident investigators, and many other readers when she published *The Challenger Launch Decision* in 1996 [Vaughan 1996]. After the Columbia space shuttle lost mechanical integrity upon reentry in 2003, Professor Vaughan was invited to join the Columbia Accident Investigation Board (CAIB). Her participation on the team helped reveal that the NASA organization still had not learned from the 17-year-old, and deeply investigated, mistakes of the Challenger disaster. Unacceptable risks had been taken. Normalized deviance had crept back into NASA's daily practices regarding hazardous operations in spite of an ultimate lesson-learned experience.

During an interview, Dr. Vaughan described the concept of "social normalization of deviance." This is when people are so used to deviance that they don't consider it as deviance, even if the deviant behavior violates the organization's own rules for safety. The problem with social normalization is that workers get used to it and do not even think they are deviating from the rules or procedures [Vaughan 2008].

1.4.1 Regulatory Influences

Regulations and industry guidelines can influence our worldviews regarding deviance from them. In *Controlling Unlawful Organizational Behavior: Social Structure and Corporate Misconduct*, Dr. Vaughan notes the nature of the rules and laws we establish may influence deviations from those rules [Vaughan 1983].

Her examples of how regulations and rules affect deviation follow:

1. **Number:** Ignoring a large number of guidelines related to an industry may defy mastery or result in some regulations. Large numbers of laws and rules are difficult to monitor which reduces the likelihood of detecting deviations.
2. **Recency:** The age of a regulation or law may affect its legitimacy, knowledge of its existence, or the number of interpretations and precedents available for guidance. These factors can affect the desire to conform or deviate.
3. **Relevance:** Whether the organizational consensus agrees with the law in comparison with the larger purpose of their goals can influence willingness to comply.
4. **Complexity:** When regulations and laws are very complex and interrelated, they can be subject to different interpretations. It can cause deviance through simple misunderstanding.
5. **Vagueness:** Guidelines or laws that are unspecific or unclearly written can cause deviation from the rules' intent.
6. **Acceptability:** Does the facility or industry accept the rule? Does it match their focus; is it costly to adhere to in terms of resources? The

strength and consistency of enforcement fines and sanctions can affect deviation from the regulations.

Consider how the chemical industry views the nature of process safety rules around the world in light of the six categories above. What is the likelihood, or risk factor, that your facility or company is pushed toward deviation due to the six dimensions listed above?

1.4.2 Unique Worldviews

Dr. Vaughan's statement on the "Social normalization of deviance..." is about the individual and organizational worldviews of the people within the organization. That would be the chemical and petrochemical process industry. We are constantly evaluating our perceptions of the universe to create our individual conception of the world. As it is based upon perception, it varies from person to person and organization to organization as well as in every team or department. Additionally, it refers to the framework of ideas and beliefs forming a global description through which an individual, group, or culture watches and interprets the world and interacts with it. Other entities—humans and organizations—seem to be the most interesting subjects for us to evaluate. A special personality state is needed for us to know ourselves well enough to critique our personal mental models and identify when they need alteration.

The same case applies to organizations. The internal politics and status issues of the organization, which is made up of individuals who work in the boardroom as well as those who work in the boiler room, make it difficult for any organization to hold cohesive, organizational self-awareness. There is one holistic worldview held by the group, but it is often difficult to describe easily from inside the group. The group culture is best determined through observing displays of it in group decisions and actions.

Cultural influences can also affect people's worldview and normalization of deviance. Some influences include:

- **World and regional influences.** Particularly important for a large multinational, integrated company.
- **Local influences, within one country or continent.** Even within a country, depending on where you are in the country, the regional environment can influence personal risk tolerance. For example, in the United States, not all states require compliance with National Fire Protection Association (NFPA), or the National Board Inspection Code (NBIC) for boilers and pressure vessels. Design, maintenance, and inspection practices can vary significantly between states that require code compliance and those that do not. This can become a catalyst for acceptance of deviance within the workplace.
- **Rural versus Urban influence.** Plant management for plants located in rural areas (particularly where the workforce comes from an agricultural background) report that they need to essentially reprogram new hires' mindsets. Many new workers have spent their lives being rewarded for finding shortcuts. In an agriculture based economy, shortcuts equal more

food on the table, or money in the bank. The desire to take uncontrolled shortcuts must be prohibited in the workplace.

- **Economic influences.** Socioeconomic issues come into play at both the personal and organizational level. The capital or operating budget may be squeezed by some other force, such as the market or an internal drive for increased profit. Also, are the workers receiving equitable pay for the effort and skills they bring?

How do we determine when we are experiencing a normalized deviation at our facility? Is our individual worldview in the way? Is our organizational worldview skewed because of a long run of good luck or a brand that implies our organization is excellent and can do no wrong? Is it such a small change from our process that we justify it in our own minds and clear a path for normalized deviance to progress?

1.5 WORK PROCESS KNOWLEDGE IS ESSENTIAL IN DETERMINING THE EXISTENCE OF DEVIATION

*If you can't describe what you are doing as a process,
you don't know what you're doing.*

W. Edwards Deming

This quote could be considered a description of the foundation of process safety as a concept. Deming's words emphasize the proposition that an organization must know all of its business processes, from manufacturing operations to back office, in order to truly understand them and then try to improve them. For example, you must have process knowledge of all types in order to build or improve a process safety management system; process safety information, business process information, and accurate real-time process data are examples. Easy access to accurate process information supports process safety improvements, environmental performance, product quality, and provides for long-term economic viability.

The optimal time to identify and address normalization of deviance is the first time a work process deviation that had no immediate consequences is noticed but, by our definition and means test, normalized deviation as such has not truly occurred in the single first instance. The first deviance that is noticed and ignored is the first step toward a normalized deviation. In order to recognize deviations at your facility, you must know the requirements of the processes that make up your total business management process. From a process safety standpoint, we can then focus upon those managerial, supervisory, administrative, safety, environmental protection, operating, maintenance, shipping and related processes critical to preventing the release of highly hazardous chemicals. Chapters 4, 5 and 6 will describe techniques to recognize

and deal with deviance. To do this you first require a well-designed integrated process safety management system for a facility.

1.6 NORMALIZED DEVIATION AND TRADITIONAL PROCESS SAFETY CONCEPTS

How does normalization of deviation tie into traditional process safety concepts? Every process, whether an accounting process, a sales process, a management system process, a chemical plant unit operation, or a maintenance process, presents opportunity for deviation from that process.

A simple incident causation model that applies to normalization of deviation is the Hazard-Barrier-Target (HBT) theory (also called the Swiss Cheese Model) [Reason 1990]. This model provides an interesting view of the multiple-cause or system theory of incident causation. In HBT, an investigator starts with the understanding that a process has one or more inherent hazards. The hazard is a property of the process such as toxicity of a chemical, stored energy such as pressure much higher or lower than ambient, and electrical hazards. The target can be a person or the environment, and in an abstract sense, some interpret the target to be any loss impact. For example, the target could be product and lower quality could be the impact. The barriers are actually layers of protection that prevent the hazard from having a negative impact on the target. One important concept stressed in HBT is that ALL barriers have weaknesses; therefore, each barrier has some probability of not working when needed. These weakness are represented as a hole in the barrier. The most important concept for any incident investigator to learn may be the following statement:

No layer of protection is perfect.

Incidents occur when all barriers fail to prevent harm and a near miss occurs when one or more barriers fail. HBT is an excellent teaching tool for incident mechanisms and for describing the probabilistic nature of incidents, even for protected systems. For the purposes of this book, a deviation that could escalate to normalized deviance is the removal or neutralization of at least one barrier so that the hazard is more likely to affect the target [CCPS 2003].

Traditional process safety concepts that drive process safety excellence include the following [Amyotte 2011]:

- Risk management
- Inherently safer design
- Human error and human factors
- Safety management systems
- Safety culture

Normalized deviance can occur when implementing any of these general concepts. However, when programs are well designed, effectively implemented, and audited for compliance, they can:

- work to reduce the frequency of normalized deviations
- find deviations from the normal processes
- help abate normalized deviances found
- let us know when our normal process needs to be changed

1.6.1 Process Safety Around The Globe

Worldwide recognition of the benefits of process safety to workers and the environment became obvious beginning in the 1980s. Many governments and industry groups adopted process safety related standards or guidelines, continuing the sharing of information. Table 1.1 lists organizations and an example document they produced to recommend or require process safety elements be implemented.

For the purposes of this book and our discussions of deviance from administrative processes, we will use the model of the twenty CCPS RBPS elements [CCPS 2007]. In addition, there are specific regulations and directives that may apply to different locations (some examples are noted in Table 1.1). To keep this book's scope manageable, this book will note the similar regulatory elements in the *U.S. OSHA Process Safety Management (PSM) standard* and in sections of the *U.S. EPA Risk Management Program (RMP) Compliance Plan*. The following list summarizes the core of these U.S. PSM/RMP regulations [OSHA 1992, EPA 2017]:

- **Develop and maintain written safety information** identifying workplace chemical and process hazards, equipment used in the processes, and technology used in the processes.
- **Perform a workplace hazard assessment**, including, as appropriate, identification of potential sources of releases, identification of any previous release within the facility that had a potential for catastrophic consequences in the workplace, estimation of the effects of a range of releases, and estimation of the health and safety consequences of such a range on employees.
- **Consult with employees and their representatives** on the conduct of hazard assessments, and incident prevention/process safety plans. Provide access to these and other records required under the standard.
- **Establish a system to respond to the workplace hazard assessment findings**, which need to address prevention, mitigation, and emergency responses.
- **Periodically review the workplace hazard assessment** and response system.
- **Develop and implement written operating procedures for the chemical processes**, including procedures for each operating phase, operating limitations, and safety and health considerations.

Table 1.1 Examples of Global Process Safety Regulations and Guidance

Note. Please consult your local region or jurisdiction for specific requirements.

Australia Australian National Standard for Control of Major Hazard Facilities	Australian National Standard for the Control of Major Hazard Facilities, NOHSC: 1014, 2002. www.docep.wa.gov.au/
Canada Canadian Environmental Protection Agency, Environmental Emergency Planning	Environmental Emergency Regulations (SOR / 2003- 307), Section 200, Environment Canada. www.ec.gc.ca/CEPARRegistry/regulations
China Guidelines for Process Safety Management	Guidelines for Process Safety Management, AQ/T3034-2010; Effective 01-May-2011.
Europe European Commission Seveso III Directive	Control of Major-Accident Hazards Involving Dangerous Substances, European Directive Seveso- III (Directive 2012/18/EU). ec.europa.eu/environment/seveso/legislation.htm
France Ministry of Interior Orsec	Orsec (Organisation de la réponse de sécurité civile). Translated: Organization of the civil protection response. www.interieur.gouv.fr/Actualites/Dossiers/Le-plan- Orsec-a-60-ans .
Korea Korean Occupational Safety and Health Agency, Process Safety Management	Korean Occupational Safety and Health Agency, Industrial Safety and Health Act, Article 20, Preparation of Safety and Health Management Regulations. Korean Ministry of Environment, Framework Plan on Hazards Chemicals Management, 2001-2005. english.kosha.or.kr/main
Malaysia Department of Occupation Safety and Health Ministry of Human Resources Malaysia	Malaysia, Department of Occupational Safety and Health (DOSH) Ministry of Human Resources Malaysia, Section 16 of Act 514. www.dosh.gov.my/doshV2/
Mexico, Secretary of Labor and Social Welfare	Secretary of Labor and Social Welfare = Secretaría del Trabajo y Previsión Social (STPS), Mexican Standard NOM-028-STPS-2012, System For The Occupational Administration - "Safety In The Critical Processes And Equipment That Handle Hazardous Chemical Substances."
United Kingdom Health and Safety Executive COMAH Regulations	Control of Major Accident Hazards Regulations (COMAH), United Kingdom Health & Safety Executive (HSE), 1999 and 2005. www.hse.gov.uk/comah/
United States EPA Risk Management Program (RMP) Regulation	Accidental Release Prevention Requirements: Risk Management Programs Under Clean Air Act Section 112(r)(7), 40 CFR Part 68, U.S. Environmental Protection Agency, June 20, 1996 Fed. Reg. Vol. 61[31667-31730]. www.epa.gov
United States OSHA Process Safety Management (PSM) Standard	Process Safety Management of Highly Hazardous Chemicals (29 CFR 1910.119), U.S. Occupational Safety and Health Administration, May 1992. www.osha.gov

- **Provide written safety and operating information for employees and employee training** in operating procedures, by emphasizing hazards and safe practices that must be developed and made available.
- **Ensure contractors and contract employees** are provided with appropriate information and training.
- **Train and educate employees and contractors in emergency response procedures** in a comprehensive manner.
- **Establish a quality assurance program** to ensure that process-related equipment, maintenance materials, and spare parts are fabricated and installed consistent with the initial design specifications. (See RBPS Asset Integrity Management)
- **Establish maintenance systems for critical process-related equipment**, including written procedures, employee training, appropriate inspections, and testing of such equipment to ensure ongoing mechanical integrity. (Note: RBPS Asset Integrity element)
- **Conduct pre-startup safety reviews** of all newly installed or modified equipment. (Note: RBPS Operational Readiness element)
- **Establish and implement written procedures for managing change** to process chemicals, technology, equipment, and facilities.
- **Investigate every incident that results in or could have resulted in a major release** in the workplace, with any findings to be reviewed by operating personnel and modifications made, if appropriate.
- **Develop an emergency response plan for protecting the public and the environment** and coordinate activities with the community emergency planners. Facilities whose employees are expected to respond to releases of hazardous substances must develop an emergency response plan for protecting the public and the environment and must coordinate their activities with the community emergency planners and responders. Facilities whose employees will not respond do not have to prepare an emergency response plan; however, they must have an appropriate mechanism in place for notifying emergency responders in case of an incident.

It is important to note that normalized deviance can occur in any organization anywhere in the world, no matter which regulation, directive, or corporate standard applies.

Management system documents are written by an organization with the intent of establishing minimum standards and recommended internal guidelines to support performance based compliance with the applicable regulations. These documents become organizationally imposed rules. Many of them address very prescriptive aspects of the regulation, but also must address the choices an organization has in how it implements the process safety management system. When designing the system one should address the organizational culture and

establish the resource levels that will be applied. Work processes are more likely to be followed when they match the organizational culture and make sense to the person implementing them.

When this group of interwoven documents is developed with the cooperation and consensus of the workers, technical staff, and a representative of every department or group that has a role in implementing a process safety element, it provides a tapestry of enhanced risk management. The audit team needs to pay special attention when they recognize that a deviation may actively be normalized within the organization in regard to this program.

A well-documented and maintained process safety management system will augment organizational memory. Up-to-date piping and instrument diagrams (P&IDs), accurate procedures, hazardous area classification drawings, and a thoroughly documented and implemented management of change and pre-startup safety review system are prime examples of how the system creates memories. Maintenance of organizational memory should be reinforced continuously throughout the life cycle of a processing facility.

Maintaining accurate configuration data in real time and holding regular emergency drills are common practice in the commercial nuclear power industry. This promotes the concept of a healthy sense of vulnerability. Management encourages everyone to maintain a calm sense of awareness that the worst-case scenario can happen right now and that we need to be ready to follow our response procedures. Extensive training, strict document control for all critical procedure performance, configuration management, and other good practices keep this in the front of each employee's mind. A healthy sense of vulnerability is an attitude you should encourage and develop within your organization. Do not rely on a history of no catastrophic incidents as a sign of good performance. That history may just be good luck.

Table 1.2 gives some examples of how the RBPS PSM elements fight normalization of deviation element by element. You should be aware, however, that a PSM system could become a cause of deviance if it becomes too cumbersome. Solutions to this systems issue are described in Appendix G, *Guidelines for Management of Change for Process Safety* [CCPS 2008a].

When these specific concepts are implemented effectively as an interwoven system, they work to reduce the frequency of normalized deviation occurrences, find deviations from the normal processes, help abate the normalized deviances found, and occasionally, let us know when our normal process needs to be changed.

A movement over the past few decades toward developing an integrated management system approach in the refining and chemical processing industry (sometimes referred to as an operational excellence management system) has shown how these traditional process safety methods serve to support all of the other drivers and their needs. The overlap provides leverage for building a total business management system. *Guidelines for Integrating Management Systems and Metrics to Improve Process Safety Performance* covers integrated management systems in more detail [CCPS 2016a].

Table 1.2 Process Safety Elements: How They Reduce Normalized Deviance

Process Safety Element	How it Reduces Normalized Deviance
Process Safety Culture	A good process safety culture enables an organization to establish a high standard of performance and enables effective implementation of the other PSM elements. Employees will know the organization values process safety and will provide the resources to control risks.
Compliance with Standards	Compliance with standards will help a company design, operate and maintain a safe facility by taking advantage of the knowledge contained in the codes and complying with regulations.
Process Safety Competency	Competent people can transform information into knowledge. This allows people at all levels in the organization to understand and manage the process risks.
Workforce Involvement	Involving employees at all levels in new process safety program development or in maintaining and overseeing mature plans raises overall awareness of the level of operational discipline needed for rigorous process safety. Participants understand the “whys” of the administrative program better. They are more likely to communicate error up through the organization when it is perceived as a valued behavior.
Stakeholder Outreach	This element includes establishing relationships with professional groups such as the CCPS, American Petroleum Institute (API), International Electrotechnical Commission (IEC), IChemE, European Process Safety Centre (EPSC), etc. and encourages sharing of information and lessons learned with similar facilities and organizations.
Process Knowledge Management	Maintaining accurate process safety information (PSI) is a core information need for fighting normalized deviance. Not maintaining PSI effectively is often an example of normalized deviance. When allowed to continue, it can trigger separate deviations by inaccurate PSI and well-intended shortcuts taken by employees to address the PSI deficiency. Accurate PSI can discourage deviations like these.

Table 1.2 Process Safety Elements: How They Reduce Normalized Deviance (continued)

Process Safety Element	How it Reduces Normalized Deviance
Hazard Identification and Risk Analysis (HIRA)	Performing and maintaining accurate and up-to-date process hazard analyses provides core information needed for fighting normalized deviance. PHA helps identify the most critical physical and operational aspects of a process that normalized deviance can affect. It allows the organization's vigilance to be more focused on areas that represent the highest risk.
Operating Procedures	Writing and revising effective procedures gives workers reliable information to prevent deviations and their subsequent normalization. At a minimum focus on: operations procedures, safe work practices, maintenance procedures, and emergency response plan procedures. Other categories can be controlled as required by regulations. This also supports basic lean manufacturing techniques and consistent levels of operational excellence.
Safe Work Permits	This safe work practice, which applies in any manufacturing facility, can prevent very specific deviations related to common work practices involving control of ignition source, lock-out/tag-out, entry into confined spaces, etc.
Asset Integrity and Reliability	High quality maintenance of a well-designed physical process prevents process operation deviations. Workers will deal less with mechanically based operating issues that may encourage deviation. Also having a set of critical maintenance procedures effects a protection layer on the methods used to maintain equipment consistently. Training maintenance workers on the process and its hazards helps them have a better understanding of their roles in process safety.
Contractor Management	An effective program to select qualified contractor suppliers with good safety and work quality records, and training the contract workers on the unique hazards of the client facility can prevent imported deviations as well as newly developed homegrown ones. Imported deviations can come from a contractor's previous experience in facilities that may have had a very different risk profile.

Table 1.2 Process Safety Elements: How They Reduce Normalized Deviance (continued)

Process Safety Element	How it Reduces Normalized Deviance
Training and Performance Assurance Training Program	Providing effective training for new employees and updating existing employees with training on process changes that affect their jobs is a preventative measure against normalization of deviation. A formal training program minimizes the passing on of deviations from trainer to trainee. A well-trained employee will tend to confirm their knowledge when they encounter process related steps or conditions of which they are unsure. Encourage all employees to learn on their own and share what they find with the organization to improve each other's process knowledge and skills.
Management of Change (MOC)	Working with PSSR, the management of change element reduces the opportunity of introducing new deviations through thorough analysis, approval to proceed, and preparation for controlling permanent and temporary changes in process chemicals, technology, equipment, procedures, and process facilities. MOC provides for accurate data update and training and documented steps to help avoid the first deviation when starting up a change. Personnel understand the need to review a change before implementing it is a key part of catching deviations before they become part of normal practice.
Conduct of Operations	Conduct of operations includes, but is broader in scope than, operating discipline. It involves first planning and documenting the work to be done and then executing according to the plan. ("Plan the Work--Work the Plan"). Conduct of operations implies procedures are understood and followed, equipment is maintained, and changes are controlled. It also applies to engineering as well as operations. Design standards are followed, with up to date PSI and P&IDs are provided when the plant is handed over.

Table 1.2 Process Safety Elements: How They Reduce Normalized Deviance (continued)

Process Safety Element	How it Reduces Normalized Deviance
Operational Readiness	This element works with management of change to provide a two-tier check of any configuration changes from the current design. The purpose of the operational readiness review (commonly known as the Pre-Startup Safety Review (PSSR)) is to ensure that the change was implemented as approved in the MOC and that all of the required procedures and training have been accomplished so that the affected personnel are well prepared to begin operating and maintaining the changed process. It also documents that the organization is reducing the likelihood of introducing a deviation through analysis, study, and preparation for a change. Clear definition of PSSR critical deliverables (both new facilities and modifications to an existing facility) is the first step. A robust PSSR program is a hard stop. Evidence of completeness for each deliverable needs to exist prior to authorization to proceed to startup. Including an additional authorizer, one independent of the project, reduces opportunities to deviate.
Emergency Management	This element plans for reasonable contingencies in order to avoid deviation during a very stressful time for employees and the organization. Drills and training are essential pieces of this element as those present the only opportunity to notice deviations in practice prior to a live emergency.
Incident Investigation	In spite of effective performance in other elements, incidents can still occur at a site. Learning from incidents and near misses helps prevent repeat deviations that could become normalized. Thorough investigation also captures data on when normalized deviance was documented as a definite contributing factor to an incident. Near misses are often an early warning that a deviation has become normalized and a part of an organization’s culture.

Table 1.2 Process Safety Elements: How They Reduce Normalized Deviance (continued)

Measurement and Metrics	You don't improve what you don't measure. Uses of metrics enable an organization to identify areas that need improvement, and can identify where normalization of deviance has occurred, for example, the organization tolerates late inspections or inadequate follow-up of recommendations from PHAs
Auditing	This element forces a period of organizational self-reflection regarding process safety performance. It focuses attention on the administration of the program itself and allows a team to look for and find examples of normalized deviations.
Management Review and Continuous Improvement	Routine management review of metrics, audit findings, incident and near miss investigations enables management to identify areas where normalization of deviance may be lurking.

1.6.2 Implementing a New PSM System

The book *Guidelines for Implementing Process Safety Management Systems* lists the following steps for creating a new PSM system [CCPS 2016b]:

1. Develop the design specification for the PSM system (by reviewing existing frameworks to determine the one preferred going forward). This includes performing a gap assessment between the PSM system to be implemented and existing processes and procedures.
2. Create element and system workflows (as appropriate).
3. Estimate the workloads and resources needed to implement the new elements and system.
4. Develop written programs and procedures for the elements and system.
5. Roll out the elements and system at a single site to act as a pilot program before rolling them out to the entire company.
6. Monitor implementation and initial performance, and modify the elements and/or system to make them work for the pilot site. Once the PSM system is rolled out to the entire company, monitor its progress every six months and share the results with management.

You are encouraged to use this book if you are creating or modifying a system within your process safety and risk management program. For example, Figure 1.2 illustrate an approach for developing and maintaining a Process Hazards Analysis (PHA) system. This approach applies to process safety management in the same way it works with quality management systems, environmental management systems, business management systems, and occupational safety management systems. This model can aid in creating an organization that can achieve sustainable development and long-term operability. Equally important, a well-designed PSM system can help an organization develop a culture that supports safety excellence.

Many corporations integrate their management systems for Process Safety, Personal Safety, Health, Environmental, Security, and Quality to streamline procedures. You are encouraged to read *Guidelines for Integrating Management Systems and Metrics to Improve Process Safety Performance* for a general approach to process safety program development and maintenance [CCPS 2016a].

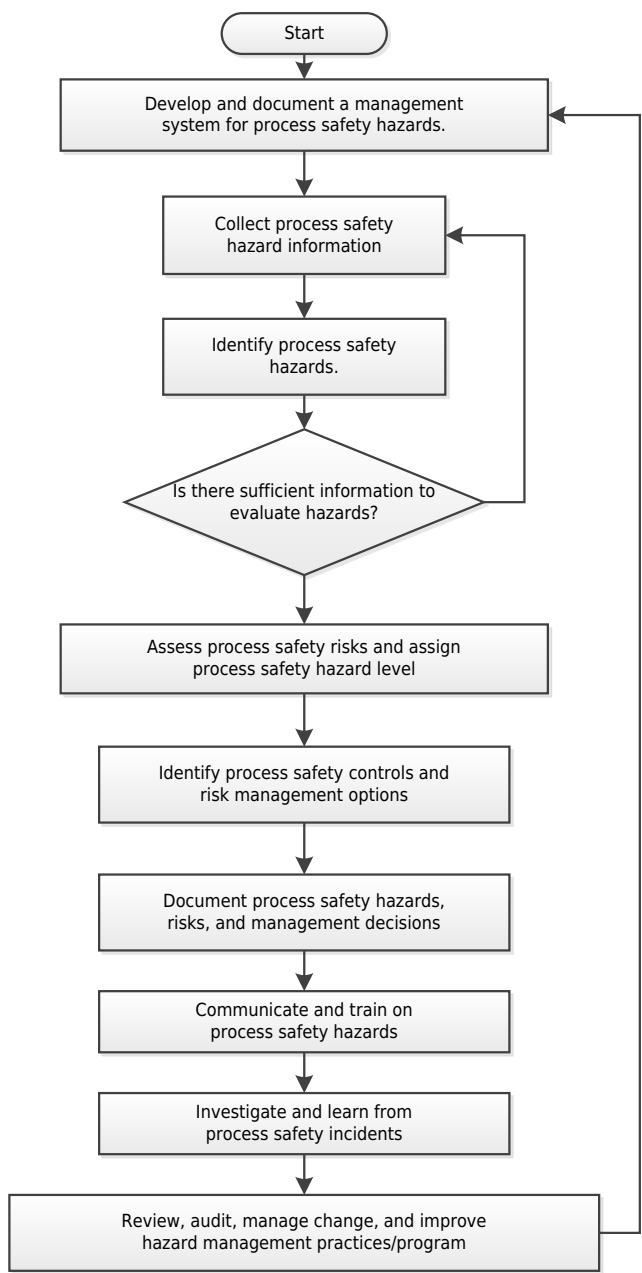


Figure 1.2. PHA Management System Development and Maintenance

