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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
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.
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.  

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 prestartup 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.

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.

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:

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**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.
• 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.

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).

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.