WASTE AUDIT STUDY

DRUG MANUFACTURING AND PROCESSING INDUSTRY

PREPARED FOR
ALTERNATIVE TECHNOLOGY SECTION
TOXIC SUBSTANCES CONTROL DIVISION
CALIFORNIA DEPARTMENT OF HEALTH SERVICES

PREPARED BY
ICF TECHNOLOGY INC.
UNIVERSAL CITY, CALIFORNIA

May 1989
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ABSTRACT

This is a study of hazardous waste in the drug manufacturing and processing industry. Waste generation and current waste management practices are discussed. Waste minimization including source reduction, recycle and recovery, and alternative treatment is investigated. Waste audits of three plants within the pharmaceutical industry are included as case studies. Based on study findings and audit results, a self-audit format for use by the industry is provided.

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All text pertaining to law and regulations contained within this report are provided for general information only. That information is not reliable for use as a legal reference. The generator must contact the appropriate legal sources and regulatory authorities for up-to-date regulatory requirements, and their interpretation and implementation.
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1. SUMMARY AND CONCLUSIONS

1.1 Study Summary and Findings

This study identifies opportunities for waste minimization in the drug manufacturing and processing industry. It provides a self-audit format for industry use. This study also discusses the types of waste generated by the industry and the currently available methods for waste management. Waste minimization options covered in this study include source reduction, recycle and recovery, and alternative treatment.

Included in this report are case study waste audits of three plants within the pharmaceutical industry. The audited plants are representative of the types of operations performed by the industry. The processes and activities evaluated by the waste audits are fermentation, chemical synthesis, product formulation, and research and development.

The audit procedures and findings are used to develop a self-audit format for use by the industry. The format assesses current waste management practices and suggests improvements. It can be used by firms lacking the in-house expertise for a waste minimization program, typically small quantity generators.

The major findings developed from this study are summarized below.

- The drug manufacturing and processing industry has a diverse range of raw materials, products, and processes. Common processes include fermentation, natural extraction, and chemical synthesis. The majority of drugs are produced by chemical synthesis.

- The wastestreams vary greatly in type, composition, and volume.

- Because of the diversity of processes and wastestreams, many waste minimization opportunities for source reduction, recycling, and treatment are plant specific.

- A waste audit is an important first step in identifying waste minimization opportunities.

- Source reduction through product reformulation is an unlikely waste minimization alternative. Barriers include time requirements for product testing, FDA reapproval, and consumer acceptance of the new product.

- Solvents are widely used for product recovery, product purification, and as reaction media. Solvents are typically recycled back into manufacturing processes.

- Manufacturers proprietary information may be a barrier to dissemination of waste minimization techniques.
1.2 Audit Findings and Conclusions

**Plant A**

Plant A produces erythromycin base and erythromycin derivatives using batch fermentation. Findings and results of the waste audit performed for this study are summarized below.

- The major wastestreams generated by Plant A are filter cake wastes from fermentation broth processing, solvent recovery wastes from spent solvent recycle operations, and nonhazardous process washwaters.
- Current waste management practices are: landfilling of filter cake wastes, incineration of solvent wastes, and sewer discharge of washwaters.
- Plant A uses on-site recovery processes to recycle over ninety-nine percent of solvents used.
- Filter cake wastes are the most significant wastestream generated by Plant A.
- Byproduct uses for filter cake wastes from fermentation broth processing include use as feed additives, fertilizers, and soil additives.
- Analyses of the filter cake material showed it to be unsuitable for use as a fertilizer.
- Third parties interested in the use of the filter cake as a soil or feed additive were identified.
- Continue to emphasize good operating practices.

**Plant B**

Plant B formulates a wide range of dermatological and ophthalmological products. In addition, Plant B operates a research and development (R&D) section. The findings of the waste audit performed at Plant B are summarized below.

- Recycling of spent sulfuric acid to battery manufacturers should be implemented as soon as possible.
- To eliminate sulfuric acid usage, it is strongly recommended that direct marking of glassware be replaced by removable labels.
- To reduce waste volumes sent to landfills, the components of each product should be evaluated for compatibility with sewer discharge.
- The potential for on-site solvent recycle should be investigated.
- A standard operating procedure for waste management in the R&D section should be developed.
- Close supervision of R&D chemical inventories should be continued.

**Plant C**

Plant C produces sophisticated biochemicals, pharmaceutical compounds, and immunochemicals. Products are produced in batch through chemical synthesis and fermentation processes. The findings of the waste audit performed at Plant C are summarized below.

- Wastestreams include spent solvents, acid and solvent vapors, acidic and caustic solutions, and non-hazardous solid waste.
- Spent solvent is incinerated in cement kilns. Spent solvents are usually not recycled or recovered due to the extent of contamination. Further investigation into recovery is recommended.
- The acid and solvent vapors are sent to a scrubber system. The acidic and caustic solutions are neutralized then discharged to the sewer. Non-hazardous waste is discarded in a municipal landfill.
- Plant C is planning several steps to increase waste minimization and management efficiency. Plans include installing above ground tanks for industrial waste treatment prior to discharge to the sewer. Treatment will include batch settling of suspended solids and automated pH control for acidic and caustic solutions.
2. RECOMMENDATIONS

These recommendations can improve waste management within the drug manufacturing and processing industry.

2.1 Source Reduction

- Management should commit itself to a waste minimization program. Waste minimization goals should be established. Included in these goals should be the reduction or elimination of all hazardous waste disposed to landfills.

- Firms lacking the in-house expertise to establish a waste minimization program should seek technical assistance from qualified sources. Some government agencies have guidance material. Some private consultants specialize in waste management.

- Waste audits, such as the ones developed in this report, should routinely be performed.

- Producers of capsules or coated tablets should consider switching from solvent-based production methods to water-based methods.

2.2 Recycling

- Firms not currently recycling waste solvents should do so. Generators of large quantities of waste solvents should consider on-site recycling. Whenever possible, waste solvents should be segregated by solvent type to improve recyclability.

- Byproduct uses for wastestreams should be investigated.

- Generators of filter cake wastes from fermentation processes should investigate alternatives for reuse as feed additives, soil amendments, and fertilizers.

- Waste exchange services for recycle or reuse should be investigated.

2.3 Treatment

- Alternative treatment technologies to reduce waste volumes or toxicities should be investigated.

- For rejected packaged products, formulators should consider separating products from packaging to improve waste management options.

2.4 Land Disposal

Hazardous waste land disposal is rapidly becoming impractical as a waste management option. Many land disposal facilities are closing down. Some close unpredictably due to violations or environmental impairment. The
remaining few are often distant and costly to utilize. Disposal costs are high and rising. Environmental impairment liability risks are great for a generator using the facility. Increasingly, facility operators refuse to accept some wastes because of public relations concerns.

Because of these liabilities and uncertainties, land disposal of hazardous waste or the hazardous residue from its treatment cannot be recommended for a generator's long-term waste management plans.
3. INTRODUCTION

3.1 Study Purpose and Objectives

The California Department of Health Services (DHS) has a broad program to reduce land disposal of hazardous waste. This program includes technical support to California industries for improving hazardous waste management practices. Improved waste management practices can reduce waste quantities. Hazardous waste reduction can help protect the environment of the state and also reduce long-term costs for the industry.

As part of the program, DHS is procuring waste audit studies for selected California industries. The studies address waste management options and provide a waste audit format. Industries selected are those having generators which lack both the awareness of hazardous waste issues and the in-house expertise to implement a waste audit program. Typically these are small quantity generators.

DHS contracted ICF Technology to perform a waste audit study for the drug manufacturing and processing industry. This industry includes firms manufacturing and/or processing botanicals, biological products, chemicals, and preparations (SIC 283). The objectives of this study are to present current industry practices, identify waste reduction and treatment options, and to develop a self-audit format for industry use.

3.2 Study Methodology

The study methodology involved three steps: (1) industry characterization, (2) case studies, and (3) self-audit format development. Industry characterization was used to determine typical processes used and waste generated. From this characterization, plants representative of the industry were selected for case study waste audits. Waste audits were performed to identify current waste reduction opportunities and to aid in developing the self-audit format.

A waste audit is an essential starting point from which waste minimization and management alternatives can be implemented. The waste audits performed addressed the following issues:

- How much waste is produced?
- What are the hazardous components of the wastestreams?
- What are the disposal costs for the major wastestreams?
- What is the efficiency of the processes in use?
- Are there any unaccounted material losses?

To identify candidate firms to participate in case studies, the Pharmaceutical Manufacturers Association (PMA) and the Generic Pharmaceutical Industry Association were contacted. The list from contacting these organizations was
supplemented with pharmaceutical firms known to ICF.

To select plants for the study, each candidate firm was interviewed by phone. Each was briefed on the scope, purpose, and objectives of the study. Candidate firms were selected for audit based on their willingness to participate in the study, implement waste minimization alternatives, and share potentially proprietary information. Candidate firms were informed that their identity would be kept confidential in the waste audit report.

The three plants selected represent different aspects of the drug manufacturing and processing industry. The selected firms consisted of a manufacturer using batch fermentation, a formulator with a large research and development laboratory, and a plant manufacturing drugs through chemical synthesis. The waste audit methodology is described below.

Once the plants were selected, an initial visit was scheduled. To maximize the gathering of information during initial plant visits, a pre-visit questionnaire and a data gathering form were developed.

The pre-visit questionnaire covered aspects of the plants operations. It included types of products, types of processes used, raw material usage, descriptions of research activities, current and proposed waste minimization/management and pollution control efforts, and regulatory compliance status. A copy of the pre-visit questionnaire is presented in Appendix I. Prior to the initial plant visits, the pre-visit questionnaire was sent to each firm. The questionnaire provided the audit team with basic plant and process background prior to the initial visit and informed the plant contacts of the focus of the waste audit.

The data gathering form assisted in gathering all necessary data during the initial visit. Thus minimizing the need to return to the plant for additional data collection. The data gathering form covered the following areas:

- Basic Operations;
- Raw Material Usage;
- Product Information;
- Process Information;
- Solvent Usage;
- Waste Generation;
- Waste Management Practices;
- Spill Prevention and Control;
- Past, Present, and Future Waste Minimization Activities; and
- Regulatory Data.
A copy of the data gathering form is presented in Appendix J.

During the initial plant visits, auditors became familiar with operations and collected data. An interview of the plant contacts provided an overview of operations and information concerning past, present, and future waste management strategies. A tour of the plant followed. The plant tour familiarized auditors with the processes and helped identify areas to be focused on in more detail. Following the plant tour, background information was collected. This information included process flows, raw material usage, product information, waste management practices, production scheduling, waste generation rates, and waste disposal practices and costs.

The collected data was analyzed to identify areas were waste management practices could be improved. In addition, data gaps also were identified. Additional data needs were filled by correspondence with plant contacts.

The waste audit results were presented to each firm in report form. The report included a general plant description, raw material information, process descriptions, listings of wastestreams generated, discussions of current waste management practices, and a series of waste minimization/management alternatives. For each alternative, the potential for waste reduction, applicability of the wastestream to the alternative, and cost information were discussed, as appropriate.

The experience and information obtained during the waste audits was used to develop the self-audit format. The data gathering form served as a prototype for the self-audit format. It was discovered that the data gathering form was difficult to fill out in the field. For some sections of the form, notes were taken during the plant visits and the section was completed after the visit. The self-audit format, therefore, contains a series of checklist and fill in the blank questions which can be easily answered.

The self-audit format is intended for use by a lay person with little or no training. It highlights those areas where waste management procedures can be improved and identifies the potential for waste reduction and cost savings.

3.3 Report Organization

Chapter 4 presents a general characterization of the drug manufacturing and processing industry. This chapter discusses the processes used and typical wastestreams generated. Chapter 5 discusses available waste minimization/management options. The chapter includes source reduction, recycle and recovery, and treatment. Regulations pertinent to the drug manufacturing and processing industry are outlined in Chapter 6. Chapter 7 discusses the economics of waste minimization. Case study waste audits are presented in Appendices A, B, and C. Appendix G presents the self-audit format.
4. INDUSTRY CHARACTERIZATION

4.1 General Description

Drugs are manufactured and processed in bulk and in small quantities. Some operations formulate and package drugs into dosage form. California has just over eight percent of the nationwide pharmaceutical industry [1]. There are 75 pharmaceutical manufacturing plants located in the state. These plants are mostly located in Los Angeles (35), Orange (17), and Santa Clara Counties (10) [2].

Some California has just

Drugs are manufactured and processed in batch, semi-batch, and continuous operations. Batch operations account for 87 percent of all operations nationwide [1]. Pharmaceutical manufacturing includes fermentation, chemical synthesis, and natural extraction. Pharmaceutical processing formulates and packages drugs into dosage forms.

Because of the diversity of operation and products, characterization of the industry based on specific unit operations and their resulting wastestreams is impractical. Instead, the industry is characterized based on general manufacturing processes.

4.2 Drug Manufacturing Processes

The industry can be characterized into five activity areas based on the operations involved. These activity areas are:

1) fermentation,
2) chemical synthesis,
3) natural extraction,
4) formulation and packaging, and
5) research and development.

The processes, raw materials, and wastes of these five areas are discussed in the following sections.

4.2.1 Fermentation

Steroid and antibiotics are typically produced using batch fermentation processes [3]. Fermentation consists of three steps: inoculum and seed preparation, fermentation, and product recovery.

Inoculum preparation begins with a carefully maintained population of a microbial strain. A few cells from this culture are matured into a dense suspension through a series of test tubes, agar slopes, and shaker flasks. The cells are then transferred to a seed tank for further propagation. The
seed tank operates like a full scale fermenter and is designed for maximum cell growth. The final seed tank volume occupies from 1 to 20 percent of the volume used in full scale production [4].

The sterilized fermenter is charged from the seed tank through a series of sterilized lines and valves. Sterilized nutrient materials are added to the vessel and fermentation commences. During fermentation, the vessel contents are agitated and aerated via a sparger. Air inflow and temperature are carefully monitored throughout the fermentation cycle.

Following cell maturation, the fermenter broth is filtered. Filtering removes the solid remains of the inoculum microorganisms (i.e., mycelia). The resulting filter beer is then processed to recover the product drug. Product recovery processes include solvent extraction, precipitation, and ion exchange or adsorption [4].

In solvent extraction, the aqueous filter beer is contacted with an organic solvent to concentrate the product into the solvent phase. The product is recovered by further extraction processes, precipitation, or evaporation. Typical solvents used in recovery include methylene chloride, benzene, chloroform, 1,1-dichloroethylene, and 1,2-trans-dichloroethylene [5].

In precipitation processes, the product is precipitated from the fermenter broth. Product is then recovered from the solids. The remaining broth also is filtered to remove product. Ion exchange resins or activated charcoal also are used to remove product from fermentation broths.

Fermentation raw materials include sugars, starches, proteins, nitrogen, phosphate, and other nutrient sources. Solvents used for product extraction typically are recycled at the plant (6). Solvents are purchased to make up for process losses.

The fermentation process generates large volumes of spent fermentation medium. Filtration processes result in large quantities of solids in the form of spent filter cake. The filter cake waste material includes mycelia, filter aids, and some residual product. After product recovery, spent filtrate is discharge as a wastewater. Additional sources of wastewater are equipment cleaning operations and fermenter vent gas scrubbing. Wastewaters from fermentation operations typically are high BOD, COD, and TSS streams with a pH range of 4.0 to 8.0 [1]. Solvent recycling processes generate still bottoms and other hazardous wastes.

4.2.2 Chemical Synthesis

Most drugs today are produced by chemical synthesis [3]. In a typical manufacturing plant, one or more batch reactor vessels are used in series to make the desired product. Product recovery steps may involve separation or purification. The types of chemical reactions, recovery processes, and chemicals used are very diversified.
Within a plant, reaction vessels and ancillary equipment are often arranged into separate process units. Each process unit is capable of producing all or part of several different products. Dedicated process units are used for the highest throughput products.

Pharmaceutical products are manufactured in campaigns. Individual campaigns produce a single product. Each campaign will last a few weeks or a few months depending upon the need for the product. During a campaign, operators or computerized controllers add the required reagents and monitor process functions (i.e., flow rates and temperatures) according to a preset plan. At the end of a campaign, process equipment is thoroughly cleaned. Campaign schedules are tightly controlled to ensure that sufficient raw materials and process equipment are available.

Chemical synthesis operations use a wide range of chemicals including organic and inorganic reactants and catalysts. In addition, synthetic manufacturers uses a wide variety of solvents listed as priority pollutants [1]. Solvents are used for product recovery, purification, and in reactions. The most widely used organic solvents are benzene and toluene. Other six carbon ring compounds such as xylene and cyclohexane also are used [7].

Wastestreams from chemical synthesis operations are complex due to the diverse operations and reactions used. Synthetic production processes generate acids, bases, cyanides, and metals. Typically, spent solvents are recovered on-site in closed-loop processes (e.g., distillation or extraction) [6]. Solvent recovery wastes such as still bottoms are generated as a result of these processes.

Aqueous wastestream sources include spent solvents, filtrates, concentrates, equipment cleaning, wet scrubbers, and spills. Because of the wastestream concentration or toxicity, pretreatment may be required prior to sewer discharge. Wastewaters from synthesis processes typically have high BOD, COD, and TSS levels and pHs from 1 to 11 [1].

4.2.3 Natural Extraction

Natural extraction describes the production of pharmaceuticals from natural materials. Sources include roots, leaves, animal glands, and fungi. The pharmaceuticals that are extracted from natural sources typically are too complex to synthesize commercially. Synthesis of these products is difficult due to their large molecule size. Another difficulty is that commercial synthesis may result in several stereoisomers with only one having a pharmacological value. Drugs produced by natural extraction include allergy relief medicines, insulin, and morphine [1].

The amount of pharmaceutical produced is very small compared to the natural source used. During each process step, the volume of material being worked can greatly diminish. Final purification may occur on volumes less than one-thousandth of the initial volume. Because of these volume reductions,
conventional batch and continuous processes typically are not suitable for natural extraction operations.

Product recovery and purification includes precipitation and solvent extraction. Lead and zinc are used as precipitating agents. Common solvents include benzene, chloroform, and 1,2-dichloroethane [8]. Solvents are used for product recovery and to dissolve fats and oils which would contaminate the product. Ammonia, in salt or anhydrous forms, is used for pH control.

Wastes include spent raw materials such as leaves and roots, spent solvents, and wastewaters. Extraction wastewaters typically are low BOD, COD, and TSS levels and a pH in the range of 6.0 to 8.0 [1].

4.2.4 Formulation

Pharmaceutical formulation is the preparation of dosage forms such as tablets, capsules, liquids, parenterals, and creams and ointments [9]. A more complete listing of dosage forms is presented in Table 4.1. The raw materials are used in bulk quantities. These include the ingredients, fillers, and binders.

Tablets are produced in three varieties: plain compressed, coated, and molded. Tablets account for over ninety percent of all medicines taken orally [9]. The tablet form depends upon the desired release characteristics of the active ingredient. The release can be slow, fast, or sustained. Tablets can be coated or plain. Tablets are coating by spraying or tumbling the tablet with a coating material, followed by drying.

Tablets are produced by blending the active ingredient with fillers such as starch or sugar and binders such as corn starch. The blend is then compressed. Production methods include wet granulation, direct compression, or slugging.

In wet granulation, the powdered active ingredient and filler are blended and then wetted with a binder solution. Coarse granules are formed, dried, and mixed with lubricants, such as magnesium stearate. The mix is then compressed into tablets.

A tablet press is a die which to holds a measured amount of material and a punch which compresses the tablet. Multi layered tablets are produced using presses with several feed hoppers. The tablet is partially compressed each time a layer is added. It is completely compressed after the final layer is added.

Slugging is a process used for drugs that are unstable under wet granulation procedures or for formulations which cannot be directly compressed. Slugging uses heavy duty tablet presses. The process blends and compresses relatively large 20 to 30 grams tablets. The large tablets are ground and screened to a desired mesh size, then recompressed into final tablets.

Capsules are the next most widely used oral dosage form for solid drugs. Capsules are prepared in hard or soft form. Hard capsules consist of two
<table>
<thead>
<tr>
<th>Dosage Form</th>
<th>CONSTITUENTS, PROPERTIES</th>
<th>USES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aerosols</td>
<td>Gaseous solutions, dispersions</td>
<td>External or internal</td>
</tr>
<tr>
<td>Capsules</td>
<td>Small-dose bulk powder enclosed in gelatin shell; active ingredient plus diluent</td>
<td>Internal</td>
</tr>
<tr>
<td>Elixirs</td>
<td>Sweetened hydroalcoholic solution; may be medicated</td>
<td>Flavor or medicinal</td>
</tr>
<tr>
<td>Emulsions</td>
<td>Oil-in-water or water-in-oil</td>
<td>Oral, external, or injection</td>
</tr>
<tr>
<td>Extracts</td>
<td>Concentrated preparations of vegetable or animal origin with water, alcohol, or ether as a solvent</td>
<td>Flavoring agent</td>
</tr>
<tr>
<td>Lotions</td>
<td>Oil-in-water or water-in-oil</td>
<td>External</td>
</tr>
<tr>
<td>Lozenges</td>
<td>Prepared by piping and cutting or disk candy technology; compounded with glycerogelatin</td>
<td>Slow dissolution in mouth</td>
</tr>
<tr>
<td>Parenter als</td>
<td>Sterile, pyrogen-free, isotonic, pH close to that of blood; oily or aqueous suspension</td>
<td>Intravenous, intramuscular, subcutaneous injection</td>
</tr>
<tr>
<td>Pills</td>
<td>Adhesive or binding agents facilitate compounding; prepared by massing and piping</td>
<td>External</td>
</tr>
<tr>
<td>Powders</td>
<td>Comminuted or blended, dissolved in or mixed with water</td>
<td>External or internal</td>
</tr>
<tr>
<td>bulk powder</td>
<td></td>
<td></td>
</tr>
<tr>
<td>effervescent powder</td>
<td>Carbon dioxide releasing base ingredients</td>
<td>Oral</td>
</tr>
<tr>
<td>DOSAGE FORM</td>
<td>CONSTITUENTS, PROPERTIES</td>
<td>USES</td>
</tr>
<tr>
<td>----------------</td>
<td>------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------</td>
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<tr>
<td>dusting powder</td>
<td>Contain absorbents</td>
<td>Skin treatment</td>
</tr>
<tr>
<td>insufflations</td>
<td>Insufflator propels medicated powder into body cavity</td>
<td>Body cavities</td>
</tr>
<tr>
<td>lyophilized powders</td>
<td>Reconstitution by pharmacist from unstable products</td>
<td>Various uses, including parenteral and oral</td>
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<tr>
<td>Solutions</td>
<td>Water, chemicals</td>
<td>Internally or externally formulating aids</td>
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<tr>
<td>Sprays</td>
<td>Solutions of various drugs in oily or aqueous vehicles applied by an atomizer (nebulizer)</td>
<td>Internal</td>
</tr>
<tr>
<td>Suspensions</td>
<td>Powder suspended in water, alcohol, glycol, or an oil</td>
<td>Oral, skin application</td>
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<tr>
<td>Suppositories</td>
<td>Theobroma oil, glycerinated gelatin, or polyethylene glycol base plus medicinal agent</td>
<td>Insertion in body cavity</td>
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<td>Syrups</td>
<td>Sweetener, solvent, medicinal agent</td>
<td>Flavoring agent, medicinal</td>
</tr>
<tr>
<td>Tablets</td>
<td>Dissolved or mixed with water; great variety of shapes and formulations</td>
<td>Oral and external</td>
</tr>
<tr>
<td>Tinctures</td>
<td>Natural drugs, extracted with appropriate solvent; 10-20 g/cc</td>
<td>External or internal</td>
</tr>
</tbody>
</table>

separate pieces. The pieces are formed by dipping pins into a solution of gelatin maintained at a specified temperature. When removed, a gelatin film is deposited on the pins. The temperature of the gelatin affects the viscosity and, hence, the wall thickness of the capsule. After drying and trimming, the separate sections of the capsule are filled and joined.

Soft capsules are prepared during the formulation process. Two continuous gelatin films are placed between rotary die plates. The plates form the two halves of the capsule. As the plates are brought together and sealed, the drug, usually a nonaqueous solution or soft mass, is injected into the capsule.

Liquid dosage forms are prepared for injection and oral use. Dosage forms include aqueous solutions, syrups, elixirs, suspensions, and tinctures [9]. Liquid dosage forms are usually prepared by mixing the solutes with a selected solvent. The mixing is performed in a jacketed glass-lined or stainless-steel vessel that resembles a chemical reactor. Solutions are then filtered under high pressure through filter plates or filter aids, then pumped into storage tanks for quality control inspection prior to placement in containers. Suspensions and emulsions are prepared using colloid mills and homogenizers, respectively.

To prevent mold and bacterial growth, liquid dosage forms are prepared with preservatives. Solutions prepared for oral or topical use do not require sterilization. Prescriptions and ethical preparations for ophthalmic use must be sterilized. These are, therefore, prepared in a manner similar to parenteral products.

Parenteral dosage forms are injected into the fluid systems of the body. Common methods of injection are intradermal, hypodermic, intramuscular, intravenous, intrathecal, intracisternal, and peridural [9]. Parenteral dosage are prepared as solutions, dry solids which are dissolved immediately before injection, suspensions, dry insoluble solids which are suspended before injection, and emulsions. The injection vehicle can be aqueous or nonaqueous. Nonaqueous vehicles include water-miscible solvents such as ethyl alcohol, polyethylene glycol, and propylene glycol and fixed oils such as corn oil, cottonseed oil, peanut oil, and certain esters.

When possible, parenteral dosages are sterilized as soon as possible after filling and sealing of the product container. Sterilization usually is performed with dry or moist heat under pressure. Products which are degraded by heat can be passed through bacterial retaining filters into sterile containers. These are then sealed under aseptic conditions.

Ointments and creams are semisolid dosage forms prepared for topical use. Ointments are usually prepared by melting a base. This is typically the petroleum derivative petrolatum. It is then blended with the drug. The cooled mixture is passed through a colloid or roller mill. Creams are manufactured in a similar manner. Creams are oil-and-water or water-and-oil
emulsions.

Wastes result from cleaning, sterilizing, spills, and rejected products. During mixing or tabletting operations, dust is generated. Typically, dusts are recycled into the formulation process. Small amounts of waste dust, however, are generated. Air emissions of solvent materials are associated with tablet coating and capsule manufacturing operations. The primary wastewater source is equipment washouts. Wastewaters may contain inorganic salts, sugars, and syrups. Formulation wastewaters typically are low BOD, COD, and TSS; with near neutral pH [1].

4.2.5 Research and Development

Research and development in the pharmaceutical industry is diverse. It includes chemical research, microbiological research, and biological research. The development of a new drug requires the cooperative efforts of a large number of trained personnel specializing in organics, synthesis, medicinal and analytical chemistry, microbiology, biochemistry, physiology, pharmacology, toxicology, and pathology. As a result of the diverse nature of pharmaceutical research and development, a wide range of chemical and biological laboratory wastes are produced. Examples of the more common wastes produced from pharmaceutical research and development include halogenated and non-halogenated solvents, photographic chemicals, radionuclides, bases, and oxidizers [9].
4.3 Chapter 4 References


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5. WASTE MINIMIZATION AND AUDITING

5.1 Introduction

The pharmaceutical industry, is characterized by a low ratio of finished product to raw materials [1]. In particular, natural extraction generates large amounts of extraction waste. Depending on the processes and materials involved, waste streams may or may not contain hazardous components.

In the past, landfilling was the most popular form of hazardous waste disposal. Landfills were low cost and simple disposal. In 1981 an estimated eighty percent of all hazardous wastes generated in the United States were disposed in landfills [2]. The Hazardous and Solid Waste Amendments (HSWA) of 1984 have changed this.

HSWA established a national policy for reducing or eliminating hazardous waste. Additional incentives include increased disposal costs, land disposal restrictions, future liability, employee and public health, and increased public awareness. Barriers to waste minimization include lack of awareness of potential benefits, concern that changes will reduce product quality, and a lack of in-house expertise or technical staff [3].

The three basic options for waste minimization are presented in Figure 5-1. Source reduction is preferable. It includes all activities which reduce or eliminate waste generation in the process or plant. Recycling is the next most preferable option. Recycling is the reuse or reclamation of part or all of a wastestream. Treatment is the least preferable option. Treatment reduces wastestream volume or toxicity without producing a net material or energy value.

The following chapters discuss each of the basic waste minimization options.

5.2 Waste Minimization Audits

Waste minimization audits develop and screen waste minimization options. These options include source reduction, recycling, and treatment. Opportunities to reduce waste generation and disposal costs are identified during a waste audit. Appendices A, B, and C presents case study waste minimization audits.

5.3 Environmental Audits

The purpose of an environmental audit is to improve environmental quality management, to check environmental performance, and to ensure compliance with applicable regulations. An environmental audit can list all discharges from the plant. Each discharge can be identified and quantified. In addition, the ultimate disposition of the waste can be cataloged.
Figure 5-1

BASIC ELEMENTS OF WASTE MINIMIZATION

Waste Minimization Options

Source Reduction
- product reformulation
- materials substitution
- process modification
- good operating practices

Recycle and Recovery
- on-site recycle
- off-site recycle

Treatment
The three types of environmental audits are: emergency audit, specific audit, and general audit. An emergency audit focuses on eliminating a specific problem which may threaten plant closure. A specific audit is aimed at an easily identifiable problem. It is usually short-range. A general audit looks at a plant, a portion of a plant, or a general problem within a plant. This includes quantifying discharge volumes and indicating immediate actions required. Audits identify methods of regulatory mitigation as well as applications of waste minimization.

Environmental audits correct problems. Periodic environmental audits keep a company’s hazardous substances management system up to date. Audits lessen the occurrence of environmental accidents, violations, and fines. Audits also compile environmental cost information and alert employees to environmental requirements.
6. SOURCE REDUCTION

Source reduction is changes in products, input materials, process technologies, and procedural and organizational practices. The following sections discuss the source reduction alternatives shown in Figure 6-1.

6.1 Product Reformulation

Product reformulation is the substitution of one or more raw materials. These substitutions reduce the volume or toxicity of waste generated. For the pharmaceutical industry, however, product reformulation is likely to have a significant impact. One potential drawback is the time required for product redevelopment and testing. Testing is required to ensure that the reformulation has the same medicinal effect as the original drug. Furthermore, time is required for FDA approval of the reformulated drug. An additional concern is the effect of reformulation on product quality. Changes in characteristics such as taste, color, or dosage form could cause users to switch to another product. Revenue lost from customer rejection could render this option uneconomical.

6.2 Material Substitution

One example is hazardous materials used in product manufacturing and processing are replaced by non-hazardous materials. Material substitution also may reduce waste volume, toxicity, or hazardous residue. The product is not changed by the substitution.

Tablet coating processes typically result in air emission of volatile organics. These must be controlled to meet air quality regulations. In one study, the cost of pollution control equipment was estimated at $180,000. Developing a water-based solvent and new spray equipment for application eliminated the need for pollution control equipment. The resulting savings in solvent costs was $15,000 per year [4]. Another tablet operation reduce methylene chloride use from 60.0 tons/year to 8.0 tons/year by converting from conventional film coating to aqueous film coating [5].

Other areas for material substitution include using of aqueous based cleaning solutions instead of solvent-based solutions and the replacement of chlorinated solvents with non-chlorinated solvents.

6.3 Process Modification

Process modification may also involve material substitution.

Waste generation can be reduced through process modification or modernization. Process modification involves changes in process equipment and/or changes in operating parameters. Modernization includes installing updated control mechanisms or increasing control levels. Increasing process automation is another form of modernization.

Wastes are generated by incomplete chemical reactions. In addition, the
formation of byproducts during reactions generates wastes. Potential causes include inadequate feed flow control or reactor temperature control. Installing updated control systems can improve reactor efficiency and reduce byproduct formation. Increased automation can reduce operator errors. Automated systems for material handling and transfer such as conveyor belts for bagged materials can reduce spillage.

Fouling deposits are caused by crystallization, sedimentation, and corrosion. These will reduce process operating efficiencies and increase waste generation [6]. Fouling deposits can be inhibited by increasing process agitation or altering operating temperatures. Redesigning chemical transfer systems can reduce material losses. For example, replacing gas-pressurization with a pumping mechanism eliminates the tank pressurizing step and its associated material losses [6]. Other design considerations for waste minimization include modifying tank and vessel dimensions to reduce clinging, installation of internal recycle systems for cooling waters and solvents, selection of new or improved catalysts, switching from batch to continuous processes, and parameter optimization to increase operating efficiency.

Material substitutions can result in beneficial design changes. For example, the substitution of permanganate in the manufacturing of vitamin C for another oxidant eliminated the need for a manganese dioxide filtration operation [7]. The wastes generated by the filtration process also were eliminated.

While significant waste reduction can be achieved, there are barriers to process modification. Extensive process changes can be very expensive. Capital outlay is required. Down time will occur when production is stopped for new equipment installation. New processes must be tested and certified to ensure that the resulting product is acceptable. In addition, management may be reluctant to change a working process.

6.4 Good Operating Practices

Good operating practices can reduce hazardous waste generation and material losses. Table 6-1 presents some good operating practices. The following sections describe these practices in more detail.

6.4.1 Management Initiatives

Because of rising disposal costs and environmental responsibilities, many firms are now instituting environmental programs. Management initiatives can result in recycling or the reduction of waste generation. An incentive awards program can encourage new ideas for cost savings or new product development.
Table 6-1
GOOD OPERATING PRACTICES

PLANT MANAGEMENT:
- Management incentives
- Closer supervision
- Employee training
- Production scheduling
- Additional documentation

RAW MATERIALS HANDLING
- Materials tracking and inventory control
- Spill prevention and control programs
- Material handling and storage procedures
- Preventative maintenance

WASTE MANAGEMENT
- Waste/environmental audits
- Waste tracking and inventory control
- Wastestream segregation
- Waste handling and storage procedures
6.4.2 Employee Training

To be effective, a waste management program must contain an employee training program. All personnel operating equipment or handling hazardous wastes must be trained in safe operating procedures, proper equipment use, process control specifications, and industrial hygiene. Training should occur prior to a job assignment and be ongoing during the period of employment.

Employees should be informed of the materials which they will handle and the possible health effects from exposure to these materials. They should be fitted for any necessary protective equipment and trained in proper equipment care. Training should include equipment operation, material handling, and spill cleanup. Employees should be taught methods for detecting chemical releases. Employees should be briefed on regulatory requirements.

Regularly scheduled drills and safety meetings are necessary. Supervisory review of industrial hygiene, materials handling, and emergency practices should be part of ongoing employee training. Employees should be aware of waste disposal costs and liabilities. In addition, they should understand the causes of waste generation.

6.4.3 Closer Supervision

Closer supervision of plant personnel and operations can increase production efficiency and reduce waste generation. Closer supervision can reduce material losses, spills, and off-spec products. Closer supervision increases coordination within the overall plant operation. This increases opportunities for early detection of mistakes.

6.4.4 Additional Documentation

Documentation of process procedures ensures that job duties are precisely defined. A good operating manual informs employees how each job fits into the overall process. It describes startup, shutdown, emergency, special, and normal operating procedures; identifies control parameters; defines job responsibilities; and describes potential personnel hazards. The manual should outline effluent sampling procedures and equipment failure procedures. Accurate procedural guidelines will reduce waste generation during maintenance or emergency shutdowns.

6.4.5 Material/Waste Tracking and Inventory Control

Accurate material, product, and waste tracking improves material handling and storage procedures. A computer can monitor inventories and track materials. A large portion of hazardous waste often results from overstocking. Computerized monitoring and control can reduce overstocking.

6.4.6 Scheduling

Effective scheduling can reduce the waste generation. Proper scheduling ensures raw materials are used before expiration and products are recovered.
and processed efficiently.

6.4.7 Spill and Leak Prevention

Spillage or leaking of hazardous chemicals generates hazardous waste. Washing down spilled toxic chemicals generates liquid hazardous waste. Cleanups using absorbent materials generate solid waste. Spill and leak prevention are essential to waste minimization.

This includes:

- conducting hazard assessment studies;
- using properly designed storage tanks and process vessels;
- equipping all liquid containers with overflow alarms;
- testing alarms;
- maintaining the physical integrity of containers;
- setting up administrative controls;
- installing sufficient secondary containment;
- having a good valve layout;
- having interlock devices to stop flow to leaking sections;
- disallowing the operators to bypass the interlock or to alter the set points;
- isolating equipment or process lines that are not in service; and
- documenting spillage and related dollar values.

6.4.8 Maintenance Programs

A maintenance program can be preventive, corrective, or a combination of both. It can cut production costs stemming from repairs, waste disposal, and business interruptions. Proper maintenance prevents hazardous waste generation caused by equipment failure.

Preventive maintenance minimizes equipment breakdown and malfunction. Scheduled preventive maintenance programs include cleaning, making minor adjustments, lubrication, testing, measuring, and replacing minor parts. Typically, the following record keeping documents are used: equipment data card, master prevention maintenance schedule, deferred preventive maintenance report, equipment history card, and equipment breakdown report.

Corrective maintenance repairs an unexpected failure. Corrective maintenance
plans review design concepts, operating conditions, and maintenance demand. Maintenance and operating data sheets should be prepared for each piece of equipment and process.

6.4.9 Waste Stream Segregation

Hazardous waste hauled off site is often a mixture of two or more wastestreams. Wastestream segregation involves segregating hazardous materials from nonhazardous materials; segregating hazardous waste by contaminant; and segregating liquid and solid waste. Wastestream segregation reduces waste haulage volumes, simplifies disposal, and facilitates recycle and recovery.

6.4.10 Material Handling and Storage

Most processes involve the storage and transfer of raw materials, products, and wastes. Proper handling and storage ensures that materials reach production process without spills, leaks, or other forms of waste generation.

Proper storage of hazardous materials includes adequate spacing between rows of drums, storage based on chemical compatibility, insulating electrical circuitry, raising drums off the ground to prevent corrosion, and using large drums (greater than 55 gal.) for storage. All storage containers should clearly identify the material in the container. Health hazard warnings, storage, handling, first aid, and spill procedures also be on the storage containers. Material Safety Data Sheets (MSDSs) provide proper handling information.
7. RECYCLE AND RECOVERY

7.1 Introduction

Recycling and recovery includes direct reuse of the waste material, reclamation by recovering secondary materials for a separate use, and removing impurities from waste to obtain a relatively pure substance [8]. The goal of this option is to recover materials for reuse in the process or for reuse in a different application. Because of strict quality control requirements, recovered materials in manufacturing processes require a high degree of purity.

As indicated, quality control requirements restrict reuse opportunities in the pharmaceutical industry. However, reuse opportunities do exist.

Large quantities of aluminum chloride are used in the synthesis of Intal (sodium cromoglycate and asthma prophylaxis). This material is recovered and sold for use in the manufacture of a sludge dewatering aid [9].

Ammonium chloride can be economically recovered by evaporation. In one example, a recovery rate of 3,600 kg/day resulted from a capital expenditure of $300,000. With operating costs of $280/day, a marginal profitability was achieved in a 5.8 year payout period [10].

Other pharmaceutical byproducts include ammonium sulphate and sodium sulfate. Ammonium sulfate can be used in fertilizer material [8]. Sodium sulphate can be concentrated and dried for sale to the glass industry [11].

Fermentation wastes may be used as supplements to animal feeds, soil amendments, and fertilizers [1]. In one case, processing wet mycelia waste generated an excess of 32 tons/day of high protein product amenable for sale as a feed supplement [11]. Additional information on the reuse of fermentation wastes is presented in Appendix A.

The decision to recycle on-site or off-site depends on the capital investment, operating costs, and expertise needed. If waste volumes are small or in-house expertise is unavailable, off-site recycle is the more likely alternative [12].

Spent solvents are particularly amenable to recycle. Solvents are used for equipment cleaning, reaction mediums, extraction mediums, and coating mediums. Table 7-1 lists some commonly used solvents.

The following sections describe recycling with an emphasis on solvent wastestreams. A listing of commonly recycled solvents is presented in Table 7-2.
<table>
<thead>
<tr>
<th>Solvent</th>
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<td>Benzene</td>
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<td>Toluene</td>
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<td>Xylene</td>
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<td>Cyclohexane</td>
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<tr>
<td>Chloroform</td>
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<td>1,2-Dichloroethane</td>
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<td>Methylene chloride</td>
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<td>1,1-Dichloroethylene</td>
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<td>t-1,2-Dichloroethylene</td>
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<tr>
<td>Methanol</td>
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<td>Acetate</td>
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<td>Butyl alcohol</td>
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<td>Isobutyl ketone</td>
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<tr>
<td>COMMONLY RECYCLED SOLVENTS</td>
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<td>---------------------------</td>
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<tr>
<td>Tetrachloroethylene</td>
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<tr>
<td>Trichloroethylene</td>
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<tr>
<td>Methylene chloride</td>
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<tr>
<td>1,1,1-Trichloroethane</td>
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<tr>
<td>Carbon tetrachloride</td>
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<td>Chlorofluoromethanes and ethanes</td>
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<td>Chlorobenzene</td>
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<td>Xylene</td>
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<td>Acetone</td>
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<td>Ethyl acetate</td>
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<td>Ethyl benzene</td>
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<td>Butanol</td>
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<td>Methanol</td>
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<tr>
<td>Nitrobenzene</td>
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<td>Toluene</td>
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<tr>
<td>Methyl ethyl ketone</td>
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<tr>
<td>Isobutanol</td>
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<td>Pyridine</td>
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7.2 On-site Recycle

On-site recycle can be integral to a process or a separate process. Advantages include:

- reduced waste leaving the plant;
- management control of reclaimed material purity;
- reduced cost and liability of waste transported off site;
- reduced reporting requirements;
- lower unit costs for raw materials use.

Disadvantages include:

- capital expenditure for recycle equipment;
- additional operational and maintenance costs;
- potential additional permitting requirements;
- increased operator training;
- increased risks to workers.

7.3 Off-site Recycle

Off-site recycling is well suited for small quantity generators and firms unwilling to accept the technical, economic, and managerial requirements of on-site recycling. Off-site recycling is performed at commercial recycling facilities. The recycler may charge the generator a straight fee or base fees on waste volumes. In some instances, a credit for the value of saleable wastes is given to the generator. The value of a waste depends on the type, market value, purity, quantity and frequency of generation, and distance between the generator and the recycling operation.

Generators can be held liable for future clean up cost of wastes leaving their plants. It is, therefore, important to select a recycler that is reliable. Table 7-3 list some of the factors which should be considered in selecting a commercial recycler. A list of solvent, metal, and acid waste recycling and treatment facilities is provided in Appendix D.
Table 7-3

FACTORS TO BE CONSIDERED IN SELECTING RECYCLERS

OPERATING FACTORS:

- Types of solvent wastes managed.
- Ability to reliably meet solvent purity specifications if the solvent is to be returned to the generator.
- Distance to the recycling facility and associated transportation costs.
- Available laboratory facilities and analytical procedures.
- Availability of custom recycling services.
- Vendor owned recycling units that can be operated on the generator's property.
- Expertise on in-plant waste management strategies and process controls.
- Disposal procedures for still bottoms and solvents that cannot be recycled.
- Current customers' comments on the facility.

REGULATORY AND LIABILITY FACTORS:

- Permits held by the facility.
- Availability of registered trucks to transport the solvent wastes.
- Record keeping practices.
- Insurance for recycling/treatment/disposal operations.
- State regulatory agency's compliance records on the facility.
- Facility's financial stability.
7.4 Solvent Waste Recycling

The following steps can improve solvent wastes recyclability:

- Segregate solvent wastes; specifically:
  - chlorinated from non-chlorinated solvent wastes;
  - aliphatic from aromatic solvent wastes;
  - freon from methylene chloride; and
  - water wastes from flammables.

- Minimize solids concentration in solvent wastes.

- Label all solvent wastes and record compositions and methods of generation.

7.5 Waste Exchanges

An alternative to on-site or off-site recycling is waste exchange. Waste exchanges are private or government-subsidized organizations. Waste exchanges can help to identify the supply and demand of various wastestreams. Waste exchange involves the transfer of a waste to another company for reuse as is or reuse after treatment.

The three types of waste exchange are information exchanges, material exchanges, and waste brokers. Information exchanges are clearing houses for information on waste supply and demand. Information is typically a newsletter or catalog. Material exchanges take temporary possession of a waste for transfer to a third party. Waste brokers do not take possession of the waste. Instead, they locate sellers, users, or processors of the material for a fee. Appendix D lists some of the waste exchange services available.

Because of their high recovery value, metals and solvents are the most frequently recycled materials via waste exchange. Other waste commonly recycled through waste exchanges include acids, alkalis, other inorganic chemicals, organics, and metal sludges. Of the total materials listed with waste exchanges, approximately 20 to 30 percents are exchanged [15,16,17,18].

7.6 Solvent Recycle Technologies

Common processes for solvent recovering from concentrated wastestreams include distillation, evaporation, extraction, sedimentation, decantation, centrifugation, and filtration. A brief discussion of each of these technologies is presented below.

7.6.1 Distillation

Distillation separates components of a mixture based on the differences in component volatility. In the distillation process, lighter (lower boiling point) components are concentrated into a vapor phase while heavier (higher
boiling point) components are concentrated into a liquid phase. It is the oldest and most popular form of solvent recovery. Distillation processes may operate in batch, semi-batch, or continuous modes. The type of operation selected depends on the quantity and type of waste to be distilled.

In batch distillation, the solvent bearing waste is placed in a heated evaporation chamber. Evaporated solvents are continuously drawn from the top of the chamber. At the end of the batch cycle, the bottoms are removed for disposal. Solvent recovery can be single or multistage batch distillation processes. Single stage separation processes are most common. Batch distillation is most effective for components with greatly differing vapor pressures.

Continuous or fractional distillation is typically used when large volumes of material are processed, component volatilities are similar, and a high purity distillate is required. Fractional distillation is performed in a column equipped with packing or a series of trays. Each tray of the column acts as a single equilibrium stage. The trays and packing maximize the contacting of the liquid and vapor phases in the column. Packed columns typically are chosen for smaller operations. Tray columns are used in larger scale operations due to cost considerations.

During operation, the feed stream enters the side of the column and is partially vaporized. The feed location is optimized during design. The downward flowing liquid and upward moving vapor are contacted. Lighter components are concentrated into the vapor phase and heavier components are concentrated into the liquid phase. The distillate is removed from the top of the column and condensed. Part of the condensed distillate is reintroduced at the top of the column. Heavier components are removed from the bottom of the column (still bottoms). Intermediate draw offs can be used to recover a number of solvents from a mixture.

Small packaged distillation systems are available from vendors. The majority of these systems are designed as single-stage batch processes. Typical batch capacities range from 0.8 to 1,000 gallons. Options for semi-batch processes are available. These have limited applications. Fractional distillation systems usually are custom designed processes. They are, therefore, available from a smaller number of suppliers. A listing of still manufacturers for solvent recovery is presented in reference 13.

7.6.2 Evaporation

Evaporation is used to recover solvents from sludges or distillation still bottoms. In a turbulent film evaporator, rotating blades spread a thin film of solvent bearing waste against a heated wall. Solvents are vaporized and exit the top of the unit. They are then condensed for use or additional processing. The heavier solid and sludge materials fall to the bottom of the unit and are removed.

Other evaporative processes for solvent recovery include drum dryers and vacuum rotary dryers. In drum dryers, viscous waste is continuously
introduced between two counter-rotating drums. The heated drum surfaces vaporize the volatile components of the waste. Vapors exit the top of the unit and are collected. Nonvolatile components of the waste form a dry film on the drum surfaces. These are scraped off. Recovery efficiencies range from 90 to 95 percent [14].

7.6.3 Extraction

Extraction involves the contacting of a wastestream with a liquid that acts as a solvent to the component to be recovered. The solvent is immiscible with the remaining components. Extraction processes can be single stage operations. The solvent and wastestream are placed into a holding tank and allowed to separate into phases. Solvent extractions typically are operated counter currently in multiple stages. This configuration improves removal efficiencies. Separation of the recovered solvent from the extraction solvent usually requires distillation.

Extraction is a proven method for recovering phenol, acetic acid, and salicylic acids from aqueous solutions. Extraction processes are used to recover methylene chloride from isopropyl alcohol, freon from organic waste streams containing oil and alcohol, and mixtures of chlorinated hydrocarbons from alcohol or acetone. Extraction efficiencies can reach 98 percent. The major difficulty in developing an extraction process is finding a low cost solvent that is high in extraction efficiency and easily separable from the extracted material.

7.6.4 Sedimentation

Sedimentation is used for removing suspended solids. It also is used as a preliminary step for filtration. In the sedimentation process, liquids with suspended solids are placed in a settling tank. Suspended solids are allowed to settle out under the force of gravity. The clarified liquid is then removed. Deposited solids must be periodically disposed and may require treatment.

Sedimentation processes are simple and have low capital and operating costs. Disadvantages include long settling times and low removal efficiencies for finely dispersed solids and the potential for significant air emissions of volatile organic components.

7.6.5 Filtration

Filtration processes separate suspended solids from a liquid using a porous filter medium. As the liquid-solids mixture passes through the filter, particles larger than the pore size of the filter are entrained. Gravity or pressure force the liquid through the filter. Filters require periodic cleaning or replacement due to solids deposition.

Factors affecting filtration equipment selection include throughput requirements, solution viscosity, and the particle size distribution of suspended solids. Additional environmental considerations are caused by the
need to dispose of filtered solids, spent filter media, and washwaters generated during filter clean out.

7.6.6 Decantation

Decantation uses gravity to separate immiscible liquids with dissimilar densities. As the immiscible liquids are introduced into the decantation unit the lighter liquid is raised to the surface. The two liquid phases separate and coalesce and are removed. To improve operation, it may be necessary to filter the wastestream prior to separation.

7.6.7 Centrifugation

Centrifugation separates liquids or solids from another liquid having a similar density. Two types of centrifugal separation processes are sedimentation centrifugation and filtration centrifugation. In sedimentation centrifugation, the denser solids are force to the inner wall of the unit by centrifugal force. Deposited solids typically are continuously removed by displacement or by a conveyor system inside the unit. In filtration centrifugation, the inner wall of the unit is a porous filter medium. The liquid to be separated is forced through the filter as solids are retained on the filter medium.
8. TREATMENT TECHNOLOGIES

Typical components of pharmaceutical wastewaters include organics, heavy metals, and solvents. Cyanide or cyanide compounds also may be present. Solid waste generated during pharmaceutical manufacturing and processing include solvent recovery wastes such as still bottoms, filtration wastes such as filter cakes, and rejected products. The following sections discuss some treatment alternatives for wastewaters and waste solids.

8.1 Wastewater Treatment Technologies

Wastewater treatment technologies are divided into two classes: in-plant and end-of-pipe. In-plant treatment is directed at treating specific process wastes before they are diluted with other wastewater. End-of-pipe technologies treat combined wastewaters containing a number of pollutants. Primary, biological, and tertiary treatment and solids removal are types of end-of-pipe treatment. Tertiary treatment is any treatment following biological treatment. It may be applied for the removal of specific pollutants.

8.1.1 In-Plant Cyanide Destruction

8.1.1.1 Chlorination

Chlorine gas under alkaline conditions or sodium hypochlorite is used to destroy cyanide. Cyanide is first oxidized to cyanate. Then additional chlorine is added to oxidize cyanate to carbon dioxide and bicarbonate. It is necessary to have excess chlorine to break down any cyanogen chloride that forms during the oxidation process. Approximately 8 parts chlorine to 1 part cyanide is necessary for complete oxidation to carbon dioxide and nitrogen gas [1]. Iron, nickel, and ammonia interfere with alkaline chlorination of cyanide wastes.

The advantages to this method are it is a relatively low cost, it requires uncomplicated equipment, it fits well into the facility flow scheme, it operates effectively at ambient conditions, and it is well suited for automatic operation. A disadvantage is that toxic, volatile intermediates may be formed. If chlorine is consumed, other materials in the wastestream may be oxidized. This will interfere with cyanide treatment. In addition, a potentially hazardous situation exists when storing and handling gaseous chlorine.

8.1.1.2 Ozonation

Ozonation is used to oxidize cyanide to cyanate. With the help of copper and manganese catalysts, ozone oxidizes many cyanide complexes that are not broken down by chlorine. Oxidation occurs in approximately 15 minutes. It is almost instantaneous in the presence of copper. Oxidation of cyanate to nitrogen and bicarbonate is much slower and more difficult. For this reason, ozonation is often combined with another process such as dialysis or biological oxidation. Ozonation operates effectively at ambient conditions. It is well suited for automatic operation. Because ozone is generated on site, procurement,
storage, and handling problems are eliminated. Another advantage of ozonation is that the generated oxygen is beneficial to the treated wastewater. Ozonation has toxicity problems similar to chlorination. The capital and operating costs are higher than chlorination. Other oxidizable matter in the wastestream can increase ozone demand. In most cases, cyanide is not effectively oxidized beyond the cyanate level.

8.1.1.3 Alkaline Hydrolysis

In alkaline hydrolysis the principal treatment action is the application of heat and pressure. First, a caustic solution is added to the wastewater to raise the pH to between 9.0 and 12.0. Next, the wastewater is heated to 165-185°C at pressures from 90 to 110 psi for approximately 1.5 hours. Because there are no specific chemical reactants, there are no procurement, storage, or handling problems. Alkaline hydrolysis is well suited to automatic control. For economic reasons, wastewaters having high cyanide concentrations more likely to be treated by this method.

8.1.2 In-Plant Metal Removal

8.1.2.1 Chemical Reduction

Chemical reduction is one way of removing metals from waste water. Some metals must be reduced from their high valence states before they can be precipitated. This treatment is well suited to automatic control. It may be used under ambient conditions. One disadvantage is that careful pH control is required. Also, the reducing agent may be consumed by other reducible matter in the waste water. A potentially hazardous situation exists when storing and handling sulfur dioxide which is used as a reducing agent.

8.1.2.2 Alkaline Precipitation

Alkaline precipitation can precipitate metal hydroxides. First, the wastewater pH is adjusted to slightly alkaline by lime addition. Then the solid metal hydroxides are coagulated in a clarifier and deposited as sludge. This occurs with the help of a coagulating agent. If sulfur compounds are in the wastewater, sodium hydroxide may be used instead of lime. This avoids the massive sludge volume caused by calcium sulfate precipitate. A pH of greater than 10.0 is required to effectively precipitate cadmium or nickel [1]. Before discharging the wastewater, the pH must be lowered by acid addition.

Alkaline precipitation is an established wastewater treatment technology. It is suited to automatic control and operates under ambient conditions. Another advantage is that preceding treatment steps may adjust the waste to aid the alkaline precipitation process. Therefore, costs may be substantially lower than those for other processes. One disadvantage is that some mixed wastes interfere with precipitation. Also, non-hazardous co-precipitates cause it to generate high quantities of sludge requiring disposal.

8.1.2.3 Sulfide Precipitation
Heavy metals can be removed by sulfide precipitation. A very slightly soluble metal sulfide is fed into a precipitator. The excess sulfide is retained in a sludge. The sludge acts as a reservoir of available sulfide and captures colloidal particles. This process is applicable for the treatment of all heavy metals. Sulfide sludges are less subject to leaching than hydroxide sludges. With this method, hexavalent chromium wastes do not have to be isolated and reduced to the trivalent form. Sulfide precipitation produces greater sludge volumes and requires greater expenditures for chemicals than alkaline precipitation.

8.1.3 Steam Stripping of Volatiles

Steam stripping can reduce pollutants in wastewater. In steam stripping, volatile constituents transferred to the vapor phase as steam is passed through preheated wastewater. Solvent contaminated wastewaters and condensed overhead vapors from the stripper are accumulated in a gravity separation tank. In the tank two immiscible liquid layers are formed. One layer contains the immiscible solvents. The other is an aqueous solution saturated with solvents. The solvent layer is pumped to storage. The aqueous layer is pumped through a preheater into the top or middle of the column. The solution flows by gravity through the stripper. Flash tanks, packed towers, and plate columns are used for steam stripping. Steam stripping is suitable for methylene chloride, toluene, chloroform, and benzene removal.

8.1.4 Carbon Adsorption

Carbon adsorption is the adhesion of dissolved molecules to the surface of granular activated carbon particles. Adsorption may be preceded by filtration or clarification. Carbon may be reactivated by heating to 870° - 980°C. Carbon adsorption is used primarily for the removal of dissolved organics. It may also remove some chromium, mercury and cyanide. The potential use of this method in the pharmaceutical industry is limited. Previously discussed methods are more cost effective than carbon adsorption.

8.1.5 Primary Treatment

In primary treatment, large solids are removed. Gravity separation removes settleable solids and floating materials. Solids removal, sedimentation, chemical flocculation/clarification, and dissolved air flotation are commonly used for primary treatment. Clarification, flotation, and filtration also remove solids. These three typically are used after biological treatment.

8.1.5.1 Clarification

Clarification removes suspended or colloidal solids by gravity sedimentation. Flocculants or coagulants may be added to increase settling. A clarifier is usually a large vessel with a continuous water throughput. A conventional system rapidly mixes chemicals with the entering wastewater. The wastewater is then subjected to slow agitation. The clarifier contains a provision for removing settled solids.
8.1.5.2 Filtration

Filtration is a basic solids removal technology. A gravel support material is covered with a media such as silica sand, anthracite coal, or a similar inert granular material. Wastewater passes through the filter bed and solids collect in the spaces between the filter particles. Filters are periodically cleaned by back washing. A gravity filter is the most common type of system.

8.1.5.3 Flotation

Flotation is used when suspended solids have densities less than that of water. Air-assisted flotation is used for solids slightly heavier than water. Flocculants are often used to enhance the efficiency.

8.1.6 Biological Treatment

Biological treatment relies on aerobic and/or anaerobic microorganisms for the removal of oxygen-demanding compounds. Common forms of biological treatment are aeration, trickling filters, and the rotating biological contactor.

8.1.6.1 Aeration

Aeration provides oxygen for aerobic biodegradation. An aerated lagoon is a biological treatment system consisting of a stabilization basin to which air is added. A detention time of three or more days is required for breakdown and removal of organics. The activated sludge process includes an aerated biological reactor, a clarifier which separates biomass, and pipes to return the separated biomass to the biological reactor.

8.1.6.2 Trickling Filter

A trickling filter contains a supporting medium which is coated by a thin-film biological slime. The slime coat consists of bacteria, protozoa, and fungi. The coating material feeds on the waste. The most suitable medium in a trickling filter is crushed stone or gravel of uniform size.

8.1.6.3 Rotating Biological Contactor

A rotating biological contactor is a series of corrugated plastic disks mounted on a horizontal shaft. These are placed in a tank and immersed to approximately 40% of the diameter. Wastewater is passed through the tank as the disks rotate. A biological film grows on the surface of the disks and feeds on the waste.

8.1.7 Sewer Use and Pretreatment

The diluted nature and/or low volume of certain hazardous liquid wastes has resulted in some pharmaceutical companies obtaining permission from the local sanitary district to discharge these solutions to the sewer. For instance, acidic or basic solutions are routinely discharged to the sewer after neutralization. The sanitary districts' ability to allow such discharge
derives from the pretreatment program authorization (see 22 CAC 66392).

Pretreatment provides neutralization, oil removal, treatment of toxic materials, and solids removal.

8.2 Solid Waste Treatment Technologies

Research and development into treatment technologies is needed because of the gradual phase out of hazardous wastes land disposal. There are many new and innovative treatment technologies for solid hazardous wastes. Treatment technologies fall into one of the following categories: thermal treatment; solidification; chemical treatment; biological treatment; and physical treatment such as evaporation or filtration. The chemical and physical properties of the waste are major factors in selecting the appropriate treatment process. Location, cost, and quantity of the waste also influence selection.
8.3 Chapters 5-8 References


4) Institute for Local Self-Reliance, Proven Profits from Pollution Prevention: Case Studies in Resource Conservation and Waste Reduction, Case Study 14, pp. 82-84, 1986.


9) J.L. Strachau and W. Campbell, Prog Water Tech., 8 (2/3) 1, 1976.


9. CURRENT REGULATORY ASPECTS

This chapter highlights applicable regulations regarding treatment, disposal, storage, handling, and non-accidental release of materials used in the pharmaceutical manufacturing industry. The appropriate local, state, or federal authorities have current, complete regulatory information.

9.1 Relevant Laws and Regulations

Appendix E lists codes and regulations by category relevant to the pharmaceutical industry. The categories include the following: air quality; hazardous materials; waste treatment, recycling, or disposal; wastewater discharge; land disposal; and specific requirements for pharmaceutical manufacturers. Federal and California regulations are included in the appendix. Several regulations just recently promulgated and implemented should be noted. Treatment standards for the F001 through F005 wastewaters (Pharmaceutical Industry) in the land disposal restriction regulations have been set. New reporting and notification requirements have been set in SARA Title III, Emergency Planning and Community Right-to-Know Act. The CFR citation for detailed explanations of these regulations are listed in Appendix E.

Regulations involving notification of an accidental release were not included in the appendix. These are not listed because they are not routine requirements but necessary only upon the releases of a CERCLA chemical above the reportable quantity. Also excluded is information on infectious waste.

9.2 Regulatory Agencies and Information Sources

Appendix F lists Federal and State agencies that can provide help in obtaining or clarifying requirements on the treatment, storage, handling, or disposal of wastes from the pharmaceutical manufacturing industry. Figures F-1 and F-2 provide geographical information on state agencies listed in Appendix F.

Appendix E contains a copy of Form DHS 8400 which can be used to order copies of hazardous waste control laws and regulations administered by the California Department of Health Services.

9.3 Regulatory Caveat

All text pertaining to law and regulations contained within this report are provided for general information only. That information is not reliable for use as a legal reference. The generator must contact the appropriate legal sources and regulatory authorities for up-to-date regulatory requirements, and their interpretation and implementation.

Doc 845D
10. ECONOMICS OF WASTE MINIMIZATION

General economics are discussed here. This chapter and other sections of this report also contain economics specific to waste management options. An economic analysis should include thorough comprehension of regulatory requirements.

10.1 General Considerations

Recent regulatory requirements placed on hazardous waste generators and waste disposal facilities have resulted in increases in the cost of waste management. The economic goal of waste minimization is to reduce or eliminate these costs. Cost reductions through waste minimization can be in terms of present and/or future storage, treatment, and off-site waste management costs.

The costs associated with implementing a waste minimization alternative is important in determining alternative feasibility. Changes in raw material, storage, transportation, treatment, and other waste management costs can significantly affect the economy of waste minimization projects. As these costs require less effort to estimate, they typically are taken into consideration first when evaluating a waste minimization project. Economic considerations for waste minimization also include capital investment, operating, and maintenance costs. Capital costs include equipment design, purchase, and installation. Indirect capital costs may include permitting costs, consultant and contractor fees, start-up, interest payments, and training and contingency costs. Operating and maintenance costs may include labor, spare parts, and utilities.

Source reduction is often the least expensive waste minimization. Many of the good operating practices discussed in Chapter 5 can be implemented with little capital investment.

Costs for recycling will vary depending upon the technology chosen and the location of recycle. Selecting off-site recycle will eliminate capital costs but add costs for storage, pick up, and delivery.

Costs for treatment will vary with the technology selected and whether or not the treatment is performed on-site. Factors affecting the treatment economics include the quantity of waste generated, waste composition, and current waste management costs.

Capital intensive waste minimization options are, in general, more applicable to larger firms. The cost of implementation must be compared to the resulting benefits. In addition to reducing the cost discussed above, waste minimization may result in a marketable byproduct. Conversely, process modifications could increase operation and maintenance costs. An economic analysis is a necessary part of the evaluation of a waste minimization alternative.
10.2 Estimated Costs For Waste Management

The U.S. EPA provides the following 1988 estimates for off-site industrial waste management [1]:

**Disposal of drummed hazardous waste**

<table>
<thead>
<tr>
<th>Type</th>
<th>Cost Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solids</td>
<td>$75 - $110 per drum</td>
</tr>
<tr>
<td>Liquids</td>
<td>$65 - $120 per drum</td>
</tr>
<tr>
<td>Bulk solids</td>
<td>$120 per cubic yard</td>
</tr>
<tr>
<td>Bulk liquids</td>
<td>$0.6 - $2.3 per gallon</td>
</tr>
<tr>
<td>Lab packs</td>
<td>$110 per drum</td>
</tr>
</tbody>
</table>

**Transportation**

<table>
<thead>
<tr>
<th>Mode</th>
<th>Cost Range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$65 - $85 per hour at 45 miles per hour round trip</td>
</tr>
</tbody>
</table>

**Waste analysis**

<table>
<thead>
<tr>
<th>Analysis</th>
<th>Cost Range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$200 - $300 per drum.</td>
</tr>
</tbody>
</table>

Costs do not include internal costs including taxes, fees, labor, storage, handling, and record keeping. The costs are based on large quantities of drummed wastes. Disposal costs for small quantities of drummed waste can be four times higher per drum.

Cost estimates for 1988 off-site hazardous waste management in California are [2]:

**Solids Disposal**

<table>
<thead>
<tr>
<th>Method</th>
<th>Cost Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Landfilling</td>
<td>$40 per drum or $120 per cubic yard</td>
</tr>
<tr>
<td>Treatment</td>
<td>$125 per drum or $175 per ton</td>
</tr>
</tbody>
</table>

**Liquids Disposal**

<table>
<thead>
<tr>
<th>Method</th>
<th>Cost Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stabilization and burial</td>
<td>$140 per drum</td>
</tr>
<tr>
<td>Stabilization and landfilling</td>
<td>$65 per drum</td>
</tr>
<tr>
<td>Solar evaporation</td>
<td>$140 per drum</td>
</tr>
</tbody>
</table>

**Transportation**

<table>
<thead>
<tr>
<th>Mode</th>
<th>Cost Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flat bed truck</td>
<td>$65 per hour</td>
</tr>
<tr>
<td>Vacuum truck</td>
<td>$70 per hour</td>
</tr>
<tr>
<td>Roll-Off bin</td>
<td>$67.5 per hour</td>
</tr>
</tbody>
</table>

Roll-off bin rental fee is $10 per day plus $60 per liner.

Cost estimates for disposal at a municipal waste landfill range from $13.5 per ton to $18.5 per ton, depending upon the material disposed [3].

10-2
10.3 Chapter 10 References


2) Chemical Waste Management, Inc., phone conversations and company literature.

3) Scholl Canyon Landfill, Glendale, California, phone conversations
# Glossary of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOD</td>
<td>Biochemical oxygen demand</td>
</tr>
<tr>
<td>COD</td>
<td>Chemical oxygen demand</td>
</tr>
<tr>
<td>DHS</td>
<td>Department of Health Services (California)</td>
</tr>
<tr>
<td>EPA</td>
<td>Environmental Protection Agency (U.S.)</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration (U.S.)</td>
</tr>
<tr>
<td>HSWA</td>
<td>Hazardous and Solid Waste Amendments</td>
</tr>
<tr>
<td>PMA</td>
<td>Pharmaceutical Manufacturers Association</td>
</tr>
<tr>
<td>SIC</td>
<td>Standard Industrial Classification</td>
</tr>
<tr>
<td>TSS</td>
<td>Total Suspended Solids</td>
</tr>
</tbody>
</table>
12.0 GLOSSARY OF TERMS

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active ingredient:</td>
<td>The chemical component of a medicine which is responsible for its activity.</td>
</tr>
<tr>
<td>Agar slope:</td>
<td>An agar slope is made by solidifying a sterile nutritive medium in an included test tube using agar, a polysaccharide derived from seaweed. Agar slopes are used to incubate cells in the preparation of fermentation inoculum.</td>
</tr>
<tr>
<td>Batch process:</td>
<td>An unsteady-state process which has a single or incremental addition of raw materials and a single or incremental extraction of product.</td>
</tr>
<tr>
<td>Biochemical Oxygen Demand:</td>
<td>The quantity of oxygen required to oxidize the organic material in a sample of waste water in a specified time and at a specified temperature.</td>
</tr>
<tr>
<td>Chemical Oxygen Demand:</td>
<td>A measure of the oxygen consuming capacity of organic and inorganic material present in a waste water. It is expressed as the amount of oxygen consumed from a chemical oxidant (i.e., potassium dichromate) in a specific test.</td>
</tr>
<tr>
<td>Chemical synthesis:</td>
<td>The process by which two or more chemical constituents are combined into a single chemical substance.</td>
</tr>
<tr>
<td>Continuous process:</td>
<td>A process which has a continuous input of raw materials and output of product.</td>
</tr>
<tr>
<td>Fermentation:</td>
<td>A chemical change caused by living organisms, enzymes, or microorganisms living in unicellular plants such as yeast, fungi, or mold.</td>
</tr>
<tr>
<td>Filter cake:</td>
<td>Wet solids generated during the filtration of solids from a liquid.</td>
</tr>
<tr>
<td>Formulation:</td>
<td>The preparation of bulk quantities of drugs into dosage forms.</td>
</tr>
<tr>
<td>Inoculum:</td>
<td>The initial feed to a fermentation vessel</td>
</tr>
<tr>
<td>Mycelia:</td>
<td>The filamentous material comprising the vegetative body of a fungus.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Natural extraction:</td>
<td>The process by which pharmaceuticals are prepared from natural sources such as roots, glands, and leaves.</td>
</tr>
<tr>
<td>Parenterals:</td>
<td>Solutions prepared for injection into the body.</td>
</tr>
<tr>
<td>Product reformulation:</td>
<td>The replacement of a product material intended for intermediate or final use with a material suitable for the same use.</td>
</tr>
<tr>
<td>Recycle and recovery:</td>
<td>The reuse or reclamation of a material.</td>
</tr>
<tr>
<td>Reclaim:</td>
<td>The processing of material to regenerate it or to recover a usable product.</td>
</tr>
<tr>
<td>Reduction of volume:</td>
<td>The reduction in total amount of waste generated, treated, stored, or disposed of in terms of volume.</td>
</tr>
<tr>
<td>Reduction of toxicity:</td>
<td>The reduction of waste toxicity by alteration of toxic constituents to less-toxic or non-toxic forms or lowering the concentration of toxic constituents in the waste.</td>
</tr>
<tr>
<td>Reused:</td>
<td>A used material is reused if it is employed as an ingredient in an industrial process to make a product or if it is employed in a particular function or application as an effective substitute for a commercial product.</td>
</tr>
<tr>
<td>Semi-batch process:</td>
<td>A process which has an intermittent flow of either raw materials or product.</td>
</tr>
<tr>
<td>Source reduction:</td>
<td>Any activity designed to reduce or eliminate waste generation at the source of generation.</td>
</tr>
<tr>
<td>Stereoisomers:</td>
<td>Two or more isomers composed of the same number and type of atoms linked in identical chains but differing in spatial arrangement.</td>
</tr>
<tr>
<td>Still bottom:</td>
<td>Residue resulting from the distillation of material.</td>
</tr>
<tr>
<td>Treatment:</td>
<td>Methods used to reduce waste volume or toxicity without generating a usable material.</td>
</tr>
<tr>
<td>Waste exchange:</td>
<td>The transfer of waste from the generator to</td>
</tr>
</tbody>
</table>
Waste minimization:

The reduction, to the extent feasible, of waste, namely hazardous waste, that is generated, stored, or disposed. Waste minimization includes all source reduction and recycle activities that result in the reduction of volume or toxicity or both of waste.

Wastewater:

Water which, during manufacturing or processing, comes into contact with or results from production or the use of raw materials, intermediates, products, or waste streams.
APPENDIX A

WASTE AUDIT REPORT FOR PLANT A
A.1 PLANT DESCRIPTION

Plant A produces erythromycin base and erythromycin derivatives using batch fermentation. Erythromycin derivatives include erythromycin thiocyanate, erythromycin stearate, and erythromycin estolate. Large quantities of base product and its derivatives are manufactured in bulk for sale to the formulation industry for further processing. At the time of the waste audit, Plant A was producing erythromycin thiocyanate. Erythromycin thiocyanate is used as a growth promoter and disease preventative in animal feed or is sold for further processing.

It was noted that the plant was recently purchased by the current management, full scale production has not yet been implemented. At the time of the waste audit, Plant A was operating at approximately fifty percent of full production capacity.

A.2 RAW MATERIALS

The raw materials used by Plant A include inoculum and nutrients for fermentation; solvents for product recovery; ammonium thiocyanate and acetic acid for processing; a diatomaceous earth filteraid for fermentation broth processing; and sodium carbonate, sulfuric acid, and sodium hydroxide for pH control. Raw material storage and management procedures are designed to be in compliance with the good manufacturing practices detailed in 21 CFR 211.

Nutrient materials (e.g., sugar, flour, and fillers) are purchased in bulk shipments and arrive in bags in powder form. Upon delivery, nutrient materials are kept segregated and are stored in an on-site warehouse. The identity of all components are verified by quality control inspection prior to usage.

Solvents used at Plant A for product extraction and processing consist of acetone and amyl acetate. Acetone is used for product recovery during erythromycin base campaigns and amyl acetate is used during base derivative campaigns. During processing, spent solvents are sent to stripper and evaporation units for recovery then placed in storage tanks for reuse.

A.3 PROCESS DESCRIPTION

The following paragraphs present a generalized description of the manufacturing process in use at Plant A. Figure A-1 shows the block flow diagram for this process.

Inoculum is delivered to a 2,000 gallon seed tank. After an initial fermentation period, seed tank components are transferred to a 67,000 gallon fermentation vessel. Transfer lines are steam sterilized prior to transfer. The fermentation batch cycle runs for seven days with nutrients being added during the cycle. During the fermentation cycle, the vessel contents are aerated and mechanically stirred. Fermentation off-gas is vented to the atmosphere. Upon maturation, harvest solution containing erythromycin base is transferred to a holding tank prior to filtration.
FIGURE A-1
PLANT A PROCESS FLOW DIAGRAM

INOCULUM

SEED TANK

FERMENTOR

ROTARY VACUUM FILTER

SOLVENT EXTRACTION

CRYSTALLIZER UNIT

CENTrifuge

DRYER

NUTRIENTS

AIR

VENT TO ATMOSPHERE

FILTERED SOLIDS TO DISPOSAL

LIQUID PRECOAT TO SEWER

WATER

SOLVENT (AMYL ACETATE OR ACETONE)

SPENT SOLVENTS TO RECOVERY

SPENT BROTH TO SOLVENT RECOVERY

SPENT SOLVENT TO RECOVERY

PRODUCT TO WAREHOUSE

VENT TO ATMOSPHERE
Under current scheduling, an average of five batches are harvested each week. This rate will approximately double when full scale operations commence.

To remove erythromycin base from the fermentation broth, rotary vacuum filtration is used. Filtration units are precoated with a mixture of water and the filteraid. During filtration, the liquid precoat is discharged to the sewer. Filtered solids are scraped from the filter drum, drop onto conveyor belts, and are collected in a large disposal bin. Spent solids are removed from the plant by a waste hauler. Filter beer containing the erythromycin base is sent to the solvent extraction process.

Erythromycin base is removed from the filter beer using a multistage countercurrent liquid-liquid extraction process. Spent solvent and filter broth containing some spent solvent are sent to recovery units for recycle.

The extracted erythromycin and solvent are then sent to a crystallizing unit for product removal. Crystallized erythromycin base is separated by centrifugation; the resulting centrifuge cake is sent to a fluid bed dryer. Spent solvent is recycled. Dried product is drummed and sent to the warehouse for storage and quality control inspection. Dryer off-gas is vented to the atmosphere.

Approximately one-half of one percent of all product fails to meet the specifications set by quality control. The off-spec product is currently stored on site and reworked.

To produce erythromycin thiocyanate, erythromycin base is reacted with ammonium thiocyanate prior to crystallization. Erythromycin thiocyanate is then crystallized, centrifuged, and dried. Dried product is drummed and stored in a warehouse.

A.4 WASTESTREAMS AND WASTE MANAGEMENT

The principal wastestreams generated at Plant A include the following:

- Filtration process wastes;
- Solvents;
- Equipment cleaning washwaters; and
- Spills.

The process source, components, and waste management technique for each of these wastestreams is discussed in the following sections.

A.4.1 Filtration Process Wastes

To remove erythromycin base from the fermentation broth, harvests are filtered using rotary vacuum filters coated with a liquid precoat and a filteraid. Wastestreams from this process consist of the liquid precoat and filter cake.

Liquid precoat material is generated continuously at a rate of approximately 1100 kg/hr during harvest filtration. This material is not a hazardous waste
and is discharged to the local sewer.

During filtration, each rotary vacuum unit generates solid filter cake waste continuously at a rate of 1243 kg/hr. The filter cake, consisting of mycelia and filteraid, is mechanically scraped off the filtration drum and drops onto a conveyor belt system. The waste cake is directed into large waste bins for disposal. Shipments for disposal range from five to ten tons per load, with an average of nine tons per load. The filter cake material is a nonhazardous waste and is disposed in a municipal landfill.

Because of the volume of material produced, filter cake solids are the major wastestream generated by Plant A. Filter cake disposal is contracted out to a waste hauler at a price of $160 for the first 6 tons plus $16 per ton for each ton thereafter. Seven to 10 five-to-ten ton loads are disposed each week. The amount of filter cake waste produced is expected to increase significantly as Plant A reaches full scale production.

To reduce the amount of filter cake waste generated, Plant A is considering replacing the rotary vacuum filters currently in use with an ultrafiltration process. This option is currently under investigation.

A.4.2 Solvents

Spent solvents are generated from processing and recovery operations. From two to three thousand gallons of solvent is used in processing a single fermentation harvest. Under current management practices spent solvent solutions are transferred to storage tanks. Spent solvents are then recovered and recycled back into the production process. Solvent recovery processes generate an average of two 55 gallon drums of still bottoms per week. A discussion of solvent recovery operations and an estimate of savings is presented later in this report.

A.4.3 Equipment Cleaning Wastes

Process equipment is thoroughly cleaned between manufacturing campaigns to ensure product purity and to maintain operating efficiency. Washwaters are generated intermittently depending upon process scheduling. Periodically, a caustic solution is used to clean out fermentation vessels. Washwaters are routinely discharged to the local sewer system; the quantity of washwater generated was not determined.

A.4.4 Spills

Spills are the result of inadvertent material discharges during operations. Two types of spills were noted during the plant visits, spillage of filteraid material and filter cake waste.

Prior to filtration, the rotary vacuum filter surfaces are precoated with a powdered filteraid material. The filteraid material is purchased in bags and spills can occur as a result of the bags being handled. During the audit, it was noticed that some filteraid material was being deposited on the ground and equipment in the filtration area. The quantity of spilled filteraid was not
excessive and, therefore, was not determined.

As noted earlier, filter cake is scraped from the filtration unit surface and allowed to fall onto a conveyor belt located beneath the scraper bar. During operation, small quantities of filter cake, relative to that which is generated, fail to land on the conveyor belt and fall to the ground below. Spilled filter cake material is either shoveled up for disposal or washed into sewer sumps with water. Filter cake material accumulating in the sumps is periodically shoveled out for disposal.

A.5 WASTE MINIMIZATION AND MANAGEMENT ALTERNATIVES

This section presents waste minimization and management alternatives developed for Plant A. The alternatives presented in this section are geared toward specific wastestreams identified during the waste audit. The wastestreams selected for evaluation are the filter cake waste and spills of filter aid and filter cake materials. Waste minimization and management alternatives for each of these wastestreams are presented below along with a summary of the waste source, generation rate, and the current disposal practice and disposal cost.

A.5.1 Alternatives for Filtration Process Wastes

Filtration process wastestreams consist of the liquid precoat material and waste filter cake. The potential for waste reduction and waste minimization alternatives for each of these wastestreams is discussed below.

As discussed earlier, the liquid precoat material is not a hazardous waste and no pretreatment is required prior to sewer discharge. Because of these factors, the liquid precoat is not considered a high priority for waste minimization and alternatives are not presented for this wastestream.

The potential for waste reduction from use of filter cake as a byproduct is significant. At current production rates, the average quantity of waste generated is seven to ten loads per week, or 364 to 520 loads per year. Assuming an average load weight of 9 tons, this results in 3,276 to 4,680 tons per year of filter cake waste being disposed by landfilling. According to plant personnel, filter cake waste generation will increase significantly.

Using the waste quantities specified above, and a disposal cost of $208 per 9 ton load, the current yearly disposal cost for filter cake waste is between $75,712 and $108,160. Disposal cost is based upon a rate per load of $160 for the first 6 tons plus $16 per ton thereafter. The estimated disposal cost for filter cake during full scale production is approximately $250,000 per year. To reduce the amount of material disposed via landfiling, and the associated disposal cost, byproduct uses of the filter cake material should be investigated. As indicated above, potential cost savings under current operating conditions are in the range of $100,000 per year. At full scale operations, a cost savings in the range of $250,000 per year could be realized. These savings would be augmented by the additional revenue generated from the sale of the filter cake material. Fermentation waste filter cakes have the potential for byproduct use as fertilizers, soil...
amendments, and feed additives. Each of these potential uses is discussed in the following sections.

A.5.1.1 Use as a Fertilizer

According to the USDA, in order for a byproduct to be considered usable as a fertilizer, the nitrogen, phosphorous, and potassium (N+P+K) content must be greater than five percent\(^1\). Based on mineral analyses, the N+P+K content of the filter cake is less than two percent. Therefore, it is unlikely that the filter cake generated by Plant A is usable as a fertilizer.

A.5.1.2 Use as a Soil Additive

To evaluate the potential for use as a soil additive, soil specialists from the University of California campuses at Davis and Riverside were contacted. Both sources believed the analyses of the filter cake showed that it has the basic components of regular soil and recommended using the material as a soil additive.

The KC Mattson Company, a fertilizer manufacturer in San Marino, expressed interest in utilizing the filter cake as a soil additive. Concerns affecting the potential for use as a soil additive included the amount of odor produced by the material, the moisture content, and the price per unit. As the filter cake is moist (approximately 64 percent water) and does generate an odor, additional treatment may be required before use as a soil additive. Water content may be reduced by heating the filter cake as it is transported along conveyor belts to the disposal bins or by batch drying. A sample of the filter cake would be needed in order for the Mattson KC Company to fully evaluate this alternative.

A.5.1.3 Use as a Feed Additive

According to the Food and Drug Administration (FDA), mycelium presscakes and other byproducts from the production of antibiotics by fermentation are widely sold for use as potential protein source supplements for animal feed\(^2\). The FDA does not object to the use of mycelia and other byproducts in animal feeds provided that the antibiotic activity does not exceed two grams per ton of cake and no more than three pounds of cake is used per ton of feed.

To determine the usefulness of the filter cake as a feed additive, additional analyses should be performed. Kruse OH Grain & Milling of El Monte has expressed a strong interest in obtaining a sample of the filter cake to analyze it for Co, Se, and vitamin B contents. As was the case for use as a soil additive, moisture content and odor may need to be reduced prior to use as a feed additive.

A.5.2 Alternatives for Solvents

\(^1\) Source: Stewart Pettigrove, UC Davis - Agriculture Department.

\(^2\) Source: Food and Drug Administration Policy Guide 7126.31
Under current waste management practices, spent solvent solutions of amyl acetate and acetone are recycled. In addition, small quantities of spent solvent left in the fermentation broth after product recovery also are recycled. Solvent recovery processes include a stripping column, an evaporator, and a rectifying column. Recovery operations result in the recycle of over 99 percent of solvents processed.

The solvent requirement per harvest is two to three thousand gallons. Based on a cost of $1.78 per gallon of raw solvent, a savings of approximately $3,520 to $5,290 per harvest is achieved with a 99 percent recycle of spent solvents. These estimated savings are offset by the costs of recovery unit operation, still bottoms disposal, and makeup for non-recovered solvent.

Solvent recovery operations on average generate 2 fifty-five gallon drums per week of still bottoms. Solvent recovery wastes are disposed by off-site incineration at a cost of $250 to $300 per drum, depending on the solvent being recovered.

With current recycle processes operating in excess of 99 percent, additional solvent recovery or recycle is a low priority at this time and is not pursued as a waste minimization alternative. It is recommended, however, that solvent recovery be continued.

A.5.3 Alternatives for Equipment Cleaning Washwaters

Washwaters generated during equipment cleaning are nonhazardous and require no treatment prior to sewer discharge. Therefore, washwaters are not considered a high priority for waste minimization and alternatives are not developed for this wastestream.

A.5.4 Alternatives for Spill Reduction

As noted previously, filter cake from fermentation broth filtration is scraped from rotary vacuum filters onto conveyor belts for collection and disposal. During this operation, some of filter cake material misses the conveyor belts and falls to the ground. The amount of filter cake falling to the ground could not be determined but is believed to be small compared to the total amount of material generated. Under current practices, spilled filter cake is periodically shoveled up and placed into bins for disposal.

Because the spent filter cake may have use as a byproduct, and hence some monetary value, it would be beneficial to ensure all of the material is collected. Preventing the filter cake from falling on the ground prevents it from coming into contact with wastewaters or other materials, i.e., filteraid, which have been spilled. The intermixing of filter cake with other spilled materials could prevent the sale of filter cake as a byproduct.

---

Source: Chemical Marketing Reporter, cost is for acetone purchased in tanks.
Spillage to the ground can be prevented by installing v-shaped guides beneath the rotary vacuum filters which direct the scraped filter cake onto the center of the conveyor belt. Installation would require minimum capital investment, no operating cost, and could be accomplished between filtration batches.

An potential source of spilled material at Plant A is the filteraid material used to precoat the rotary vacuum filters. Continued emphasis on good operating practices will keep filteraid spillage to a minimum.

A.5.3 Recommendations

Based on the waste audit and the discussion of alternatives presented above, the following recommendations for waste management were prepared for Plant A:

- Provide the KC Mattson Company and Kruse OH Grain and Milling with filter cake samples and any other data required to establish the usefulness of the material as a soil or feed additive, any subsequent treatments required, and the value of the material as a byproduct.

- Investigate methods for reducing water content and odor levels in filter cake wastes (i.e., drying of filter cake material).

- Install guides beneath each rotary vacuum filtration unit to prevent filter cake materials from missing the conveyor belts and falling onto the ground.

- Continue to emphasize good operating practices.

- Continue to recycle spent solvents.
DATA GATHERING FORM -- DRUG MANUFACTURING AND PROCESSING

ICF Team:

Date of Visit:

Plant Identification

Firm Name: PLANT A

Street Address:

Mailing Address:

EPA Identification

Contacts

<table>
<thead>
<tr>
<th>Name</th>
<th>Phone #</th>
<th>Position</th>
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</table>

(1) OVERVIEW OF OPERATIONS

Brief description of the activities conducted at this facility:

ERYTHROMYCIN BASE AND ERYTHROMYCIN DERIVATIVES ARE PRODUCED FROM Bacterial FERMENTATION. ERYTHROMYCIN DERIVATIVES INCLUDE THIOCYANATE, SULFATE, AND SULFONATE.

How many employees work at the plant?

APPROX. 150
What types of skills and training do plant personnel have?

ENGINEERS, LAB, ETC.

How old is the plant? How old is the process equipment?

15 TO 20 YEARS OLD

Obtain a facility layout or create a sketch:

FACILITY LAYOUT PROVIDED BY PLANT
Is there room for new equipment? Where?

There is room for new equipment on the property.

(2) RAW MATERIAL INFORMATION

Use provided sheets to record raw material data (include cleaning materials).

What are the hazardous components of the raw materials?

None.

Are material safety data sheets available?

Where and how are raw materials stored?

Raw materials (nutrients) are stored in an on-site warehouse. Materials are separated as per Good Manufacturing Practices.

What are the self-lives of the raw materials?
<table>
<thead>
<tr>
<th>Raw Material</th>
<th>Quantity Used</th>
<th>Process Source</th>
<th>Manufacturer and Product Name</th>
<th>Mode of Transport</th>
<th>Container Size</th>
<th>Cost/Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>INOCCULUM</td>
<td>VARIABLE</td>
<td>FERMI</td>
<td>-</td>
<td>MOST</td>
<td>PRODUCED ON SITE</td>
<td>-</td>
</tr>
<tr>
<td>NUTRIENTS</td>
<td>VARIABLE</td>
<td>FERMI</td>
<td>-</td>
<td>SHIPPED IN BAGS</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
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</tbody>
</table>
How are raw materials transferred to processes?

- Nutrient materials (e.g., sugar) are transferred by conveyers to blenders, then to the fermentor by auger-like feed system. Inoculum is charged to seed tanks then transferred by lines to the fermentor vessel.

(3) Products information

What products are produced at the plant?

- Erythromycin base and erythromycin derivatives (e.g., thymolvanolic, stearate, and estolate)

What is the required product purity?

- Erythromycin requirements specified in 21 CFR 311

What is the form of the final product (i.e., liquid, tablet, capsules)

- Powder form

What non-reactives are added to create drug formulations (e.g., fillers, diluents, lubricants, binders)? In what quantities?

- Not used.
What are the production rates?

Currently producing an average of five batches per week. Production rate is variable as the current operations are relatively new. Full scale operation not in effect.

How much revenue is generated from product sales?

Variable, not determined.

What percentage of final products are off-spec? What is the main cause of off-spec products?

Estimated to be 1/2% to 1/3% of product produced.

What is done with off-spec products?

Off-spec product is stored on-site. Unable to dispose of to sewer until a method of processing the material is found. Some off-spec product is used for laboratory test work.

Where and how are products stored? How are these transported off-site (include container types and transport modes)?

Products are drummed for on-site storage.

Stored in quarantine. Full scale deliveries of products have not commenced yet.
Are there plans for increased/decreased production or additional products?

Currently operating at approx 50% of full capacity (3 of 16 fermentors in use)

Are multiple products produced in the same equipment?

Products produced in campaigns using the same equipment

(4) PROCESS INFORMATION

(4a) General Information

Process descriptions: Obtain a process flow diagram or sketch one for each process line. Include emission sources. Obtain copies of design diagrams and vendor literature.

flow directions produced by plant
Are equipment lists and equipment specifications/operating manuals available for each unit operation?

**EQUIPMENT LISTS PROVIDED**

Are material and energy balances available, including design and operating data, for each unit operation?

**MATERIAL AND ENERGY BALANCES ARE ON FLOW DIAGRAMS.**

Are there any planned modifications to the current processes?

**NO PROCESS MODIFICATIONS PLANNED. INCREASED PRODUCTION PLANNED.**

What are these changes and how will they impact waste generation?

**INCREASED PRODUCTION WILL INCREASE WASTE GENERATION.**

(4b) Chemical Synthesis and Batch Fermentation

What type of process is used (e.g., chemical synthesis, solvent extraction from natural sources, fermentation)?

**BATCH FERMENTATION WITH SUBSEQUENT RECOVERY AND PROCESSING.**

What type of reactor vessels are used (i.e. fermentors, plug-flow reactors, batch reactors)?

**BATCH FERMENTORS**
How many reactors are in use? What are their sizes?

**Eight of sixteen 2,000 gallon fermentation vessels currently in use**

What products are produced in each reactor?

*Fermentors produce only erythromycin base. This may be a product, or it can be processed into a derivative.*

How are multiple product batches scheduled for each reactor?

*Not applicable*

What is the operating schedule for each reactor (e.g., hours/day)?

**Seven days for fermentation cycle with one day for clean out and prep for next batch cycle**

Is equipment manufacturer data available?

*Not obtained*

Are reactor vent gases scrubbed? What type of scrubber is used? How are the scrubber waters disposed? Do you have an air permit?

*Gases not scrubbed. AQMD permit for*
How long is the batch cycle or retention time?

**SEVEN DAYS**

Are bad batches encountered? What causes this? What happens to bad batches?

**YES. APPROXIMATELY 1/3 OF BATCHES FALL**

Do Spec's.

Is the reaction catalyzed? What is the catalyst?

**NO**

How is spent catalyst disposed?

**N/A**

How often are reactor vessels cleaned?

**AFTER EACH BATCH**

Are squeegees or some other technique used to collect product for the vessel walls prior to cleaning?

**NO**

What materials are used for cleaning?

**WATER AND SOMETIMES A CAUSTIC SOLUTION.**
Describe the cleaning process.

Vessels are rinsed out with water and sometimes a caustic solution of material build up on the walls requires it.

How are cleaning wastes disposed?

Wash waters are discharged to the sewer.

---

(4c) Filtration Equipment

Does the process include a filtration step? If yes, what is the purpose of the filtration?

Yes, fermentor broth is filtered to remove biomass erythromycin base is recovered from filter cake.

What type of filtration equipment is used? (Include vendor information if available) How many units are in operation?

Three rotary vacuum filters are used.

Is filtration continuous or batch?

Semi-batch used after each harvest, operates as a continuous process when in use.
What type of filter medium is used?

**DICALITE (a filter aid) with a liquid precipitant**

How often is filter medium changed out (# of batches)?

**FILTER MEDIA IS SCRAPPED OFF DURING OPERATION AND MUST BE PREPARED FOR EACH BATCH**

How much filter cake is produced? What is its composition?

**THE FILTER CAKE CONSISTS OF MYCELIUM AND WATER WITH SOME OTHER MATERIALS (GENERATION RATE IS FIVE TO TEN LOADS PER WEEK WITH AN AVERAGE LOAD BEING NINE TONS IN WEIGHT**

How is the filter cake disposed?

**STORED IN DISPOSAL BINS FOR A WASTE HAULER**

**LOADS REMOVED DAILY AND DISPOSED OF IN LANDFILLS**

How often is the equipment cleaned? How is it cleaned and how are wash materials disposed?

**CLEANED AFTER EACH USE, WASHWATERS ARE DISCHARGED TO THE SEWER**

(4d) Product Recovery/Formulation

How are products recovered from the reactor effluent (e.g., solvent purification, filtration, solvent extraction, etc.)?

**RECOVERED FROM FILTER BEER BY COUNTER-CURRENT LIQUID EXTRACTION.**
How often and for how long are product recovery processes operated?

**VARIABLE — DEPENDING ON PRODUCTION RATE**

How often is the product recovery equipment cleaned? How is it cleaned and how are wash materials disposed? Are squeegees used prior to cleaning?

**EXTRACTION EQUIPMENT THOROUGHLY CLEANED**

**BETWEEN CAMPAIGNS SQUEEGEES NOT USED**

Are coated tablets or capsules produced at this plant? If yes, do the coatings contain volatile organics? How are the coatings applied? How are coatings dried? Are emissions controlled during application? Are emission inventories available?

**NO**

**(4e) Solvent Usage**

List solvent applications and the solvents used:

**AMYL ACETATE AND ACETONE ARE USED.**

Are used solvents recovered and recycled? How are solvents recovered and how
(5) WASTE GENERATION DATA

Use provided sheets to record wastestream data (include hazardous and non-hazardous waste, wastewater discharges, and air emissions).

Are there any particular waste streams that are difficult to handle or dispose? Are there particular components that cause the difficulties?

The filter cake is the waste stream of concern because of the quantity of waste generated.

Are there any known fugitive releases? If yes, are estimates of emission rates available? Do you have air permits? Is air pollution control equipment in place? If yes, describe.

Process equipment is permitted by sampling.

No fugitive emissions evident.

Where and how are wastes stored? How are these transported to disposal?

Filter-pressed wastes placed in bins and removed.
<table>
<thead>
<tr>
<th>Waste Stream</th>
<th>Quantity Generated</th>
<th>Continuous or Intermittent Generation</th>
<th>Process Source</th>
<th>Wastestream Analysis Available (y/n)</th>
<th>Major Constituents and %</th>
<th>Waste Management Technique</th>
<th>Disposal Cost/Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter Cake</td>
<td>5-10 TON BULK PER WEEK, 1 TON AVG.</td>
<td>CONT.</td>
<td>FILTRATION</td>
<td>YES</td>
<td>MYCELIA, H₂O, OTHERS</td>
<td>LANDFILL</td>
<td>$120/TON</td>
</tr>
<tr>
<td>Solvent Waste</td>
<td>25 GALLONS PER WEEK</td>
<td>INT.</td>
<td>SOLVENT RECOVERY</td>
<td>NO</td>
<td>SPENT SOLVENTS</td>
<td>INCINERATION</td>
<td>$250-300 PER CENT</td>
</tr>
<tr>
<td>Liquid Precip</td>
<td>CONT.</td>
<td>FILTRATION</td>
<td>NO</td>
<td>H₂O</td>
<td>SEWER</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Spills</td>
<td>UNKNOWN INT.</td>
<td>FILTRATION</td>
<td>NO</td>
<td>FILTER CAGE</td>
<td>LANDFILL</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

Note: Wastestreams may include washwaters and disinfectants, spent fermentation medium, spent filter medium, wastewaters from solvent extraction, etc.
Daily, solvent recovery wastes are stored in 55-gallon drums in a separate storage area. An average of two drums are generated per week.

Are hazardous waste manifests and biennial hazardous waste reports available?

Are waste streams kept separated or are they combined? If yes, which streams are combined?

Wastes kept separated.

(6) SPILL CONTROL/MANAGEMENT

Is there a spill control/management plan in use at the plant?

Yes

What materials/procedures are used for spill control?

Spills are shoveled up for disposal.

How are spilled materials disposed?

Spilled filter cake wastes are shoveled up for disposal.

Are plant operators and personnel trained in spill control/management?

Yes
(7) WASTE MINIMIZATION INFORMATION

Have any waste minimization options been implemented? What were these and how well did they work (percentage reduction in waste)?

Solvents are recovered on site. Recovery is greater than 99%.

Is any documentation available and can we have copies?

Yes, flow sheets provided.

Are any waste minimization activities planned for the future? If yes, what are they and how effective are they expected to be?

None indicated.

Have any waste minimization options been considered but rejected? Identify what options were rejected and why.

To reduce filter cake waste, ultrafiltration was considered. Not implemented due to cost.

Is any documentation available for rejected options and can we have copies?

Yes.

What are the main operating constraints for each process?

Quality control as part of good manufacturing practices.
Do you recover solvents?

Yes

Have you considered recovering product from reactor washwater?

Not practical because of QC limitations

Have you considered water-based tablet coatings?

N/A

Are cooling waters recycled and used as boiler feed?

Have you considered selling fermentation wastes as a protein source for animal feed supplement?

Yes - started to pursue this option

Have you considered treating wastewaters prior to discharge?

Not required

Do you generate an ammonium chloride byproduct? Have you considered recovering this byproduct of sale (e.g., as a sludge dewatering aid)?

No

Do you generate an ammonium sulfate byproduct? Have you considered recovering this byproduct for sale (e.g., as a fertilizer)?
Do you generate a sodium sulphate byproduct? Have you considered recovery of this byproduct for sale (e.g., to the glass industry)?

No

Waste minimization techniques currently used in this facility (ICF observations):

Sewage treatment

(8) REGULATORY INFORMATION

List all permits required for plant operations:

SCAQM PERMITS FOR EQUIPMENT

PROCESS VALIDATION AND EQUIPMENT CERTIFICATION FOR FDA

Are copies of permits and permit applications available?

COPIES AT PLANT
APPENDIX B

WASTE AUDIT REPORT FOR PLANT B
B.1 PLANT DESCRIPTION

Plant B produces a wide range of dermatological and ophthalmological products. In addition, Plant B operates a research and development (R&D) section. The various pharmaceutical compounds are formulated in the production section. The objective of the R&D section is to produce new active ingredients through chemical synthesis or to modify chemical synthesis procedures. The R&D section is divided into two major groups, 1) synthetic chemistry division and, 2) product development division.

B.2 RAW MATERIALS

B.2.1 Raw Materials, Production Section

The raw materials used by Plant B in the production section consists of a large variety of active ingredients and fillers. Fillers include oils, fatty acids, surfactants, alcohols, and water to prepare the various ointments and liquid bases. Raw material storage and management procedures are designed to be in compliance with good manufacturing practices as detailed in 21 CFR 211.

B.2.2 Raw materials, R&D Section

The R&D section uses a large number of chemicals in small quantities. The materials in use at a given time will vary depending upon the focus of the R&D program. Chlorinated and non-chlorinated solvents are commonly used for extraction and analysis. Chlorinated compounds include chloroform and methylene chloride. Major non-chlorinated solvents include methanol, acetonitrile, acetone, ethyl ether, xylene and hexane. Acetonitrile and methanol are extensively used as carrier liquid in HPLC analysis. Annual consumption is 400 gal for acetonitrile and 991 gal for methanol. Sulfuric acid is the most widely used acid with an annual consumption of 450 gal. In addition, a large quantity of sulfuric acid is used during glassware washing. The annual acid consumption for glassware washing is approximately 1,080 gal.

B.3 PROCESS DESCRIPTION

B.3.1 Process Description, Production Section

The following categories of products are formulated at the ophthalmological section:

- Contact lens cleaners;
- Saline solutions;
- Ophthalmic ointments;
- Eye drops; and
- Disinfecting solutions.
The following categories of products are formulated at the dermatological section:

- Shampoos including dandruff shampoos;
- Creams;
- Sun tan lotions;
- Acne medication; and
- Itch soothing preparations.

Ophthalmological and dermatological compounds are produced in batches. The raw materials are mixed in 1,000 gal vessels according to detailed compounding directives. To avoid spillage, raw materials are carefully poured into the vessels. Steam and cooling water are used in the vessel's jacket for heating and cooling purposes. The finished compound is sampled and analyzed by the QA/QC laboratory. At the Dermatological section, the supervisor reported that no batches were rejected in the last 15 months as a result of tight QA/QC during the formulation stage.

After satisfactory analysis, the formulated compounds are released and packaged into a finished product. Periodically, finished products are sampled by QA/QC personnel. A minimal amount of rejects are generated during packaging operations. In the dermatological section, less than 0.3% of finished products are rejected. This corresponds to approximately 12,000 units per year.

B.3.2 Process Description, R&D Section

The R&D section includes the Synthetic Chemistry division and the Product Development division. In the Synthetic Chemistry division, new active ingredients and processes are developed by performing laboratory scale experiments.

The Product Development division performs scale up operations for new products developed by the Synthetic Chemistry division and tests their stability. A wide range of different processes are used including mixing and extraction. Compared to the Synthetic Chemistry division, Product Development activities are more homogenous, with single processes being tested for several months until the desired performance is achieved.

In both R&D divisions, synthesized products are analyzed using High Pressure Liquid Chromatography (HPLC). The HPLC uses mixtures of solvent and water as carriers for these analyses.

B.4 WASTESTREAMS AND WASTE MANAGEMENT

B.4.1 Wastestreams and Waste Management, Production Section

The principal wastestreams generated by the production section include the
The following sections describe the source of generation and the waste management technique for each of these wastestreams.

B.4.1.1 Equipment and floor cleaning washwater

After usage, process equipment (i.e. vessels and filling apparatus) is thoroughly cleaned with water. Washwaters are generated intermittently and are disposed to the local sewer system. This washwater will typically include residues from the formulated batch. Depending on the manufactured products, the wastewater will have low to medium BOD, COD, TSS, and TDS concentrations. Floor cleaning washwater typically includes traces of the manufactured products. This wastewater is discharged according to an industrial sewer discharge permit. The quantity of washwater generated was not determined.

B.4.1.2 Rejected finished products

Only a small percentage of the finished products are defective and thus rejected. At the dermatological section, rejected items constitute 0.3% of the total number of finished products. This equates to approximately 12,000 items per year. Currently, 25% of these items are disposed by washing the finished product from the packaging into the sewer, with the used packaging sent to a municipal landfill. The disposal operation is performed manually. On the average, 50 finished product rejects are processed hourly.

The remaining 75% of rejected finished products are disposed to a class 1 landfill. These items are not accepted by a municipal landfill due to the liquid nature of the material (i.e. the material failed the compression test) or high alcohol content or, for one product, high selenium concentration.

B.4.2 Wastestreams and Waste Management, R&D Section

The principal wastestreams generated by the R&D section are:

- Solvent wastes;
- Sulfuric acid waste; and
- Expired chemicals.

Description of the waste source, characteristics, and current waste management techniques for these wastestreams are described below.

B.4.2.1 Solvent wastes

Two different procedures are implemented for collecting solvent waste in the R&D section. In one alternative, each chemist accumulates the generated waste
into a 5 gallon container which is referred to as a safety can. In this method, different types of solvents are gathered into a single container. The second alternative consists of segregating waste solvents by type (i.e. halogenated, non-halogenated and methylene chloride), with each type having dedicated safety cans. All cans are labelled to show waste types and concentrations. The safety cans are then taken to the hazardous waste storage area. For disposal, the cans are emptied into appropriate containers by a contractor for shipment off site.

Several off-site disposal methods are used for solvent wastes including:

- recycling;
- use as fuel supplement at a cement kiln; and
- incineration at hazardous waste incinerator.

Currently, only methylene chloride wastes with a minimum purity of 75% are recycled. The majority of solvent wastes generated consist of non-halogenated solvents. These wastes are sent to cement kilns for use as fuel supplement. The remaining waste is sent to a hazardous waste incinerator. This category includes halogenated solvents and solvent mixtures containing heavy metal residues.

During the audit, it was noted that solvent wastes also were collected in four-liter glass bottles. Solvent wastes are transferred from the four-liter collection bottles into containers for off-site disposal by the waste disposal contractor. The glass bottles are broken and subsequently disposed at a hazardous waste landfill.

B.4.2.2 Sulfuric acid waste

Sulfuric acid is used to remove glassware labels made with indelible markers. In order to remove the markings, the glassware is loaded onto a steel basket and is dipped into a sulfuric acid bath for 5 to 10 minutes. The basket is then removed and rinsed with water prior to placing the glassware into a commercial dishwasher. The sulfuric acid bath is reused several times prior to replacement.

The spent sulfuric acid is currently sent to an off-site facility for treatment and disposal. In the very near future, Plant B plans to send the spent sulfuric acid to a battery manufacturer for reuse as production material.

B.4.2.3 Expired chemicals

Expired compounds are discarded periodically. These materials are transferred to the storage area. The waste disposal contractor consolidates them into lab-packs prior to disposal into a hazardous waste landfill.

B.5 WASTE MINIMIZATION AND MANAGEMENT ALTERNATIVES
This section presents waste minimization and management alternatives developed for Plant B. The alternatives presented in this section are geared toward general procedures and toward specific wastestreams identified during the waste audit. Alternatives are presented for both the production and R&D sections of Plant B.

B.5.1 Alternatives for Production Section Wastes

As discussed earlier, equipment and floor cleaning washwaters generated by the production section are disposed to the sewer. This type of waste management is acceptable and no alternatives are presented for this wastestream.

Currently, 25% of rejected finished products are disposed by washing out the product material from the packaging and disposing the used packaging into a municipal landfill. The remaining 75% of product rejects are disposed to a class 1 landfill. This disposal practice is due to the liquid nature of the material (failed the compression test), the high alcohol content of some compounds, or, in one case, the higher selenium concentration. The current disposal cost for materials sent to a class 1 landfill is $200/drum (55-gallon).

As an alternative to landfilling, the material disposed to a class 1 facility also can be disposed to the sewer. As is the case for 25% of product rejects. Alcohol (i.e. ethanol) is a biodegradable compound and is accepted by the local sewer. Discharges will be prohibited only if the effluent alcohol concentration exceeds the flammability limit. It is noted that this type of material already is disposed to the sewer as a result of vessels cleaning. Regarding the dandruff shampoo containing selenium as one of its constituents, it also can be disposed to the sewer. The sewer disposal permit would have to be updated to reflect this change. Again, it is noted that this material already is disposed to the sewer as a result of production vessel cleaning. All of the used packaging can then be disposed into a municipal landfill at a unit cost of $50/ton. All of the costs quoted above do not include transportation fees.

Currently, washing out materials from the packaging is performed manually at an average rate of 50 items/hour. This process could be automated using a mechanical shredder with a screen. A cost analysis to assess the feasibility of installing such a system is recommended.

B.5.2 Waste Minimization and Waste Management Alternatives for the R&D Section

B.5.2.1 General procedures

Currently, two different methods for solvent waste collection are implemented at the R&D section as described in section B.4.2.1. In order to have an effective waste management program, it is imperative to have a formalized and unique waste collection system, applicable for all concerned employees. To facilitate solvent recovery, waste segregation should be encouraged as much as possible. Solvent collection in non-reusable containers such as the glass 4 liter bottles should be discouraged. Disposing of glass containers is an added cost that can easily be eliminated. A single waste collection system
and all relevant waste management details should be formalized in a Standard Operating Procedure (SOP) for the R&D waste.

To minimize waste generated by expired chemicals, material purchasing and inventory should be controlled very closely. Under current practices, R&D personnel purchase their own chemicals through Plant B's purchasing department. As the purchasing department is not unique to the R&D section, orders are not checked for duplication. This can result in an overstocking of chemicals. To improve the purchasing and inventory tracking procedures of the R&D section, Plant B should consider the following alternatives:

- Installation of a computerized inventory system;
- Implementation of a centralized purchasing department; and
- Creation of a chemical stock room.

The installation of a computerized inventory system will provide R&D personnel with an up to date listing of currently available chemicals. This will allow personnel to locate needed chemicals on-site rather than purchasing new stocks. Establishing a centralized purchasing department for the R&D section will reduce overstocking through duplication of orders. Furthermore, by grouping orders, chemicals will be purchased in the most efficient volumes for R&D needs. Creation of a chemical stock room, preferably with a computerized inventory system, would serve as a centralized purchase location. All orders for new stocks would be handled by the stock room. Individuals would be required to check out chemicals from the stock room. By this procedure, the location of chemicals and usage requirements could be closely monitored. Commonly used chemicals would be routinely kept in stock while specialty chemicals could be ordered as needed.

B.5.2.2 Alternatives for solvent waste management

More than 19 types of solvents are used at the R&D section. Several of them are used in quantities large enough to consider recycling. Currently, only methylene chloride waste, with a minimum of 75% concentration is recycled. Recycling is performed by an off-site facility at a cost of $120/drum. By recycling as opposed to incineration, however, Plant B saves on disposal costs by not having to pay the associated tax. Incineration costs at a hazardous waste incinerator and at a cement kiln are $320/drum (excluding packing and transportation costs) and $200-270/drum (including packing and transportation costs), respectively.

On-site recycling can be performed using a reflux apparatus. Implementation of this process will require laboratory space to set up the equipment and minimum supervision. The recovered product should be analyzed to verify its purity. On-site recycling will generate savings in new material purchases and will reduce disposal costs. Only distillation bottoms will require disposal.

B.5.2.3 Alternatives for spent sulfuric acid

The spent sulfuric acid generated from washing procedure, is currently sent
off-site for treatment and disposal at a cost of $380/drum excluding transportation fees. The proposed waste management alternative to provide the spent acid to a battery manufacturer will eliminate the cost of off-site treatment and disposal. This reuse will generate savings by eliminating the tax paid for hazardous waste disposal.

As the purpose sulfuric acid is to remove ink markings from glass, it is recommended that labels be used to mark containers instead of indelible markers. By using labels, the need for sulfuric acid will be eliminated at the source. This will translate into savings in sulfuric acid purchase and disposal costs. The estimated cost of sulfuric acid purchasing is $7,668/year and the estimated cost of disposal is $7,600/year. The resulting annual savings from replacing markers with labels will be approximately $15,268.

B.6 RECOMMENDATIONS

Based on the waste audit and the discussion of alternatives presented above, the following recommendations are given:

- Evaluate the composition of each finished product to determine compatibility with sewer disposal and make appropriate changes in the industrial sewer discharge permit.
- Prepare a comparative cost analysis for manual disposal versus automated disposal of the finished product rejects.
- Prepare a SOP manual for R&D waste management.
- Implement on-site recycling of solvents.
- Implement the use of the spent sulfuric acid by the battery manufacturer as soon as possible.
- It is strongly recommended that replacement of direct marking on the glassware with labels be investigated as a means for reducing sulfuric acid usage.
- To reduce waste generated from expired chemicals, the purchasing and inventory tracking procedures of the R&D section should be reviewed and revised.
DATA GATHERING FORM -- DRUG MANUFACTURING AND PROCESSING

ICF Team:

Date of Visit: August 2, 19??

Facility Identification

Facility Name: PLANT B
Building Number: 
Street Address: 
Mailing Address: 
EPA Identification Number: 

Contacts

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(1) OVERVIEW OF OPERATIONS

Brief description of the activities conducted at this facility:

Operations consist of R&D, formulation, and manufacturing.

For R&D, new product ideas are tested.

For manufacturing, a major component is the dermatology section
and an ophthalmic section. Raw materials are mixed
and preparations made. Facility also retains administrative

How many employees work at the plant?

1800
What types of skills and training do plant personnel have?

Chemists

Manufacturing

How old is the plant? How old is the process equipment?

Obtain a facility layout or create a sketch:

Manufacturing:

Batch Process: Reactor size: 3600 L (1000 gal)

Steam

Cooling water

Wastewater generated during cleaning of reactor
Is there room for new equipment? Where?


(2) RAW MATERIAL INFORMATION

Use provided sheets to record raw material data (include cleaning materials).

What are the hazardous components of the raw materials?

Manufacturing:

- Alkali metal hydroxides
- Hydrogen chloride
- Acetonitrile

Are material safety data sheets available?

Where and how are raw materials stored?

What are the self-lives of the raw materials?
<table>
<thead>
<tr>
<th>Raw Material</th>
<th>Quantity Used</th>
<th>Process Source</th>
<th>Manufacturer and Product Name</th>
<th>Mode of Transport</th>
<th>Container Size</th>
<th>Cost/Unit</th>
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</table>
How are raw materials transferred to processes?

(3) PRODUCTS INFORMATION

What products are produced at the plant?


What is the required product purity?


What is the form of the final product (i.e., liquid, tablet, capsules)


What non-reactives are added to create drug formulations (e.g., fillers, diluents, lubricants, binders)? In what quantities?


What are the production rates?

How much revenue is generated from product sales?

What percentage of final products are off-spec? What is the main cause of off-spec products?

0.3% of finished product caused by defective packaging.

What is done with off-spec products?

Sent to smaillies or content washed into sewer.

Where and how are products stored? How are these transported off-site (include container types and transport modes)?
Are there plans for increased/decreased production or additional products? 

[Manufacturing Section]

Are multiple products produced in the same equipment?

Yes, batch process

(4) PROCESS INFORMATION

(4a) General Information

Process descriptions: Obtain a process flow diagram or sketch one for each process line. Include emission sources. Obtain copies of design diagrams and vendor literature.
Are equipment lists and equipment specifications/operating manuals available for each unit operation?

Are material and energy balances available, including design and operating data, for each unit operation?

Are there any planned modifications to the current processes?

N/A

What are these changes and how will they impact waste generation?

N/A

(4b) Chemical Synthesis and Batch Fermentation  N/A

What type of process is used (e.g., chemical synthesis, solvent extraction from natural sources, fermentation)?

What type of reactor vessels are used (i.e. fermentors, plug-flow reactors, batch reactors)?
How many reactors are in use? What are their sizes?

What products are produced in each reactor?

How are multiple product batches scheduled for each reactor?

What is the operating schedule for each reactor (e.g., hours/day)?

Is equipment manufacturer data available?

What is the initial volume and composition of the batch charge or fermentation medium?
Are nutrients or chemicals added during batch processing? At what rate and composition?

What are the agitation and aeration rates of the reactor?

Are reactor vent gasses scrubbed? What type of scrubber is used? How are the scrubber waters disposed? Do you have an air permit?

What is the final volume and composition of the batch or fermentation medium?

What is the product yield?

How long is the batch cycle or retention time?

Are bad batches encountered? What causes this? What happens to bad batches?

What is the feed rate and composition for continuous reactors?
Is the reaction catalyzed? What is the catalyst?

How is spent catalyst disposed?

What is the reactor temperature? How is excess heat removed?

Is the reactor operated at atmospheric pressure? If not, what is the reactor pressure?

What is the operating cost of the reactor?

How often are reactor vessels cleaned?

Are squeegees or some other technique used to collect product for the vessel walls prior to cleaning?
What materials are used for cleaning?

Describe the cleaning process.

How are cleaning wastes disposed?

(4c) Filtration Equipment

Does the process include a filtration step? If yes, what is the purpose of the filtration?

What type of filtration equipment is used? (Include vendor information if available) How many units are in operation?
Is filtration continuous or batch?

What type of filter medium is used?

How often is filter medium changed out (# of batches)?

How much filter cake is produced? What is its composition?

How is the filter cake disposed?

How often is the equipment cleaned? How is it cleaned and how are wash materials disposed?

(4d) Product Recovery/Formulation
How are products recovered from the reactor effluent (e.g., solvent purification, filtration, solvent extraction, etc.)?

How often and for how long are product recovery processes operated?

How often is the product recovery equipment cleaned? How is it cleaned and how are wash materials disposed? Are squeegees used prior to cleaning?

Are coated tablets or capsules produced at this plant? If yes, do the coatings contain volatile organics? How are the coatings applied? How are coatings dried? Are emissions controlled during application? Are emission inventories available?

(4e) Solvent Usage

List solvent applications and the solvents used:

Solvents are used in R&D: Methanol, Methylene Chloride and Acetonitrile.
Are used solvents recovered and recycled? How are solvents recovered and how efficient is the recovery process? Do you have an air permit?

No solvent recovery.

Methylene chloride waste and concentrator > 75%

We sent off-site for recycling.

How are solvent recovery wastes (i.e., distillation bottoms) disposed?

(5) WASTE GENERATION DATA

Use provided sheets to record wastestream data (include hazardous and non-hazardous waste, wastewater discharges, and air emissions).

Are there any particular waste streams that are difficult to handle or dispose? Are there particular components that cause the difficulties?

Are there any known fugitive releases? If yes, are estimates of emission rates available? Do you have air permits? Is air pollution control equipment in place? If yes, describe.
## WASTESTREAM DATA

<table>
<thead>
<tr>
<th>Waste Stream</th>
<th>Quantity Generated</th>
<th>Continuous or Intermittant Generation</th>
<th>Process Source</th>
<th>Wastestream Analysis Available (y/n)</th>
<th>Major Constituents and %</th>
<th>Waste Management Technique</th>
<th>Disposal Cost/Unit</th>
</tr>
</thead>
</table>

Note: wastestreams may include washwaters and disinfectants, spent fermentation medium, spent filter medium, wastewaters from solvent extraction, etc.
Where and how are wastes stored? How are these transported to disposal?

- Waste are stored at the Hazardous Waste Staging Area for ≤ 90 days.
- Once or twice per month, a contractor packages and removes the waste from premises.

Are hazardous waste manifests and biennial hazardous waste reports available?

Yes

Are waste streams kept separated or are they combined? If yes, which streams are combined?

- Methylene chloride
- Halogenated solvents
- Non-halogenated solvents
- Lab packs
- Non-hazardous solid waste

(6) SPILL CONTROL/MANAGEMENT

Is there a spill control/management plan in use at the plant?

What materials/procedures are used for spill control?

How are spilled materials disposed?
Are plant operators and personnel trained in spill control/management?

(7) WASTE MINIMIZATION INFORMATION

Have any waste minimization options been implemented? What were these and how well did they work (percentage reduction in waste)?

Is any documentation available and can we have copies?

Are any waste minimization activities planned for the future? If yes, what are they and how effective are they expected to be?

Have any waste minimization options been considered but rejected? Identify what options were rejected and why.

Is any documentation available for rejected options and can we have copies?
What are the main operating constraints for each process?

Do you recover solvents?

No

Have you considered recovering product from reactor washwater?

Vessels are wiped for material prior to washing. Estimate 1 or 2 lbs of product left.

Have you considered water-based tablet coatings?


Are cooling waters recycled and used as boiler feed?


Have you considered selling fermentation wastes as a protein source for animal feed supplement?

NA

Have you considered treating wastewaters prior to discharge?


Do you generate an ammonium chloride byproduct? Have you considered recovering this byproduct of sale (e.g., as a sludge dewatering aid)?
Do you generate an ammonium sulfate byproduct? Have you considered recovering this byproduct for sale (e.g., as a fertilizer)?

NO

Do you generate a sodium sulphate byproduct? Have you considered recovery of this byproduct for sale (e.g., to the glass industry)?

NO

Waste minimization techniques currently used in this facility (ICF observations).

off- site recycling of methylene chloride

(8) REGULATORY INFORMATION

List all permits required for plant operations:

Sewer discharge permit

Extremely hazardous waste disposal permit

Are copies of permits and permit applications available?
APPENDIX C

WASTE AUDIT REPORT FOR PLANT C
C.1 PLANT DESCRIPTION

Plant C produces sophisticated biochemicals, bulk pharmaceutical compounds, and immunochemicals by non-repetitive batch processing. In this audit, the production processes for a pharmaceutical raw material, an anti-convulsive drug, and a livestock antibiotic - referred to hereon as Product A, Product B and Product C, respectively - and a pH buffer, Tris-HCl, are examined. The pharmaceutical compounds products B and C are in the research and development phase and are awaiting FDA approval.

Plant C was recently purchased by the current management. Under the previous management the focus of production was for diagnostics. The company no longer produces diagnostics, and is focusing more on the production of biochemicals.

C.2 RAW MATERIALS

Raw materials used by Plant C include solvents for product processing and recovery; sulfuric and hydrochloric acid for pH control and product processing; sodium hydroxide and ammonia for pH control; and a filter aid (Celite). Solvents used include methanol, butyl acetate, chloroform, acetone, and isopropyl alcohol. Raw materials bought in bulk supply include solvents, acids, caustics, and other reagents. These are purchased in 55 gallon drums and are stored outdoors in a fenced off storage area approximately 100 ft. behind the building. Stored materials are brought to a dispensing area, as needed, where smaller containers are filled and brought inside to the production site. Many raw materials are purchased in smaller quantity, especially reagents for the sophisticated biochemicals produced in smaller quantities, and are stored where the products are made.

C.3 PROCESS DESCRIPTION

The following sections present generalized descriptions of the four processes investigated.

C.3.1 Product A

Product A is made via chemical synthesis (see figure C-1). Potassium permanganate, Product A precursor, and water are mixed in a 3000 gal reactor. Manganese dioxide precipitate is formed and is removed from the solution by a rotary drum filter coated with celite (a filter aid). The filter cake (manganese dioxide precipitate and celite) is deposited into trash bins for disposal at a municipal landfill.

The filtrate is neutralized with sulfuric acid and sent to a climbing film evaporator. Removed water is collected and discharged to the sewer. The Product A solution is then sent to a 800 gallon pfaudler where final pH adjustment is made with sulfuric acid.

The mixture is cooled and potassium sulfate crystallizes. The potassium sulfate crystals are removed from the solution by centrifugation, and are then dissolved in water and discharged to the sewer. Butyl acetate is added to the supernatant and the mixture is azeotropically dried. In a continuous process,
Figure C-1: Process Flow Diagram for Product A

- **Reactants**
  - Mixing Tank
  - Rotary Drum Filter
  - Neutralization Tank
  - Climbing Film Evaporator
  - Water

- **Manganese Dioxide/Celite**
  - Centrifuge
  - Filter Unit
  - Crystallizer
  - Pfauider

- **Potassium Sulfate**
  - Butyl Acetate
  - Pfauider
  - Centrifuge

- **Butyl Acetate Vapor**
  - Tumble Dryer
  - Product

- **Butyl Acetate**
  - Centrifuge
the water is collected off the bottom and discharged to the sewer while the butyl acetate is taken off the top and returned to the mixture. This is continued until all of the water is removed. The mixture is then filtered to remove any remaining salt.

The filtered solution is then cooled, Product A crystallizes and is separated by centrifugation. Butyl acetate is recovered and stored for reuse. The product is sent to a tumble dryer for further drying prior to packaging. Vented butyl acetate vapor is condensed and recovered for reuse.

This year Plant C estimates it will produce six batches of Product A yielding approximately 250 kg per batch.

C.3.2 Product B

Product B is also made via chemical synthesis (see figure C-2). A mixture of valproic acid and Na-methylate (25% wt/vol in methanol) is first heated and then cooled in a 150 gallon tank. The cooled mixture is placed onto trays in a vacuum drying oven for 1 to 2 days. Methanol vapor is vented to a scrubber system. The dried product is ground, sieved, and packaged.

This year Plant C will make two batches of Product B yielding 100 to 200 kg product per batch.

C.3.3 Product C

Product C is an intracellular bacterial fermentation product (see figure C-3). The batch fermentation is done on-site. The cells are harvested and separated from the broth by centrifugation. The nutrient medium is discharged to the sewer without any treatment and the cell paste is sent off-site for lyophilization. The fermenters are cleaned with a caustic solution (NaOH). This solution is neutralized before being discharged to the sewer.

To extract the product from the cells, the lyophilized cells are mixed with a 2:1 methanol to chloroform solution. After being stirred for one day, the mixture is filtered under vacuum. The filtrate, which contains Product C, methanol, and chloroform, is passed through charcoal, if necessary, to remove any color caused by fermentation products. It is then sent to a climbing film evaporator to be concentrated. The concentrated mixture is cooled and the product crystallizes. The methanol and chloroform from the evaporator and the crystallizing unit are recycled to the filter unit for further extraction of the cells. Fresh chloroform or methanol is added to adjust the methanol-chloroform ratio. After the third extraction, the solvent coming off the crystallizing unit is put into storage drums for reuse in the next batch.

The crystals from each extraction are combined and washed with methanol. The methanol also is put into storage tanks for disposal. The crystals are dried in a vacuum shelf dryer and are packaged. The dryer off-gas is vented to the scrubber system.

Plant C will produce two batches of Product C this year yielding 10 kg per batch.
Figure C-2: Process Flow Diagram for Product B

- Reactants
- Mixing Tank
- Vacuum Shelf Dryer
- Product
- Methanol Vapor
Figure C-3: Process Flow Diagram for Product C

- Nutrient Medium
- Cell Cake (off-site lyophilization)
- Centrifuge
- Fermentor
- Inoculum
- Nutrient Medium
- Crystallization Unit
- Climbing Film Evaporator
- Filter Unit
- Mixing Tank
- Solvents
- Lyophilized Cells
- Vacuum Dryer
- Methanol Vapor

Recycled Solvent
Cell Cake
Product
C.3.4 Tris-HCl buffer

Tris-HCl (and all buffers made at Plant C) is produced via chemical synthesis (see figure C-4). Crude tris amino and hydrochloric acid are mixed in a 200 gallon tank until the reaction is complete. The mixture is then filtered to remove any trace insolubles and is sent to a crystallization unit. Cold filtered methanol is added and the product crystallizes. The crystals are washed with 2 smaller aliquots of methanol and are then vacuum dried, sieved and packaged. The methanol is collected and stored for disposal. The dryer off-gas is sent to the scrubber system.

This year, Plant C will produce three 300 kg batches of Tris-HCl.

C.4 WASTESTREAMS AND WASTE MANAGEMENT

The principal wastestreams generated at Plant C include the following:

- Spent solvents
- Acid and solvent vapors
- Acidic and caustic solutions
- Non-hazardous solid waste

The sources, components, and waste management technique for each of these wastestreams is discussed in the following sections.

C.4.1 Spent Solvents

Solvents are used for product processing and recovery. The solvents used in the processes described in this report include methanol, chloroform, and butyl acetate. Butyl acetate used in Product A processing is recovered and recycled. The methanol/chloroform solution used to extract Product C from cell cake is recycled three times and is then stored for reuse. Methanol used for crystallization of Tris-HCl buffer is not recovered or recycled.

Spent solvent is temporarily stored in 200 gallon tanks. The solvent in these tanks is eventually transferred to 1100 gallon storage tanks to await disposal. The spent solvent, sent to Systech in Lebec, CA, is burned as supplemental fuel (25% spent solvent and 75% coal/coke) in cement kilns. The recovered heat is used in cement manufacturing. The solvent is transported to Lebec in 6800 to 7000 gallon loads and must meet a BTU content requirement and not surpass a maximum of 1% chlorinated solvents. The cost of transportation is $600 per load; the cost of recycling paid to Systech is $0.35 per gallon. In 1987, 30,409 gallons were sent to Systech for a total cost (including transportation) of $13,351. If this solvent were incinerated instead of being recycled by Systech, the disposal cost, including transportation, would be approximately be $110,000, based on a disposal cost of $200 per 55 gallon drum. Thus, recycling is much more practical than incineration.
Figure C.4: Process Flow Diagram for Tris-HCl Buffer
C.4.2 Acid and Solvent Vapors

Off-gases from the plant are sent to the house vacuum system for disposal. This includes methanol vapor coming off when drying Product B, Product C and Tris-HCl buffer. Figure C-5 shows a block diagram of the house vacuum and scrubber systems. Volatile organic compounds from the vacuum shelf dryer pass through an oil seal vacuum pump to the house vacuum line. Condensible and non-condensible compounds are separated in the receiver. The non-condensible compounds are sent to the scrubber while the condensible compounds pass through the liquid ring vacuum pump to the sewer.

Vapor emissions from various places in the plant (including reactor gases and volatiles from the vacuum system described above) pass through a 4-stage scrubber system containing either a caustic solution or water. Water also is continuously passed through all 4 stages and is sent to the sewer. The volatiles that are not neutralized by the caustic solution or entrapped by the water are vented to the atmosphere.

The tumble dryer used for Product A processing utilizes a liquid ring vacuum pump separate from the system described above as a source of vacuum. A condenser cooled with chilled ethylene glycol is used to condense and recover the butyl acetate evaporating in the dryer. The butyl acetate which is not recovered is sent to the scrubber system described above.

C.4.3 Acidic and Caustic Solutions

Acidic and caustic solutions, such as the caustic solutions used to clean fermenters, are placed in an underground tank for neutralization and then are discharged to the sewer. The industrial waste discharged to the sewer also is passed through tanks containing baffles used to inhibit the flow and allow suspended solids to settle.

In 1987, approximately 33,000 gallons of 5% HCl and 6,500 gallons of 5% NaOH were generated at the plant. The spent acidic and caustic solutions are neutralized with fresh caustic and acidic solutions, respectively.

C.4.4 Non-hazardous Solid Waste

The non-hazardous solid waste generated at Plant C includes manganese dioxide/celite, potassium sulfate, and cell cake. As they are not hazardous, manganese dioxide/celite and cell cake are deposited into trash bins for disposal at a municipal landfill, and potassium sulfate is dissolved in water and discharged to the sewer. The volumes produced are 24,000 kg, 10,200 kg, and 600 kg per year of wet manganese dioxide/celite, wet potassium sulfate, and cell cake, respectively.

C.5 WASTE MINIMIZATION AND MANAGEMENT ALTERNATIVES

Plant C has taken great care to consider waste minimization and management. The processes have been designed to minimize the waste generated, and solvents have been recycled or recovered whenever possible to do so. Plant C is also
Figure C-5: Vacuum Piping and Scrubber Systems

Reactors or misc. air from plant → Four-Stage Scrubber → Water to sewer

Water Vent to atmosphere → Non-condensibles to scrubber

Vacuum Shelf Dryer → Volatiles → Oil Seal Vacuum Pump → House Vacuum Line → Receiver → Liquid Ring Vacuum Pump

Condensibles to sewer
planning to hire a staff person who would be devoted to waste minimization and management.

The following sections outline the current practices and future plans for waste minimization and management.

C.5.1 Alternatives for Spent Solvent

Plant C currently disposes of spent solvent at Systech where it is burned as supplemental fuel in cement kilns. The cost of disposing the 30,409 gallons of spent solvent generated in 1987, including transportation, was $13,351.

Wherever possible, however, the solvents are recycled and recovered, especially with chlorinated solvents because of the difficulty of disposal. During Product A processing, 1500 liters of butyl acetate are used per batch. Approximately 1350 liters of butyl acetate are recovered when recovering the Product A crystals. Based on the purchase price of $0.22/liter for fresh butyl acetate, the savings from this recovery is approximately $292 per batch of Product A made.

Plant C has considered more extensive recycling of spent solvents by distillation. However, because of contamination from other solvents, product, and water, and the relatively small volume of spent solvent generated per process, recovery of solvents for reuse would require a very sophisticated system. Plant C has determined that such a sophisticated system would not be economically feasible at this time.

Recovery and recycling spent solvents may be feasible if they are segregated by type of solvent, i.e., if spent methanol is stored separately from spent isopropanol. The distillation system required for recovering one solvent from a solution is less complex than the distillation system required for recovering many solvents from one solution. Further investigation into solvent segregation is recommended as both the purchase of fresh solvent and the disposal of spent solvent are costly.

C.5.2 Alternatives for Acid and Solvent Vapors

Acid and solvent vapors generated in the plant such as methanol and butyl acetate are sent to a house vacuum system for disposal. Non-condensibles pass through a scrubber system before being released to the atmosphere. Condensible compounds are discharged to the sewer. The solvent vapors are not recovered from this system because of the probable contamination by other solvents from the vacuum lines.

The tumble dryer used to dry Product A crystals has a separate source of vacuum from the house vacuum system. Because the only product processed in this unit is Product A, it is possible to recover the butyl acetate vapor from the dryer off-gas without the problem of contamination from other solvents. An additional 100 to 120 liters of butyl acetate vapor coming off the tumble dryer are recovered by a condenser. The 30 to 50 liters not recovered are sent to the scrubber system on the house vacuum line. Based on the purchase price of $0.22/liter for fresh butyl acetate, the savings from this recovery

C-10
is an additional $26 per batch. This increases the savings due to butyl acetate recovery to $318 per batch of Product A made.

C.5.3 Alternatives for Acidic and Caustic Solutions

In 1987, 33,000 gallons of 5% HCl and 6,500 gallons of 5% NaOH were generated. These solutions were neutralized with fresh solutions of HCl or NaOH. The cost of the fresh acid and caustic used to neutralize the spent solutions generated in 1987 is approximately $470 and $155, respectively.

Future plans include a new industrial waste treatment system in above-ground tanks. The above-ground tanks can be monitored more closely than underground tanks, thereby reducing the potential for leaks and spillage. The treatment will include batch clarification and automated pH control of the waste before discharge to the sewer. The automation of pH adjustment will decrease labor costs and increase efficiency.

C.5.4 Alternatives for Non-hazardous Solid Waste

The manganese dioxide/celite, potassium sulfate and cell cake generated are non-hazardous. The manganese dioxide/celite and cell cake are disposed in a municipal landfill; the potassium sulfate is dissolved and discharged to the sewer. As these wastes are non-hazardous, no alternative minimization or management practices are presented.
ICF Team:

Date of Visit:

Facility Identification

Building Number: PLANT C
Street Address:
Mailing Address:
EPA Identification Number: ____________________________

Contacts

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(1) OVERVIEW OF OPERATIONS

Brief description of the activities conducted at this facility:

Manufacture sophisticated biochemicals in bulk, pharmaceutical compounds, immunochemicals. Production is organic chemical synthesis and fermentation, including extraction, precipitation, crystallization, purification and fractionation.

How many employees work at the plant?

85
What types of skills and training do plant personnel have?

[Handwritten answer]

How old is the plant? How old is the process equipment?

[Handwritten answer]

Obtain a facility layout or create a sketch:
Is there room for new equipment? Where?

---

(2) RAW MATERIAL INFORMATION

Use provided sheets to record raw material data (include cleaning materials).

What are the hazardous components of the raw materials?
- Acid (HCl, HNO3)
- Base (NaOH, ammonia)
- Phenol, phenol-related chemicals, butyl acetate, acetone

Are material safety data sheets available?
- Yes

Where and how are raw materials stored?
- Stored in 55-gallon drums outside. They are brought to a dispensing site where they are dispensed into smaller containers for use inside.

What are the shelf lives of the raw materials?
- There is a two-year shelf life for raw materials. No significant issues with raw materials.
<table>
<thead>
<tr>
<th>Raw Material</th>
<th>Quantity Used</th>
<th>Process Source</th>
<th>Manufacturer and Product Name</th>
<th>Mode of Transport</th>
<th>Container Size</th>
<th>Cost/Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methanol</td>
<td>1,200 gal/yr</td>
<td>Thiostreptin probe</td>
<td>-</td>
<td>Truck</td>
<td>55 gallon drums</td>
<td>$3.41/L</td>
</tr>
<tr>
<td>HCl</td>
<td>32,000 gal/yr</td>
<td>Thiostreptin probe</td>
<td>-</td>
<td>Tanker truck</td>
<td>10,000 gallon tank</td>
<td>9.12/L</td>
</tr>
<tr>
<td>NaOH</td>
<td>250,000 gal/yr</td>
<td>Fermentation</td>
<td>-</td>
<td>Tanker truck</td>
<td>10,000 gallon tank</td>
<td>9.12/L</td>
</tr>
<tr>
<td>Butyl acetate</td>
<td>400,000 gal/yr</td>
<td>HMG C</td>
<td>-</td>
<td>Truck</td>
<td>55 gallon drums</td>
<td>9.54/L</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3.21/L</td>
</tr>
</tbody>
</table>
How are raw materials transferred to processes?

(3) PRODUCTS INFORMATION

What products are produced at the plant?

buffers (i.e., Tris-HCl)
HMG
Na-D-valine
Thiocapron → fermentation

What is the required product purity?

What is the form of the final product (i.e., liquid, tablet, capsules)?

powder or crystalline

What non-reactives are added to create drug formulations (e.g., fillers, diluents, lubricants, binders)? In what quantities?

none
What are the production rates?

The production rate per batch is 200 kg. The production rate per week is 1000 kg.

How much revenue is generated from product sales?

Some text...

What percentage of final products are off-spec? What is the main cause of off-spec products?

Can we fix off-spec products?

What is done with off-spec products?

Where and how are products stored? How are these transported off-site (include container types and transport modes)?

Some text...
Are there plans for increased/decreased production or additional products?

Are multiple products produced in the same equipment?

(4) PROCESS INFORMATION

(4a) General Information

Process descriptions: Obtain a process flow diagram or sketch one for each process line. Include emission sources. Obtain copies of design diagrams and vendor literature.
Are equipment lists and equipment specifications/operating manuals available for each unit operation?

Are material and energy balances available, including design and operating data, for each unit operation?

Are there any planned modifications to the current processes?

What are these changes and how will they impact waste generation?

(4b) Chemical Synthesis and Batch Fermentation

What type of process is used (e.g., chemical synthesis, solvent extraction from natural sources, fermentation)?

What type of reactor vessels are used (i.e. fermentors, plug-flow reactors, batch reactors)?
How many reactors are in use? What are their sizes?

300, 500, 750, 3000 gallon jacketed reactors

What products are produced in each reactor?

How are multiple product batches scheduled for each reactor? variable

What is the operating schedule for each reactor (e.g., hours/day)? variable

Is equipment manufacturer data available? no

What is the initial volume and composition of the batch charge or fermentation medium?

1000L fermentation variable wash culture
Are nutrients or chemicals added during batch processing? At what rate and composition?

_________________________________________________________

What are the agitation and aeration rates of the reactor?

_________________________________________________________

Are reactor vent gasses scrubbed? What type of scrubber is used? How are the scrubber waters disposed? Do you have an air permit?

_________________________________________________________

What is the final volume and composition of the batch or fermentation medium?

_________________________________________________________

What is the product yield?

_________________________________________________________

How long is the batch cycle or retention time?

_________________________________________________________

Are bad batches encountered? What causes this? What happens to bad batches?

_________________________________________________________

What is the feed rate and composition for continuous reactors?

not applicable
What materials are used for cleaning?

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Describe the cleaning process.

for fermentors, \( \text{NaOH} \) is added when cleaning

- Filtered with citric acid

Line is changed to cleaner

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

How are cleaning wastes disposed?

see above

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

(4c) Filtration Equipment

Does the process include a filtration step? If yes, what is the purpose of the filtration?

- Filter product from cell cake

- Filter product solution from precipitate

________________________________________________________________________
________________________________________________________________________

What type of filtration equipment is used? (Include vendor information if available) How many units are in operation?

________________________________________________________________________
Is the reaction catalyzed? What is the catalyst?

How is spent catalyst disposed?

What is the reactor temperature? How is excess heat removed?

Is the reactor operated at atmospheric pressure? If not, what is the reactor pressure?

What is the operating cost of the reactor?

How often are reactor vessels cleaned?

Are squeegees or some other technique used to collect product for the vessel walls prior to cleaning?
Is filtration continuous or batch?
- batch

What type of filter medium is used?

How often is filter medium changed out (# of batches)?

How much filter cake is produced? What is its composition?
- variable

How is the filter cake disposed?
- nonhazardous - so disposed to municipal land fill

How often is the equipment cleaned? How is it cleaned and how are wash materials disposed?

(4d) Product Recovery/Formulation
How are products recovered from the reactor effluent (e.g., solvent purification, filtration, solvent extraction, etc.)?

Filtration, solvent extraction

How often and for how long are product recovery processes operated?

How often is the product recovery equipment cleaned? How is it cleaned and how are wash materials disposed? Are squeegees used prior to cleaning?

Are coated tablets or capsules produced at this plant? If yes, do the coatings contain volatile organics? How are the coatings applied? How are coatings dried? Are emissions controlled during application? Are emission inventories available?

No coatings

(4a) Solvent Usage

List solvent applications and the solvents used:

Methanol, acetone, butyl acetate, chloroform
Are used solvents recovered and recycled? How are solvents recovered and how efficient is the recovery process? Do you have an air permit?

- Methanol and chloroform are recycled in the process.
- Butyl acetate is recovered and reused.

How are solvent recovery wastes (i.e., distillation bottoms) disposed?
- Sent to System to be burned as supplemental fuel in cement kilns.

(5) WASTE GENERATION DATA

Use provided sheets to record wastestream data (include hazardous and non-hazardous waste, wastewater discharges, and air emissions).

Are there any particular waste streams that are difficult to handle or dispose? Are there particular components that cause the difficulties?

Are there any known fugitive releases? If yes, are estimates of emission rates available? Do you have air permits? Is air pollution control equipment in place? If yes, describe.

No
<table>
<thead>
<tr>
<th>Waste Stream</th>
<th>Quantity Generated</th>
<th>Continuous or Intermittent Generation</th>
<th>Process Source</th>
<th>Wastestream Analysis Available (y/n)</th>
<th>Major Constituents and %</th>
<th>Waste Management Technique</th>
<th>Disposal Cost/Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solvents</td>
<td>9.449 gal yr</td>
<td>Intermittent</td>
<td>All processes</td>
<td>Y</td>
<td>27% methanol</td>
<td>Collected and incinerated</td>
<td>$1,347</td>
</tr>
<tr>
<td>Cell cake</td>
<td>36 kg/batch</td>
<td>Intermittent</td>
<td>Fermentation products</td>
<td>N</td>
<td>Cell lysed cells</td>
<td>Sent to municipal landfill</td>
<td></td>
</tr>
<tr>
<td>Solvent + acidic vapors</td>
<td></td>
<td>Intermittent</td>
<td>All</td>
<td>N</td>
<td>?</td>
<td>Chemical treatment</td>
<td></td>
</tr>
<tr>
<td>Wet salt</td>
<td>6000 kg/yr</td>
<td>Intermittent</td>
<td></td>
<td>Y</td>
<td>51% NaCl</td>
<td>Municipal landfill</td>
<td></td>
</tr>
<tr>
<td>Acid/base solutions</td>
<td>3300 lb/gal</td>
<td>Intermittent</td>
<td></td>
<td>Y</td>
<td>5% HCl or 5% NaOH</td>
<td>Neutralized and discharged</td>
<td></td>
</tr>
</tbody>
</table>

Note: Wastestreams may include washwaters and disinfectants, spent fermentation medium, spent filter medium, wastewaters from solvent extraction, etc.
Where and how are wastes stored? How are these transported to disposal?

- Storage: Organic wastes are stored in original tanks and shipped by tanker trucks to a nearby disposal site.

Are hazardous waste manifests and biennial hazardous waste reports available?

Yes

Are waste streams kept separated or are they combined? If yes, which streams are combined?

- All solvent streams are combined.

(6) SPILL CONTROL/MANAGEMENT

Is there a spill control/management plan in use at the plant?

Yes

What materials/procedures are used for spill control?


How are spilled materials disposed?

- Not really a problem
Are plant operators and personnel trained in spill control/management?

Yes

(7) WASTE MINIMIZATION INFORMATION

Have any waste minimization options been implemented? What were these and how well did they work (percentage reduction in waste)?

Yes - processes were designed to recover and recycle solvents (percent or amount reduced) as much as possible.

Is any documentation available and can we have copies?

Yes

Are any waste minimization activities planned for the future? If yes, what are they and how effective are they expected to be?

To hire a staff employee as environmental specialist who would manage hazardous waste minimization development and implementation.

Have any waste minimization options been considered but rejected? Identify what options were rejected and why.

More recycling and recovering of solvents rejected because not cost effective.

Is any documentation available for rejected options and can we have copies?
What are the main operating constraints for each process?


Do you recover solvents?


Have you considered recovering product from reactor washwater?


Have you considered water-based tablet coatings?


Are cooling waters recycled and used as boiler feed?


Have you considered selling fermentation wastes as a protein source for animal feed supplement?


Have you considered treating wastewaters prior to discharge?


Do you generate an ammonium chloride byproduct? Have you considered recovering this byproduct of sale (e.g., as a sludge dewatering aid)?
Do you generate an ammonium sulfate byproduct? Have you considered recovering this byproduct for sale (e.g., as a fertilizer)?

No

Do you generate a sodium sulfate byproduct? Have you considered recovery of this byproduct for sale (e.g., to the glass industry)?

No

Waste minimization techniques currently used in this facility (ICF observations).

- Recovery + recycle solvents
- Treat waste streams

(8) REGULATORY INFORMATION

List all permits required for plant operations:

APCD               SARA
Hazardous Waste Estab
Industrial Waste
Radioactive permit
Registered for 3777

Are copies of permits and permit applications available?

Yes
APPENDIX D

WASTE RECYCLERS AND WASTE EXCHANGE SERVICES
### Table D-1

**SOLVENT RECYCLERS**

<table>
<thead>
<tr>
<th>Company Name</th>
<th>Address</th>
<th>Contact</th>
<th>Service</th>
<th>EPA ID No.</th>
<th>Authorization Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAD Distribution</td>
<td>2306 E. 38th Street Vernon, CA 90058</td>
<td>Harry Pourat</td>
<td>Hauler, processor, and seller</td>
<td>CAT 080011059</td>
<td>Permit</td>
</tr>
<tr>
<td>Acto-Kleen</td>
<td>P.O. Box 278 Pico Rivera, CA 90660</td>
<td>Sheldon Eisenman</td>
<td>Hauler and seller</td>
<td>CAD 095631719</td>
<td>ISD</td>
</tr>
<tr>
<td>American Labs</td>
<td>5701 Compton Ave. 213-588-7161</td>
<td>David Valencia</td>
<td>Hauler, transfer facility, and recycler</td>
<td>CAD 981459175</td>
<td>ISD</td>
</tr>
<tr>
<td>Baron-Blakeslee, Inc.</td>
<td>3596 California Street San Diego, CA 92101</td>
<td>David L. Thompson</td>
<td>Hauler, processor, and seller</td>
<td>CAT 000618652</td>
<td>ISD</td>
</tr>
<tr>
<td>Detrex Chemical Industries, Inc.</td>
<td>3027 Fruitland Avenue Los Angeles, CA 90058</td>
<td>Darrell W. Craft</td>
<td>Hauler and processor</td>
<td>CAD 020161642</td>
<td>Permit</td>
</tr>
<tr>
<td>Bayday Chemical</td>
<td>2096-B Walsh Avenue Santa Clara, CA 95050</td>
<td>Thomas Taylor</td>
<td>Hauler and processor</td>
<td>CAT 080012263</td>
<td>ISD</td>
</tr>
<tr>
<td>Bud's Oil Service, Inc.</td>
<td>1340 West Lincoln Street Phoenix, AZ 85007</td>
<td>Chuck Peterson</td>
<td>Processor</td>
<td>AZD 049318009</td>
<td>Out-of-State</td>
</tr>
<tr>
<td>Conservation Services, Inc.</td>
<td>2525 New York Street Wichita, KS 67219</td>
<td>David or Chuck Trombold</td>
<td>Processor</td>
<td>KSD 007246846</td>
<td>Out-of-State</td>
</tr>
<tr>
<td>EKOTEC</td>
<td>27833 Avenue Hopkins Valencia Industrial Park Building 1, Unit 1 Valencia, CA 91355 805-257-9390</td>
<td>Ray Rozen; Bonnie McFarland</td>
<td>Processor and recycler</td>
<td>UTD 093119196</td>
<td>Out-of-State</td>
</tr>
<tr>
<td>Company Name</td>
<td>Address</td>
<td>Service(s)</td>
<td>EPA ID No.</td>
<td>Authorization Status</td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>----------------------------------------------</td>
<td>-------------------------------------</td>
<td>------------------</td>
<td>----------------------</td>
<td></td>
</tr>
<tr>
<td>Heat Energy Advanced Technology, Inc.</td>
<td>4460 Singleton Blvd. Dallas, TX 75212</td>
<td>Processor</td>
<td>TXC 980624035</td>
<td>Out-of-State</td>
<td></td>
</tr>
<tr>
<td>Holchem/Service Chemical</td>
<td>1341 East Maywood Santa Ana, CA 92706</td>
<td>Service</td>
<td>CAT 00061333</td>
<td>ISD</td>
<td></td>
</tr>
<tr>
<td>Oil and Solvent Process Company</td>
<td>1704 West First Street Azusa, CA 91702</td>
<td>Hauler, processor, and seller</td>
<td>CAD 008302903</td>
<td>Permit</td>
<td></td>
</tr>
<tr>
<td>Omega Recovery Services</td>
<td>12504 East Whittier Blvd. Whittier, CA 90602</td>
<td>Hauler, processor, and seller</td>
<td>CAD 042245001</td>
<td>ISD</td>
<td></td>
</tr>
<tr>
<td>Orange County Chemical Company</td>
<td>1230 East Saint Gertrude Place Santa Ana, CA 92707</td>
<td>Service</td>
<td>CAD 029363876</td>
<td>ISD</td>
<td></td>
</tr>
<tr>
<td>Petroleum Recycling Corporation</td>
<td>1835 E. 29th Street Signal Hill, CA 90806</td>
<td>Processor</td>
<td>CAT 080011059</td>
<td>ISD</td>
<td></td>
</tr>
<tr>
<td>Rho-Chem Corporation</td>
<td>425 Isis Avenue Inglewood, CA 90301</td>
<td>Hauler, processor, and recycler</td>
<td>CAD 009364432</td>
<td>Permit</td>
<td></td>
</tr>
<tr>
<td>Romic Chemical Corporation</td>
<td>2081 Bay Road East Palo Alto, CA 94303</td>
<td>Hauler and processor</td>
<td>CAD 099452657</td>
<td>Permit</td>
<td></td>
</tr>
<tr>
<td>Safety-Kleen Corp.</td>
<td>8125 Sunset Ave., Suite 259 Fair Oaks, CA 95628</td>
<td>Hauler, storage-transfer, and processor</td>
<td>CAD 093459485</td>
<td>Permit</td>
<td></td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Contact</th>
<th>Service</th>
<th>EPA ID No.</th>
<th>Authorization Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solvent Services</td>
<td>1021 Berryessa Road</td>
<td>Tom Dinette</td>
<td>Hauler and processor</td>
<td>CAD 059494310</td>
<td>Permit</td>
</tr>
<tr>
<td>South West Industrial Recyclers</td>
<td>P.O. Box 5004, Chandler, AZ</td>
<td>Benjamin Fisler</td>
<td>Hauler and processor</td>
<td>AZD 009015389</td>
<td>Out-of-State</td>
</tr>
<tr>
<td>U.S. Pollution Control, Inc.</td>
<td>2000 Classen Center Bldg.</td>
<td>Staff</td>
<td>Recycler</td>
<td>UTD 991301748</td>
<td>Out-of-State</td>
</tr>
<tr>
<td>Van Waters and Rogers, Inc.</td>
<td>5353 Jillson Street</td>
<td>Phil Loncar</td>
<td>Hauler and seller</td>
<td>CAD 020745246</td>
<td>Permit</td>
</tr>
<tr>
<td>Van Waters and Rogers, Inc.</td>
<td>2256 Junction Avenue</td>
<td>Ron Haydel</td>
<td>Hauler and seller</td>
<td>CAD 010925576</td>
<td>Permit</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>METAL RECYCLERS</th>
<th>ChemWest Industries, Inc.</th>
<th>13425 San Bernardino</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fontana, CA 92335</td>
<td>415-421-8745</td>
</tr>
<tr>
<td></td>
<td>Contact: Mack Atkinson</td>
<td>Service: Processor</td>
</tr>
<tr>
<td></td>
<td>EPA ID No.: CAD 040520975</td>
<td>Authorization Status: ISD</td>
</tr>
<tr>
<td>Imperial West Chemical Co.</td>
<td>P/O Box 696</td>
<td>Antioch, CA 94509</td>
</tr>
<tr>
<td></td>
<td>415-757-8230</td>
<td>Contact: Frank Belliss</td>
</tr>
<tr>
<td></td>
<td>Service: Processor, and recycler</td>
<td>EPA ID No.: CAD 0006265572</td>
</tr>
<tr>
<td></td>
<td>Authorization Status: ISD</td>
<td></td>
</tr>
<tr>
<td>Inspiration Consolidated Copper Co.</td>
<td>P/O Box 4444</td>
<td>Claypool, AZ 85532</td>
</tr>
<tr>
<td></td>
<td>602-473-7080 or 7135</td>
<td>Contact: Larry LeCompte or Janet Daniels</td>
</tr>
<tr>
<td></td>
<td>Service: Recycler, processor, and reuser</td>
<td>EPA ID No.: AZD 060624251</td>
</tr>
<tr>
<td></td>
<td>Authorization Status: Out-of-State</td>
<td></td>
</tr>
<tr>
<td>U.S. Pollution Control, Inc.</td>
<td>2000 Classen Center Bldg.</td>
<td>Suite 400, South</td>
</tr>
<tr>
<td></td>
<td>Oklahoma City, OK 73106</td>
<td>405-528-8371</td>
</tr>
<tr>
<td></td>
<td>Contact: Staff</td>
<td>Service: Recycler</td>
</tr>
<tr>
<td></td>
<td>EPA ID No.: UTD 991301748</td>
<td>Authorization Status: Out-of-State</td>
</tr>
<tr>
<td>World Resources Company</td>
<td>8113 West Sherman Street</td>
<td>Phoenix, AZ 85043</td>
</tr>
<tr>
<td></td>
<td>602-233-9166</td>
<td>Contact: Allan Charbonneau</td>
</tr>
<tr>
<td></td>
<td>Service: Recycler</td>
<td>EPA ID No.: AZD 980735500</td>
</tr>
<tr>
<td></td>
<td>Authorization Status: Out-of-State</td>
<td></td>
</tr>
<tr>
<td>Anoics Corporation</td>
<td>1326 W. Gaylord Street</td>
<td>Long Beach, CA 90813</td>
</tr>
<tr>
<td></td>
<td>213-436-0268</td>
<td>Contact: Bob Orlosky</td>
</tr>
<tr>
<td></td>
<td>Service: Processor, and refiner</td>
<td>EPA ID No.: CAD 981678998</td>
</tr>
<tr>
<td></td>
<td>Authorization Status: Out-of-State</td>
<td></td>
</tr>
<tr>
<td>Environmental Pacific Corporation</td>
<td>5285 SW Meadows Road, Suite 120</td>
<td>Lake Oswego, OR 97035</td>
</tr>
<tr>
<td></td>
<td>916-989-5130</td>
<td>503-226-7331</td>
</tr>
<tr>
<td></td>
<td>Contact: Richard Hill</td>
<td>Service: Processor and recycler</td>
</tr>
<tr>
<td></td>
<td>EPA ID No.: ORD 980777334</td>
<td>Authorization Status: Out-of-State</td>
</tr>
<tr>
<td>GNB, Inc. -- Metals Division</td>
<td>2700 South Indiana Street</td>
<td>Los Angeles, CA 90023</td>
</tr>
<tr>
<td></td>
<td>213-262-1101</td>
<td>Contact: Ken Clark</td>
</tr>
<tr>
<td></td>
<td>Service: Processor</td>
<td>EPA ID No.: CAD 097854541</td>
</tr>
<tr>
<td></td>
<td>Authorization Status: ISD</td>
<td></td>
</tr>
<tr>
<td>Kinsbursky Bros. Supply, Inc.</td>
<td>1314 N. Lemon Street</td>
<td>Anaheim, CA 92801</td>
</tr>
<tr>
<td></td>
<td>714-738-8516</td>
<td>Contact: Company representative</td>
</tr>
<tr>
<td></td>
<td>Service: Recycler</td>
<td>EPA ID No.: CAD 088504881</td>
</tr>
<tr>
<td></td>
<td>Authorization Status: ISD</td>
<td></td>
</tr>
<tr>
<td>RSR Quemetco, Inc.</td>
<td>720 South 7th Ave.</td>
<td>City of Industry, CA 91746</td>
</tr>
<tr>
<td></td>
<td>800-527-9452</td>
<td>Contact: Carl Fisher</td>
</tr>
<tr>
<td></td>
<td>Service: Processor</td>
<td>EPA ID No.: CAD 066233966</td>
</tr>
<tr>
<td></td>
<td>Authorization Status: ISD</td>
<td></td>
</tr>
<tr>
<td>Company Name</td>
<td>Address</td>
<td>City, State, Zip</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>----------------------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>Bethlehem Apparatus Company</td>
<td>Front and Depot Streets</td>
<td>Hellertown, PA 18055</td>
</tr>
<tr>
<td>D.F. Goldsmith Chemical and Metal</td>
<td>909 Pitner Ave.</td>
<td>Evanston, IL 60202</td>
</tr>
<tr>
<td>Quicksilver Products, Inc.</td>
<td>200 Valley Drive, Suite 1</td>
<td>Brisbane, CA 94005</td>
</tr>
<tr>
<td>American Chemical &amp; Refining</td>
<td>12121 E. Barringer Street</td>
<td>South El Monte, CA 91733</td>
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<tr>
<td>American-Diversified Silver, Inc.</td>
<td>1431 N. Daly Street</td>
<td>Anaheim, CA 92806</td>
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<tr>
<td>David H. Fell and Company, Inc.</td>
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<td>Berkeley, CA 94710</td>
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<tr>
<td>Englehard Industries West, Inc.</td>
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<td>Anaheim, CA 92807</td>
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<tr>
<td>J&amp;B Enterprises</td>
<td>342 Laurelwood Road</td>
<td>Santa Clara, CA 95050</td>
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<tr>
<td>Micrometallics Corporation</td>
<td>1695 Monterey Highway</td>
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<tr>
<td>Mikey Corporation</td>
<td>206 Donahue Street</td>
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<tr>
<td>Pease and Curren Reliable Recovery</td>
<td>1315 Brashear Street</td>
<td>Anaheim, CA 92807</td>
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Table D-2

METAL RECYCLERS (CONT)

PGP Industries, Inc.
13429 Alondra Blvd.
Santa Fe Springs, CA 90670
213-926-9489
Contact: Dan Hernandez
Service: Processor
EPA ID No.: CAD 060398229
Authorization Status: ISD

Rafidain Refiner, Inc.
3060 Roswell Street
Los Angeles, CA 90065
213-256-4522
Contact: Krikor Mahrouk
Service: Processor and recycler
EPA ID No.: CAD 981382831
Authorization Status: ISD

TSM Recovery & Recycling Co., Inc.
3422 W. Pico Blvd.
Los Angeles, CA 90019
213-735-9443
Contact: Steven or Mike Mitsunaga
Service: Hauler and processor
EPA ID No.: CAD 108040858
Authorization Status: ISD

### Table D-3

**ACID RECYCLERS**

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<td>Mack Atkinson</td>
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<tr>
<td></td>
<td>Cloverdale, CA 95425</td>
<td></td>
<td></td>
<td>415-421-8745</td>
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<tr>
<td>General Chemical Co.</td>
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<td>William Readdy</td>
<td>Processor</td>
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<tr>
<td></td>
<td>Richmond, CA 94801</td>
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<td></td>
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<tr>
<td>Imperial West Chemical Co.</td>
<td>P/O/ Box 696</td>
<td>Frank Belliss</td>
<td>Processor, recycler</td>
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<tr>
<td></td>
<td>Antioch, CA 94509</td>
<td></td>
<td></td>
<td>415-757-8230</td>
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<td>ETICAM</td>
<td>One East First Street, Suite 904</td>
<td>Dick Kistner</td>
<td>Processor</td>
<td>NVD 980895338</td>
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<tr>
<td>Stauffer Chemical Company</td>
<td>636 California Street</td>
<td>Tim Guigino</td>
<td>Processor</td>
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<tr>
<td></td>
<td>San Francisco, CA 94108</td>
<td>Robert Dixon</td>
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<tr>
<td>Arizona</td>
<td>Dr. Nicholas Hild</td>
<td>Western Waste Exchange</td>
<td>ASU Center for Environmental Studies</td>
<td>(602) 965-1858</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Krause Hall</td>
<td></td>
</tr>
<tr>
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<td></td>
</tr>
<tr>
<td>California</td>
<td>Robert McCormick</td>
<td>California Waste Exchange</td>
<td>Department of Health Services</td>
<td>(916) 324-1807</td>
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<tr>
<td></td>
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<td></td>
<td>Toxic Substances Control Division</td>
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<tr>
<td>Florida</td>
<td>Walker Banning</td>
<td>Southern Waste Information Exchange</td>
<td>Florida State University</td>
<td>(914) 644-5516</td>
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<tr>
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<td></td>
<td>Institute of Science and Public Affairs</td>
<td></td>
</tr>
<tr>
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</tr>
<tr>
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<td></td>
<td>Tallahassee, Florida 32313</td>
<td></td>
</tr>
<tr>
<td>Illinois</td>
<td>Diane Shockey</td>
<td>Industrial Material Exchange Services</td>
<td>P.O. Box 19276</td>
<td>(217) 782-0450</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2200 Churchill Road, No. 24</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Springfield, Illinois 62794-9276</td>
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</tr>
<tr>
<td>Indiana</td>
<td>Shelley Whitcomb</td>
<td>Indiana Waste Exchange</td>
<td>Environmental Quality Control</td>
<td>(317) 634-2142</td>
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<tr>
<td></td>
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<td></td>
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<tr>
<td></td>
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<td></td>
<td>Indianapolis, Indiana 46206</td>
<td></td>
</tr>
<tr>
<td>Michigan</td>
<td>William Stough</td>
<td>Great Lakes Regional Waste Exchange</td>
<td>P/O Box 8330</td>
<td>(403) 450-5461</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Postal Station F</td>
<td></td>
</tr>
<tr>
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</tr>
<tr>
<td>Montana</td>
<td>Don Ingels</td>
<td>Montana Industrial Waste Exchange</td>
<td>Montana Chamber of Commerce</td>
<td>(406) 442-2405</td>
</tr>
<tr>
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<td>P.O. Box 1730</td>
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<tr>
<td>New Jersey</td>
<td>William E. Payne</td>
<td>Industrial Waste Information Exchange</td>
<td>New Jersey Chamber of Commerce</td>
<td>(201) 623-7070</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5 Commerce Street</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Newark, New Jersey 07102</td>
<td></td>
</tr>
<tr>
<td>New York</td>
<td>Lewis M. Cutler</td>
<td>Northeast Industrial Waste Exchange</td>
<td>90 Presidential Plaza, Suite 122</td>
<td>(315) 422-6572</td>
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<td></td>
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<td>Syracuse, New York 13202</td>
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<tr>
<td>North Carolina</td>
<td>Mary McDaniel</td>
<td>Southeast Waste Exchange</td>
<td>Urban Institute-UNCC</td>
<td>(704) 547-2307</td>
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<td></td>
<td>Charlotte, North Carolina 28223</td>
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<tr>
<td>Tennessee</td>
<td>Janet Goodman</td>
<td>Tennessee Waste Exchange</td>
<td>Tennessee Association of Business</td>
<td>(615) 256-5141</td>
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<tr>
<td></td>
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<td>226 Capitol Boulevard, Suite 800</td>
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<td>Alberta Canada</td>
<td>Karen Beliveau</td>
<td>Alberta Waste Materials Exchange</td>
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<td>Manitoba Canada</td>
<td>James Ferguson</td>
<td>Manitoba Waste Exchange</td>
<td>c/o Biomass Energy Institute</td>
<td>(204) 257-3891</td>
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<td>1329 Niakwa Road East</td>
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<td>Canada R2J 3T4</td>
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APPENDIX E

STATUTES AND REGULATIONS AFFECTING
HAZARDOUS WASTE GENERATORS
STATUTES AND REGULATIONS AFFECTING
HAZARDOUS WASTE GENERATORS

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<td>E.2.4 Hazardous Waste Manifests</td>
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<tr>
<td>E.2.6 Packaging, Labeling and Marketing Requirements for Generators</td>
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<td>E.3 RECYCLABLE WASTES</td>
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<td>E.5.2 Federal Occupational Safety and Health Act</td>
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<td>E.6 SOLVENT WASTES</td>
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<td>ORDER FORM FOR CALIFORNIA HAZARDOUS WASTE CONTROL LAWS AND REGULATIONS</td>
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<td>E-4 SUMMARY OF GENERAL REGULATORY REQUIREMENTS</td>
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<td>E-5 SELECTED CODES AND REGULATIONS RELEVANT TO HAZARDOUS WASTE GENERATION AND MANAGEMENT</td>
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E.1 INTRODUCTION

California generators, transporters and storage facilities must comply with laws for handling hazardous materials and wastes. The California Department of Health Services (DHS) is the state agency responsible for controlling and monitoring hazardous waste management. This chapter will discuss state laws that apply to generation, treatment, storage, and/or disposal of hazardous waste.

This appendix provides a summary of the relevant regulations in Tables E-4 and E-5. Persons involved in regulated activities should become familiar with the regulations and statutes. If needed, additional help can be obtained from the agencies listed in Appendix J.

E.2 GENERATOR STANDARDS

Article 6, Chapter 30, Division 4, Title 22, California Code of Regulations (CCR) details requirements with which all generators of hazardous waste must comply. These requirements are described below.

E.2.1 Determination of Waste Classification

The generator of a waste must determine if the waste is hazardous. To do this, the generator must determine if the waste is specifically listed as a hazardous waste (Article 9, CCR), and/or if it is a characteristic hazardous waste (ignitable, corrosive, toxic, reactive) (Article 11, CCR). Certain wastes are also classified as "extremely hazardous wastes." These are listed in Article 9, CCR and their characteristics are identified in Article 11, CCR.

E.2.2 Generator Requirements

Hazardous waste generators must fulfill the following requirements:

- Determine if each generated waste is hazardous.
- Obtain an EPA Identification Number.
- Prepare a manifest form for all off-site shipments of hazardous waste.
- Prepare and submit biennial reports covering generator activities of the previous year with respect to hazardous waste.
- Ship hazardous wastes off-site within 90 days or obtain a hazardous waste storage facility permit from DHS and comply with other requirements applicable to facility operators.
- Ensure that all wastes prior to shipment off-site follow Department of Transportation regulations for proper packaging, labeling, and marking.

The generator is responsible for meeting other requirements that may not be specified in this report.

E.2.3 EPA Identification Number For Generators

Any generator of hazardous waste must obtain from EPA or DHS an identification number. (At press time, DHS issued all numbers except numbers of generators of federally regulated hazardous wastes in quantities greater than 100 kg per month). This number must be used on all official documents involving waste generation, transportation, treatment, storage, and/or disposal. This number must also appear on all required reports. A generator shall not offer his hazardous waste to a transporter or to an operator of a treatment, storage, and/or disposal facility who does not have an EPA Identification Number.

E.2.4 Hazardous Waste Manifests

A generator who offers for transportation a hazardous waste for treatment, storage and/or disposal off-site must prepare a manifest before shipping the waste off-site. The manifest is a multicopied document that allows the generator and the state to track shipments of hazardous waste. The manifest also provides the state with data on waste generation throughout the state.

The generator must designate on the manifest one facility which is permitted to handle the waste described on the manifest. Copies of the manifest must be sent to the DHS, and maintained by the generator for at least three years.

The HSWA require that the manifest include a waste minimization certification. The generator must certify "that I have a program in place to reduce the volume and toxicity of waste generated to the degree I have determined to be economically practicable." This language appears as Item 16 on the EPA uniform hazardous waste manifest. The generator must also certify that he or she has chosen the safest method of treatment or disposal.

E.2.5 Reports

A generator who ships his hazardous waste off-site shall prepare and submit a biennial report to the California Department of Health Services by March 1 of each even numbered year. The report covers generator activities with respect to hazardous wastes during the previous calendar year. Another report must be sent to the State Board of Equalization for taxation purposes.

E.2.6 Packaging, Labeling and Marking Requirements for Generators

Hazardous waste must be packaged in accordance with Department of Transportation (DOT) requirements prior to shipment to a treatment, storage and/or disposal facility. Marking and labeling must also be in accordance with DOT guidelines. A hazardous waste label must be affixed to all hazardous waste containers.
E.3 RECYCLABLE WASTES

If a hazardous waste such as a spent solvent can be recycled and used on-site, it might be exempt from many of the above listed requirements, as well as from DHS permit requirements. The recycling must generally be done continuously without storing the waste prior to reclamation. The recycled material is to considered a waste. Other conditional exemptions for recycling of hazardous waste also exist (Section 25143.2, California Health and Safety Code [CH&SC]).

The DHS' regulations provide a list of recyclable hazardous wastes and suggest methods for recycling them. If a "recyclable" waste is disposed of, the DHS may require the generator to explain why the waste was not recycled. The generator must respond. (See Section 25175, CH&SC and Sections 66763 and 66796, CCR).

By 1990, any hazardous waste that has greater than 3000 Btu/lb must be incinerated or go through an equivalent treatment process. Also, in 1990, hazardous wastes containing volatile organic compounds in concentrations exceeding standards to be determined by treatment process.

E.4 "LAB PACKS"

Most laboratory generated waste is disposed of in lab packs. Lab packs are steel drums containing small containers of compatible hazardous wastes. The small containers in the drum are packaged in chemical adsorbent. The drum is then sent to a hazardous waste landfill. As of July 8, 1989 certain waste chemicals in lab packs are restricted from landfills. These are listed in Table E-2.

If a lab pack includes a hazardous waste that contains any of the above elements/compounds at or in excess of any of the limits stated above, it cannot be disposed on land on and after July 8, 1989.

E.5 OTHER STATE AND FEDERAL STATUTES RULES AND REGULATIONS

There are many federal statutes and regulations requiring compliance. Many of these federal laws are the same as California laws. Some of these federal and state laws are discussed below.

E.5.1 Federal Clean Water Act

The Federal Clean Water Act (CWA) mandates the establishment of pretreatment standards for discharges to "publicly owned treatment works" (POTW). Institutions that are connected to public sewers must comply with the CWA pretreatment standards. This could result in not allowing certain compounds down the drain even if diluted (e.g. formaldehyde cannot be discharged to a POTW even in minute quantities with abundant dilution).

The CWA has also established the National Pollutant Discharge Elimination System (NPDES) program which regulates discharges to surface waters. The California
State Water Resources Control Board and its 9 regional boards carry out the NPDES program in California.

E.5.2 Federal Occupational Safety and Health Act

The Federal Occupational Safety and Health Act (OSHA) and State occupational safety laws regulate chemical handling on public and private campuses. OSHA's "Right-to-Know" laws have increased the awareness of chemical hazards in schools, and they have given impetus to the creation of hazardous waste management programs.

There is currently pending in the California Legislature a bill called the "Student-Right-To-Know" bill which would require educational institutions to develop a safety program for students who handle hazardous materials.

E.5.3 California Proposition 65

Proposition 65 requires private campuses to post warnings for person handling carcinogenic compounds, and restricts all discharges of carcinogenic compounds. This is a new law that at present does not affect public institutions. However, state legislation is pending that will require public institutions to comply.

E.6 SOLVENT WASTES

The 1984 Hazardous and Solid Waste Amendments (HSWA) to RCRA mandated the November 8, 1986 federal restriction on the land disposal of halogenated and non-halogenated solvent wastes. Restricted solvent wastes are numbered F001-F005 as defined in Section 261.31, Title 40, Code of Federal Regulations. On November 7, 1986, EPA announced a conditional extension on the implementation. According to the modified restriction, solvent wastes were prohibited from land disposal starting on November 8, 1986, unless one or more of the following conditions applies:

1. The generator of the solvent waste is a small quantity generator of 100-1000 kgs/month of hazardous waste.

2. The waste contains less than 1 percent total of F001-F005 solvent constituents.

3. The solvent waste is generated due to cleanup or other remedial action taken under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended.

However, the solvent wastes listed in Items 1 to 3 above are restricted from land disposal effective November 8, 1988.

E.7 PERTINENT STATUTES AND REGULATIONS

Table E-5 contains a list of federal and state codes and regulations that are relevant to hazardous waste generators. The list includes legislation on raw
material handling, waste disposal, air quality, and sewer discharge.

E.8 REGULATORY AGENCIES AND INFORMATION

Appendix F identifies regulatory agencies that may be contacted with questions on the management of hazardous wastes.
**TABLE E-1**

**RECYCLABLE WASTES**

Commercial chemical products including unused laboratory grade products.

Solvents, used or contaminated including:

- Halogenated solvents such as trichloroethane, perchloroethylene, methylene dichloride, chloroform, carbon tetrachloride, and Freons (R);

- Oxygenated solvents, such as acetone, methyl ethyl ketone, methanol, ethanol, butanol, and ethyl acetate; and

- Hydrocarbon solvents, such as hexanes, Stoddard, benzene, toluene, xylenes, and paint thinner.

Used or unused petroleum products, including motor oils, hydraulic fluids, cutting lubricants, and fortified weed oils.

Unspent acids, such as hydrochloric, hydrofluoric, nitric, phosphoric, and sulfuric, and acetylene sludge.

Unrinsed empty containers of iron or steel used for pesticides or other hazardous chemicals:

- Pesticide containers; and
- Hazardous chemical containers.
<table>
<thead>
<tr>
<th>Element/Compound</th>
<th>Concentration Limit of Restriction</th>
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<td>1. Liquid Hazardous waste containing free cyanides</td>
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<tr>
<td>2. Liquid hazardous waste containing one or more of the following:</td>
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<td>Arsenic and/or arsenic compounds</td>
<td>≥ 500 mg/liter</td>
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<tr>
<td>Cadmium and/or cadmium compounds</td>
<td>≥ 100 mg/liter</td>
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<td>Chromium VI and/or chromium VI compounds</td>
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<td>Lead and/or lead compounds</td>
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<td>Mercury and/or mercury compounds</td>
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<td>Nickel and/or nickel compounds</td>
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<td>Selenium and/or selenium compounds</td>
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<td>Thallium and/or thallium compounds</td>
<td>≥ 130 mg/liter</td>
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<td>3. Liquid hazardous waste with a pH less than or equal to 2.0</td>
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<td>4. Liquid hazardous waste containing polychlorinated biphenyls (PCBs)</td>
<td>≥ 50 mg/liter</td>
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<tr>
<td>5. Liquid hazardous waste containing halogenated organic compounds (i.e. chlorinated solvents)</td>
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<td>Waste Code</td>
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<tr>
<td>F001</td>
<td>The following spent halogenated solvents used in degreasing: tetrachloroethylene, trichloroethylene, methylene chloride, 1,1,1-trichloroethane, carbon tetrachloride, and chlorinated fluorocarbons; spent solvent mixtures/blends used in degreasing containing, before use, a total of 10 percent or more (by volume) of one or more of the above halogen solvents or those solvents listed in F002, F004, and F005; and still bottoms from the recovery of these spent solvents and spent solvent mixtures.</td>
</tr>
<tr>
<td>F002</td>
<td>The following spent halogenated solvents: tetrachloroethylene, methylene chloride, trichloroethylene, 1,1,1-trichloroethane, chlorobenzene, 1,1,2-trichloro-1,2,2-trifluoroethane, orthodichlorobenzene, and trichlorofluoromethane; all spent solvent mixture/blends containing before a total of 10 percent or more (by volume) of one or more of the above halogenated solvents or those solvents listed in F001, F004, and F005; and still bottoms from the recovery of these spent solvents and spent solvent mixtures.</td>
</tr>
<tr>
<td>F003</td>
<td>The following spent nonhalogenated solvents: xylene, acetone, ethyl acetate, ethyl benzene, ethyl ether, methyl isobutyl ketone, n-butyl alcohol cyclohexanone, and methanol; all spent solvent mixture/blends containing, before use, one or more of the above nonhalogenated solvents, and a total of 10 percent or more (by volume) of one or more of the solvents listed in F001, F002, F004, and F005; and still bottoms from the recovery of these spent solvents and spent solvent mixtures.</td>
</tr>
<tr>
<td>F002</td>
<td>The following spent halogenated solvents: tetrachloroethylene, methylene chloride, trichloroethylene, 1,1,1-trichloroethane, chlorobenzene, 1,1,2-trichloro-1,2,2-trifluoroethane, orthodichlorobenzene, and trichlorofluoromethane; all spent solvent mixture/blends containing before a total of 10 percent or more (by volume) of one or more of the above halogenated solvents or those solvents listed in F001, F004, and F005; toluene, methyl ethyl ketone, carbon disulfide, isobutanol, and pyridine; all spent solvent mixtures/blends containing, before use, a total of 10 percent or more (by volume) of one or more of the above nonhalogenated solvents or those solvents listed in F001, F002, and F004; and still bottoms from the recovery of these spent solvents and spent solvent mixtures.</td>
</tr>
</tbody>
</table>

1 January 14, 1986 at 51 CFR 1763; 40 CFR 268.30(b).
## TABLE E-4

### SUMMARY OF GENERAL REGULATORY REQUIREMENTS

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>REQUIREMENT</th>
<th>AGENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HAZARDOUS WASTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waste Generation</td>
<td>Shipments of waste must be accompanied by a manifest; agency must be notified. Prepare biennial report concerning the volume of waste generated. If wastes are temporarily stored on site, the generator must comply with handling procedures, personnel requirements, etc. Generators disposing of &quot;recyclable wastes&quot; may be asked to provide justification for not recycling.</td>
<td>DHS, county hazardous material regulators</td>
</tr>
<tr>
<td>Process Modification;</td>
<td>If the new process involves treatment of a hazardous waste, a treatment, storage and disposal (TSD) permit may be necessary. Process must comply with fire codes and occupational health requirements.</td>
<td>DHS</td>
</tr>
<tr>
<td>Material Substitution</td>
<td></td>
<td></td>
</tr>
<tr>
<td>On-site Treatment</td>
<td>In general, a treatment, storage and disposal permit is required. DHS may grant variances for activities adequately regulated by other agencies.</td>
<td>DHS</td>
</tr>
<tr>
<td>On-site Recycling</td>
<td>Same as above; however, some on-site recycling activities are categorically exempt from permit requirements.</td>
<td>DHS</td>
</tr>
<tr>
<td>Off-site Recycling</td>
<td>Commercial recycling activities require a TSD permit. Commercial recyclers must submit an annual report. Some resource recovery facilities are eligible for Series 'A', 'B', or 'C' resource recovery permits in lieu of a TSD permit.</td>
<td>DHS</td>
</tr>
</tbody>
</table>
### TABLE E-4 (continued)

**SUMMARY OF GENERAL REGULATORY REQUIREMENTS**

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>REQUIREMENT</th>
<th>AGENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HAZARDOUS WASTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disposal</td>
<td>In California, several classes of hazardous waste are restricted from land disposal.</td>
<td>DHS</td>
</tr>
<tr>
<td></td>
<td>A national land disposal restriction program is being implemented.</td>
<td>EPA</td>
</tr>
<tr>
<td></td>
<td>Disposal facilities must have a TSD permit and comply with technical and financial regulations.</td>
<td>DHS</td>
</tr>
<tr>
<td><strong>AIR POLLUTION</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Industrial</td>
<td>All devices emitting air pollutants must be permitted or exempted.</td>
<td>Local APCD/AQMD</td>
</tr>
<tr>
<td></td>
<td>If changes in equipment or procedures result in an increase of any pollutant above a specified level, a permit is required.</td>
<td>Local APCD/AQMD</td>
</tr>
<tr>
<td></td>
<td>If certain designated toxic air contaminants are emitted, the generator must comply with rules established under the toxic air contaminant program.</td>
<td>Local APCD/AQMD</td>
</tr>
<tr>
<td></td>
<td>If there is an increase in an &quot;attainment pollutant&quot; by a significant amount (generally 25 to 40 tons/yr), a TSD permit may be necessary.</td>
<td>EPA Region IX</td>
</tr>
<tr>
<td><strong>WATER POLLUTION</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Industrial</td>
<td>Discharge of industrial waste to sewer requires a sewer permit.</td>
<td>Local sewer agency</td>
</tr>
<tr>
<td></td>
<td>Discharge of waste to land requires a discharge permit.</td>
<td>Regional Water Quality Control Board</td>
</tr>
<tr>
<td></td>
<td>Discharge of waste to public waters requires an NPDES permit.</td>
<td>Regional Water Quality Control Board</td>
</tr>
<tr>
<td>Category</td>
<td>Regulations/Rules</td>
<td>Description</td>
</tr>
<tr>
<td>---------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Air quality</td>
<td>SCAQMD Rule 442&lt;br&gt;SBAQMD Rule 317&lt;br&gt;MBUAPCD Rule 416&lt;br&gt;BAAQMD Rule 8,&lt;br&gt;</td>
<td>Restricts discharge of organic materials into the atmosphere from equipment</td>
</tr>
<tr>
<td></td>
<td>Rule 35&lt;br&gt;KCAPCD Rule 410&lt;br&gt;SLOCAPCD Rule 407 H(1)&lt;br&gt;VAPCD Rule 66&lt;br&gt;SCAQMD</td>
<td>in which solvents are used.</td>
</tr>
<tr>
<td></td>
<td>Rule 443&lt;br&gt;SCAQMD Rule 1113&lt;br&gt;SBAQMD Rule 323&lt;br&gt;MBUAPCD Rule 426&lt;br&gt;BAAQMD</td>
<td>Requires coatings and solvents to be labeled to indicate their photochemical</td>
</tr>
<tr>
<td></td>
<td>Regulation 8,&lt;br&gt;Rule 3&lt;br&gt;KCAPCD Rule 407 H(3)&lt;br&gt;SCAQMD Rule 1141.1&lt;br&gt;BAAQMD</td>
<td>reactivity.</td>
</tr>
<tr>
<td></td>
<td>regulation 8,&lt;br&gt;MBUAPCD Rule 429&lt;br&gt;KCAPCD Rule 413&lt;br&gt;SBAQMD Rule 322&lt;br&gt;SOLCA</td>
<td>Establishes VOC standards for architectural and specialty architectural coats</td>
</tr>
<tr>
<td></td>
<td>PCD Rule 407 H(2)&lt;br&gt;SBAQMD Rule 324&lt;br&gt;KCAPCD Rule 410.2&lt;br&gt;BAAQMD Regulation 8,&lt;br&gt;</td>
<td>ings.</td>
</tr>
<tr>
<td></td>
<td>Rule 39&lt;br&gt;SLOCAPCD Rule 407 H(4)&lt;br&gt;</td>
<td>Establishes operating requirements for coatings and inks manufacturing.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Deals with the storage of organic liquid.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Deals with organic liquid loading.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prohibits photochemically reactive metal surface coating thinners and reduce</td>
</tr>
<tr>
<td></td>
<td></td>
<td>in the district.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Deals with the disposal and evaporation solvents.</td>
</tr>
</tbody>
</table>
### TABLE E-5 (Continued)

**SELECTED CODES AND REGULATIONS RELEVANT TO HAZARDOUS WASTE GENERATION AND MANAGEMENT**

<table>
<thead>
<tr>
<th>Category</th>
<th>Regulations/Rule</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solvent storage</td>
<td>CCR Title 23, Chapter 3, SubChapter 16</td>
<td>Underground storage of solvents.</td>
</tr>
<tr>
<td></td>
<td>CH&amp;SC Division 20, Chapter 6.7</td>
<td>Regulates underground storage of hazardous substances.</td>
</tr>
<tr>
<td></td>
<td>CCR Title 22, Div. 4, Ch. 30, Article 24</td>
<td>Regulates the use and management of containers.</td>
</tr>
<tr>
<td></td>
<td>CCR Title 22, Chapter 30, Article 6</td>
<td>Sets requirements for generators of hazardous waste including restrictions on how long wastes can be accumulated without the storage facility being permitted.</td>
</tr>
<tr>
<td></td>
<td>CH&amp;SC 25123.3</td>
<td>Definition of storage.</td>
</tr>
<tr>
<td></td>
<td>CH&amp;SC Chapter 6.95</td>
<td>Requires local government agencies to implement hazardous material management programs requiring local businesses to business plans and inventories for the storage and handling of hazardous materials.</td>
</tr>
<tr>
<td></td>
<td>CCR Title 22, Ch. 30, Div. 4, Sec. 66470 to Sec. 66515</td>
<td>Requires generators of hazardous waste to store, label, and manifest hazardous wastes properly.</td>
</tr>
<tr>
<td>Hazardous Materials</td>
<td>CCR Title 22, Ch. 30, Div. 4, Section 66680</td>
<td>Lists specific elements, compounds, and generic materials and wastes that are potentially hazardous wastes when they are no longer useful. Solvents are listed as potentially hazardous based on the ignitability criterion.</td>
</tr>
<tr>
<td></td>
<td>CAC Title 22, Division 2</td>
<td>Requires clear and reasonable warning that a substance that may cause cancer, birth defects, or other reproductive harm is present.</td>
</tr>
<tr>
<td>Category</td>
<td>Regulations/Rule</td>
<td>Description</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------</td>
<td>-------------</td>
</tr>
<tr>
<td></td>
<td>40 CFR 355</td>
<td>Requires businesses to notify administering agencies that a EHS above the TPQ is present at the facility. Businesses must notify administering agencies of a facility emergency coordinator.</td>
</tr>
<tr>
<td></td>
<td>40 CFR 370</td>
<td>Requires businesses with specified quantities of a hazardous substance to submit a MS1 and Tier I form to the administering agencies.</td>
</tr>
<tr>
<td></td>
<td>40 CFR 372</td>
<td>Requires manufacturers to submit a Toxical Release Inventory Form to the administering agencies.</td>
</tr>
<tr>
<td></td>
<td>40 CFR 372</td>
<td>Requires manufacturers to submit a Toxical Release Inventory Form and notify customers that a Section 313 chemical is present in their product.</td>
</tr>
<tr>
<td></td>
<td>40 CFR 268</td>
<td>Federal regulations that restrict the disposal of spent solvents and solvent containing wastes.</td>
</tr>
<tr>
<td></td>
<td>CCR Title 22, Ch. 30, Div. 4, Sec. 66693</td>
<td>Lists the criteria for determining whether a waste is considered hazardous or extremely hazardous using criteria for ignitability, toxicity, corrosivity, and reactivity.</td>
</tr>
<tr>
<td></td>
<td>CH&amp;SC Sec. 25180 to Sec. 25196</td>
<td>Identifies sanctions for non-compliance with hazardous waste regulations.</td>
</tr>
</tbody>
</table>
TABLE E-5 (Continued)

SELECTED CODES AND REGULATIONS RELEVANT TO HAZARDOUS WASTE GENERATION AND MANAGEMENT

<table>
<thead>
<tr>
<th>Category</th>
<th>Regulations/Rule</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPDES regulations 40 CFR 122</td>
<td>Regulations on the reduction of pollutant discharges into the waters of the United States.</td>
<td></td>
</tr>
<tr>
<td>CCR Title 23 Subchapter 9</td>
<td>State regulation governing the discharge of waste waters to surface waters. Includes provisions for issuance of permits and setting effluent limitations.</td>
<td></td>
</tr>
<tr>
<td>Local municipal codes addressing discharges POTWs</td>
<td>Discharge requirements set by local POTWs to restricting the concentrations of pollutants in waste waters discharged to sanitary sewers.</td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>Regulations/Rule</td>
<td>Description</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Waste treatment, recycle or disposal</td>
<td>CH&amp;SC 25175</td>
<td>Authorizes DHS to list is treatment, provide a listing of recyclable hazardous wastes found by DHS to be economically and technically feasible to recycle. Also authorizes fee penalties for failure to do so, as specified.</td>
</tr>
<tr>
<td></td>
<td>Title 22, CCR 66796</td>
<td>Provides a list of recyclable wastes and suggests methods for recycle.</td>
</tr>
<tr>
<td></td>
<td>Title 22, CCR 66763 and CH&amp;SC, Sec. 25175</td>
<td>If a &quot;recyclable&quot; waste is disposed then DHS may request the generator to explain why the waste was not recycled. The generator must respond. DHS can assess penalties for failure to comply.</td>
</tr>
<tr>
<td></td>
<td>CH&amp;SC, Sec. 25143.2</td>
<td>Exempts recyclable materials from hazardous waste control requirements if they meet certain conditions.</td>
</tr>
<tr>
<td></td>
<td>CH&amp;SC 25190</td>
<td>Sanctions specified for generator non-compliance with the regulations.</td>
</tr>
<tr>
<td></td>
<td>CH&amp;SC 25186(c)</td>
<td>Sanctions specified for facilities with permits, non-compliance with the regulations.</td>
</tr>
<tr>
<td></td>
<td>CH&amp;SC 25155.5(a)</td>
<td>Requires incineration or equivalent treatment of hazardous wastes with greater than 3000 BTU/lb.</td>
</tr>
<tr>
<td>Code/Regulation</td>
<td>Description</td>
<td>Effective Date</td>
</tr>
<tr>
<td>-----------------</td>
<td>-------------</td>
<td>----------------</td>
</tr>
<tr>
<td>CH&amp;SC 25155.5(b)</td>
<td>Requires incineration or equivalent treatment of hazardous wastes containing volatile organic compounds in concentrations exceeding standards to be determined by DHS.</td>
<td>Existing law becomes effective in 1990.</td>
</tr>
<tr>
<td>CH&amp;SC 25202.9</td>
<td>Requires annual certification by hazardous waste generators who operate TSD on-site facilities that have a waste minimization program in operation. Further, they must certify that the treatment, storage, or disposal methods minimize threats to human health and environment.</td>
<td></td>
</tr>
<tr>
<td>CH&amp;SC 25244.4</td>
<td>Generators are required to submit a report every two years on waste reduction status.</td>
<td></td>
</tr>
<tr>
<td>CH&amp;SC 25179</td>
<td>Prohibit land disposal of all untreated hazardous wastes.</td>
<td>Effective 1990.</td>
</tr>
<tr>
<td>40 CFR 165</td>
<td>Recommends procedures for the disposal and storage of pesticides and pesticide containers.</td>
<td></td>
</tr>
<tr>
<td>32A CFR 650</td>
<td>Hazard and toxic materials management (bibliography and tables)</td>
<td></td>
</tr>
<tr>
<td>Land disposal CH&amp;SC 25122.7 and Title 22, CCR 66900-66935</td>
<td>Specifies land disposal restrictions. List therein of restricted hazardous wastes which includes wastes containing more than 1000 mg/kg of halogenated organic compounds.</td>
<td>Effective 1/1/ for liquid halogenated organics and postponed 7/8/89 for organics containing halogenated compounds.</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>RCRA 3004(e) (1)</td>
<td>Prohibits land disposal of most solvents unless treatment levels (2 ppm for most constituents) are met.</td>
<td>Effective November 8, 1986.</td>
</tr>
<tr>
<td>40 CFR 268.3</td>
<td>Prohibits land disposal of dilute waste waters containing solvents and having 1% or less total organics.</td>
<td>Effective November 8, 1988.</td>
</tr>
<tr>
<td>40 CFR 265.314 and CCR Title 22, Ch. 30, Div. 4, Sec. 67422</td>
<td>Prohibits land disposal of bulk or non-containerized liquid hazardous wastes or hazardous wastes containing free liquids.</td>
<td></td>
</tr>
<tr>
<td>General 40 CFR 446</td>
<td>EPA Guidelines and standards for paint formulating industry.</td>
<td></td>
</tr>
<tr>
<td>Specific 21 CFR 211 Requirements for Pharmaceutical Manufacturers</td>
<td>Sets requirements for the personnel, consultants, buildings, and equipment involved in the manufacture of drugs. Controls the production, packaging, labelling, storage, distribution and salvaging of drugs and drug products. Stipulates proper laboratory controls in the manufacturing of pharmaceuticals.</td>
<td></td>
</tr>
</tbody>
</table>
TABLE E-5 (Continued)

SELECTED CODES AND REGULATIONS RELEVANT TO HAZARDOUS WASTE GENERATION AND MANAGEMENT

KEY CODE:

CAC - California Administrative Code  
CFR - Code of Federal Regulations  
mg/kg - milligram per kilogram  
ppm - parts per million  
RCRA - Resource Conservation and Recovery Act  
SQG - small quantity generator

SOURCES:


NOTE:

The generator should contact the appropriate local, state, or federal authority for complete, detailed and updated regulatory information.
**ABBREVIATIONS:**

- **APCD** - Air Pollution Control District
- **AQMD** - Air Quality Management District
- **BA** - Bay Area
- **BTU** - British Thermal Units
- **CCR** - California Code of Regulations
- **CFR** - Code of Federal Regulations
- **CH&SC** - California Health and Safety Code
- **DHS** - Department of Health Services
- **KC** - Kern County
- **MBU** - Monterey Bay Unified
- **NPDES** - National Pollutant Discharge Elimination System
- **POTW** - Publicly Owned Treatment Works
- **RCRA** - Resource Conservation and Recovery Act
- **SB** - Santa Barbara
- **SC** - South Coast
- **SLOC** - San Luis Obispo County
- **TSD** - Treatment, Storage, or Disposal
- **USC** - United States Congress
- **VOC** - Volatile Organic Compounds
- **V** - Ventura
ORDER FORM FOR CALIFORNIA HAZARDOUS WASTE CONTROL
LAWS AND REGULATIONS

Copies of hazardous waste control laws and regulations administered by the California Department of Health Services may be ordered by completing the form below and mailing it with the applicable payment to:

Department of General Services, Publications Section
P.O. Box 1015
North Highlands, CA 95660
(916) 973-3700

The laws and regulations are not identical, so both are generally needed to obtain complete information.

The laws (Chapters 6.5 through 6.98, Division 20, California Health and Safety Code) were enacted by the Legislature. Recent history indicates that the laws change to some extent each year, usually effective January first. To keep up to date with the laws, reorder them each year, because no amendment service is available.

The regulations (Chapter 30, Division 4, Title 22, California Code of Regulations) were adopted by the Department of Health Services within the scope of the DHS' authority under the laws. The regulations may change at any time during the year according to specified administrative procedures. Therefore, continuous amendment service is available by subscription. The amendment service is useful only in conjunction with the complete regulations (i.e., Division 4, Title 22, CCR).

I. Please check all applicable boxes and complete all applicable blanks.

☐ Please send me _________ copy(ies) of Item No. 7540-958-1016-6, Hazardous Waste Control Law (Chapters 6.5 – 6.98, Division 20, Health and Safety Code), at $25.00 per copy, including postage, taxes, and handling costs. $ ______

☐ Please send me _________ copy(ies) of the regulations (Division 4, Title 22, California Code of Regulations [CCR]) at $8.48 per copy, including postage, taxes, and handling costs. (Item Number 0030-0224-7) $ ______

☐ Please accept my _________ subscription(s) to the continuous amendment service for the regulations (Division 4, Title 22, CCR) at $12.00 per subscription per year, including postage and handling costs. The complete regulations must be ordered separately by checking the applicable box. (Item Number 22-04-00) $ ______

Make check or money order for the total amount payable to: State of California.

TOTAL AMOUNT $ ______

II. Please print or type your mailing address and telephone number below; then sign and date the form.

Name/Company Name ________________________________________________________________

Attention __________________________________________________________

Address ________________________________________________________________

City __________________________ State _______ Zip __________________________

Telephone Number __________________________ (In case we need to contact you about your order)

Signature __________________________________________________________ Date ______

DHS.6400 (2/89)
APPENDIX F

FEDERAL AND STATE AGENCIES
# Table F-1
## Federal and State Agencies

### Federal Agencies

<table>
<thead>
<tr>
<th>Agency</th>
<th>Hotline Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Environmental Protection Agency</td>
<td>800-424-9346</td>
</tr>
<tr>
<td></td>
<td>Title</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Region XI - San Francisco</td>
</tr>
<tr>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>U.S. Department of Transportation</td>
<td>Information Hotline</td>
</tr>
<tr>
<td></td>
<td>Southern California (El Monte)</td>
</tr>
<tr>
<td></td>
<td>Northern California (Sacramento)</td>
</tr>
<tr>
<td>U.S. Coast Guard/National Response Center</td>
<td></td>
</tr>
<tr>
<td>U.S. Public Health Service, National Health Information Clearinghouse</td>
<td></td>
</tr>
</tbody>
</table>

### Other

<table>
<thead>
<tr>
<th>Agency</th>
<th>Hotline Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Manufacturers Association</td>
<td>CHEMTREC (transportation accidents) 800-424-9300</td>
</tr>
<tr>
<td></td>
<td>National Pesticide Telecom Network 800-858-7378</td>
</tr>
<tr>
<td></td>
<td>National Animal Poison Control Center 217-333-3611</td>
</tr>
</tbody>
</table>

### State Agencies

<table>
<thead>
<tr>
<th>Agency</th>
<th>Hotline Information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Used Oil Recycling and Regulatory Information</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Office of Emergency Services</td>
<td>800-852-7550</td>
</tr>
<tr>
<td></td>
<td>24-Hour Number for Reporting Spills/Releases</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>California State Water Resources Control Board</td>
<td>916-445-9552</td>
</tr>
<tr>
<td></td>
<td>Water Quality Division</td>
</tr>
<tr>
<td>California Waste Management Board</td>
<td>916-322-3300</td>
</tr>
<tr>
<td>---------------------------------------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>General Information on Solid Waste</td>
<td>800-553-2962</td>
</tr>
<tr>
<td>Used Oil Recycling Center Locations</td>
<td></td>
</tr>
</tbody>
</table>

| California Highway Patrol/Motor Carrier Section         | 916-445-6211 |

<table>
<thead>
<tr>
<th>California Local Air Pollution Control Districts</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Amador County APCD (Mountain Counties)</td>
<td></td>
</tr>
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<td>Bay Area AQMD (San Francisco Bay Area)</td>
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<td>Butte County APCD (Sacramento Valley)</td>
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<td>Calaveras County APCD (Mountain Counties)</td>
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<td>Colusa County APCD (Sacramento Valley)</td>
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<td>El Dorado County APCD (Lake Tahoe and Mountain Counties)</td>
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<td>Fresno County APCD (San Joaquin Valley)</td>
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<td>Glenn County APCD (Sacramento Valley)</td>
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<tr>
<td>Great Basin Unified APCD (Great Basin Valleys)</td>
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<tr>
<td>Imperial County APCD (Southeast Desert)</td>
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<td>Kern County APCD (San Joaquin Valley and Southeast Desert)</td>
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<td>Lassen County APCD (Northeast Plateau)</td>
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<td>Madera County APCD (San Joaquin Valley)</td>
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<td>Mariposa County APCD (Mountain Counties)</td>
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<td>Mendocino County APCD (North Coast)</td>
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<td>Merced County APCD (San Joaquin Valley)</td>
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<td>Modoc County APCD (Northeast Plateau)</td>
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<td>Monterey Bay Unified APCD (North Central Coast)</td>
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<td>Mountain Counties Air Basin</td>
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<td>North Coast Unified AQMD (North Coast Air Basin)</td>
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<tr>
<td>Northern Sierra AQMD (Mountain Counties Air Basin)</td>
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<td>Northern Sonoma County APCD (North Coast)</td>
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<td>Placer County APCD (Lake Tahoe, Mountain Counties, and Sacramento Valley)</td>
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<td>Sacramento County APCD (Sacramento Valley)</td>
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<tr>
<td>San Bernardino County APCD (Southeast Desert)</td>
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<td>San Diego County APCD</td>
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<td>San Joaquin County APCD (San Joaquin Valley)</td>
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<td>San Luis Obispo County APCD (South Central Coast)</td>
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<td>Santa Barbara County APCD (South Central COast)</td>
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<tr>
<td>Shasta County APCD (Northeast Plateau and Sacramento Valley)</td>
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<td>Siskiyou County APCD (Northeast Plateau)</td>
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<td>South Coast AQMD (Los Angeles Basin)</td>
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<td>Stanislaus County APCD (San Joaquin Valley)</td>
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<td>Sutter County APCD (San Joaquin Valley)</td>
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<td>Tehama County APCD (Sacramento Valley)</td>
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<td>Tulare County APCD (San Joaquin Valley)</td>
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<td>Tuolumne County APCD (Mountain Counties)</td>
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<td>Yolo-Solano APCD (Sacramento Valley)</td>
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<tr>
<td>Yuba County APCD (Sacramento Valley)</td>
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</tbody>
</table>
APPENDIX G

SELF-AUDIT FORMAT
SELF-AUDIT FORMAT
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INTRODUCTION

This self-audit format is a waste minimization assessment for industry use. The self-audit covers the following areas:

- General plant information;
- Material handling and storage;
- Process operations;
- Waste generation;
- Waste management practices;
- Waste minimization opportunities.

This format can be the starting point for the generator's waste minimization program. Detailed evaluations involving major process changes are not within the scope of this format. The format can be expanded by the generator to meet specific process applications.

The self-audit identifies current practices and sources of waste generation. In addition, cost effective operating and management practices are highlighted. The ultimate goal of this format is to implement waste minimization and effective waste management, thereby reducing waste generation and waste management costs. To achieve this the self-audit identifies waste minimization opportunities. In addition, existing or future waste management problems can be identified.

The self-audit format can be used by firms lacking in-house expertise in waste minimization. These typically are small quantity generators. It can be used by persons without a detailed knowledge of process operations or waste minimization. It is strongly recommended, however, that plant personnel knowledgeable of plant processes be part of the audit team. To be successful, the waste minimization program must involve plant management.

Where appropriate the preferable answer to each question is indicated by capital letters (e.g., NO or YES). If the response to a question is not the indicated one, a plan for implementing changes in the area addressed by the question should be developed. Worksheets for prioritizing waste management practices not currently in use are provided. Practices identified as high priorities should be considered for implementation. All implementation plans developed should be attached to the completed self-audit format.
SELF-AUDIT FORMAT

1.0 GENERAL PLANT INFORMATION

Company Name: ____________________________________________________________

Company Address: __________________________________________________________

EPA Generator Number: ______________________________________________________

Audit Team Leader: ____________ Phone Number: ________________________________

Audit Team Staff: ____________________________________________________________

Date of Completion: _______________________________________________________

Briefly describe the operations conducted at the plant

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

How many employees work at the plant? _______________________________________

How old is the plant? _______________________________________________________

Are there any planned changes to the plant and its operations in the near future? yes__ no__

If yes, describe the proposed changes. _______________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
2.0 HAZARDOUS MATERIAL STORAGE AND HANDLING INFORMATION

2.1 Raw Material Storage

Before continuing, fill out Worksheet 2.1 for raw materials and Worksheet 2.2 for products. It may be useful to complete this section for each material or group of materials.

Where are raw materials stored?

Does the layout of the plant minimize travel distances between raw material storage and point of use? YES ___ no ___

Is this a high traffic area? yes ___ NO ___

Can traffic through the storage area be reduced? yes ___ NO ___

Are raw materials stored to prevent damage, spillage, or weather exposure? YES ___ no ___

Are hazardous raw materials stored separately from nonhazardous raw materials? YES ___ no ___

Is sufficient distance kept between different types of chemicals and materials to prevent cross contamination in the event of a spill? YES ___ no ___

Are all raw materials verified by quality control before being accepted? YES ___ no ___

Are off-spec raw materials returned to supplier? YES ___ no ___

If not, how are off-spec raw materials disposed?

☐ Municipal landfill
☐ Hazardous waste landfill
☐ Sewer discharge
☐ Other ________________
### Worksheet 2.1 Hazardous Raw Material Information

<table>
<thead>
<tr>
<th>Raw Material</th>
<th>Quantity Used</th>
<th>Process Use</th>
<th>Shelf Life</th>
<th>Supplier</th>
<th>Frequency of Resupply</th>
<th>Cost/Unit</th>
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</thead>
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</tbody>
</table>

G-4
**Worksheet 2.2 Product Information**

List all products that use hazardous materials as ingredients or reactants, and all products whose manufacture generates hazardous waste or hazardous byproducts.

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Annual Production</th>
<th>Product Form</th>
<th>Total Annual Sales ($)</th>
<th>Hazardous Raw Materials</th>
<th>Hazardous Byproducts or Wastes</th>
</tr>
</thead>
<tbody>
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</tr>
</tbody>
</table>
Are all containers inspected for damage by quality control personnel before being accepted?  

YES  no

Describe the handling procedure for damaged containers

2.2 Raw Material Inventory

Are materials used on a first-in first-out basis to prevent material expiration?  

YES  no

Are waste materials generated because material has exceeded its shelf-life?  

yes  NO

Does the supplier of raw materials accept expired materials?  

YES  no

Are expired materials shipped back to the supplier?  

YES  no

Is the inventory of raw materials minimized to prevent material expiration?  

YES  no

Is your inventory system computerized?  

YES  no

If no, how is inventory tracked?

How often are complete inventory checks of raw materials performed?

☐ Continuously  ☐ Quarterly

☐ Daily  ☐ Annually

☐ Weekly  ☐ As-needed

☐ Monthly  ☐ Other ________
2.3 Products Storage

Where are finished products stored?

Does the layout of the plant minimize travel distances between production areas and product storage areas? __YES__ __no__

Is this a high traffic area? __yes__ __NO__

Can traffic through the product storage area be reduced? __yes__ __NO__

Are products stored to prevent damage or spillage? __YES__ __no__

Are all products inspected by quality control personnel before leaving the plant? __YES__ __no__

What percentage of products are rejected by quality control as non-spec? ________________

How are these rejected products handled? __☐__ Reworked __☐__ Municipal landfill

☐ Hazardous waste landfill __☐__ Sewer discharge __☐__ Other __________

2.4 Spill Prevention and Management

Is spillage monitored during material transportation? __YES__ __no__

Are drums and tanks for storage adequately spaced to allow for visual inspection of each container? __YES__ __no__

Are liquid storage tanks monitored for leaks? __YES__ __no__

If yes, how? __☐__ Visual __☐__ Leak detector __☐__ Other __________

How often are inspection made? __☐__ Daily __☐__ Weekly __☐__ Monthly __☐__ Other __________

Are storage tanks fitted with overflow alarms? __YES__ __no__

G-7
If yes, are these alarms tested regularly? 

YES ___ no ___

Are secondary containments in place? 

YES ___ no ___

Are storage tanks fitted with vapor recovery systems? 

YES ___ no ___

Is there a spill control/management plan in use at the plant? 

YES ___ no ___

Are employees trained to handle materials in a manner that is safe and designed to reduce spillage? 

YES ___ no ___

How often is employee training given? 

☐ Monthly ☐ Annually 

☐ Quarterly ☐ Other ____________

Are measures employed to prevent liquid spillage during dispensing? 

YES ___ no ___

Are spill containment measures in use at the plant? 

YES ___ no ___

How are liquid materials transferred to points of use? ______________________________________

_______________________________________

_______________________________________

List all safeguards used to prevent spillage of liquid materials. ______________________________________

_______________________________________

_______________________________________

Describe the procedures for liquid spill clean up. ______________________________________

_______________________________________

_______________________________________

How are solid materials transferred to points of use? ______________________________________

_______________________________________

_______________________________________
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are spilled materials disposed of as wastes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are spilled raw materials or products collected for reuse?</td>
<td>YES</td>
<td>no</td>
</tr>
<tr>
<td>Describe the procedures for solid spill clean up.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>List all safeguards used to prevent spillage of solid materials.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are all spills documented?</td>
<td>YES</td>
<td>no</td>
</tr>
<tr>
<td>Are practice drills for spill clean up performed?</td>
<td>YES</td>
<td>no</td>
</tr>
<tr>
<td>If yes, how often are these drills performed?</td>
<td>Monthly</td>
<td>Annually</td>
</tr>
<tr>
<td></td>
<td>Quarterly</td>
<td>Other</td>
</tr>
</tbody>
</table>

G-9
Worksheet 2.3

For each hazardous material indicate which material storage and handling practices are currently in use at the plant.

<table>
<thead>
<tr>
<th>Material Storage/ Handling Practice</th>
<th>In Use? (Yes/No)</th>
<th>Need¹</th>
<th>Potential for Implementation²</th>
<th>Score³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Materials Inspection</td>
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<tr>
<td>Proper Handling</td>
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<tr>
<td>Proper Storage</td>
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<tr>
<td>Reduced Traffic in Storage Area</td>
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<tr>
<td>Material Segregation</td>
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<tr>
<td>Inventory Tracking</td>
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<tr>
<td>Material Usage Based on First-in First-out</td>
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<tr>
<td>Minimized Distance Between Storage or Points of Use</td>
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<tr>
<td>Tank Monitoring</td>
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<tr>
<td>Employee Training</td>
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<tr>
<td>Employee Incentives</td>
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<tr>
<td>Spill Prevention Plan</td>
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</tbody>
</table>

1 Indicate the need of the practice on a scale of 1 to 5. Practices that are most valuable or necessary to minimize a serious risk should be given a need of 1.

2 Indicate the potential for implementation of each practice not currently in use, based on economic or technological feasibility.

3 The score is determined by multiplying the need and potential scores together. Potential scores are as follows: high = 1, medium = 2, low = 3. The scores developed on this worksheet should be used to prioritize the implementation of the listed practices. For those practices with the lowest scores, an implementation plan should be developed and attached to this sheet.
3.0 PROCESS INFORMATION

Complete Worksheet 3.1 for each discrete process unit or operation currently in use. Next, fill out Worksheet 3.2 for the process streams associated with the processes and operations identified in Worksheet 3.1.
Worksheet 3.1 Process Information

Process Unit/Operation: ____________________________

Type of Operation:  Continuous  Batch  Semi-Batch  Other

<table>
<thead>
<tr>
<th>Document</th>
<th>Complete? (Y/N)</th>
<th>Current? (Y/N)</th>
<th>Last Revision</th>
<th>Document Number</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process Flow Diagram</td>
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<tr>
<td>Material/Energy Balance</td>
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<td>Design</td>
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<td>Operating</td>
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<td>Flow/Amount Measurements</td>
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<tr>
<td>List Process Streams 1.</td>
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<td>List Process Streams 2.</td>
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<td>List Process Streams 3.</td>
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<tr>
<td>Analyses/Assays</td>
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<td>List Process Streams 1.</td>
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<td>List Process Streams 2.</td>
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<td>List Process Streams 3.</td>
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<td>Process Description</td>
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<td>Equipment Specifications</td>
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<td>Work Flow Diagrams</td>
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<td>Permit/Permit Applications</td>
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<td>Batch Sheet(s)</td>
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<tr>
<td>Material Safety Data Sheets</td>
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<td>Operator Logs</td>
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<tr>
<td>Production Schedules</td>
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<tr>
<td>Product Composition Sheets</td>
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</tbody>
</table>
# Worksheet 3.2 Process Stream Information

Process Unit/Operation: __________________________________________

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Stream Name/ID</td>
<td>Source¹</td>
<td>Destination²</td>
</tr>
<tr>
<td>Flow Rate/Quantity³</td>
<td>Mode of Transport⁴</td>
<td>Input Stream (Y/N)⁵</td>
</tr>
<tr>
<td>Product Stream (Y/N)</td>
<td>Hazardous Waste Stream (Y/N)</td>
<td>Hazardous Material (Y/N)</td>
</tr>
<tr>
<td>List Hazardous Components or Components of Concern</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹ e.g., raw material storage, fermentation process
² e.g., disposal, product recovery process
³ Specify units of measure
⁴ e.g., pipe, forklift, conveyor belt
⁵ Indicate yes or no
4.0 WASTE GENERATION AND STORAGE INFORMATION

Before continuing, fill out Worksheet 4.1 for each hazardous wastestream. Use process information from Section 3.0 to help identify wastestreams. Identify all wastestreams including washwaters and disinfectants, wastewaters from solvent extraction, and any others not identified in Section 3.0. For each wastestream identified in Worksheet 4.1, complete Worksheet 4.2.
## Worksheet 4.1 Wastestream Identification

<table>
<thead>
<tr>
<th>Wastestream</th>
<th>Physical State</th>
<th>Hazardous Characteristics</th>
<th>Quantity Generated</th>
<th>Process Source</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>
Worksheet 4.2 Wastestream Generation

Wastestream: _____________________________________________________________

What is the source of the Wastestream?
☐ Process by-product or residue
☐ On-site recycling or recovery residue
☐ On-site treatment residue
☐ Other ______________________

How is the wastestream is generated?
☐ Continuously
☐ Intermittently
☐ Other ______________________

Where is the waste stored on site before disposal? ____________________________________________

How is the waste stored (check all that apply)
☐ Drum ☐ Underground Tank
☐ Sump ☐ Dumpster
☐ Tank ☐ Other ______________

Is the wastestream
☐ Mixed with other hazardous wastestreams?
☐ Diluted with water?
☐ Mixed with non-hazardous wastestreams?
☐ Other ________________________________

If mixed, what is the rationale for mixing? ________________________________________________
Worksheet 4.2 (cont.)

List the components and percentage of composition for the wastestream. Indicate the hazardous characteristics, if any.

<table>
<thead>
<tr>
<th>Component</th>
<th>Percentage of Composition</th>
<th>Hazardous Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

Is the wastestream routinely analyzed to verify compositions? yes ___ no ___

Are laboratory results readily available? yes ___ no ___

Is the wastestream difficult to handle or dispose? yes ___ no ___

List the components of the stream that make its management a problem and the difficulties associated with the component. ____________________________________________________________

Describe the management practice for the wastestream:

☐ Stored onsite until a specific volume or quantity is generated
☐ Transported offsite immediately
☐ Treated onsite immediately
☐ Other ___________________________________________
Worksheet 4.2 (cont.)

How is the waste removed from the site (check all that apply)?

☐ Private waste hauler
☐ Recycler/reclaimer
☐ Public collection system
☐ Other ________________

Are manifests received from the hauler for off-site disposal? yes ___ no ___

Does the wastestream fall under any regulatory classifications? yes ___ no ___

Does the wastestream contain a valuable by-product or material that can be reused? yes ___ no ___

If yes, list the valuable components.

________________________________________________________________________

________________________________________________________________________

List all regulations applicable to the wastestream.

________________________________________________________________________

________________________________________________________________________

What is the final disposition of the wastestream?

☐ On-site recycle
☐ Off-site recycle
☐ Off-site reclamation
☐ Waste exchange
☐ Off-site incineration
☐ On-site incineration
☐ Off-site sanitary landfill
☐ On-site sanitary landfill
☐ Off-site hazardous waste landfill
☐ On-site hazardous waste landfill
☐ Other ________________

If recycled, treated, or incinerated on-site, what is final disposition of the residue?

☐ Off-site reclamation
☐ Waste exchange
☐ Off-site sanitary landfill
☐ On-site sanitary landfill
☐ Off-site hazardous waste landfill
☐ On-site hazardous waste landfill
☐ Other ________________
Worksheet 4.2 (cont.)

Complete the following table to determine total management cost of the wastestream.

<table>
<thead>
<tr>
<th>Cost Component:</th>
<th>Present Method</th>
<th>Cost Per Unit</th>
<th>Backup Method*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onsite storage and handling</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pretreatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Containerization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transport Fee</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Off-site management Fee</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Local Tax</td>
<td></td>
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<tr>
<td>State Tax</td>
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<td></td>
<td></td>
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<tr>
<td>Federal Tax</td>
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<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total management cost</strong></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

*The backup method is that alternative which would be used in the event that the present method becomes temporarily or permanently unavailable.

**Transfer the total management cost per unit and the total management cost to columns 3 and 4, respectively, in Worksheet 6.1 on page G-27 for each wastestream.
5.0 WASTE MINIMIZATION PROGRAM

5.1 Plant Operations and Management

Has the management of the plant committed itself to a waste reduction program? 
YES __ no __

Have any specific goals been set for this program? 
YES __ no __

If yes, what are these goals.
__________________________________________________________________________

Have these goals been achieved? 
YES __ no __

Are production schedules and product campaigns designed to decrease waste generation? 
YES __ no __

If yes, how successful has this practice been?  □ Very successful □ Limited success
□ Moderately successful □ Unsuccessful

Are process maintenance and cleaning activities scheduled together to avoid unnecessary cleaning? 
YES __ no __

Is preventative maintenance employed to reduce the risk of spills, leaks, and malfunction? 
YES __ no __

5.2 Employee Training

Is there a periodic operator training program in place at the plant? 
YES __ no __

How often is operator training performed?  □ Monthly □ Annually
□ Quarterly □ Other _____________

Is there a formal personnel training program in place for waste management? 
YES __ no __

How often is personnel training performed?  □ Monthly □ Annually
□ Quarterly □ Other _____________

Are there one or more plant employees designated for tracking wastestreams? 
YES __ no __

Who? __________________________
5.3 Employee Awareness

Are employee education programs used to minimize waste generation? YES no

Is there an employee incentive program for waste minimization? YES no

Are employees made aware of the disposal costs and liabilities associated with hazardous wastes? YES no

Are employees made aware of the causes of waste generation as it relates to their area of responsibility? YES no

Has the plant considered closer supervision of the workplace in order to reduce waste generation? YES no

5.4 Regulatory Awareness

Are plant personnel fully aware of all applicable federal, state, and local regulations? YES no

Is there a listing of all permits currently held by the plant? YES no

Is this list readily accessible? YES no

Who is in charge of preparing and submitting permit applications? ________________________________

5.5 Environmental Audits

Has the plant conducted an environmental audit to ensure compliance with all applicable regulations? YES no

What were the findings of this audit? __________________________________________________________
________________________________________________________
________________________________________________________

Have the recommendations of this audit been implemented? YES no

If not, why not? __________________________________________________________________________

If yes, describe what changes were made and the effects of these changes. __________________________
________________________________________________________
5.6 Waste Management and Reporting

Are each individual wastestream and its management costs tracked from beginning to end?       YES _ no _

Are waste manifests readily accessible?                                                   YES _ no _

Who is in charge of hazardous and nonhazardous waste manifests?                          

Are biennial hazardous waste reports prepared for the plant?                             YES _ no _

If yes, who prepares these reports?                                                     

Are copies readily accessible?                                                           YES _ no _

Has the plant conducted a waste audit or survey in the past?                             YES _ no _

What were the findings of this study?                                                   

Have the recommendations of this study been implemented?                                YES _ no _

If not, why not?                                                                          

If yes, describe what changes were made and the effects of these changes.              

WORKSHEET 5.1

For the waste minimization techniques listed below, indicate which are currently used at the plant.

<table>
<thead>
<tr>
<th>Waste Minimization Technique</th>
<th>In Use? (Yes/No)</th>
<th>Need¹</th>
<th>Potential for Implementation²</th>
<th>Score³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establishment of Waste Minimization goals</td>
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<tr>
<td>Production Scheduling</td>
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<tr>
<td>Operator/Employee Training</td>
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<tr>
<td>Employee Incentives</td>
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<tr>
<td>Closer Supervision</td>
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<tr>
<td>Waste Audit</td>
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<tr>
<td>Environmental Audit</td>
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</tbody>
</table>

1. Indicate the need of the technique on a scale of 1 to 5. Techniques that are most valuable or necessary to minimize a serious risk should be given a need of 1.

2. Indicate the potential for implementation of each technique not currently in use, based on economic or technological feasibility.

3. The score is determined by multiplying the need and potential scores together. Potential scores are as follows: high = 1, medium = 2, low = 3. The scores developed on this worksheet should be used to prioritize the implementation of the listed techniques. For those techniques with the lowest scores, an implementation plan should be developed and attached to this sheet.
6.0 WASTE MINIMIZATION OPPORTUNITIES

Have any waste minimization options been implemented?  YES  no

What were these and how well did they work? Provide quantities and percentage reductions if possible.

_________________________________________________________________
_________________________________________________________________
_________________________________________________________________
_________________________________________________________________
_________________________________________________________________

Are any waste minimization activities planned for the future?  YES  no

If yes, what are they and how effective are they expected to be?
_________________________________________________________________
_________________________________________________________________
_________________________________________________________________
_________________________________________________________________
_________________________________________________________________

Have any waste minimization options been considered but rejected?  yes  no

Identify what options were rejected and why.
_________________________________________________________________
_________________________________________________________________
_________________________________________________________________
_________________________________________________________________
_________________________________________________________________

6.1 SOURCE REDUCTION

Has product reformulation been investigated as a method of waste minimization?  YES  no
Has material substitution within manufacturing or processing operations been investigated as a method of waste minimization?  
YES ___ no ___

Has plant modernization been investigated as a method of waste minimization?  
YES ___ no ___

Has process redesign or automation been investigated as a method of waste minimization?  
YES ___ no ___

Are liquid and solid wastes separated?  
YES ___ no ___
Are hazardous and nonhazardous wastes separated?  YES ___ no ___

Are multistage cleaning systems used in the plant?  YES ___ no ___

6.1.1 Solvent Waste Minimization

Are solvent wastes segregated from aqueous wastes?  YES ___ no ___

Are different spent solvent wastestreams kept separate?  YES ___ no ___

Can chlorinated solvents be replaced by non-chlorinated solvents in plant operations?  YES ___ no ___

Can solvent-based cleaning solutions be replaced by aqueous-based cleaning solutions?  YES ___ no ___

Are biodegradable solvent substitutes available?  YES ___ no ___

If coated tablets or capsules are produced, can solvent-based processess be converted to aqueous-based operations?  YES ___ no ___
**Worksheet 6.1 Waste Management Cost Summary**

Fill out Worksheet 6.1 to determine the potential for waste minimization and cost savings at the plant.

<table>
<thead>
<tr>
<th>Wastestream</th>
<th>Quantity Generated</th>
<th>Waste Management Cost/Unit</th>
<th>Total Waste Management Cost</th>
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</thead>
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</table>

Total Quantity: ______________________  Total Cost: ______________________
Worksheet 6.2

For the source reduction techniques listed below, indicate which are currently in use.

<table>
<thead>
<tr>
<th>Source Reduction Techniques</th>
<th>In Use? (Yes/No)</th>
<th>Need¹</th>
<th>Potential for Implementation²</th>
<th>Score³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Reformulation</td>
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<tr>
<td>Material Substitution</td>
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<tr>
<td>Plant Modernization</td>
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<tr>
<td>Process Redesign</td>
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<tr>
<td>Process Automation</td>
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<tr>
<td>Wastestream Tracking</td>
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<tr>
<td>Wastestream Segregation</td>
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<td></td>
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<tr>
<td>Multistage Cleaning</td>
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</tbody>
</table>

1 Indicate the need of the technique on a scale of 1 to 5. Techniques that are most valuable or necessary to minimize a serious risk should be given a need of 1.

2 Indicate the potential for implementation of each technique not currently in use, based on economic or technological feasibility.

3 The score is determined by multiplying the need and potential scores together. Potential scores are as follows: high = 1, medium = 2, low = 3. The scores developed on this worksheet should be used to prioritize the implementation of the listed techniques. For those techniques with the lowest scores, an implementation plan should be developed and attached to this sheet.
6.2 RECYCLE AND RESOURCE RECOVERY

What steps are taken to improve waste recycling?

☐ Substitution with recyclable materials  ☐ Minimizing cross contamination
☐ Waste segregation  ☐ Other ____________________
☐ Minimizing dilution

6.2.1 Waste Solvents

Are spent solvents sent to an off-site recycler? yes ___ no ___

Are spent solvents recovered on site? yes ___ no ___

If not, has on-site solvent recovery been considered? yes ___ no ___

If yes, why was solvent recovery rejected? _______________________________________

____________________________________

If waste solvent generation is too small to justify recycling, can solvent usage be standardized, thereby generating recyclable solvent wastestreams? yes ___ no ___

6.2.2 Wastewater

Are wastewaters treated prior to discharge? yes ___ no ___

Can treated wastewaters be used for any of the following operations (check all that apply)?

☐ Container rinsing  ☐ Floor Washing
☐ Equipment Cleaning  ☐ Other ____________________

Is product recovered from process washwater? YES ___ no ___
6.2.3 Quality Control

What percentage of products are rejected by quality control?

Are rejected products from quality control recovered for use? YES ___ no ___

Are products rejected due to packaging errors (i.e., illegible labels) recovered for repackaging? YES ___ no ___

Can rejected products be separated from their packaging to permit easier waste management (i.e., sewer discharge as opposed to landfill)? yes___ no ___

6.2.4 Waste Exchanges and Reuse Opportunities

When blending solids, is the dust collected for recycle? YES ___ no ___

Has off-site recycle/reuse through waste exchange or waste brochure services been investigated? YES ___ no ___

If yes, what were the results? ____________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________

Have any attempts been made to blend various wastestreams to produce usable by-products? YES ___ no ___

Have you considered selling fermentation wastes as a protein source for animal feed supplement, fertilizer, or soil amendment? yes ___ no ___

Does the plant generate an ammonium chloride byproduct? yes ___ no ___

Have you considered recovering this byproduct for sale (e.g., as a sludge dewatering aid)? yes ___ no ___

Does the plant generate an ammonium sulfate byproduct? yes ___ no ___
Have you considered recovery of this byproduct for sale (e.g., to the glass industry)?  **YES** ___  **no** ___

**Worksheet 6.3**

For the recycle/recovery techniques listed below, indicate which are in use at the plant.

<table>
<thead>
<tr>
<th>Recycle/Recovery Techniques</th>
<th>In Use? (Yes/No)</th>
<th>Need¹</th>
<th>Potential for Implementation²</th>
<th>Score³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waste Exchange</td>
<td></td>
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<tr>
<td>On-Site Solvent Recycle</td>
<td></td>
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<tr>
<td>Off-Site Solvent Recycle</td>
<td></td>
<td></td>
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<tr>
<td>Product Recovery From Waste Waters</td>
<td></td>
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<tr>
<td>Dust Recycle</td>
<td></td>
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<td></td>
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<tr>
<td>Wastewater Treatment and Reuse</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Byproduct Recovery</td>
<td></td>
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</tbody>
</table>

¹ Indicate the need of the technique on a scale of 1 to 5. Techniques that are most valuable or necessary to minimize a serious risk should be given a need of 1.

² Indicate the potential for implementation of each technique not currently in use, based on economic or technological feasibility.

³ The score is determined by multiplying the need and potential scores together. Potential scores are as follows: high = 1, medium = 2, low = 3. The scores developed on this worksheet should be used to prioritize the implementation of the listed techniques. For those techniques with the lowest scores, an implementation plan should be developed and attached to this sheet.
6.3 ALTERNATIVE TREATMENTS

Have bench-scale treatability tests been performed on wastestreams in an attempt to reduce waste volumes or toxicities? YES ___ no ___

If yes, indicate which wastestreams were tested and give the result of the test. ____________________________________________________________________

_____________________________________________________________________________________

Does the plant management keep up to date regarding the latest treatment technologies for pharmaceutical related wastes? YES ___ no ___

For each of the treatment technologies listed below, indicate which are currently in use and what wastestreams are treated.

<table>
<thead>
<tr>
<th>Treatment Technology</th>
<th>In Use (Yes/No)</th>
<th>Wastestreams</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbon Adsorption</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxidation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ion Exchange</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Steam/Air Stripper</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Precipitation</td>
<td></td>
<td></td>
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<tr>
<td>Evaporation</td>
<td></td>
<td></td>
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<tr>
<td>Incineration</td>
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<tr>
<td>Biological Treatment</td>
<td></td>
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<tr>
<td>Combustion and Heat Recovery</td>
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</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX H

BIBLIOGRAPHY
Self-Audit Format Bibliography


APPENDIX I

PRE-VISIT QUESTIONNAIRE
PRE-VISIT QUESTIONNAIRE

1) **Facility Information**
   
   Company name: ___________________________________________
   
   Site location: ___________________________________________
   
   Contact(s) who will take part in the waste audit:
   
<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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2) **Overview of Operations**
   
   Briefly describe the activities conducted at this site:
   
   ___________________________________________
   
   ___________________________________________
   
   ___________________________________________
   
   ___________________________________________
   
   ___________________________________________
   
   How many employees work at the site? _____
   
   List the major products produced at the site:
   
   ___________________________________________
   
   ___________________________________________
   
   ___________________________________________
   
   ___________________________________________
   
   ___________________________________________
   
   ___________________________________________
What raw materials are used in the production of these products?

Briefly describe the types of equipment and operations used at the site:

What are the typical wastes generated by these operations?

Are there any planned changes to the facility and its operations in the near future?

If yes, briefly describe the proposed changes:
Briefly describe any research activities conducted at the facility: __________

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
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________________________________________________________________________

3) **Waste Minimization and Pollution Control Activities**

Briefly describe the waste minimization/management and pollution prevention equipment and programs currently in use: __________

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Are any additional waste minimization/management and pollution prevention activities planned for the near future? ______

Briefly describe these activities: __________

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
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________________________________________________________________________

4) **Regulatory History**

Are any current or proposed facility operations/activities subject to government regulation? ______
If yes, list these operations/activities:

__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________

List all key permits currently held:

__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
APPENDIX J

DATA GATHERING FORM
DATA GATHERING FORM -- DRUG MANUFACTURING AND PROCESSING

ICF Team: __________________________

Date of Visit: __________

Plant Identification

Firm Name: __________________________

Street Address: __________________________

Mailing Address: __________________________

EPA Identification Number: __________________________

Contacts

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(1) OVERVIEW OF OPERATIONS

Brief description of the activities conducted at this facility:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

How many employees work at the plant?

________________________________________________________________________
What types of skills and training do plant personnel have?

How old is the plant? How old is the process equipment?

Obtain a facility layout or create a sketch:
Is there room for new equipment? Where?


(2) RAW MATERIAL INFORMATION

Use provided sheets to record raw material data (include cleaning materials).

What are the hazardous components of the raw materials?


Are material safety data sheets available?


Where and how are raw materials stored?


What are the self-lives of the raw materials?
How are raw materials transferred to processes?

(3) PRODUCTS INFORMATION

What products are produced at the plant?

What is the required product purity?

What is the form of the final product (i.e., liquid, tablet, capsules)

What non-reactives are added to create drug formulations (e.g., fillers, diluents, lubricants, binders)? In what quantities?
What are the production rates?

How much revenue is generated from product sales?

What percentage of final products are off-spec? What is the main cause of off-spec products?

What is done with off-spec products?

Where and how are products stored? How are these transported off-site (include container types and transport modes)?
(4) PROCESS INFORMATION

(4a) General Information

Process descriptions: Obtain a process flow diagram or sketch one for each process line. Include emission sources. Obtain copies of design diagrams and vendor literature.
Are equipment lists and equipment specifications/operating manuals available for each unit operation?

Are material and energy balances available, including design and operating data, for each unit operation?

Are there any planned modifications to the current processes?

What are these changes and how will they impact waste generation?

(4b) Chemical Synthesis and Batch Fermentation

What type of process is used (e.g., chemical synthesis, solvent extraction from natural sources, fermentation)?

What type of reactor vessels are used (i.e. fermentors, plug-flow reactors, batch reactors)?
How many reactors are in use? What are their sizes?

What products are produced in each reactor?

How are multiple product batches scheduled for each reactor?

What is the operating schedule for each reactor (e.g., hours/day)?

Is equipment manufacturer data available?

Are reactor vent gasses scrubbed? What type of scrubber is used? How are the scrubber waters disposed? Do you have an air permit?
How long is the batch cycle or retention time?

Are bad batches encountered? What causes this? What happens to bad batches?

Is the reaction catalyzed? What is the catalyst?

How is spent catalyst disposed?

How often are reactor vessels cleaned?

Are squeegees or some other technique used to collect product for the vessel walls prior to cleaning?

What materials are used for cleaning?
Describe the cleaning process.

How are cleaning wastes disposed?

(4c) Filtration Equipment

Does the process include a filtration step? If yes, what is the purpose of the filtration?

What type of filtration equipment is used? (Include vendor information if available) How many units are in operation?

Is filtration continuous or batch?
What type of filter medium is used?

How often is filter medium changed out (# of batches)?

How much filter cake is produced? What is its composition?

How is the filter cake disposed?

How often is the equipment cleaned? How is it cleaned and how are wash materials disposed?

(4d) Product Recovery/Formulation

How are products recovered from the reactor effluent (e.g., solvent purification, filtration, solvent extraction, etc.?)
How often and for how long are product recovery processes operated?

How often is the product recovery equipment cleaned? How is it cleaned and how are wash materials disposed? Are squeegees used prior to cleaning?

Are coated tablets or capsules produced at this plant? If yes, do the coatings contain volatile organics? How are the coatings applied? How are coatings dried? Are emissions controlled during application? Are emission inventories available?

(4e) Solvent Usage

List solvent applications and the solvents used:

Are used solvents recovered and recycled? How are solvents recovered and how
efficient is the recovery process? Do you have an air permit?

How are solvent recovery wastes (i.e., distillation bottoms) disposed?

(5) WASTE GENERATION DATA

Use provided sheets to record wastestream data (include hazardous and non-hazardous waste, wastewater discharges, and air emissions).

Are there any particular waste streams that are difficult to handle or dispose? Are there particular components that cause the difficulties?

Are there any known fugitive releases? If yes, are estimates of emission rates available? Do you have air permits? Is air pollution control equipment in place? If yes, describe.

Where and how are wastes stored? How are these transported to disposal?
Note: wastestreams may include washwaters and disinfectants, spent fermentation medium, spent filter medium, wastewaters from solvent extraction, etc.
Are hazardous waste manifests and biennial hazardous waste reports available?

Are waste streams kept separated or are they combined? If yes, which streams are combined?

(6) SPILL CONTROL/ MANAGEMENT

Is there a spill control/management plan in use at the plant?

What materials/procedures are used for spill control?

How are spilled materials disposed?

Are plant operators and personnel trained in spill control/management?
(7) WASTE MINIMIZATION INFORMATION

Have any waste minimization options been implemented? What were these and how well did they work (percentage reduction in waste)?

____________________________________________________________________________________________________________________

____________________________________________________________________________________________________________________

____________________________________________________________________________________________________________________

____________________________________________________________________________________________________________________

Is any documentation available and can we have copies?

____________________________________________________________________________________________________________________

____________________________________________________________________________________________________________________

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Are any waste minimization activities planned for the future? If yes, what are they and how effective are they expected to be?

____________________________________________________________________________________________________________________

____________________________________________________________________________________________________________________

____________________________________________________________________________________________________________________

____________________________________________________________________________________________________________________

Have any waste minimization options been considered but rejected? Identify what options were rejected and why.

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____________________________________________________________________________________________________________________

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Is any documentation available for rejected options and can we have copies?

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What are the main operating constraints for each process?

____________________________________________________________________________________________________________________

____________________________________________________________________________________________________________________

____________________________________________________________________________________________________________________

____________________________________________________________________________________________________________________
Do you recover solvents?

Have you considered recovering product from reactor washwater?

Have you considered water-based tablet coatings?

Are cooling waters recycled and used as boiler feed?

Have you considered selling fermentation wastes as a protein source for animal feed supplement?

Have you considered treating wastewaters prior to discharge?

Do you generate an ammonium chloride byproduct? Have you considered recovering this byproduct of sale (e.g., as a sludge dewatering aid)?

Do you generate an ammonium sulfate byproduct? Have you considered recovering this byproduct for sale (e.g., as a fertilizer)?
Do you generate a sodium sulphate byproduct? Have you considered recovery of this byproduct for sale (e.g., to the glass industry)?

Waste minimization techniques currently used in this facility (ICF observations).

(8) REGULATORY INFORMATION

List all permits required for plant operations:

Are copies of permits and permit applications available?