

# Revalidating Process Hazard Analyses

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# Revalidating Process Hazard Analyses

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*EQE International, Inc.*



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# Preface

The American Institute of Chemical Engineers (AIChE) has a 30-year history of involvement with process safety for chemical processing plants. Through its strong ties with process designers, builders, operators, safety professionals and academia the AIChE has enhanced communication and fostered improvement in the high safety standards of the industry. AIChE publications and symposia have become an information resource for the chemical engineering profession on the causes of accidents and means of prevention.

The Center for Chemical Process Safety (CCPS), a directorate of AIChE, was established in 1985 to develop and disseminate technical information for use in the prevention of major chemical accidents. The CCPS is supported by a diverse group of industrial sponsors in the chemical process industry and related industries who provide the necessary funding and professional guidance for its projects. The CCPS Technical Steering Committee selects the projects to be developed, with approval of the Advisory Board, and oversees the individual projects selected.

In 1992, CCPS published *Guidelines for Hazard Evaluation Procedures, Second Edition, with Worked Examples* to provide information to organizations for conducting hazard evaluations of processes handling potentially hazardous materials. While many companies had previously adopted the practice of reviewing process hazard analyses on periodic basis, there are now regulatory requirements mandating such revalidations for certain processes.

The goal of this guideline is to provide plant management, operating personnel, engineering groups, and safety professionals with supplemental information and methods to achieve well-executed revalidations, recognizing that there are many alternate routes to achieving a high level of quality in process hazard reviews.



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The members of the PHA Revalidation Subcommittee who worked with EQE International, Inc. to produce this text deserve special recognition for their dedicated efforts, technical contributions, and overall enthusiasm for creating a useful addition to the CCPS Concept series.

The members of the Subcommittee were:

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Ray E. Witter was the CCPS staff liaison and was responsible for the overall administration of the project.

EQE International, Inc. was the contractor for this project and Walter L. Frank and David K. Whittle were the principal authors of the text. The

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# Glossary

**Alternative Release Scenario (ARS)** The basis for an off-site consequence analysis required by the EPA RMP Rule. This release scenario is less conservative, and more likely to occur than the Worst Case Scenario.

**Consequences** The direct, undesirable result of an accident sequence usually involving a fire, explosion, or release of toxic material. Consequence descriptions may be qualitative or quantitative estimates of the effects of an accident.

**Covered Process** A process subject to regulatory requirements established under the OSHA PSM Standard or the EPA RMP Rule.

**Essential Criteria** Criteria defining the required content or conduct of a PHA based upon company or regulatory requirements.

**Hazard** An inherent physical or chemical characteristic that has the potential for causing harm to people, property, or the environment.

## **Hazard Evaluation**

**(HE)** The analysis of the significance of hazardous situations associated with a process or activity. Uses qualitative techniques to pinpoint weaknesses in the design and operation of facilities that could lead to accidents.

**Human Factors** A discipline concerned with designing machines, operations, and work environments to match human capabilities, limitations, and needs.

**Incident Investigation** The management process by which underlying causes of undesirable events are uncovered and necessary steps are taken to prevent similar occurrences.

**Likelihood** A measure of the expected probability or frequency of an event's occurrence.

**Management Of Change (MOC)** A system to identify, review and approve all modifications to equipment, procedures, raw materials and process-

ing conditions, other than “replacement in kind,” prior to implementation.

**Node** Sections of equipment with definite boundaries (e.g., a line between two vessels) within which process parameters are investigated for deviations. The locations on P&IDs at which the process parameters are investigated for deviations (e.g., a reactor). The concept of dividing a process into nodes for analysis is commonly, but not exclusively, used in HAZOPs.

**Pre-Startup Safety Review (PSSR)** A system to confirm, before the introduction of hazardous chemicals, that new or modified facilities are in accordance with design specifications; adequate procedures are in place; appropriate hazard analyses or management of change reviews have been conducted; and training of affected personnel has been completed.

**Process Hazard Analyses (PHA)** An organized effort to identify and evaluate hazards associated with chemical processes and operations to enable their control. This review normally involves the use of qualitative techniques to identify and assess the significance of hazards. Conclusions and appropriate recommendations are developed. Occasionally, quantitative methods are used to help prioritize risk reduction efforts.

**Process Safety Information (PSI)** Physical, chemical, and toxicological information related to the chemicals, process, and equipment. It is used to document the configuration of a process, its characteristics, its limitations, and as data for process hazard analyses.

**Process Safety Management (PSM)** A program or activity involving the application of management principles and analytical techniques to ensure the safety of chemical process facilities. Sometimes called process hazard management. Each principle is often termed an “element” or “component” of process safety.

**Program Level 1** An implementation program level under the EPA RMP Rule. Applies to those facilities perceived to have a negligible potential for serious off-site consequences in the event of an accidental release. There are no requirements for an accidental release prevention program for this program level.

**Program Level 2** An implementation program level under the EPA RMP Rule. Applies to certain facilities perceived to have the potential for off-site consequences in the event of an accidental release. The accidental release prevention program requirements for this program level are less rigorous than the Program Level 3 requirements.

**Program Level 3** An implementation program level under the EPA RMP Rule. Applies to certain facilities perceived to have the potential for off-site consequences in the event of an accidental release. The accidental release prevention program for this program level contains the most rigorous and detailed requirements under the RMP Rule.

**Recommendation** A suggested course of action intended to prevent the occurrence (or recurrence) of an accident event sequence, or to mitigate its consequences.

**Redo** To conduct a new PHA.

**Retrofit, Update, and Revalidate** To correct substantive deficiencies in the prior PHA, and then update and revalidate it (See Update and Revalidate).

**Risk Management Program (RMP) Rule** EPA's accidental release prevention Rule, which requires covered facilities to prepare, submit, and implement a risk management plan.

**Update and Revalidate** To revise a prior PHA, as required, to reflect any changes that have occurred since the prior PHA; new learnings about the hazards of the process; changes in risk management requirements; etc.

**Worst Case Scenario (WCS)** The basis for an off-site consequence analysis required by the EPA RMP Rule. This intentionally conservative accident scenario assumes the release of the entire inventory of a vessel, under the most unfavorable conditions, and with the failure of most protective features.



# Acronyms and Abbreviations

|              |                                                                                  |
|--------------|----------------------------------------------------------------------------------|
| <b>ACC</b>   | American Chemical Council; formerly the Chemical Manufacturers Association (CMA) |
| <b>AIChE</b> | American Institute of Chemical Engineers                                         |
| <b>API</b>   | American Petroleum Institute                                                     |
| <b>ARS</b>   | Alternative Release Scenario                                                     |
| <b>CAA</b>   | Clean Air Act                                                                    |
| <b>CCPS</b>  | Center for Chemical Process Safety                                               |
| <b>CMA</b>   | Chemical Manufacturers Association (See ACC)                                     |
| <b>CPI</b>   | Chemical Process Industry                                                        |
| <b>DCS</b>   | Distributed Control System                                                       |
| <b>EPA</b>   | Environmental Protection Agency                                                  |
| <b>FMEA</b>  | Failure Mode and Effects Analysis                                                |
| <b>FTA</b>   | Fault Tree Analysis                                                              |
| <b>HAZOP</b> | HAZard And OPerability (Study)                                                   |
| <b>HE</b>    | Hazard Evaluation                                                                |
| <b>MOC</b>   | Management of Change                                                             |
| <b>OSHA</b>  | Occupational Safety and Health Administration                                    |
| <b>PHA</b>   | Process Hazard Analysis                                                          |
| <b>PSI</b>   | Process Safety Information                                                       |
| <b>PSM</b>   | Process Safety Management                                                        |
| <b>PSSR</b>  | Pre-Startup Safety Review                                                        |
| <b>RMP</b>   | Risk Management Plan                                                             |
| <b>WCS</b>   | Worst Case Scenario                                                              |



# Introduction

## Why Was This Book Written?

Formal Process Hazard Analyses (PHAs) have been performed in the chemical process industries (CPI) for nearly 40 years, and most companies have included requirements for the conduct of PHAs in their company process safety programs. CCPS and industry organizations such as the American Petroleum Institute (API) and the American Chemical Council (ACC, formerly the Chemical Manufacturers Association) have followed industry's lead and have incorporated PHA as one of the elements in model process safety management (PSM) programs prepared for their member companies.

Many organizations include a periodic update requirement in their PHA programs. Such updates are intended to address considerations such as changes in processes and procedures, or increased knowledge about the hazards of the process. For example, CCPS in its *Plant Guidelines for Technical Management of Chemical Process Safety* provides guidance for process risk management assessments, which include a PHA. CCPS states:

It is suggested that the frequency of a process risk management assessment should be every 3 to 5 years... The frequency... may also be influenced by incidents or accidents, process changes, etc.

API in its Recommended Practice 750, *Management of Process Hazards*, suggests that (API 1990):

PHAs should be reviewed and updated periodically, with typical review intervals ranging from 3 to 10 years. ... changes in technology or in the facility... should be considered in establishing the review frequency...

Finally, ACC, in the Technology section of its Process Safety Code of Management Practices, suggests the "*Periodic assessment and documentation of process hazards...*" (ACC 1990).

Working with considerable input from industry, OSHA promulgated its Process Safety Management (PSM) Standard (29 CFR 1910.119) in February

1992 and EPA followed with its Risk Management Program (RMP) Rule (40 CFR Part 68) in June 1996 (OSHA 1992, EPA 1996). Both regulations require that regulated facilities conduct PHAs for covered processes and that PHAs be updated and revalidated at an interval not to exceed five years.

A properly conducted PHA can involve a significant investment of time and organizational resources. Thus, it is important that the PHA effort (both initial and revalidation) be wisely directed and implemented to properly steward limited resources. A considerable body of literature has been written on procedures and practices for conducting PHAs. The CCPS publication, *Guidelines for Hazard Evaluation Procedures, Second Edition, with Worked Examples* (subsequently referred to in this book as the *HEP Guidelines*), provides detailed guidance on topics such as preparing for the study, application of the various techniques, and analysis follow-up considerations (CCPS G-1).

This book addresses the need, identified by CCPS, for supplemental guidance with respect to considerations unique to the PHA revalidation task.

### Scope of This Book

This book provides one approach, and a number of tools, which should be applicable in a variety of situations. However, it does not provide a “one-size-fits-all” solution to the revalidation task. Neither is it intended to provide the “one true solution” to the task. Readers should develop procedures based upon an evaluation of their specific requirements.

This book assumes that the reader has at least a basic familiarity with the conduct of a PHA. While some introductory material is provided in Chapter 1, this book is not intended as an instructional text covering the general conduct of a PHA. Readers needing such detail are referred to the *HEP Guidelines*.

This book is a supplement to the *HEP Guidelines* and is premised on the same concept stated in this earlier work:

This book does not contain a complete program for managing the risk of chemical operations, nor does it give specific advice on how to establish a hazard analysis program for a facility or an organization. However, it does provide some insights that should be considered when making risk management decisions and designing risk management programs.

This book outlines a demonstrated, commonsense approach for resource-effective PHA revalidation. This approach first examines a number of factors such as the quality of the prior PHA; the frequency and magnitude of changes that have occurred within the process; the adequacy of the prior

PHA documentation; and the frequency of incidents and near-misses within the process. A revalidation plan is developed based upon this input.

This book is intended to be a concise reference for both the plant PHA practitioner and those with management responsibility for PSM implementation. Flowcharts, checklists, and worksheets provide the reader with valuable tools for use in the revalidation process.

## The CCPS Workshop

CCPS, at the September 1999 Technical Steering Committee meeting in San Francisco, made PHA Revalidation the topic of an afternoon workshop. This workshop included breakout sessions where participants had a chance to share their thoughts and experiences on the topic. The breakout groups addressed three basic questions:

1. What tasks should be completed before or during the team reviews of the PHA under consideration?
2. What criteria should be used to decide whether a PHA is valid in its current form, portions of the PHA must be revised, or the entire PHA needs to be redone?
3. What learnings can be applied to making future revalidations easier?

The work product from the workshop has been incorporated into this book.

## How This Book Is Organized

Chapter 1 provides an introductory overview of process hazard analysis and what it is intended to accomplish. A brief synopsis of the more common PHA techniques is provided.

Chapter 2 provides a general background on PHA revalidation: What is it? Why is it important? When should it be done?

Chapter 3 discusses the efforts involved in preparing for the revalidation task. Topics include preplanning the revalidation, and identifying, collecting, and preparing the information needed to support the task.

Chapter 4 provides instructions for evaluating the completeness and quality of the prior PHA.

Chapter 5 provides background and detailed instructions for identifying the changes that have been introduced into the process, equipment, and facilities since the prior PHA was completed. These changes will be considered during the revalidation.

Chapter 6 describes the alternative approaches available for use in the PHA revalidation and provides guidance on how to identify the appropriate revalidation methodology.

Chapter 7 provides guidance on conducting the PHA revalidation study sessions.

Chapter 8 addresses the documentation of the PHA revalidation study.

Finally, Appendices are provided containing supporting information and valuable checklists for use in conducting PHA revalidations.

# I

## Refresher on the Basics

Before getting into the specifics of process hazard analysis (PHA) revalidation, it might be helpful to briefly review the intent and conduct of PHAs.

### 1.1. What a PHA Is Intended to Accomplish

In 1992, CCPS updated and republished its *Guidelines for Hazard Evaluation Procedures*. In this second edition, CCPS stated:

A hazard is an inherent physical or chemical characteristic that has the potential to do harm (to people, property, or the environment). A hazard evaluation (HE) study is an organized effort to identify and analyze the significance of hazardous situations associated with a process or activity. . . . [It is] used to pinpoint weaknesses in the design and operation of facilities that could lead to accidental chemical releases, fires, or explosions. . . . [It provides] organizations with the information to help them improve the safety and manage the risk of their operations.

As shown in Figure 1.1, the PHA process involves five steps:

1. Identify the hazardous characteristics within the process. These may be characteristics of the process materials (e.g., toxicity or flammability), characteristics of the process (e.g., high temperature or high pressure), or characteristics of the equipment;
2. Identify potential equipment failures or human errors that could lead to accident scenarios that might result in harm;
3. Evaluate the magnitude of the harm (consequences) that could result from the accident scenarios and the likelihood of the accident scenarios occurring, then determine the associated risk based upon the likelihood and consequence;
4. Decide whether that level of risk is tolerable; and
5. For high-risk scenarios, propose risk reduction alternatives (recommendations) to reduce risk to a tolerable level.

**HEP...PHA??**

CCPS uses the term “hazard evaluation procedures” to encompass a broad range of applications for the analytical tools described in the Guideline. Process Hazard Analysis is one such specific application.

Thus, a PHA is a proactive exercise intended to identify the safety-related weaknesses in a process, its equipment design, its operating practices and procedures, its maintenance practices, etc. Recommended upgrades are proposed to address those weak spots that pose an intolerable risk to personnel, property, or the environment.

## I.2. Brief Review of the More Common PHA Methodologies

While there are many factors that go into making a good PHA, proper selection of methodology is one of the most basic. In practical application, six techniques are more commonly used:

1. What-If;
2. Checklist;
3. What-If/Checklist;
4. Hazard and Operability Study (HAZOP);
5. Failure Mode and Effects Analysis (FMEA); and
6. Fault Tree Analysis (FTA).

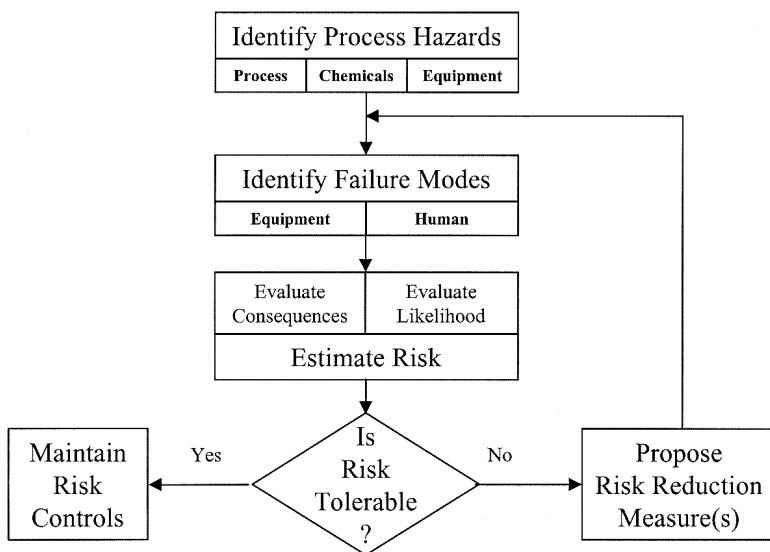


Figure I.1. Process Hazard Analysis Flow Chart .

A detailed discussion and comparison of the various PHA methodologies is beyond the scope of this book; readers unfamiliar with the various methodologies may wish to refer to the CCPS *HEP Guidelines* for guidance on technique selection. For our purposes here, short descriptions of these methodologies have been abridged from the *HEP Guidelines*, and are provided below.

**What-If.** The What-If Analysis technique is a brainstorming approach in which team members familiar with the subject process ask questions or voice concerns about possible undesired events. The purpose of a What-If Analysis is to identify hazards, hazardous situations, or specific accident events that could produce an undesirable consequence. An experienced group of people identifies possible accident situations, their consequences, and existing safeguards, then suggests alternatives for risk reduction. The method can involve examination of possible deviations from the design, construction, modification, or operating intent. The What If Analysis requires a basic understanding of the process intention, along with the ability to mentally combine possible deviations from the design intent that could result in an accident.

The concerns (often phrased in the form of *what if?* questions) are formulated based on experience and applied to existing drawings and process descriptions for an operating plant. There may be no specific pattern or order to these questions, unless the leader provides a logical pattern such as dividing the process into functional systems. The questions can address any abnormal condition related to the plant, not just component failures or process variations.

**Checklist.** A Checklist Analysis uses a written list of items to verify the status of a system. Frequently, checklists are created by simply organizing information from current relevant codes, standards, and regulations. A checklist is typically completed with “yes,” “no,” “not applicable,” or “needs more information” answers to the questions. Qualitative results vary with the specific situation, but generally, they lead to a decision about compliance with standard procedures and recognized practices. In addition, knowledge of any discovered deficiencies allows development of a list of possible safety improvement recommendations for consideration. The Checklist Analysis method is versatile. The type of evaluation performed with a checklist can vary. It can be used quickly for simple evaluations or for more extensive in-depth evaluations.

**What-If/Checklist.** The What-If/Checklist Analysis technique combines the creative, brainstorming features of the What-If Analysis method with the systematic features of the Checklist Analysis method. The hybrid method

capitalizes on the strengths and compensates for the individual shortcomings of the separate approaches. For example, the Checklist Analysis method is an experience-based technique, and the quality of a PHA performed using this approach is highly dependent on the experience of the checklist's authors. If the checklist is not complete, then the analysis may not effectively capture a hazardous situation. The What-If Analysis portion of the technique encourages the team to consider potential accident events and consequences that are beyond the experience of the checklist authors and, thus, are not covered on the checklist. Conversely, the checklist portion of this technique lends a more systematic nature to the What-If Analysis.

***Hazard and Operability Study (HAZOP).*** The purpose of a HAZOP is to carefully review a process or operation in a systematic fashion to determine whether process deviations can lead to undesirable consequences. In a HAZOP, the team uses a creative, systematic approach to identify hazard and operability problems resulting from deviations from the design intent of the process that could lead to undesirable consequences. An experienced team leader systematically guides the team through the plant design using a fixed set of words (called "guide words"). These guide words are applied at specific points or "study nodes" in the plant design and are combined with specific process parameters to identify potential deviations from the plant's intended operation. For example, the guide word "No" combined with the process parameter "flow" results in the deviation "No Flow."

The HAZOP team lists potential causes and consequences of the deviation as well as existing safeguards protecting against the deviation. When the team determines that inadequate protection exists for a credible deviation, it usually recommends that action be taken to reduce the risk.

***Failure Mode and Effects Analysis (FMEA).*** The purpose of an FMEA is to identify and tabulate equipment and system failure modes and their effects on a system or plant. The failure mode describes how equipment fails (open, closed, on, off, leaks, etc.) The effect of the failure mode is determined by the system's response to the equipment failure. An FMEA identifies single failure modes that either directly result in or contribute significantly to an accident. An FMEA generates a qualitative, systematic reference list of equipment, failure modes, and effects. This analysis typically generates recommendations for increasing equipment reliability, thus improving process safety.

***Fault Tree Analysis.*** Fault Tree Analysis (FTA) is a deductive technique that focuses on one particular accident or main system failure, and provides a method for determining causes of that event. The fault tree is a graphical model that displays the various combinations of equipment failures and

human errors that can result in the main system failure of interest (called the Top Event). This allows the hazard analyst to focus preventive or mitigative measures on significant basic causes to reduce the likelihood of an accident.

FTA is well suited for analyses of highly redundant systems. For systems particularly vulnerable to single failures that can lead to accidents, it is better to use a single-failure-oriented technique such as What If, or HAZOP. FTA is often employed in situations where another PHA technique (e.g., HAZOP) has pinpointed an important accident of interest that requires analysis that is more detailed.

### I.3. PHA Team Make-up

Analysis team composition is a critical part of any PHA. Industry experience has shown that PHAs are most effectively conducted by a multi-disciplinary team of experienced personnel (Frank 1993). A successful team includes personnel with knowledge and experience specific to the process being analyzed to help:

- Identify hazards that are specific to the unit;
- Provide insight into how the unit responds during upset conditions;
- Relate actual operating, maintenance, and training practices;
- Determine reasonable worst-case effects from upsets; and
- Judge the adequacy of existing safeguards.

Without adequate knowledge and experience specific to the process, a PHA team may not identify unique hazards or appropriately assess potential causes, consequences, or the effectiveness of safeguards to control process hazards.

One of the most important team member selections is that of the team leader. Skilled leadership by someone practiced in the PHA technique to be applied is important to ensure the success of the PHA effort (see sidebar). Participation by someone with an engineering background to help address technical aspects of the PHA deliberations is also important. Guidance on the selection of PHA teams is provided in the *HEP Guidelines*.

#### Revalidation Study leader should be:

- Knowledgeable in PHA methodologies used;
- A thorough, effective planner;
- Familiar with relevant PSM elements, especially MOC;
- An excellent communicator with good interpersonal skills



# 2

## Revalidation—What Is It?

This chapter describes what a PHA revalidation is intended to accomplish and introduces some of the optional approaches available to consider in the PHA revalidation process.

### 2.1. The Reason for Revalidation

There are at least six basic reasons why it is important to update and revalidate a PHA on a periodic basis:

***Changes in Process or Equipment.***

Process and equipment changes must be anticipated, and most process safety management system models embody a Management of Change (MOC) element to ensure that changes are properly scrutinized and authorized prior to implementation. However, MOC requests are often evaluated within a rather narrow context; i.e., “What are the potential consequences of what I intend to do right now?” There is a risk that, for processes undergoing frequent change, the significance of a particular change may not be assessed within the context of all the other changes that have occurred since the last PHA. Further, not all changes may be captured and evaluated under the MOC program. Thus, revalidation offers an opportunity, on a periodic basis, to perform an integrated evaluation of the cumulative (and potentially synergistic) impact of all of these changes, both controlled and uncontrolled.

***Gaps and Deficiencies in Prior PHA.*** Gaps are errors of omission; i.e., failures to address the established requirements for the conduct of the PHA. Some companies have documented requirements for what a PHA must address. Also, the OSHA and EPA regulations, as will be discussed more

**re·val·i·date** (rê-vàl-î-dât') verb,  
transitive To declare valid again.

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Language, Third Edition ©1996, Houghton Mifflin  
Co.

fully later, are very specific in defining considerations that must be addressed during PHAs for covered processes; e.g., the consideration of human factors. Failure to address human factors, or some other requisite company or regulatory consideration, would be a gap that must be filled during the PHA revalidation.

Deficiencies, on the other hand, are errors in applying the PHA methodology. For example, the prior PHA Team may not have consistently traced the effects of failure scenarios to their ultimate consequences. Revalidation teams, often including several new members (or, conceivably constituted with all new members) may identify hazards that the prior team overlooked. Even if the same team is used, new learnings may be discovered during the revalidation due to the experience gained by the team members in the interim.

**New Knowledge.** PHA revalidation teams may have access to information that the prior PHA team members did not have available to them. Such information might come from new company research, from work done by others and reported in the industry literature, or from learnings from incident investigations. New information may result in new or different conclusions or recommendations in the PHA revalidation report. Each revalidation offers a new opportunity to reconsider past deliberations in the light of current knowledge.

**Unresolved Recommendations.** PHA recommendations should normally be resolved in a timely manner to ensure that protections recommended by the PHA are promptly implemented. However, extenuating circumstances can dictate a delay in implementing a recommendation. The revalidation process provides an opportunity to reevaluate the validity of previous recommendations. If there are real safety issues at stake, why hasn't the recommendation been adopted within the period between the prior PHA and the revalidation PHA? On the other hand, if there is no compelling safety urgency associated with the recommendation, why not close it out as unneeded?

On a more positive note, the revalidation process also affords the team an opportunity to affirm that the actions taken to implement a recommendation did, indeed, resolve the issue addressed by the recommendation.

**Regulatory Requirements.** Those facilities subject to either the OSHA PSM or EPA RMP regulations must satisfy the regulatory requirement that PHAs be updated and revalidated at least every five years. The relevant portions of the OSHA and EPA regulations are reproduced in Appendix A.

**Changing Requirements.** The need to update a PHA may be driven by changes in requirements established by internal or external authorities. An

example of the prior could be the revision of the company policy or procedure for the conduct of PHAs.

## 2.2. Revalidation Objective

The primary objective of a PHA revalidation is to produce an updated PHA that adequately identifies, evaluates, and proposes controls for the hazards of the process, *as they are currently understood*. There are a number of reasons why today's understanding of the hazards associated with the process might differ from the understanding that existed at the time of the prior PHA. These could include:

- Process changes have introduced new hazards or accentuated existing hazards.
- Changes in on-site or off-site occupancy patterns have changed the at-risk populations.
- New knowledge is now available to better understand the hazard potential, revealing potentially more severe consequences.
- Actual incidents have revealed scenarios not previously identified in the PHA.
- Safeguards previously credited in the PHA have been removed, compromised, or discredited.

While the factors cited above have been selected to illustrate potentially negative outcomes, positive changes that should be reflected in the PHA revalidation are also possible. Perhaps process changes have actually removed hazards from the process (e.g., through application of inherently safer design principles). Safeguards may exist for which proper credit was not taken in the prior PHA or other new safeguards may have been added in the interim. In such circumstances, the PHA can be modified to reflect the current, less severe risk perspective.

A secondary objective of the revalidation effort might be to accomplish the primary objective with the most efficient use of time, personnel, and resources. Workforces are generally getting smaller, often with more to do, and it is important that the revalidation effort be accomplished with maximum effectiveness.

## 2.3. Revalidation Concept

The revalidation concept is straightforward:

Prior PHA(s) + Update  $\xrightarrow{\text{Revalidation}}$  New PHA

Considerable time, effort, and thought likely went into conducting the prior PHA. The revalidation process attempts to protect this investment by identifying and building upon the still pertinent portions of the prior PHA. Corrections are made and new content is added to the PHA as required (i.e., the PHA is *Updated*), and the results are documented to serve as the new PHA (i.e., the PHA is *Revalidated*).

In most situations, the effort required to revalidate the PHA will be significantly less than that required to conduct a new PHA. The alternative, to *Redo* the PHA from the beginning, is typically a more costly and time-consuming approach.

The degree to which the prior PHA can be used in the revalidation will depend upon a number of factors, including the quality of the prior PHA, the amount of change that has been implemented since the last PHA, and the adequacy with which the last PHA was documented. There are three courses of action that may be chosen, based upon these considerations. These courses of action are outlined below in order of increasing labor, resource, and time demands:

- *Update and Revalidate*: This is the expedient, incremental approach where the PHA need only be revised to reflect changes that have occurred and new learnings that have been gained since the prior PHA was conducted. The update effort may be relatively modest for some processes (especially established, mature processes subject to infrequent change). For a process involving no incidents or changes, it may only be necessary to affirm the continued validity of the prior PHA.
- *Retrofit, Update and Revalidate*: In this approach, an initial effort is needed to address one or more “repairable” defects in the prior PHA. Once the defects have been repaired, the PHA can be updated and revalidated as described above.
- *Redo*: This option is indicated when a repair of the PHA is impractical due to the nature, number, or magnitude of the defects in the prior PHA, the incidents or near misses that have occurred since the prior PHA, or the changes introduced since the prior PHA. In this situation, it may be more cost and resource effective to start from the beginning with a “blank sheet of paper.”

Chapter 6 will discuss the above options in greater detail and provide implementation guidance.

## 2.4. Establishing the Revalidation Schedule

As Figure 2.1 illustrates, periodic PHA revalidations are an ongoing requirement for the life of the process.

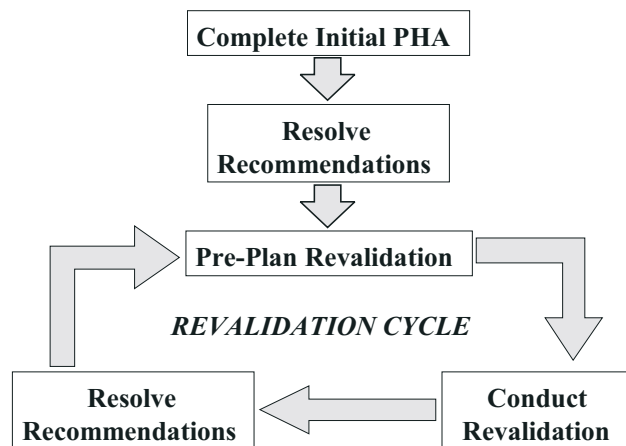


**Figure 2.1. PHA Revalidation Cycle.**

While many companies specify PHA revalidation every five years, specific facilities may elect to perform a revalidation sooner than this, for a number of reasons.<sup>1</sup>

Examples of situations where facilities may choose a more frequent revalidation include:

- Companies may decide that more frequent revalidations are more consistent with their loss prevention goals.
- If a major process or equipment revision is in progress, it may be more cost effective for a company to revalidate the unaffected portion of the process while performing the PHA of the modification;.
- MOC and prestart-up safety reviews (PSSR) are intended to maintain the integrity of original safety features designed into the process, and to ensure that any new hazards are properly managed. However, the potential that overlooked and uncontrolled hazards exist, because of unidentified interactions, increases with the number of process modifications. Some companies may wish to consider triggering a revalidation based upon the cumulative number of changes.

<sup>1</sup> This book will commonly refer to a five-year revalidation cycle. This value, while specified in the OSHA and EPA regulations, is also the approximate median value recommended by industry associations, and represents a frequency that has been commonly applied by many companies in the past. Facilities not covered by the OSHA or EPA regulations should remember that they may establish their own, appropriate revalidation frequencies. As discussed here, regulated facilities may choose to revalidate more frequently than once every five years.

- Some companies have established frequencies for revalidating PHAs based upon a risk categorization (e.g., high, medium, low); for “high” risk processes, revalidation is sometimes more frequent than every 5 years. This type of approach is consistent with API Recommended Practice 750, *Management of Process Hazards* (API 1990).
- A significant incident or an unfavorable incident trend in a process might call into question the adequacy of the prior PHA, prompting an expedited revalidation. Similarly, incidents at another company site, or even outside the company, may foster reservations with regard to the prior PHA.
- Following a merger or acquisition, there may be a perceived need to reconcile quality or protocol disparities in PHAs.
- A company might have a concern that PHAs conducted early in the development of the facility PSM program may not have been as rigorously or as effectively conducted and may warrant review by more experienced PHA teams.

#### When Should the Clock Start?

What determines the required date for beginning the PHA revalidation meetings; is it 5 years from (1) the prior PHA first meeting date, (2) the prior PHA last meeting date, (3) the date the prior PHA report was issued, or (4) some other date? PHA meetings can span weeks and the final PHA report can be issued several weeks (if not months) later.

A prudent approach is to calculate the 5-year date from the first meeting date for the prior PHA. This approach assumes that the prior PHA team had up-to-date PSI at the start of their first meeting, but did not consider in their analysis changes and incidents that occurred during the conduct of the PHA (typically, the P&IDs and related PSI are “frozen” as of the start of the PHA team meetings). This approach helps ensure that changes and incidents that may not have been factored into the prior PHA are considered in the revalidation.

Regardless of the method used to calculate the 5 year revalidation date, the objective should be to ensure that the PHA revalidation team considers all changes and incidents in the process that were not considered in the previous PHA.

In summary, various factors may influence a company to perform PHA revalidations on a more frequent basis. This decision may be made on a process-specific basis to address needs unique to that process.

### 2.5. The Role of a Revalidation Procedure

Company or site procedures or standards often outline the steps to be followed in conducting PHAs. The benefits of such procedures include:

- Establishing schedules to ensure that PHAs are conducted in a timely fashion;
- Ensuring that the conduct and documentation of the PHA complies with pertinent company and regulatory requirements;
- Providing for a consistent content and format so that those using the PHA as an information source can anticipate what information will be available and know how to find it; and
- Establishing responsibilities for key roles with respect to the PHA element, including that for recommendation follow-up.

**From the Workshop...**

A corporate standard establishing procedures for conducting PHAs and PHA revalidations, including specific criteria for evaluating PHAs, was cited by Revalidation Workshop participants as an item believed likely to ease the task of future revalidations.

Many readers may find a company or site-specific revalidation procedure to be of value. While some organizations may need to address additional considerations, it is suggested that the revalidation procedure at least cover the procedural steps that are listed below and discussed in detail in this book:

- Preparing for the revalidation (Chapter 3);
- Evaluating the completeness and quality of the prior PHA (Chapter 4);
- Identifying changes and incidents that have occurred since the prior PHA was conducted (Chapter 5);
- Identifying an appropriate revalidation methodology (Chapter 6);
- Conducting the revalidation study sessions (Chapter 7); and
- Documenting the revalidation study (Chapter 8).



# 3

## Preparing for the Revalidation Study

This book proposes one logical approach to the revalidation task, as depicted in Figure 3.1. This is not the only possible path to success; however, it is an approach distilled from numerous successful revalidation studies. This chapter discusses preparations important to the success of the revalidation effort.

### 3.1. Preplan the Revalidation

Proper preplanning of the revalidation is essential for a cost-, time-, and resource-effective effort. The preplanning may be accomplished by the study leader, with the support of other interested parties such as the process expert, production management, or the site PSM or PHA coordinator. Common issues to be considered when preplanning are discussed below.

#### 3.1.1. Establishing the Scope of the Revalidation

It is imperative that the physical and analytical scope of the revalidation effort be clearly delineated so that affected equipment, personnel, records, etc. can be identified for the revalidation.

The scope of the revalidation need not be dictated by the scope of the prior PHA. For example, some organizations chose initially to divide a single process into more manageable subsections, with a PHA conducted for each subsection. It is conceivable that an organization may choose to otherwise aggregate (or perhaps further subdivide) processes prior to the revalidation effort. For example, it might be decided to group two PHAs (one nearly five years old and one only three years old) into a single revalidation PHA. There is no apparent impediment to doing so, as long as no single PHA

goes beyond its revalidation deadline. In such circumstances, the revalidation team would need to gather information on both PHAs in order to plan the revalidation effort properly.<sup>1</sup>

It is not uncommon for specialized PHA considerations (e.g., siting or human factors) to be addressed via a separate study conducted in support of the main PHA.<sup>2</sup> It should be determined whether such adjunct studies are to be included in the revalidation effort, or whether they will be separately revalidated.

### 3.1.2. Selection of Team Members

There are two schools of thought with respect to selection of PHA revalidation team members; either, (1) for efficiency, keep the same team as before, or (2) for objectivity, select a new team. Either approach can be defended on its merit. In reality, however, organizational issues (e.g., loss or reassignment of past team members) often prevail, and the team ends up as a mix of new personnel and personnel that were involved in the prior PHA. Furthermore, experience with the prior PHA may indicate the need to supplement the revalidation team with members representing specific areas of expertise not present on the prior team (e.g., metallurgist, control engineer, R&D chemist, loader/unloader).

As is the case with any initial PHA, the responsibility rests with the study leader to ensure that a proper mix of knowledge, experience, and training is embodied in the team make-up.

Those facilities covered by the OSHA or EPA regulations should keep in mind the specific requirements for team make-up that are discussed subsequently in Section 4.1.3.

#### From the Workshop...

Revalidation Workshop participants noted that a mix of both new and prior team members might satisfy at least three goals:

- Providing some consistency of approach to the PHA effort;
- Providing fresh insight and objectivity; and
- Training participants for future PHA revalidations

<sup>1</sup> Situations where multiple PHAs exist for a single process could include projects for which PHAs were staged as different portions of the design were completed, or where a separate PHA was conducted for a control system upgrade. The revalidation PHA offers an opportunity to pull these multiple PHAs together.

<sup>2</sup> Those processes covered by the EPA RMP Rule are subject to stationary source siting requirements that are broader than the facility siting evaluation requirements established by the OSHA PSM Standard. (See Appendix A.) Where the terms "siting" is used in this book, it should be interpreted as encompassing either or both of the OSHA facility siting and the EPA stationary source siting requirements, as appropriate.

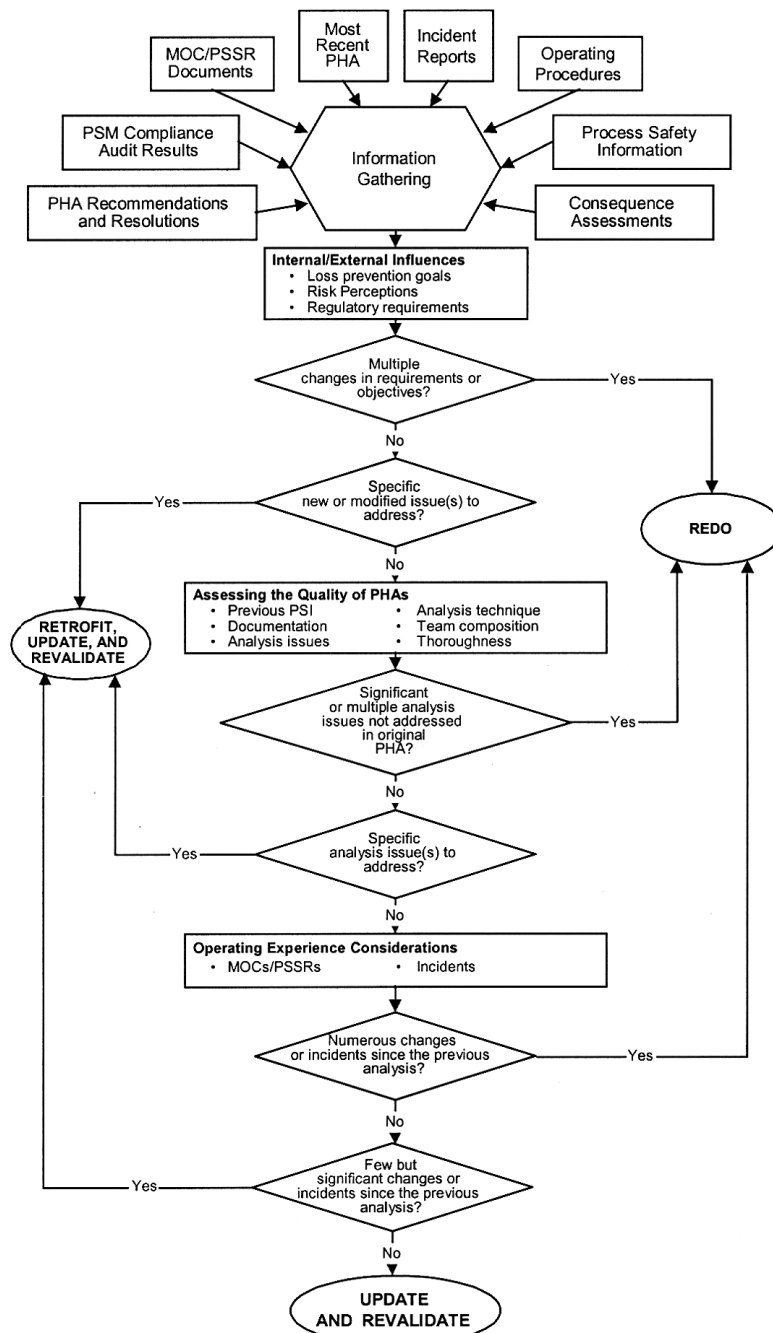


**Figure 3.1. PHA Revalidation Logic Flowchart.**

(Adapted from Crumpler and Whittle, 1996.)

### 3.1.3. Scheduling—Estimating Time and Resources

An important part of the preplanning is to establish a schedule that ensures the completion of the revalidation to meet any company or regulatory deadlines. The time needed to complete a revalidation will depend upon factors such as:

- The quality and completeness of the prior PHA;
- Availability of information from the prior PHA;
- The number of undocumented changes, if any, to be reviewed; and
- The quality of the MOC and PSSR programs.

PHA quality and completeness is likely to be one of the more important factors on the list. Refer to Chapter 4 for a discussion of factors that could negatively impact upon the prior PHA.

Experience to date allows us to place only broad boundaries on estimates of the time or resource requirements for completing a PHA revalidation. Significant content or quality problems will necessitate a *Redo* for some PHAs; for others, the number of changes to be evaluated will make a *Redo* the more cost-effective option. The time involved in completing a *Redo* should be comparable to that for an initial PHA.

For those situations where the *Update and Revalidate* option or the *Retrofit, Update and Revalidate* option are feasible, the time required for the revalidation sessions can range from 10% to 50% of the time needed for an initial PHA. Including the data gathering and preparation time, the total person-hours required for the revalidation can range from 35% to 75% of that required for an initial PHA.

Clearly, there is no such thing as a “typical situation”; however, the above figures can be used for a first approximation of the time requirements.

Another approach to estimating meeting time considers the number and complexity of the changes to be evaluated during the revalidation. For example, assume the changes are grouped into the following four categories for estimating evaluation time: small (5 minutes or less); medium (15 minutes); large (30 to 60 minutes); and very large (greater than 60 minutes). When grouping changes, it is advisable to review in more detail any change that will take longer than 60 minutes to get a more accurate time estimate. Table 3.1 gives typical examples of changes that may fit into each of these categories (Smith and Whittle, 2000).

These time estimates assume that all the modifications to the process (and any associated documentation) have been reviewed prior to the revalidation meetings by the PHA revalidation leader or other experienced personnel. This ensures that personnel who are very familiar with the modifications can explain to the full revalidation team the rationale for each change.

**TABLE 3.1****Example Modification Categories for Estimating PHA Revalidation Meeting Time**

| Category                     | Modification                                                                                                                                                                                                                                                                                                                                                                    |
|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Small<br>(5 minutes or less) | <ul style="list-style-type: none"> <li>• Replace a carbon steel coupling with a stainless steel coupling</li> <li>• Change the sampling frequency on a product tank from once per shift to once per day</li> <li>• Install an additional block valve on the drain line from a heat exchanger</li> </ul>                                                                         |
| Medium<br>(15 minutes)       | <ul style="list-style-type: none"> <li>• Replace an existing gas-fired reboiler with a shell/tube heat exchanger</li> <li>• Install a new fixed firewater nozzle on the west side of the process</li> <li>• Replace a rupture disk with a relief valve on a vessel</li> <li>• Install a 2-inch temporary hydrogen line from the hydrogen header to a reactor</li> </ul>         |
| Large<br>(30 to 60 minutes)  | <ul style="list-style-type: none"> <li>• Install a new storage tank in the tank farm</li> <li>• Tie-in an atmospheric vent line from a reactor to an existing line to a thermal oxidizer</li> <li>• Remove a nitrogen regulator from a unit's nitrogen supply header</li> <li>• Install a new bypass line around the dehydration and scrubbing system from a reactor</li> </ul> |
| Very Large<br>(> 60 minutes) | <ul style="list-style-type: none"> <li>• Install an additional process train that includes a line with a pump and two columns</li> <li>• Add a new scrubber tower and associated caustic circulation system</li> </ul>                                                                                                                                                          |

If the study worksheets (e.g., HAZOP worksheets) for the prior PHA are to be updated, the PHA revalidation leader may flag in the worksheets appropriate deviations or questions that may need updating based on this preliminary assessment of each modification. This preparation work will help accelerate the pace of the PHA revalidation meetings and allow the PHA revalidation leader to methodically guide the team through this task.

### 3.2. Identify, Collect, and Prepare Needed Information

Considerable information may be required to support a rigorous PHA effort. It should not be surprising that similar information might also be required for the PHA revalidation. In fact, the revalidation effort will likely require