

Guidelines for

PROCESS SAFETY
IN OUTSOURCED
MANUFACTURING OPERATIONS

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**PROCESS SAFETY
IN OUTSOURCED
MANUFACTURING OPERATIONS**



AMERICAN INSTITUTE OF
CHEMICAL ENGINEERS



**CENTER FOR CHEMICAL PROCESS SAFETY
of the
AMERICAN INSTITUTE OF CHEMICAL ENGINEERS**
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CONTENTS

<i>Preface</i>	<i>xi</i>
<i>Acknowledgments</i>	<i>xiii</i>
<i>Acronyms and Abbreviations</i>	<i>xv</i>

1

INTRODUCTION

1.1. This Guideline's Scope	1
1.2. The Guideline's Audience	2
1.3. What Is Outsourced Manufacturing?	4
1.4. Why Toll? Business, Technical, and Safety Considerations	5
1.5. Advantages and Disadvantages of Tolling	7
1.6. Joint Responsibilities	8
1.7. Using Process Safety to Ensure Safety, Product Quality, and Environmental Compliance	10
1.8. How to Use This Guideline	11

2

THE TOLLER SELECTION PROCESS

2.1. Potential Candidates: How to Find One—How to Be One	13
2.1.1. <i>Identifying Technical Specialties and Expertise</i>	15
2.1.2. <i>Prequalified Tollers—The Preferred Route</i>	20
2.1.3. <i>Finding a New Toller—Technical and Trade Association Networking</i>	21
2.2. The Initial Qualification Process	23
2.2.1. <i>Assessing the Candidates—Lines of Communication</i>	23
2.2.2. <i>A Typical Questionnaire</i>	23

2.2.3. <i>Weighing Special Technical Competencies</i>	24
2.2.4. <i>Financial</i>	25
2.2.4. <i>Consider Location</i>	26
2.2.6. <i>Consider the Environmental Baseline</i>	27
2.2.7. <i>Verifying Safety, Quality, and Contractual Obligations</i>	28
2.2.8. <i>Process Equipment Capabilities</i>	28
2.2.9. <i>Personnel Capabilities and Expertise</i>	29
2.2.10. <i>Capability to Scale-up Production</i>	30
2.2.11. <i>Process Safety</i>	30
2.2.12. <i>Security</i>	32
2.2.13. <i>Corporate Health, Safety, and Environmental Policies</i>	33
2.2.14. <i>Housekeeping and Appearance</i>	33
2.2.15. <i>Insurance Review and Experience Modifiers</i>	34
2.1.16. <i>Conducting a Site Visit</i>	35
2.2.17. <i>Compatibility with Ongoing Operations</i>	37
2.2.18. <i>Initial Qualification of International Tollers</i>	38
2.3. Making the Final Selection	39
2.3.1. <i>Comparing and Ranking the Initial Qualification Information</i>	40
2.3.2. <i>Audit and Verification Process</i>	40
2.3.3. <i>Confidentiality Agreements</i>	40
2.3.4. <i>Finalizing the Technology Package</i>	42
2.3.5. <i>Evaluating Proposals</i>	43
2.3.6. <i>Contract Award and Negotiation</i>	45

3

MUTUAL AGREEMENTS, OBLIGATIONS, AND CONTRACT CONSIDERATIONS

3.1. Defining the Rights and Expectations of the Parties	47
3.2. Legal Obligations, Defining Boundaries, Contract Topics	51
3.3. Technology Transfer	53
3.4. Technology Developed during Tolling Operations	54
3.5. Knowledge Enhancement for Both Parties	54
3.5.1. <i>New Learning about Processing Hazards and Production Efficiency</i>	54
3.6. Roles and Responsibilities	55
3.6.1. <i>What Is Contained in a Detailed Technology Package?</i>	56
3.6.2. <i>Scale Up Technology</i>	57
3.6.3. <i>Emergency Response Considerations</i>	57
3.6.4. <i>Wastes and Emissions</i>	58
3.6.5. <i>Establishing and Maintaining Communication</i>	59
3.6.6. <i>Participation in PHAs: Resolving the Issues</i>	59
3.6.7. <i>Training Requirements</i>	60

CONTENTS

vii

3.7. Health, Safety, and Environmental Considerations	60
3.8. Management Systems	62
3.8.1. Management of Change, Including Change of Personnel	61
3.8.2. Defining and Executing Training Requirements	62
3.9. Access and Right to Audit	63
3.10. Requalification: The Time Frame Issue	63
3.11. Equipment Selection, Preparation, and Decontamination	64
3.12. Performance Clauses and Bonuses	64
3.13. Insurance Requirements	64
3.14. Permit Requirements: Required Filings	65
3.15. Escape and Termination Clauses	65
3.16. Notification of Accidents, Incidents, Releases and Agency Inspections	66
3.17. Right to Assist in Investigation	66
3.18. Pre-startup Safety Review (PSSR)	67
3.19. Formalizing Agreements, Obligations, and Other Considerations	67

4

PRE-STARTUP AND STARTUP ACTIVITIES

4.1. The Path to a Successful Toll	81
4.2. Establishing Specifications and Analytical Techniques	83
4.3. Developing or Revising Required Procedures	83
4.3.1. Operating Procedures	84
4.3.2. Maintenance Procedures	86
4.3.3. Material Control/Purchasing Procedures	87
4.3.4. Emergency Response Plan Procedures	88
4.3.5. Safe Work Practice Procedures	88
4.3.6. Laboratory Procedures	88
4.4. Process Hazard Analysis	89
4.4.1. Defining the PHA Team	90
4.4.2. Selecting the PHA Method	92
4.4.3. Performing the PHA	93
4.5. Training the Startup Team	94
4.6. Performing a Pre-startup Safety Review	96
4.6.1. Resolving PSSR Issues and Action Items	98
4.6.2. Considerations for Restart after Extended Downtime	98



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4.6.3. <i>Defining When the Process Is Ready for Startup</i>	99
4.6.4. <i>Confirming Permits Are Complete</i>	101
4.7. Management of Change Considerations	101
4.8. Other Process Safety Elements That May Affect Startup	101
4.9. Test Runs for the Process	103
4.9.1. <i>Value of Performing Test Runs</i>	103
4.9.2. <i>Guidelines for Performing a Test Run</i>	104
4.10. Qualifying and Controlling Raw Materials	106
4.11. Starting the Process	106
4.12. Post-Startup Review	106
4.13. Monitoring Scale-up Concerns	107

5

ONGOING OPERATIONS: AUDITS AND FOLLOW-UP

5.1. Audit as Appropriate for the Process and Product	109
5.1.1. <i>Regulatory Requirements: PSM, RMP, and Others</i>	111
5.1.2. <i>Management Systems</i>	112
5.1.3. <i>Documenting the Audits</i>	112
5.1.4. <i>Auditing as Specified in the Technical Package</i>	114
5.2. Consulting	115
5.2.1. <i>Points of Contact</i>	115
5.2.2. <i>Communication</i>	116
5.2.3. <i>Periodic Visits</i>	116
5.3. Managing Issues: Guidelines and Suggestions	117
5.3.1. <i>Management of Change Issues</i>	117
5.3.2. <i>Process Issues</i>	118
5.3.3. <i>Personnel Issues</i>	121
5.3.4. <i>Acquisition of a Toller by Another Company</i>	121
5.3.5. <i>Regulatory Issues</i>	123
5.3.6. <i>Handling, Transporting, and Storing Materials and Waste</i>	126
5.3.7. <i>Incident Investigations</i>	128
5.3.8. <i>Analysis of New Hazards</i>	129
5.4. Performance Monitoring	131

6

CLOSURE AND AUDIT

6.1. Health, Safety, and Environmental Considerations	134
6.1.1. <i>Decommissioning and Clean Up</i>	136

CONTENTS

ix

6.1.2. <i>Proper Waste Disposal</i>	137
6.2. Business and Contractual Concerns	138
6.2.1. <i>Return of Proprietary Documents</i>	138
6.2.2. <i>Governmental Notification</i>	138
6.2.3. <i>Sample Retention and Record Retention</i>	138
6.3. Closure Review Checklist	139
6.4. Analysis of the Operation	144
6.5. Tolling Operation: Final Evaluation	144

Appendix A

SAMPLE TOLLER PRE-ASSESSMENT QUESTIONNAIRE	151
--	-----

Appendix B

SAMPLE TOLLER HS&E ASSESSMENT	165
-------------------------------	-----

Appendix C

SAMPLE TOLLER ASSESSMENT: QUANTITATIVE FORMAT	179
General Scoring Guidelines	180
Evaluation Summary	182
Assessment Forms	183
Audit Protocols for the Assessor	190
1. <i>Management Responsibility</i>	190
2. <i>Training</i>	192
3. <i>Quality Manual, Plan and Standards</i>	193
4. <i>The Toller of Goods or Services</i>	193
5. <i>The Client</i>	195
6. <i>Personnel</i>	195
7. <i>Operations</i>	196
8. <i>Maintenance</i>	197
9. <i>Reporting Investigating and Analysis</i>	197
10. <i>Administrative Support</i>	198
11. <i>Safety</i>	198
12. <i>Occupational Health/Environmental Protection</i>	199
13. <i>Security</i>	200
14. <i>Self-Audit</i>	201

Appendix D

THE ISD MODEL AND JOB TASK ANALYSIS TECHNIQUES	203
---	-----



Appendix E

LIST OF REFERENCED REGULATIONS	207
--------------------------------	-----

Appendix F

SELECTED RESOURCES	209
--------------------	-----

<i>Bibliography</i>	211
---------------------	-----

<i>Glossary</i>	213
-----------------	-----

<i>Index</i>	219
--------------	-----

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.

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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:

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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

AIChE	American Institute of Chemical Engineers
ARC	Accelerating Rate Calorimeter
CCPS	Center for Chemical Process Safety
cGMP	Current Good Manufacturing Practice
CMA	Chemical Manufacturers Association
CPI	Consumer Price Index
D&B	Dun and Bradstreet
DFR	Duns Financial Records Plus
DOT	Department of Transportation
EDI	Electronic Data Interchange
EMR	Experience Modification Rate
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
HS&E	Health, Safety and Environmental
Kst	Severity of Dust Explosion Scale, which is a combination of maximum pressure and rate of pressure rise.
LEL	Lower Explosive Limit
LEPC	Local Emergency Planning Committee
MACT	Maximum Achievable Control Technology
MIE	Minimum Ignition Energy
MIT	Minimum Ignition Temperature
MOC	Management of Change
MSDS	Material Safety Data Sheets
NESHAP	National Emission Standards for Hazardous Air Pollutants
NORM	Naturally occurring radioactive materials.

NO_x	Collectively refers to the combustion byproducts: NO, nitric oxide, and NO ₂ , nitrogen dioxide
OSHA	Occupational Safety and Health Administration
PROMT	Predicasts Overview of Markets and Technologies
PSSR	Pre-startup Safety Review
SARA	Superfund Amendment Reauthorization Act
SNUR	Significant New Use Regulation
SOCMA	Synthetic Organic Chemical Manufacturers Association
SPC	Statistical Process Control
TSCA	Toxic Substances Control Act
VOC	Volatile Organic Compound



1

INTRODUCTION

1.1. This Guideline's Scope

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.



Figure 1-1. A complete quality model

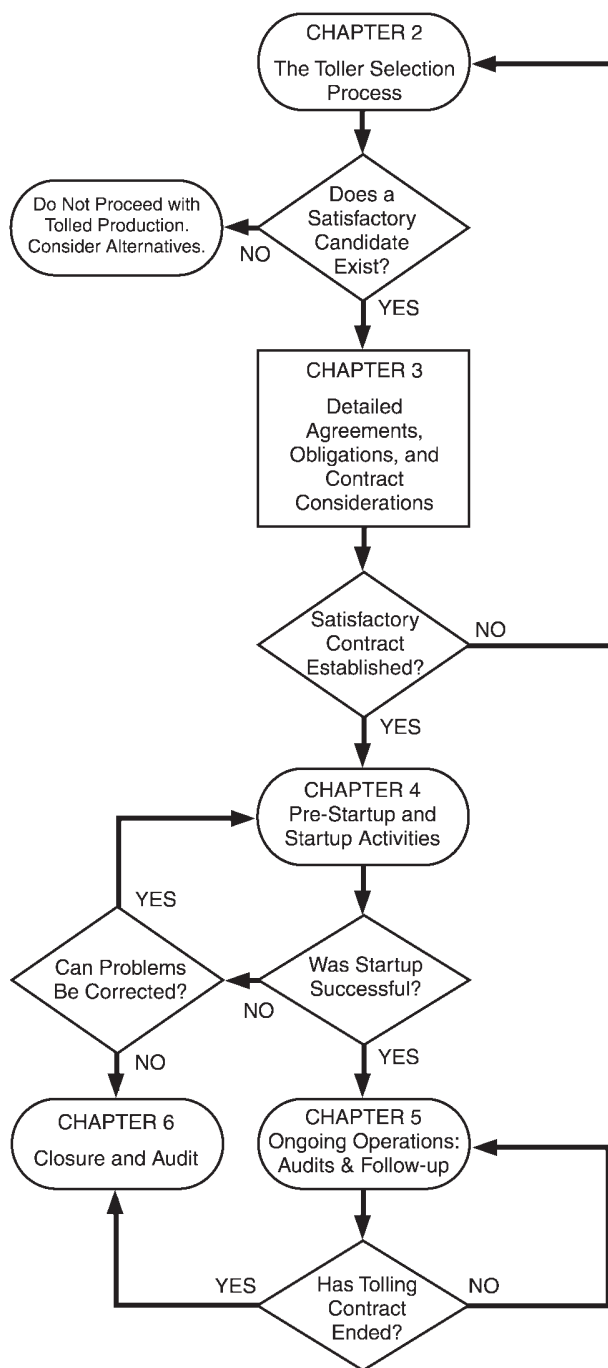
1.2. The Guideline's Audience

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.

**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. Tolloed 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.

1.4. Why Toll? Business, Technical, and Safety Considerations

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

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

guideline. Two disadvantages that may need to be considered when tolling are:

- Loss of internal manufacturing expertise or loss of the opportunity to develop it for a process.
- Loss of technology developed in-house or loss of other types of proprietary knowledge.

Some potential problems involved in tolling are listed in Table 1-1.

Examining the lists above makes it clear that a good toller-client relationship with open and honest communication of process safety information, process hazard analysis input and early recognition of issues can help avoid potential problems.

Tolling operations should be held to the same principles of public openness and communication espoused by forward thinking companies in the chemical industry. In 1988, the Chemical Manufacturers Association (CMA) initiated the Responsible Care® initiative to assist in making this possible. Its goal is to lead the chemical industry in ethical practices that increasingly benefit society, the economy and the environment.

Regulations such as the U.S. Occupational Health and Safety Administration's (OSHA) *Process Safety Management of Highly Hazardous Chemicals* and the U.S. Environmental Protection Agency (EPA) *Risk Management Program* rule complement CMA's goals. Both regulations make it very clear that government expects the chemical industry to adopt strong HS&E related management systems.

Even if tollers are not subject to these regulations, or not members of CMA or AIChE/CCPS, these are useful references in guiding operations. It is unacceptable to consider gaining an advantage by using a toller to circumvent accepted HS&E practices that would apply to in-house production.

1.6. Joint Responsibilities

This guideline emphasizes the role of both parties in fulfilling components of the relationship to achieve safe, environmentally respon-

Table 1-1. Potential Problems Encountered in the Tolling Relationship

Potential Problems for Tollers	Potential Problems for Clients
Communication breakdown with the client	Communication breakdown with the toller
Contract termination is an economic threat	Less control over the process than when it is done in-house Termination is a supply chain threat
Must rely on certain information provided by the client	Environmental issues due to unknown hazards from other ongoing tolls or a toller's past practices
Safety issues due to unknown or insufficient information on processing hazards by the client	Safety issues due to unforeseen operating and maintenance practices by the toller Agency actions or catastrophic events at the toller's facility can threaten the supply chain
For new tolls, dealing with an unknown company	For new tolls, dealing with an unknown toller
Uncertain wear and tear on equipment by unfamiliar materials or processing techniques	Uncertain management practices by the toller
Noncontractual transfer of expertise to the client	Confidentiality concerns for proprietary information
Identifying cross-contamination problems between previous and successive products and processes	Receiving product contaminated by other products and processes
Timing issues due to scheduling multiple products or batches	Timing issues due to a more complex supply chain
Late receipt of raw materials or packaging from the client	Personnel turnover can create unforeseen delays

sible performance. It provides a behind-the-scenes view of how companies assess potential tollers and can help ensure consideration from companies seeking qualified tollers. In many of the examples provided, it is clear that only tollers with high internal standards for process safety will win tolling contracts. For tollers,

this guideline should be seen as a positive way to improve their ability to gain contracts and fulfill them safely and efficiently.

There is a wide spectrum of philosophies regarding the level of participation required from the client. Some clients choose to remain at arm's length from the toll operation in an effort to establish a distinct separation of responsibilities. Such clients may audit the toller's HS&E program on a periodic basis and do little else.

At the other end of the spectrum, some clients recognize that they have much to gain by providing more substantive oversight of the production operation. While these companies don't provide day-to-day supervision of the tolled production, they may assume a greater responsibility in an effort to forestall problems associated with final product specifications, worker safety and environmental responsibility. Companies taking this posture will likely have technically oriented representatives at the toll facility on a regular basis. The responsibility of these representatives is not to supervise but rather closely monitor and guide if the need arises.

Joint OSHA/EPA investigations of past accidents in tolling operations include recommendations that emphasize the importance of communication between the toller and the client. The primary ways recommended to prevent recurrence of similar events focus on a joint understanding of the basic tenets of process safety elements.

1.7. Using Process Safety to Ensure Safety, Product Quality, and Environmental Compliance

Concepts presented in this book are a vital part of every tolling operation's vendor-client relationship.

Our objective is not to set new standards, but to encourage companies and individuals to apply existing standards and the operational discipline necessary to establish their own internal requirements that support business excellence. This guideline provides tools to help the toller and their client take a systematic approach to managing their relationship and implement applicable

portions of Responsible Care[®], CCPS's process safety practices, and other industry guidance, while reaching mutual health, safety, environmental, and quality requirements.

1.8. How to Use This Guideline

The tollor and the client essentially form a tolling operation team to mutually ensure that applicable regulatory, business, and societal responsibilities are met in a systematic way. This text is a guide to assure relevant issues are identified and addressed appropriately. The examples in this text are based upon samples provided by companies involved in tolling. They are offered for the reader's use. Recognizing the unique characteristics of process safety as applied to tolling, the reader should modify these examples to meet each situation's needs. A thorough safety, technical, and legal review is recommended prior to use.

The list below summarizes some of the major questions that are addressed in following chapters.

Chapter Two—The Toller Selection Process

- How are potential tollers identified?
- What methods are used to assess tollers?
- When does physical location affect consideration?
- How important is past performance history?

Chapter Three—Detailed Agreements, Obligations, and Contract Considerations

- What are the rights that might be established between the contracting parties?
- What legal obligations are typical in a tolling contract?
- Will the contract address compliance with regulations?
- How do you manage transfer of technology?

Chapter Four—Pre-Start Up and Start Up Activities

- How do you choose an effective Process Hazard Analysis (PHA) team?

- How do you identify and develop required procedures?
- Who needs training for this process and to what level of detail?
- How do you resolve pre-startup safety review issues and action items?
- What makes an effective post-startup review?

Chapter Five—Ongoing Operations: Audits and Follow-up

- What are some of the issues that can arise during the tolling process?
- How do you conduct audits based on appropriately managed risks and the nature of the product involved?
- How do you manage the consulting relationship between the two parties?
- What are the management of change considerations?
- What unforeseen regulatory elements may apply?

Chapter Six—Closure and Audit

- Which environmental, health and safety considerations affect closure and audits?
- How do companies ensure the return of proprietary documents?
- How can you analyze the operation for future reference?
- What are some checklist items to review during the closing phase of the toll?

2

THE TOLLER SELECTION PROCESS

Once a company decides to seek a toller for a project, the next step is to build a list of candidate companies. This section provides guidance for both sides of the tolling arrangement to use to enhance their abilities to

- make a discerning choice as a client or
- present information that allows thorough evaluation as a capable toller.

An example of a preliminary technology package form and other tools are provided here and in the appendices.

The flow chart on the next page graphically represents the use of concepts presented in this chapter. As each tolling project is unique, your application of the guidance can be tailored to describe the process as it applies to your company.

2.1. Potential Candidates: How to Find One— How to Be One

Investigations of incidents associated with tolling projects have identified that appropriate selection of a toller based upon proper equipment and expertise is important in reducing the likelihood of future process safety related incidents and environmental releases. It is likewise important to review toller safety, health, and environmental practices (current and past) in the selection process. This review can identify those practices that would need to be modified to be acceptable. Eliminating less qualified candidate firms at an early stage is a best practice.

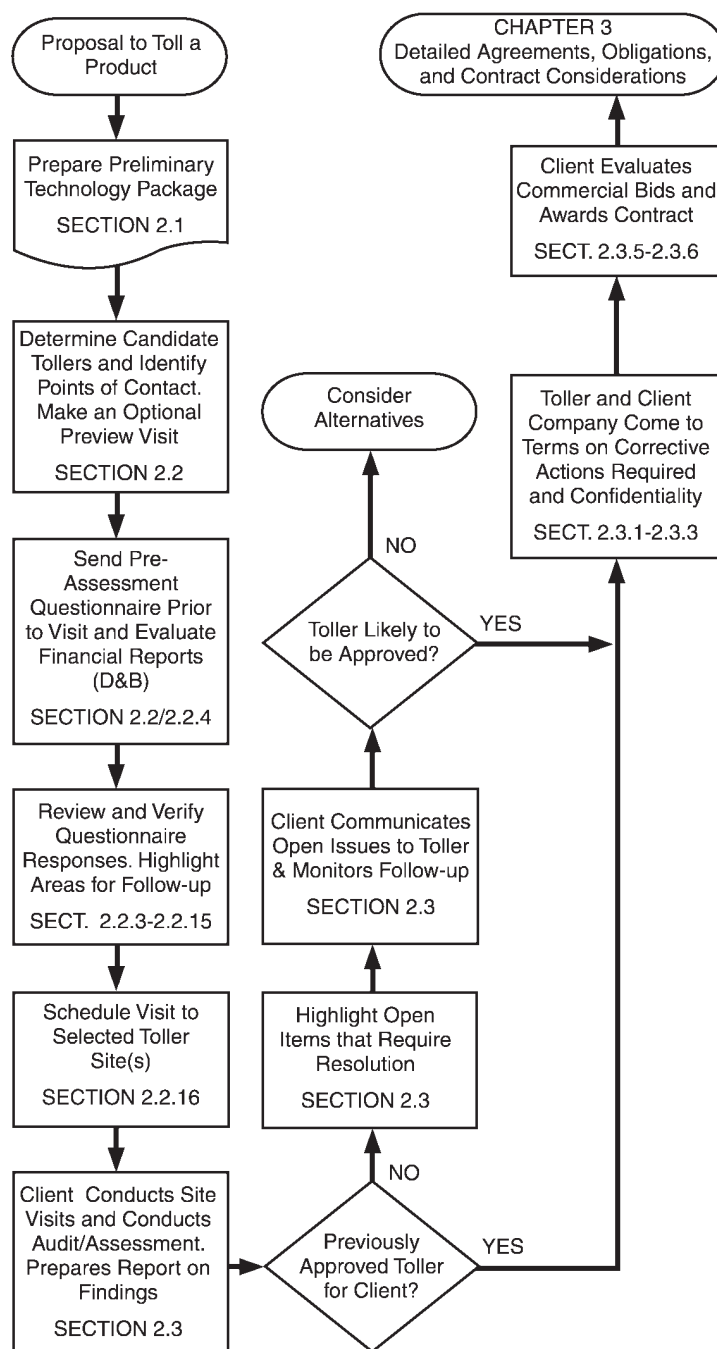


Figure 2-1. Toller selection process flowchart.

This chapter describes typical steps to consider in identifying and qualifying potential candidate tollers.

2.1.1. Identifying Technical Specialties and Expertise

The process of building a list of candidates begins with the client. By examining the specific synthesis desired or material processing and handling required, you can search for tollers that possess the skills and equipment to meet the processing scope.

The technology package for the toll should be at least partially established prior to starting the active search for a toller. This will assist you in defining the level and areas of expertise needed for the project. Some companies that frequently let toll contracts have internal service groups that assist in the toller selection process. An example of an internal questionnaire used at such a company is shown in Example 2-1. It is an excellent way to identify the expertise required for a specific tolling project.

Companies desiring to initiate a toll without the luxury of a special services group can adopt the questionnaire for their project development group to use. Candidate tollers may use this example as a preparatory tool for completing bid responses.

Example 2-1 is just a start for preparing the final technology package to be included with the contract but it provides enough information for a client to identify the special needs required of the candidate tollers. It may need to be modified to meet the specific needs of your situation.

Tolling Contract Services Group—Initial Technology Package

Following is a list of information that could be pertinent in the development of your project. You may not be able to provide information in all areas and some areas may not be applicable. Please mark N/A in areas intentionally left blank. The more information you can provide, the better we will be able to meet your needs. You can use this electronic form for filling in the information or provide information in your own format.

Example 2-1. Initial Technology Package

(Cover Letter)

Dear Internal Customer:

Subject: Tolling Contract Services Group (TCSG) Initial Technology Package Request

Attached is our businesses' Technology Package Request. This information will be helpful in allowing us to meet your needs and expectations by selecting an appropriate toller. Our department developed this list to identify issues to consider in the tolled manufacturing of your product. Any information that you are able to provide will help us considerably and expedite our evaluation process. We look forward to working with you on this opportunity.

Regards,

TCSG Manager

1. General Product Information

Introduction and background (brief project description)
Chemical and physical properties of the raw materials, intermediates, and final product
Pertinent toxicology for raw materials, intermediates, and final product
Estimate of product volume needed from toller and timing for first production

2. Process Chemistry

Chemical nomenclature
Key step definitions
Desired chemical reactions and side reactions
Reaction kinetics and thermodynamics
On what scale has this product has been made before? (for example, reactor size, throughput)
Is the toll strictly using existing technology? (If NO, please describe the changes or improvements.)

3. Material Balance

Index flow sheet
Material balance

4. Unit Operations

Block flow diagram
Technology and equipment description

5. Process Equipment

Design criteria and materials of construction (for example, vents, relief valves)

6. Environmental

Environmental treatment philosophy
Characterization of potential waste streams
Handling of potential waste streams
Environmental data (for example, material balance)
Special environmental considerations (including emergency venting, spills, or releases)

7. Physical Properties

Pure component physical properties (indicate whether liquid or solid; flashpoint; LEL; and, for powders Kst/MIE/MIT)
Mixture physical properties

8. Reactive Chemicals

Reactive chemicals test results (thermal stability, calorimetric, ARC, DSC)
Chemical compatibility chart (How do the chemicals involved react with each other if one is added in excess or the addition of one is limited; how do these chemicals react with common metals and chemicals?)
Reactive chemical considerations for each key process step (enclose data if possible)
Describe any prior reactive chemical incidents with these materials. Include previous safety studies.

9. Analytical

Raw material analysis (indicate liquid chromatography or gas chromatography)
Process stream and intermediate analysis
Byproducts analysis
Final product analysis
Analytical equipment maintenance and calibration requirements
Reference compounds and data
Special sampling requirements needed for project
How should retains be stored?
How should retains be handled?
Is a one-quart retain sufficient for needs?
How clean must equipment be prior to the start of project?
What is a good solvent for cleaning equipment used to produce your product?

10. Raw Material, Intermediate and Final Product Specifications

Raw material specifications
Supplier information
Intermediate specifications
Final product specifications

11. Packaging and Labeling for Final Products

Containers
Labeling requirements
Storage and disposal of containers
How will the final product be shipped? Fiberpak ☐ Drum ☐ Size _____ Tank Truck _____ Rail car _____ Other _____
Class shipping instructions and placard information

12. Regulatory Issues and Hazard Communications

TSCA and others
CGMP required
MSDS Please enclose MSDS for all raw materials, intermediates and final products.
Any consent orders on this product or raw materials?
Any prior process hazard analyses on this process?
Any special handling or industrial hygiene (IH) concerns not clearly indicated in the MSDS?

13. General Project Overview

Project contacts (who are the key people to contact with questions and issues?)
Overview of significant learning experiences in previous production of this material.
Process opportunities (areas to focus upon to improve cycle time or conversion)
Project volumes/production rate
Project plan and timelines
Desired start date
Desired completion date

14. Economics

Raw material costs
Target conversion cost

15. Process Research Reports and Patents

A. List of reports
B. Selected report summaries
C. List of patents, applications, and disclosures
D. Selected patent summaries

2.1.2. Prequalified Tollers—The Preferred Route

If repetitive tolls are the norm for a client, a good way to screen candidate tollers is to make use of past experience. A satisfying business relationship between a toller and a client is a prelude to the continued use of a toller and the toller's continued desire to meet a good customer's needs.

However, just asking the purchasing department for a list of companies previously used for tolling is not enough. Prior successful use of a given firm is not adequate qualification for future tolls, especially if the new toll involves a different product. At this point in the selection process the five facets mentioned in the previous chapter come into play:

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

In order to verify performance of a given toller with whom a company has worked before, it is essential to document and understand their performance history in the five areas listed above. Good documentation of prior toller performance will allow a new engineer or new manager in charge of tolling projects to base their initial selection of candidates on accurate data.

Chapter 5, *Ongoing Operations: Audits and Follow-up*, provides guidance on how to build a database of information about previous and ongoing experience with a toller. Consider using the audits to build a summary database of experience with tollers. In many companies the more difficult part of the audit process, whether internal or external audit, is tracking resolution of the findings. A ranking system may be useful to assist in building a list of candidates based upon their expertise, severity and number of findings, and their timely resolution of findings.

Communication is important to both the toller and their client company. Tollers already working on one or more active projects with a company can regularly check with their client contacts for

information about how they are doing. They can ask straightforward questions such as:

- Do you see room for improvement in the five areas?
- How can we assist in the audit process?
- Have we resolved past audit findings satisfactorily?
- Is there a technical aspect of our capabilities or equipment you would like to see strengthened?
- Do you have suggestions to help ensure consideration for future contracts?

Some approaches to quality management suggest that companies reduce the total number of suppliers for a service or material to just a few high quality entities. This allows the companies to symbiotically develop relationships. Both parties can benefit greatly by using a system designed to rank preferred tollers. However, do not let the motivation to reduce the number of suppliers inhibit the critical review of potential tollers capable of performing the toll successfully.

Another advantage of maintaining long-term relationships with a few preferred tollers is the ability to establish better communications and restrict dissemination of confidential or proprietary information.

2.1.3. Finding a New Toller—Technical and Trade Association Networking

If a tolling project demands that a company seek candidate tollers with different expertise from that required for previous tolls, or if it simply wants to expand its list of preferred tollers, other resources exist to help.

In large companies that contract tolls (those with several business groups), inquiring within the company may turn up candidate tollers of which one business group was unaware. This can often aid in evaluating the candidates if good performance data is available as described in the previous section.

When a need for fresh candidate tollers exists, the following publications represent four better-known listings and can provide

contact points that will allow a company seeking a toller to begin a dialog with the new candidates.

- The *Brandon Guide to Custom Chemical Synthesis Services: North America* is issued annually by Brandon Associates, Merrimack, New Hampshire
- The *Custom Processing Services Guide* is issued annually by the Custom Guide Company, Closter, New Jersey
- The *Commercial Guide* is issued each January by the Synthetic Organic Chemical Manufacturers Association (SOCMA), Washington, D.C.
- A *Guide to Custom Chemical Manufacturing and Processing* compiled and published by Quest Data, Inc., Nashville, Tennessee. The fourth edition is planned for publication in 2000.

These guides include information such as:

- available equipment,
- existing unit operations, and
- chemical reactions performed.

Other sources for helping identify new tollers are trade association conferences and shows. The largest U.S. gathering of tollers is the Informex exhibition presented annually by SOCMA. The Custom Manufacturing Expo sponsored by *Chemical Week* provides a similar forum for networking. Tollers typically display their capabilities in an exhibit booth, provide printed materials describing their services, and staff their exhibit with their sales manager and technical representatives (many include operating managers). This allows a company seeking new toller candidates to collect a great deal of vendor information across a wide cross-section of companies with appropriate expertise. The chance to meet with the people that you may eventually be working with is also a great benefit.

SOCMA includes a magazine version of the commercial guide free to Informex attendees. Copies of this guide are also available direct from SOCMA for a fee. The SOCMA homepage on the Internet also provides a wealth of information.

2.2. The Initial Qualification Process

At this point, a client has a list of likely candidate names. Prior to expending more effort, it is possible to screen this list for safety performance, environmental performance and financial stability. For a candidate to make the next cut, it should have a health, safety and environmental program with appropriate human and financial resources to implement effective programs. Safety and environmental performance (or lack of readily available information about performance) can be a telling indicator about a company's commitment to quality. A brief, optional preview visit to the site can give the client information about the tollers' housekeeping habits, process safety program, and general qualifications. At times, tollers are ruled out because a preview visit can reveal a company culture that is not a good fit with that of the client.

2.2.1. Assessing the Candidates—Lines of Communication

The first step in assessing the candidate tollers is to notify the candidates they are being considered for this toll, and determine their interest in further evaluation. Pending mutual interest in further consideration, the companies must establish lines of communication with commercial representatives, technical/manufacturing representatives, and health, safety and environmental (HS&E) representatives. There may be one person in a candidate company that funnels the communication from these three groups or several, especially if the HS&E function is split. Tollers should recognize these discrete needs and be prepared to respond accurately and efficiently to enhance their merited consideration.

2.2.2. A Typical Questionnaire

Companies experienced in assessing candidate tollers typically have some type of assessment questionnaire used to collect data. The assessment questionnaire is useful because it provides a relatively inexpensive tool to collect a standard set of data.

Questionnaires can be customized for each application. Such a questionnaire is commonly used as follows:

- It is sent to candidate tollers for their staff to complete.
- The company selecting a toller evaluates the data provided from each candidate and identifies which firms are qualified for a site visit.
- The company then uses the specific toller's completed questionnaire again during the site visit to verify that accurate information was provided and resolve open issues.

Some companies have more detailed forms for the site visit. One example of an assessment questionnaire is provided in Appendix A, *Sample Toller Pre-Assessment Questionnaire*.

In the example in Appendix A, candidate tollers are asked to respond to twelve topic areas:

1. Policies, affiliations, and certifications
2. Character of area around the plant
3. Personnel
4. Environmental
5. Security and maintenance
6. Storage
7. Preparedness, prevention, and emergency response
8. Health and safety
9. Production
10. Quality assurance
11. Potential exposure
12. Addendum for existing tollers

Companies evaluating tollers should modify the examples in this book to best meet their needs. Tollers may gain insight by comparing the examples to questionnaires that they have completed previously. Additional samples of assessment forms are provided in the appendices.

2.2.3. Weighing Special Technical Competencies

Assessment questionnaires may not typically require details about technical expertise the candidate tollers may possess. It is assumed that the list of candidates who will receive the questionnaire have

the appropriate technical competency based on researched evidence. This aspect of toller selection—technical competency—requires the value judgment of experienced staff. These value judgments are often based upon impressions resulting from interpersonal communication with the tollers' staff during site visits. The site visit also allows opportunities to get a better feel for the unique technical capabilities and human resources a toller can provide. During the site visit, the technical package requirements, reaction capabilities and mechanical capabilities can be compared and assessed.

In some cases, companies with frequent or challenging toller service requirements may take on long term programs and commitments to develop one or more toll firms with skills, knowledge, and equipment appropriate for the processes in question. If successful, these long-term commitments can achieve a safe, highly efficient, symbiotic relationship.

2.2.4. Financial

A toller with a good history of HS&E performance is able to obtain advantageous insurance rates and expends less of their revenue on legal problems, thus helping with their potential for cost competitiveness in the final bid. A toller in good financial standing is more likely to expend capital to install adequate safeguards.

Companies assessing tollers have at least two tools that may help with this first screening. They are:

- D&B—Duns Financial Records Plus (DFR) service (see Table 2-1)
- Predicasts Overview of Markets and Technologies (PROMT)

Both can be accessed through the Knight-Ridder Information Services—DIALOG Services Database Catalogue.

The Duns Financial Records Plus (DFR) database provides a balance sheet, income statement, and fourteen of the more widely used business ratios for measuring solvency, efficiency, and profitability. DFR also provides industry norms and percentages that can be used to compare a toller's financial position to that of their

competitors. DFR includes a brief description of company history and operations. Many companies use DFR to evaluate potential suppliers for their financial status. It is to a toller's advantage to ensure that the data provided by the DFR service is current and accurate.

The Predicasts Overview of Markets and Technologies (PROMT) is a database that provides international coverage of companies, products, markets, and applied technologies for industries. PROMT abstracts more than 1000 worldwide business publications. PROMT derives information from:

- trade journals,
- local newspapers and regional business publications,
- national and international business newspapers,
- trade and business newsletters,
- Securities and Exchange Commission (SEC) registration statements,
- investment analyst reports,
- corporate press releases, and
- company annual reports.

Environmental and safety incidents that make the news are included in PROMT's summaries. This makes PROMT a quick tool for evaluating a toller's history of major incidents.

Again, this is a high level screening. Depending on the results of a search, it could lead to either eliminating a candidate from the list or spurring a more thorough evaluation of a candidate during the next phase.

2.2.4. Consider Location

The assessment questionnaire responses can help screen candidates for proximity to sensitive local receptors. Both parties must be made aware of and understand the nature of the substances to be used or produced during the toll and the consequence potentials of both the materials and the process. In the U.S., the toll process may be conveyed under Environmental Protection Agency (EPA) Risk Management Program (RMP) issues OSHA PSM issues, or state, local or foreign requirements depending upon the substances involved in the toll. If a regulated substance is being introduced to a toll facility at

quantities above the threshold quantity identified in the applicable regulation, the toller may become subject to the regulation. They may therefore need to implement the OSHA PSM requirements and file correct plan documents under the RMP rule or resubmit their existing risk management plan. Analogous regulations exist in many other jurisdictions. The compliance requirements, related strategy, and overall toll viability may be impacted by these regulations.

Emergency response capabilities and community involvement becomes extremely important if a toller is handling toxic substances or flammable mixtures in a populated area. What liability is involved for the client? Are the candidate tollers experienced in handling the specific hazards posed by the process? Is there a difference in the level of risk each candidate toller poses to its surrounding community? Is the local emergency infrastructure, including emergency response capacity, local emergency planning committee (LEPC) capability, mutual aid groups, local professional or volunteer fire and rescue squads, consistent with toll requirements? In some cases, the answers to questions in the assessment questionnaire can help select finalists from among the candidates.

If the toller has contracted with a private emergency response contractor, specific instructions or concerns regarding the toll materials may need to be forwarded to the contractor prior to startup.

The physical location of the toller can impact logistics, transportation and distribution issues. If you have a market need in a region of your country or a foreign location, a component to consider in selection of the successful toller is the capacity to provide support to the client distribution system or shortest supply chain.

The issues of regulatory compliance, local infrastructure, and logistic concerns cannot be readily changed to achieve vastly different requirements. These concerns need be identified early in a qualification process to assure they are adequately understood and addressed.

2.2.6. Consider the Environmental Baseline

The assessment tool shown in Appendix B, *Sample Toller HS&E Assessment* is designed to draw attention to existing HS&E problems. This example may be especially appropriate for toll contracts involving materials or processes of high hazard.

Ultimately, assurance of selecting an environmentally responsible toller relies upon research, the site visit and inspection. One on one communication with the tollers' management and technical staff can help answer detailed questions about:

- Solid waste management expertise
- Site contamination history and cleanup
- Water discharges
- Air emissions
- Site compliance history

A client can research the above topics by using publicly available data sources or commercial data collection services to obtain details about a site. The commercial data collection services can compile public records of remediation activities, citations, or fines from governmental entities and other data of interest for any property. Examples of these types of firms are Vistainfo, IAO Environmental Services and Lexis/Nexis.

2.2.7. Verifying Safety, Quality, and Contractual Obligations

It may be appropriate to request that candidate tollers provide contacts at previous client facilities to allow general inquiries about their performance. This allows a company seeking a toller to determine whether the safety, environmental and quality programs are truly implemented as written. In addition, it can reveal whether the candidates made good faith efforts to meet contractual obligations.

One way to make the importance of this clear is by including a business ethics provision in the tolling contract. The CMA Responsible Care® initiative can be called out in such a provision and applied to both parties in the contract if they have both subscribed to its code of ethics. This is discussed further in Chapter 3, *Mutual Agreements, Obligations and Contract Considerations*.

2.2.8. Process Equipment Capabilities

A quality toll can only be achieved by tollers with properly designed and reliable equipment. Companies letting a toll contract should

satisfy themselves that the right equipment is available and effective routine inspection and maintenance programs are in place to detect equipment defects before they cause accidents or breakdowns.

Preventive maintenance on vital equipment should be properly scheduled, carried out and documented. This program must be separate from the regulatory inspection.

Examining a candidate toller's records of formal reporting and follow-up on mechanical deficiencies or hazardous conditions is imperative. The assessor should verify whether such a system is in place and is effective.

The assessor should also find out whether an effective testing program is in place to help ensure the serviceability of process measurement equipment. The successful toller should have an established calibration program to address the accuracy of critical measurement equipment. Safety critical process parameters should be monitored and critical process equipment should automatically interlock when monitoring instrumentation detects safety critical deviations. Interlocks should either facilitate a remedy to the critical deviation or bring the process to the zero energy state. These instruments and interlocking devices should be routinely tested to ensure operational reliability.

2.2.9. Personnel Capabilities and Expertise

Experienced and qualified people are essential to a company's performance level. Successful tolling operations may show evidence of proper personnel selection, career planning and advancement.

The confidential nature of individual records must be respected. During the site visit, the assessor may have to rely on the assurance of the toller's personnel manager to make a selection judgment. Some questions to ask when assessing a toller's personnel capabilities follow:

- Are job criteria formalized in job descriptions for each position?
- Is there a more detailed job task analysis or profile?
- What level of formal education is required for each position?
- Is there a requirement for past experience for employment or advancement?

- Is there minimum language mastery required?
- Is there a pre-employment and follow up medical examination required?
- Is there a documented interview system?
- Is there a documented training program?

Turnover rate is a key indicator of how an employer values their employees. Employees who have a career path, are rewarded for good performance, and provide contributions to the success of their employer are less likely to leave. On the other hand, companies with high turnover rates may not provide such good working conditions and the resulting turnover results in employees who may not have much experience.

2.2.10. Capability to Scale-up Production

Depending upon why a company chose to let a toll, the ability to scale up production may be an important factor. If a toll project was designed to meet a specific, short-term need for a known quantity of material, scale-up capability may not be an issue. However if the goal was to develop a wider market and eventually increase production, a small toller that meets all other criteria for selection could be excluded based upon this factor. Planning for success is essential.

Some companies that let toll contracts have been known to work with small tollers who displayed excellent technical, safety, and quality characteristics to help them achieve the necessary higher production capacity. This is feasible if the time frame allows and a closer relationship is mutually beneficial.

2.2.11. Process Safety

If a U.S.-based toll project requires threshold quantities of feedstock, intermediate or finished product that are considered:

- highly hazardous chemicals under OSHA's Process Safety Management (PSM) regulation or
- regulated substances under the EPA Risk Management Program (RMP) rule,

a candidate toller will become subject to either or both of these rules and should demonstrate understanding and thorough implementation of these regulatory elements of process safety (termed “prevention program” under the EPA rule). The capability to achieve these regulatory requirements may be a key factor in a toller’s evaluation.

When a candidate toller is not currently regulated by a governmental process safety requirement and the proposed toll project will not trigger regulation, evidence of other good process safety practices should be still be sought and evaluated. Tollers should consider the benefits to their business that come from using recognized tools available through implementing a process safety system as defined by these regulations, or similar systems as defined by CMA’s Responsible Care® Codes or CCPS publications. These include key elements such as:

- Employee participation
- Process safety information
- Process hazard analysis
- Management of change
- Operating procedures
- Mechanical integrity
- Emergency planning and response
- Training
- Contractors
- Hot work permit
- Compliance audits
- Pre-startup safety review
- Incident investigation
- Trade secrets

Non–U.S.-based operations may reference the same documents or alternative local references, such as:

- European Process Safety Institute publications
- CIA Publications (United Kingdom’s Chemical Industry Association)
- TNO Publications (The Netherlands Organization)
- HSE References (United Kingdom’s Health & Safety Executive)

Whether or not a firm is subject to these regulatory requirements, examples of questions to ask candidate tollers at this stage of initial qualification are:

- Have there been fires, explosions or chemical release incidents? If yes, request the incident investigation data, including actions taken to prevent a reoccurrence.
- Request to examine PHA reports.
- Has the facility identified, evaluated and implemented controls to reduce the risks associated with catastrophic chemical releases or accidental releases of regulated substances? Look for evidence of the following:
 - minimization of on-site hazardous chemical inventories,
 - process controls that will prevent releases,
 - substitution of lower hazard chemicals,
 - installation of early warning systems for hazardous chemical releases, and
 - procedures and equipment to mitigate or minimize releases once occurred.
- Has the facility established an effective critical-equipment maintenance program (also termed mechanical integrity program) to prevent failures that would cause hazardous conditions?
- Are there appropriate planning, training, drills, and equipment for response to emergencies? If yes, ask to review the emergency response plan and training records. Be aware that for some facilities, an acceptable plan is to evacuate and call the fire department.

One excellent sign that a candidate toller has an understanding of process safety is the existence of a written management system that describes how each applicable requirement is met.

2.2.12. Security

High value products and proprietary information are often placed in the custody of the selected toller. This can be a major concern in the decision to work with a toller. It is sometimes essential to determine

what measures are being taken by the toller to safeguard a customer's products and information, including electronic information.

The candidate tollers' security policy should emphasize the importance of protecting people, property and the operational practices against loss by intentional destruction or theft. During the site visit, check to see if appropriate methods are taken to control entry and movement of people and vehicles as a security measure. One telltale sign is that you may be denied access to an area because of another company's confidential process. Though an interference, it affirms a sound security practice. Determine whether security inspections are being held during off-duty hours.

2.2.13. Corporate Health, Safety, and Environmental Policies

Although not as informative as past performance measures or hard evidence of good programs, the existence of a company policy stating a candidate toller's commitment to health, safety and environmental responsibility should be determined. These policies, typically signed and displayed prominently in the facility, help ensure management and company executives are fully aware of their commitment to workers and the public.

2.2.14. Housekeeping and Appearance

The general appearance of a facility speaks volumes about how the site is managed. The reviewers for a client can again make some value judgements about a candidate toller by noting the general housekeeping practices during a site visit. Housekeeping can be an indicator of the company's attitude toward health, safety, and the environment. Is trash strewn throughout the facility? Are work sites maintained in a clean and orderly fashion? Is temporary equipment properly stowed when not in use? Are tools well kept and organized? Are small spills properly cleaned and disposed of in a timely fashion? Some tollers may have policies, training, or safe work practices that address housekeeping expectations for personnel. These should be reviewed if available and compared against practice.

2.2.15. Insurance Review and Experience Modifiers

Candidate tollers should be made aware of special insurance needs the proposed toll will require as soon as possible in the initial qualification process. Clients should ask to see a toller's standard insurance certificate to verify coverage. It is common to check for:

- Workmen's compensation insurance at statutory limits and employers' liability insurance
- Comprehensive general liability insurance
- Property insurance
- Pollution and environmental impairment insurance (when applicable)

An experienced candidate toller probably carries the basic insurance required for the industry but contracts are typically dependent upon proof of adequate coverage. Depending on the anticipated contract terms and the financial assessment of both firms, other insurance or bonds may need to be evaluated. These may address business interruption, third party liability, or other identified loss potential.

Examining workers' compensation insurance modified premium will give an assessor more information about past safety performance. If the experience modification rate (EMR) factor is good (calculated by a rating bureau such as the National Council on Compensation Insurance based upon historic loss and payroll data), the toller will be an attractive risk to their insurer and will receive lower premiums. On the other hand, if there are several excess losses (any single claim over \$5000) the experience modification rate factor will result in higher premiums. This signals a potential problem worthy of further investigation. Remember that the data used to calculate EMR can be over a year old depending upon how it is collected. Looking at the last three years of data is important in order to determine a trend—and to understand whether the toller is improving or not.

In general, tollers should have active insurance policies that protect themselves and to a certain extent the client from excessive loss. Make certain that the insurance coverage held by both parties works well to manage risks.