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Guidelines for

PROCESS SAFETY
IN OUTSOURCED
MANUFACTURING OPERATIONS
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Guidelines for

PROCESS SAFETY
IN OUTSOURCED MANUFACTURING OPERATIONS

CENTER FOR CHEMICAL PROCESS SAFETY
of the
AMERICAN INSTITUTE OF CHEMICAL ENGINEERS
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New York, New York 10016-5991
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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 and the technical subcommittees oversee individual projects selected by CCPS. Professional representatives of the sponsoring companies staff the subcommittees, with a member of the CCPS staff coordinating the activities of the sub-committee.

Since its founding, CCPS has published many volumes in its "Guidelines" series and in smaller "Concept" texts. Although most CCPS books are written for engineers in plant design and operations and address scientific techniques and engineering practices, several guidelines cover the subject of chemical process safety management. Successful process safety programs are the products of committed and active participation of managers at all levels who apply a systematic approach to process safety as an integral part of operations management.
This Guideline describes techniques to assist the chemical processing industry in applying the CCPS chemical process safety concepts to the tolling vendor-client relationship. This Guideline book is intended to provide guidance in fundamental safety practices to technical staff and management. It is hoped that the guidance and examples provided will aid in promoting safer, more efficient tolling operations.
ACKNOWLEDGMENTS

The American Institute of Chemical Engineers (AIChE) wishes to thank the Center for Chemical Process Safety (CCPS) and those involved in its operation, including its many sponsors whose funding made this project possible and the members of the Technical Steering Committee who conceived of and supported this guideline project. The members of the Outsourced Manufacturing Operations Subcommittee who worked with AntiEntropics Inc. to produce this text deserve special recognition for their dedicated efforts, technical contributions, and overall enthusiasm for creating a useful addition to the process safety guideline series.

The members of the Subcommittee were:

Adrian L. Sepeda, Chair, Occidental Chemical Corporation
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Ray E. Witter was the CCPS staff liaison and was responsible for the overall administration of the project.

AntiEntropics Inc. of New Market, Maryland was the contractor for this project. Robert J. Walter and Sandra A. Baker were the principal authors of the text and would like to recognize James M. Godwin for editorial support and Paul Ponton for graphics assistance.

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Lastly we wish to express our appreciation to Jack Weaver and Les Wittenberg of the CCPS staff for their support and guidance.
# ABBREVIATIONS AND ACRONYMS

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<tr>
<td>AIChE</td>
<td>American Institute of Chemical Engineers</td>
</tr>
<tr>
<td>ARC</td>
<td>Accelerating Rate Calorimeter</td>
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<td>CCPS</td>
<td>Center for Chemical Process Safety</td>
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<tr>
<td>cGMP</td>
<td>Current Good Manufacturing Practice</td>
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<td>CMA</td>
<td>Chemical Manufacturers Association</td>
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<tr>
<td>CPI</td>
<td>Consumer Price Index</td>
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<tr>
<td>D&amp;B</td>
<td>Dun and Bradstreet</td>
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<td>DFR</td>
<td>Duns Financial Records Plus</td>
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<tr>
<td>DOT</td>
<td>Department of Transportation</td>
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<tr>
<td>EDI</td>
<td>Electronic Data Interchange</td>
</tr>
<tr>
<td>EMR</td>
<td>Experience Modification Rate</td>
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<tr>
<td>EPA</td>
<td>Environmental Protection Agency</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
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<tr>
<td>HS&amp;E</td>
<td>Health, Safety and Environmental</td>
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<tr>
<td>Kst</td>
<td>Severity of Dust Explosion Scale, which is a combination of maximum pressure and rate of pressure rise.</td>
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<tr>
<td>LEL</td>
<td>Lower Explosive Limit</td>
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<tr>
<td>LEPC</td>
<td>Local Emergency Planning Committee</td>
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<tr>
<td>MACT</td>
<td>Maximum Achievable Control Technology</td>
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<tr>
<td>MIE</td>
<td>Minimum Ignition Energy</td>
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<td>MIT</td>
<td>Minimum Ignition Temperature</td>
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<td>MOC</td>
<td>Management of Change</td>
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<tr>
<td>MSDS</td>
<td>Material Safety Data Sheets</td>
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<tr>
<td>NESHAP</td>
<td>National Emission Standards for Hazardous Air Pollutants</td>
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<td>NORM</td>
<td>Naturally occurring radioactive materials.</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>NOx</td>
<td>Collectively refers to the combustion byproducts: NO, nitric oxide, and NO₂, nitrogen dioxide</td>
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<tr>
<td>OSHA</td>
<td>Occupational Safety and Health Administration</td>
</tr>
<tr>
<td>PROMT</td>
<td>Predicasts Overview of Markets and Technologies</td>
</tr>
<tr>
<td>PSSR</td>
<td>Pre-startup Safety Review</td>
</tr>
<tr>
<td>SARA</td>
<td>Superfund Amendment Reauthorization Act</td>
</tr>
<tr>
<td>SNUR</td>
<td>Significant New Use Regulation</td>
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<tr>
<td>SOCMA</td>
<td>Synthetic Organic Chemical Manufacturers Association</td>
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<tr>
<td>SPC</td>
<td>Statistical Process Control</td>
</tr>
<tr>
<td>TSCA</td>
<td>Toxic Substances Control Act</td>
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<tr>
<td>VOC</td>
<td>Volatile Organic Compound</td>
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INTRODUCTION

1.1. This Guideline's Scope

Recent incidents have illustrated that exchange of process technology and product safety information can be a major factor in the success of a contract manufacturing operation. This guideline describes methods to help the chemical processing industry apply the CCPS chemical process safety concepts to outsourced manufacturing operations, specifically the tolling vendor–client relationship. In addition to the focus on process safety, information and examples provided in this text foster good practices relative to community and worker health, and environmental responsibility.

The techniques presented in this book will help improve the performance of tollers as well as companies seeking to use tolled services in the areas of:

- Safety
- Industrial hygiene
- Catastrophic incident prevention
- Off-site and on-site environmental responsibilities, and
- Quality production and packaging of contracted materials

The final item in the list—Quality—should be measured in a way that includes how well the previous four items are achieved. This is depicted in Figure 1-1.

All five elements combine to help ensure that the tolling operation is performed safely, efficiently, and in an environmentally sound manner. The ultimate reward to industry for embracing applicable good practices presented in this guideline is a vibrant business with minimized risk. The flowchart on page 3 shows the basic process for tolling as presented in this guideline.
1.2. The Guideline's Audience

Both parties involved in a tolling operation are the intended audience for this book. Listed below are various terms used for companies that provide tolling services.

- Contract manufacturer
- Contract processor
- Custom chemical manufacturer
- External contract manufacturer
- Outsourced manufacturer
- Supplier of outside services
- Third party service provider
- Toll processor
- Toller

For simplicity's sake, we have selected the following two terms, as referenced in the definition for tolling, for the two entities involved. They will be used throughout the book. They are:

- Tollers, and
- Client or company letting the toll.
1.2. The Guideline’s Audience

Figure 1-2. Tolling operations process flowchart.
Within these two audiences, our objective is to appeal to both the technical staff and management by providing guidance and examples that can help promote safer, more efficient tolling operations. Our goal is to provide a concise reference source and template for a comprehensive health, safety, and environmental (HS&E) effort that engages both the tollers and their clients. Involving the health, safety and environmental staff up front in the tolling contract process can save time and money later.

In addition to technical staff and management, we hope to reach the commercial staff, purchasing group or marketing group within client companies. Business needs sometimes drive these groups to arrange for tolling contracts to meet special market or production requirements. Commercial staff can use the concepts presented in this text when they arrange for tolling contracts.

Although this book discusses some specific regulatory issues in the United States, its overall message is intended to apply globally. The reader should keep in mind that the U.S. regulations referenced throughout the text may be mirrored by similar regulations applicable to tolling operations performed in any other country.

1.3. What Is Outsourced Manufacturing?

Companies in the chemical processing industry use a wide range of terminology to describe the types of contractual arrangements for outsourced manufacturing (tolling) discussed in this text. This situation requires us to define what we mean by tolling. The definition that follows is intended to apply throughout this book.

"Tolling" means to provide manufacturing services for a fee by a contractor (the toller), to a company issuing (letting) a contract for those services. Tolled services can include:

- Reaction processes, formulation, blending, mixing or
- Size reduction, separation, agglomeration, packaging/repackaging, and others or
- A combination of the above.

Tolling implies that processing of materials takes place. Handling or storage of the product, such as warehousing, bulk storage
or distribution through a terminal where no processing occurs would not in itself constitute tolling, but may be incidental to other tolling activity.

The innate expertise within the two parties, plus the specific tolling situation, determine the responsibility for providing a technology package for the operation. Normally, the company letting the toll contract prepares the technology package. The package includes:

- health, safety, and environmental (HS&E) related data,
- chemical process information,
- raw material and product specifications, and
- waste characteristics and disposition instructions.

The contributions from the toller and the company issuing the contract will vary according to circumstances. However, the toller typically provides:

- equipment required,
- operating personnel,
- technical support,
- analytical resources,
- maintenance resources,
- engineering resources,
- standard raw materials,
- infrastructure,
- utilities, and
- limited warehousing.

The combination of the contributions should result in complete process safety information for the toll. As you can see in this definition, there are many facets to both sides of the tolling contract that can be impacted by either party's philosophy of process safety.


When would a company want to engage in tolling? What could make a specific toller attractive to a client? Here are some basic business
1. INTRODUCTION

reasons for considering the use of a toller or selecting between potential tollers.

**Equipment**—A client may not have the equipment required to manufacture a specific product. It may be that available capital and installation time are limited such that they simply can not design, acquire, install and test the process equipment to reach the desired capacity within the available budget and time. If a product is in the early stages of its life cycle, the capital required may be hard to justify. This could be based upon the low initial volume anticipated while developing the market or the need to take advantage of a time-sensitive business opportunity. Tolling can provide a means to safely produce introductory, short-term, or small volume products that would otherwise be uneconomic.

**Expertise**—A client may seek to issue a toll contract if it chooses to produce a new product of unfamiliar chemistry or formulation type. A toller may already have knowledge, equipment, and personnel uniquely suited for a given process that cannot be readily duplicated. A toller with expertise in that particular type of chemistry or formulation could speed production and assist them in building a higher level of in-house expertise through close interaction. This may enhance the level of process safety and personnel safety should the client ever bring the process in-house.

**Cost**—Outsourcing can often be economically advantageous. A cost comparison may show that a toller can produce a product for less than it can be manufactured in-house. Even if manufacturing costs are similar, the cost associated with distributing the product may be significantly less if the product is made and hence distributed geographically closer to the end user. However, savings in cost should not come from compromising vigilance in the areas of health, safety or environmental responsibility.

**Logistics**—If a company is geographically located such that it can not meet the desired service level and delivery requirements of its customers, tolling may provide a local production and distribution site. Shorter transportation routes for hazardous chemicals or wastes may also be a consideration.
Environmental—If a product or its raw materials require special permitting (for example, air permits) or if the client company’s facility is inappropriate for the process, tolling could provide a means to achieve the company’s production goal.

Product or Process Development—A company can develop a new product or process as a quasi-research effort with a toller while simultaneously building the in-house production capacity. This allows problems found in the toller’s intermediate scale efforts to be fixed in the large-scale process and to reduce development time and costs. It may simply be a case of a company wanting to try new raw materials in a well-known process without disrupting existing production or establishing a pilot facility. Tollers can provide a way to achieve these activities in a parallel fashion.

1.5. Advantages and Disadvantages of Tolling

There are two primary advantages of tolling that can be summarized from the previous section addressing the reasons to toll:

- Economics
- Staying Competitive

The economic advantage is typically why a client lets a toll contract and is the reason tollers exist in the first place. The economic benefit may be from overcoming the capital-intensive construction of a new process (which a toller may already have available), the simple cost per pound benefit of outsourcing, or the economics of buying the toller’s expertise. The second advantage, staying competitive, is about market timing and appropriately managed risk. The ability to rapidly meet customer needs at a reasonable cost is highly valued—tolling can help achieve this. Additionally, selecting a toller based upon expertise in hazardous operations can alter production risks, making them more manageable.

The disadvantages of tolling are less clear cut. A contract is intended to limit liabilities for at least one and hopefully both parties. Tolling liability can be limited by identifying potential problems and avoiding them using techniques presented in this