Guides to Pollution Prevention

The Pharmaceutical Industry

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Notice

This report has been subjected to the U.S. Environmental Protection Agency’s peer and administrative review and approved for publication. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

This document is intended as advisory guidance only to pharmaceutical manufacturers in developing approaches for pollution prevention. Compliance with environmental and occupational safety and health laws is the responsibility of each individual business and is not the focus of this document.

Worksheets are provided for conducting waste minimization assessments of pharmaceutical manufacturing plants. Users are encouraged to duplicate portions of this publication as needed to implement a waste minimization program.
Foreword

Pharmaceutical manufacturing plants generate a variety of wastes during manufacturing, maintenance and housekeeping operations. While maintenance and housekeeping activities are similar from one plant to the next, the actual processes used in pharmaceutical manufacturing vary widely. The pharmaceutical industry is also highly competitive, so companies are often unwilling to divulge details pertaining to their processes. With this diversity of processes comes a similarly diverse set of waste streams. Typical waste streams include spent fermentation broths, process liquors, solvents, equipment washwaters, spilled materials, off-spec products, and used processing aids.

Reducing the generation of these wastes at the source, or recycling these wastes, will benefit pharmaceutical manufacturers by increasing product yields, reducing raw material needs, reducing disposal costs, and reducing the liabilities associated with hazardous waste management. This guide provides an overview of several pharmaceutical manufacturing processes and operations that generate waste and presents options for minimizing the generation of waste materials through source reduction and recycling in such cases where suitable opportunities exist. Because of the confidential nature of each company’s specific operation, only very general discussion of material substitution and process modification can be given. The intent is to stimulate the thinking of manufacturers about their own processes, rather than provide a comprehensive set of detailed recipes for reducing waste.
Acknowledgments

This guide is based on a waste audit study for the pharmaceutical industry performed by ICF Technology Inc. for the California Department of Health Services, under the direction of Benjamin Fries of the Alternative Technology Section, Toxic Substances Control Program. Teresa Harten of the U.S. Environmental Protection Agency, Office of Research and Development, Risk Reduction Engineering Laboratory, was the project officer responsible for the preparation of this manual, which was edited and produced by Jacobs Engineering Group Inc. Denise Luckhurst served as author of this manual.

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Their contributions are hereby gratefully acknowledged.

Much of the information in this guide that provides a national perspective on the issues of waste generation and minimization for pharmaceutical manufacturers was provided originally to the U.S. Environmental Protection Agency by Versar, Inc. and Jacobs Engineering Group Inc. in Waste Minimization - Issues and Options, volume ll, report NTIS No. PB87-114369 (1986).
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Section 1
Introduction

This guide is designed to provide pharmaceutical industry personnel with waste minimization options appropriate for this industry. It also provides worksheets for carrying out a waste minimization assessment of a pharmaceutical manufacturing plant. It is envisioned that this guide be used by pharmaceutical companies, particularly their plant operators and engineers. Others who may find this document useful are regulatory agency representatives, industry suppliers, and consultants.

In the following sections of this manual you will find:

- A profile of the pharmaceutical industry and the processes used by the industry (Section 2);
- Waste minimization options for pharmaceutical firms (Section 3);
- Waste minimization assessment guidelines and worksheets (Section 4);
- Appendices, containing:
  - Case studies of waste generation and waste minimization practices of pharmaceutical firms;
  - Where to get help: additional sources of information.

The worksheets and the list of waste minimization options were developed through assessments of three pharmaceutical manufacturing companies commissioned by the California Department of Health Services (Calif. DHS 1989). The operations, manufacturing processes, and waste generation and management practices were surveyed, and their existing and potential waste minimization options were characterized.

Overview of Waste Minimization

Waste minimization is a policy specifically mandated by the U.S. Congress in the 1984 Hazardous and Solid Wastes Amendments to the Resource Conservation and Recovery Act (RCRA). As the federal agency responsible for writing regulations under RCRA, the U.S. Environmental Protection Agency (EPA) has an interest in ensuring that new methods and approaches are developed for minimizing hazardous waste and that such information is made available to the industries concerned. This guide is one of the approaches EPA is using to provide industry-specific information about hazardous waste minimization. The options and procedures outlined can also be used in efforts to minimize other wastes generated in a business.

In the working definition used by EPA, waste minimization consists of source reduction and recycling. Of the two approaches, source reduction is considered preferable to recycling. While a few states consider treatment of waste an approach to waste minimization, EPA does not, and thus treatment is not addressed in this guide.

Waste Minimization Opportunity Assessment

EPA has developed a general manual for waste minimization in industry. The Waste Minimization Opportunity Assessment Manual (USEPA 1988) tells how to conduct a waste minimization assessment and develop options for reducing hazardous waste generation at a facility. It explains the management strategies needed to incorporate waste minimization into company policies and structure, how to establish a company-wide waste minimization program, conduct assessments, implement options, and make the program an ongoing one.

A Waste Minimization Opportunity Assessment (WMOA), sometimes called a waste minimization audit, is a systematic procedure for identifying ways to reduce or eliminate waste. The four phases of a waste minimization opportunity assessment are: planning and organization, assessment, feasibility analysis, and implementation. The steps involved are shown in Figure 1 and presented in more detail below. Briefly, the assessment consists of a careful review of a plant’s operations and waste streams and the selection of specific areas to assess. After a particular waste stream or area is established as the WMOA focus, a number of options with the potential to minimize waste are developed and screened. The technical and economic feasibility of the selected options are then evaluated. Finally, the most promising options are selected for implementation.

Planning and Organization Phase

Essential elements of planning and organization for a waste minimization program are: getting management commitment for the program; setting waste minimization goals; and organizing an assessment program task force.

Assessment Phase

The assessment phase involves a number of steps:

- Collect process and site data;
- Prioritize and select assessment targets;
- Select assessment team;
- Review data and inspect site;
- Generate options; and
- Screen and select options for further study.

Collect process and site data. The waste streams at a manufacturing plant should be identified and characterized.
Figure 1. The Waste Minimization Assessment Procedure.

The Recognized Need to Minimize Waste

Planning and Organization Phase
- Get management commitment
- Set overall assessment program goals
- Organize assessment program task force

Assessment Organization & Commitment to Proceed

Assessment Phase
- Collect process and site data
- Prioritize and select assessment targets
- Select people for assessment teams
- Review data and inspect site
- Generate options
- Screen and select options for further study

Feasibility Analysis Phase
- Technical evaluation
- Economic evaluation
- Select options for implementation

Assessment Report of Selected Options

Final Report, including Recommended Options

Implementation Phase
- Justify projects and obtain funding
- Installation (equipment)
- Implementation (procedure)
- Evaluate performance

Successfully Implemented Waste Minimization Projects

Repeat the Process

Select New Assessment Targets and Reevaluate Previous Options
Information about waste streams may be available from hazardous waste manifests, National Pollutant Discharge Elimination System (NPDES) reports, routine sampling programs and other sources.

Developing a basic understanding of the processes that generate waste at a site is essential to the WMOA process. Flow diagrams should be prepared to identify the quantity, types and rates of waste generating processes. Also, preparing material balances for the different processes can be useful in tracking various process components and identifying losses or emissions that may have been unaccounted for previously.

Prioritize and select assessment targets. Ideally, all waste streams in a manufacturing plant should be evaluated for potential waste minimization opportunities. If resources are limited, however, the plant manager may need to concentrate waste minimization efforts in a specific area. Such considerations as quantity of waste, hazardous properties of the waste, regulations, safety of employees, economics, and other characteristics need to be evaluated in selecting the target streams or operations.

Select assessment team. The team should include people with direct responsibility for and/or knowledge of the particular waste stream or area of the facility being assessed. Equipment operators and people involved in routine waste management should not be ignored.

Review data and inspect site. The assessment team evaluates process data in advance of the inspection. The inspection should follow the target process from the point where raw materials enter to the point where products and wastes leave. The team should identify the suspected sources of waste. This may include the production processes, maintenance operations, and storage areas for raw materials, finished products, and work in progress. The inspection may result in the formation of preliminary conclusions about waste minimization opportunities. Full confirmation of these conclusions may require additional data collection, analysis, and/or site visits.

Generate options. The objective of this step is to generate a comprehensive set of waste minimization options for further consideration. Since technical and economic concerns will be considered in the later feasibility step, no options are ruled out at this time. Information from the site inspection, as well as from trade associations, government agencies, technical and trade reports, equipment vendors, consultants, plant engineers, and operators may serve as sources of ideas for waste minimization options.

Both source reduction and recycling options should be considered. Source reduction may be accomplished through good operating practices, technology changes, input material changes, and product changes. Recycling includes use and reuse of water, solvents and other recyclable materials, where appropriate.

Screen and select options for further study. This screening process is intended to select the most promising options for a full technical and economic feasibility study. Through either an informal review or a quantitative decision-making process, options that appear marginal, impractical or inferior are eliminated from further consideration.

Feasibility Phase

An option must be shown to be technically and economically feasible in order to merit serious consideration for adoption at a facility. A technical evaluation determines whether a proposed option will work in a specific application. Both process and equipment changes need to be assessed for their overall effects on waste quantity and product quality. A major concern is the impact of any proposed changes on the product license. Minor changes may be implemented rather easily, but major changes may require review and approval of the revised process by the FDA. The time required for this activity may render some options non-feasible.

An economic evaluation is carried out using standard measures of profitability such as payback period, return on investment, and net present value. As in any other project, the cost elements of a waste minimization project can be broken down into capital and operating costs. Savings and changes in revenue also need to be considered, as do present and future cost avoidances. In cases of increasingly stringent government requirements, actions that increase the cost of production may be necessary.

Implementation Phase

An option that passes both technical and economic feasibility reviews should be implemented. The project can be turned over to the appropriate group for execution while the WMOA team, with management support, continues the process of tracking wastes and identifying other opportunities for waste minimization. Periodic reassessments may be conducted to see if the anticipated waste reductions were achieved. Data can be tracked and reported for each implemented idea in terms such as pounds of waste per production unit. Either the initial investigations of waste minimization opportunities or the reassessments can be conducted using the worksheets in this manual.

References
Section 2
Pharmaceutical Industry Profile

Industry Description

The primary charter of the pharmaceutical industry is to produce substances that have therapeutic value for humans and animals. The industry employs about 170,000 people and produces goods valued at over 39 billion dollars in 1987 (USDC 1989). Products of the industry are split into four categories, based on the Standard Industrial Classification (SIC) system (USOMB 1987), including medicinal chemicals and botanical products (SIC 2833) pharmaceutical preparations (SIC 2834), in vitro and in vivo diagnostic substances (SIC 2835) and biological products, except diagnostic substances (SIC 2836).

Process Descriptions

The pharmaceutical industry utilizes a vast array of complex batch-type processes and technologies in the manufacture of pharmaceutical products. Due to the diversity of these processes, it is impractical to provide a general set of waste minimization guidelines that would apply to all drug manufacturing.

Along with research and development, four common methods used in the manufacture of pharmaceuticals are considered:

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

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

Research and Development

Research and development (R&D) in the pharmaceutical industry encompasses several fields, including chemical research, microbiological research, and pharmacological research. The development of a new drug requires the cooperative efforts of a large number of trained personnel specializing in medicinal, organic, and analytical chemistry; microbiology; biochemistry; physiology; pharmacology; toxicology; chemical engineering; and pathology. As a result of this diverse nature of pharmaceutical research and development, a wide range of chemical and biological laboratory wastes are produced. Examples of the more common chemical wastes produced from pharmaceutical research and development include halogenated and non-halogenated solvents, photographic chemicals, radionuclides, bases, and oxidizers (Zanowiak 1982). Biopharmaceutical research also generates significant amounts of waste materials, including biological and medical wastes.

Chemical Synthesis

Most drugs today are produced by chemical synthesis. In a typical manufacturing plant, one or more batch reactor vessels is used in a series of reaction, separation and purification steps to make the desired end product. Numerous types of chemical reactions, recovery processes, and chemicals are employed in order to produce a wide variety of drug products, each conforming to its own rigid product specification.

Within a drug manufacturing plant, reaction vessels and ancillary equipment are often arranged into separate, dedicated process units, with these dedicated units being used for the highest throughput products. Some pharmaceutical products are manufactured in single product “campaigns,” which may last a few weeks or a few months depending upon the market for the product. During a campaign, operators or computerized controllers add the required reagents and monitor process functions (i.e., flow rate, pH, temperature) according to good manufacturing practice (GMP) protocols. At the end of a campaign, process equipment is thoroughly cleaned. Campaign schedules are tightly controlled to ensure timely product delivery and availability of raw materials and process equipment.

Chemicals used in chemical synthesis operations range widely and include organic and inorganic reactants and catalysts. In addition, manufacturers use a wide variety of solvents listed as priority pollutants (USEPA 1983); these are used for product recovery, purification, and as reaction media.

Waste streams from chemical synthesis operations are complex due to the varied operations and reactions employed. Virtually every step of an organic synthesis generates a mother liquor that contains unconverted reactants, reaction byproducts, and residual product in the organic solvent base. Acids, bases, cyanides, and metals may also be generated. Typically, the spent solvents are recovered onsite by distillation or extraction (Cooper 1983), which also generate solvent recovery wastes such as still bottom tars. The use of volatile solvents can also result in air emissions, which may be reduced by employing scrubbers or condensers to reclaim the solvent vapors. An aqueous waste stream results from miscible solvents, filtrates, concentrates, equipment cleaning, wet scrubbers, and spills. Because of the waste stream concentration or toxicity, pretreatment may be required prior to sewer discharge. Waste waters from synthesis processes typically have high biological oxygen demand (BOD), chemical oxygen demand (COD), and total
Natural Product Extraction

Natural product extraction is the production of pharmaceuticals from natural material sources such as roots, leaves, and animal glands. Such pharmaceuticals, which typically exhibit unique pharmacological properties, include allergy relief medicines, insulin, morphine, alkaloids, and papaverine. Another characteristic of natural product extraction is that the amount of finished drug product is small compared to the amount of natural source material used. During each process step, the volume of material being worked can greatly diminish to the point where 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 processes include precipitation, with lead and zinc being used as precipitating agents, and solvent extraction, where common solvents include ketones and alcohols. Solvents are used in product recovery to dissolve fats and oils which would contaminate the product. Ammonia, in solution or anhydrous forms, is often used for pH control, as are the hydroxides of various cations.

Wastes from natural product extraction include spent raw materials such as leaves and roots, water-soluble solvents, solvent vapors and waste waters. Extraction waste waters typically have low BOD, COD and TSS levels and a pH in the range of 6 to 8 (USEPA 1983).

Fermentation

Steroids, Vitamin B₁₂, and antibiotics are typically produced using batch fermentation processes (Resource Integration Systems et al.). Overall, fermentation processes consist of two major steps: inoculum and seed preparation and fermentation, followed by crude product recovery and purification.

Sterile inoculum preparation begins in the lab 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 slants, and shaker flasks. For further propagation, the cells are then transferred to a seed tank which 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.

To begin fermentation, a sterilized fermenter is charged with material from the seed tank through a series of sterilized lines and valves. Once these sterilized nutrient materials are added to the vessel, fermentation commences. During fermentation, the vessel contents are usually agitated and aerated with sterile air via a sparger. Dissolved oxygen content, pH, temperature and several other parameters are carefully monitored throughout the fermentation cycle.

Following cell maturation, the fermenter broth is often filtered to remove the solid residues resulting from the fermentation process. The filtrate is then processed to recover the desired product using solvent extraction, precipitation, and ion exchange or adsorption chromatography (Bailey and Ollis 1977).

In solvent extraction, the aqueous filtrate is contacted with an organic solvent, typically methylene chloride or butyl acetate, to transfer the product into the solvent phase. The product is recovered by further extraction processes, precipitation, or crystallization. In precipitation processes, the product is recovered directly from the treated fermenter broth. Ion exchange resins are used to remove products from the treated broth for additional purification steps prior to final isolation.

The fermentation process generates large volumes of wastes such as the spent aqueous fermentation medium and solid cell debris. The aqueous medium is very impure, containing unconsumed raw materials such as corn steep liquor, fish meal, and molasses. Filtration processes result in large quantities of solids in the form of spent filter cake which includes solid remains of the cells, filter aid, and some residual product. After product recovery, spent filtrate is discharged as waste water, augmented by waste water from equipment cleaning operations and fermenter vent gas scrubbing. Waste waters from fermentation operations typically have high BOD, COD and TSS levels with a pH range of 4 to 8 (USEPA 1983). Volatile solvents used in product recovery operations may release vapors to the air.

Formulation

Pharmaceutical formulation is the preparation of dosage forms such as tablets, capsules, liquids, parenterals, and creams and ointments. These formulations are discussed in this section and a complete listing of dosage forms is presented in Table 1.

Tablets account for over 90 percent of all medications taken orally (Zanowiak 1982) and are produced in three varieties: plain compressed, coated, and molded. The tablet form depends upon the desired release characteristics of the active ingredient, which can be slow, fast, or sustained. One way of controlling the release characteristics involves spraying or tumbling the tablets with a coating material.

Tablets are produced by blending the active ingredient with fillers, such as starch or sugar; and binders, such as corn starch. The blend is compressed following one of three production methods, including 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.

Direct compression utilizes a tablet press in which a die holds a measured amount of material and a punch 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 and 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 that
Table 1. Pharmaceutical Dosage Forms

<table>
<thead>
<tr>
<th>Dosage Form</th>
<th>Constituents, Properties</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Liquid solutions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>aromatics, waters</td>
<td>volatile solids or oils, water</td>
<td>flavoring agents, carminative action</td>
</tr>
<tr>
<td>liquors or solutions</td>
<td>water, chemicals</td>
<td>internally or externally formulating aids</td>
</tr>
<tr>
<td>syrups</td>
<td>sweetener, solvent, medicinal agent</td>
<td>flavoring agent, medicinal</td>
</tr>
<tr>
<td>elixirs</td>
<td>sweetened hydroalcoholic solution, may be medicated</td>
<td>flavor or medicinal</td>
</tr>
<tr>
<td>spirits, essences</td>
<td>alcohol, water, volatile substances</td>
<td>flavor or medicinal</td>
</tr>
<tr>
<td>tinctures</td>
<td>natural drugs, extracted with appropriate solvent</td>
<td>externally or internally formulating aids</td>
</tr>
<tr>
<td>collodions</td>
<td>pyroxylin in ether, medicinal agent (castor oil, camphor)</td>
<td>for external or internal use</td>
</tr>
<tr>
<td>liniments</td>
<td>oily or alcoholic solutions, suspensions</td>
<td>external for corn and bunions</td>
</tr>
<tr>
<td>muciages</td>
<td>colloidal polymer solutions</td>
<td>external with rubbing</td>
</tr>
<tr>
<td>parenteral solution</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>ophthalmic</td>
<td>sterile, isotonic, pH close to that of tears; viscosity builder</td>
<td>eye treatment</td>
</tr>
<tr>
<td>nasal</td>
<td>aqueous, isotonic, pH close to that of nasal fluid; sprays or drops</td>
<td>nose treatment</td>
</tr>
<tr>
<td>otic</td>
<td>glycerol-based</td>
<td>ear treatment</td>
</tr>
<tr>
<td>mouthwash, gargles</td>
<td>aqueous, antiseptic</td>
<td>refreshment, short-term bacterial control</td>
</tr>
<tr>
<td>inhalations</td>
<td>administered with mechanical devices</td>
<td>medication of trachea or bronchioles</td>
</tr>
<tr>
<td>enemas, douches</td>
<td>aqueous solution or suspension, may include medicinal agent</td>
<td>irrigation of body cavity</td>
</tr>
<tr>
<td><strong>Liquid dispersions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>suspensions</td>
<td>powder suspended in water, alcohol, glycol, or an oil; viscosity builders, wetting agents, preservatives</td>
<td>oral dosing, skin application</td>
</tr>
<tr>
<td>emulsions, lotions</td>
<td>oil-in-water (o/w), or water-in-oil (w/o)</td>
<td>oral, external or injection</td>
</tr>
<tr>
<td>gels, jellies, magmas</td>
<td>viscous, colloidal dispersions</td>
<td>internal (oral), external</td>
</tr>
<tr>
<td>gaseous solutions, dispersion</td>
<td>delivered in atomizers, nebulizers, aerosols, inhalers</td>
<td>external or internal</td>
</tr>
<tr>
<td><strong>Semisolid and plastic dispersions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ointments</td>
<td>hydrocarbon (oily), absorbptive water-washable, or water-soluble bases; emulsifying agents; glycols; medicating agent</td>
<td>external</td>
</tr>
<tr>
<td>pastes and cerates</td>
<td>ointments with high dispersed solids or waxes, respectively</td>
<td>external</td>
</tr>
<tr>
<td>suppositories</td>
<td>theobroma oil, glycerinated gelatin, or polyethylene glycol base plus medicinal agent</td>
<td>insertion in body cavity</td>
</tr>
<tr>
<td><strong>Solids</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>bulk powder</td>
<td>comminuted or blended, dissolved in or mixed with water</td>
<td>external, internal</td>
</tr>
<tr>
<td>effervescent powder</td>
<td>CO₂-releasing base ingredients</td>
<td>oral</td>
</tr>
<tr>
<td>dusting powder</td>
<td>contain also 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 of unstable products</td>
<td>various uses, including parenteral and oral</td>
</tr>
</tbody>
</table>
cannot be directly compressed. Slugging requires heavy duty tablet presses to compress relatively large 20 to 30 gram tablets which are ground and screened to a desired mesh size, then recompressed into final tablets.

After tablets, capsules, prepared in hard or soft form, are the next most widely used oral dosage form for solid drugs. Hard capsules consist of two separate pieces which 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.

Unlike hard capsules, soft capsules are prepared by placing two continuous gelatin films between rotary die plates. As the plates are brought together and sealed to form the two halves of the capsule, the drug, usually a nonaqueous solution or soft mass, is injected into the capsule.

The third type of pharmaceutical formulation is the liquid dosage form prepared for injection or oral use, which includes solutions, syrups, elixirs, suspensions, and tinctures, all of which are usually prepared by mixing the solutes with a selected solvent in a glass-lined or stainless steel vessel. Solutions are then filtered and pumped into storage tanks for quality control inspection prior to packaging in final containers. Suspensions and emulsions are frequently prepared using colloid mills and homogenizers.

Liquid dosage forms are prepared with preservatives to prevent mold and bacteria growth, but they do not require sterilization if they are intended for oral or topical use. However, prescriptions and formulations for ophthalmic use must be sterilized, and are, therefore, prepared in a manner similar to parenteral products.

Parenteral dosage forms are injected into the body either intramuscularly, intravenously, or subcutaneously. Parenterals are prepared as solutions, as dry solids which are dissolved immediately before injection, as suspensions, as dry insoluble solids which are suspended before injection, and as emulsions. The injection vehicle is usually aqueous but can be nonaqueous. Terminal sterilization of parenteral dosages is performed as soon as possible after tilling and sealing of the product container, usually using moist heat in a steam autoclave. Products which are degraded by heat can be passed through bacteria-retaining filters into sterile containers, which are then sealed under aseptic conditions.

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

Waste Streams

The wastes generated during these various formulation processes result from cleaning and sterilizing equipment, chemical spills, rejected products and the processes themselves. During mixing or tableting operations, dusts can be generated which are recycled back into the formulation process, though small amounts of waste dust may be generated. The primary waste water source is equipment washwater which may contain inorganic salts, sugars, and syrups and typically has low BOD, COD, and TSS, with near neutral pH. Air emissions may result from the use of any volatile solvents in the formulation process. Table 2 lists typical waste and their process origins.
### Table 2. Pharmaceutical Process Wastes

<table>
<thead>
<tr>
<th>Waste Description</th>
<th>Process Origin</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process liquors</td>
<td>Organic syntheses</td>
<td>Contaminated solvents</td>
</tr>
<tr>
<td>Spent fermentation broth</td>
<td>Fermentation processes</td>
<td>Contaminated water</td>
</tr>
<tr>
<td>Spent natural product raw materials</td>
<td>Natural product extraction processes</td>
<td>Leaves, tissues</td>
</tr>
<tr>
<td>Spent aqueous solutions</td>
<td>Solvent extraction processes</td>
<td>Contaminated water</td>
</tr>
<tr>
<td>Leftover raw material containers</td>
<td>Unloading of materials into process equipment</td>
<td>Sags, drums (fiber, plastic, metal), plastic bottles</td>
</tr>
<tr>
<td>Scrubber water from pollution control equipment</td>
<td>Dust or hazardous vapor generating processes</td>
<td>Contaminated water</td>
</tr>
<tr>
<td>Volatile organic compounds</td>
<td>Chemical storage tanks, drums</td>
<td>Solvents</td>
</tr>
<tr>
<td>Off-spec or out-dated products</td>
<td>Manufacturing operations</td>
<td>Miscellaneous products</td>
</tr>
<tr>
<td>Spills</td>
<td>Manufacturing and lab operations</td>
<td>Miscellaneous chemicals</td>
</tr>
<tr>
<td>Waste water</td>
<td>Equipment cleaning, extraction residues</td>
<td>Contaminated water</td>
</tr>
<tr>
<td>Spent solvents</td>
<td>Solvent extraction or wash practices</td>
<td>Contaminated solvents</td>
</tr>
<tr>
<td>Used production materials</td>
<td>Manufacturing operations</td>
<td>Filters, tubing, diatomaceous earth</td>
</tr>
<tr>
<td>Used chemical reagents</td>
<td>R &amp; D operations</td>
<td>Miscellaneous chemicals</td>
</tr>
<tr>
<td>Natural gas combustion products</td>
<td>Steam boilers</td>
<td>Carbon compounds, oxides of nitrogen and sulfur</td>
</tr>
</tbody>
</table>

### References


Section 3
Waste Minimization Options for Pharmaceutical Facilities

Introduction

The pharmaceutical industry is characterized by a low ratio of finished products to raw materials (USEPA 1983), in particular, among drugs produced by natural product extraction and fermentation. Depending on the processes and materials involved, large amounts of extraction waste and fermentation media are generated which may contain hazardous components. The primary waste streams associated with pharmaceutical operations are listed in Table 3, along with suggested waste minimization options. Source reduction is always the most desirable option with recycling, the reuse or reclamation of part or all of a waste stream, being the next desired option. Both source reduction options and recycling options suited to pharmaceutical manufacturing are discussed in this section.

In addition to the specific recommendation provided below, rapidly advancing technology makes it important that companies continually educate themselves about improvements that are waste reducing and pollution preventing. Information sources to help inform companies about such technology include trade associations and journals, chemical and equipment suppliers, equipment expositions, conferences, and industry newsletters. By keeping abreast of changes and implementing applicable technology improvements, companies can often take advantage of the dual benefits of reduced waste generation and a more cost efficient operation.

Source Reduction

Source reduction of hazardous wastes can be achieved in industry through changes in products, raw materials, process technologies, or procedural and organizational practices. Various source reduction alternatives, including material substitution, process modification, and good operating practices, are provided here. Pharmaceutical manufacture is a diverse and highly competitive industry. Because of the highly specific and often confidential nature of each company’s specific operations, only very general discussions of material substitution and process modification can be given. The intent is to stimulate the thinking of manufacturers about their own processes.

Material Substitution

Material substitution is a change in one or more of the raw materials used in production in order to reduce the volume or toxicity of waste generated. For the pharmaceutical industry, however, product reformulation is likely to be very difficult due to the testing required to ensure that the reformulation has the same therapeutic effect, stability and purity profile as the original drug. Furthermore, a consider-
Table 3. Waste Minimization Methods for the Pharmaceutical Industry

<table>
<thead>
<tr>
<th>Waste Stream</th>
<th>Waste Minimization Methods</th>
</tr>
</thead>
</table>
| Containers            | Return empties to supplier
|                       | Thoroughly empty and triple rinse with minimal water
|                       | Use containers with recyclable liners
|                       | Segregate solid waste
|                       | Collect and reuse plastic from in-house molding
| Air Emissions         | Control bulk storage air emissions (e.g. internal floating roofs).
|                       | Use dedicated dust collectors and rework dust back into product
|                       | Optimize fossil fuel combustion
|                       | Use dedicated vent condensers and return condensate to source, where possible
|                       | Maintain \( N_2 \) purge rates at minimum through vapor space of agitated reactors
| Equipment Cleaning Wastes | Maximize number of campaigns to reduce cleaning frequency |
|                       | Use final rinse as prerinse on next cleaning cycle
|                       | Use wiper blades and squeegees and rework remainders into products
|                       | Use low volume, high efficiency cleaning (e.g. spray heads)
| Spills and Area Washdown | Use dedicated vacuum systems |
|                       | Use dry cleaning methods
|                       | Use recycled water
| Off-spec Products      | Rework off-spec material
|                       | Use automated processing systems
| Solvents              | Substitute aqueous systems where possible
|                       | Reduce quantity of solvent used
|                       | Regenerate/recover spent solvent
| Production Materials   | Validate cleaning and reuse

Another process modification option is to redesign chemical transfer systems to reduce physical material losses. For example, replacing gas pressurization with a pumped transfer eliminates the tank pressurizing step and its associated material losses (ICF 1987). Other design considerations for waste minimization include modifying tank and vessel dimensions to improve drainage, installing internal recycle systems for cooling waters and solvents, selecting new or improved catalysts, switching from batch to continuous processes for solvent recovery, and optimizing process parameters to increase operating efficiency.

In one case, excessive solvent emissions from the purging of autoclaves used for the manufacture of synthetic steroids were considerably reduced by installing rotameters with integral needle valves to control nitrogen flow into the reactor. Nitrogen flow and resulting solvent vapor pickup were reduced by a factor of six, compared to the baseline situation where nitrogen flow was not controlled and operated in an on/off fashion without throttling.

While process modification can result in significant waste reduction, there may be major obstacles to this approach to waste minimization. Extensive process changes can be expensive; downtime will occur when production is stopped for new equipment installation; and new processes must be tested and validated to ensure that the resulting product is acceptable. In addition, to the extent that processes and process equipment are specified in an approved drug application, FDA approval is likely to be required prior to instituting any changes.

Good Operating Practices

The good operating practices listed in Table 4 can help reduce hazardous and other waste generation and material losses.

Management Incentives. Because of rising disposal costs and environmental responsibilities, many firms are now instituting environmental programs. Management initiatives can encourage new ideas from knowledgeable employees, which result in reduction or recycling of waste.

Employee Training. To be effective, a waste management program must contain an employee training program so that all personnel operating equipment or handling wastes are trained in safe operating procedures, proper equipment use, process control specifications, and industrial hygiene. This training should occur prior to job assignment and continue during the period of employment for all supervisors, lead persons and operators.

Employees need to be informed of the materials that 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, equipment operation, material handling, and spill cleanup. Employees should be taught methods for detecting chemical releases and be briefed on regulatory requirements.

Regularly scheduled drills and safety meetings are a necessary part of employee training, as is supervisory review of industrial hygiene, material handling, and emergency practices. Employees should be aware of waste disposal costs.
and liabilities, and they should understand the causes of waste generation and potential process upsets.

**Closer Supervision.** Closer supervision of plant personnel and operations can increase production efficiency and reduce waste generation by reducing material losses, spills, and production of off-spec products. Coordination within the overall plant operation can, in turn, increase opportunities for early detection of mistakes.

**Production Scheduling.** Effective production and maintenance scheduling can help reduce waste generation. Proper scheduling ensures raw materials are used before expiration and products are recovered and processed efficiently, while maintenance scheduling makes sure that work is done on equipment at a time least likely to result in product losses. Minimization of equipment cleaning requirement should be one of the objectives of production scheduling.

**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; control parameters; job responsibilities; and potential personnel hazards. The manual also should outline effluent sampling procedures and equipment failure procedures. Having and using accurate procedural guidelines will reduce waste generation during maintenance or emergency shutdowns.

**Materials Tracking and Inventory Control.** A significant contributor to hazardous waste generation is overstocking inventory. Accurate material, product, and waste tracking improves material handling and storage procedures. A computerized inventory system can assist in controlling and tracking materials and thus in reducing overstocking. Using inventory on a first-in/first-out basis minimizes waste from expired chemicals. Some suppliers will take back expired chemicals.

**Spill Prevention.** Spillage or leakage of hazardous chemicals generates hazardous wastes: liquid waste from washing spilled toxic chemicals, and solid waste from cleanup using absorbent materials. Spill and leak prevention are critical to waste minimization, and a properly trained and equipped spill control team is needed to prevent or contain spills. Methods of reducing or preventing spills include: conducting hazard assessment studies; using properly designed storage tanks and process vessels; equipping all liquid containers with overflow alarms; and testing alarms periodically. Also, steps should be taken to maintain the physical integrity of containers; set up administrative controls; and install sufficient secondary containment. Other preventive measures include having a good valve layout; having interlock devices to stop flow to leaking sections; not allowing the operators to bypass interlocks or alter set points; and isolating equipment or process lines that are not in service. Finally, spills and their related dollar values should be documented in relation to overall operating efficiency.

**Material Handling and Storage Procedures.** Proper handling and storage ensures that raw materials reach the production process and products and wastes leave the process without spills, leaks, or other forms of waste generation. For small operations, 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 gallons) for storage. All storage containers should clearly identify the material in the container and display health hazard warnings, storage, handling, first aid, and spill procedures. Material Safety Data Sheets (MSDSs), which provide proper handling and safety information, should be available to all employees working with hazardous materials.

**Maintenance Programs.** A proper maintenance program, which includes preventive as well as corrective maintenance, can minimize waste generation caused by equipment failure or mechanical breakdown and can cut costs stemming from equipment repairs, waste disposal, and business interruptions.

Preventive maintenance programs can reduce the incidence of equipment breakdown and malfunction by routinely cleaning, making minor adjustments, lubricating, testing, measuring, and replacing minor parts. Typically, equipment data cards, master preventive maintenance schedules, deferred preventive maintenance reports, equipment history cards, and equipment breakdown reports are used as record-keeping documents.

Corrective maintenance repairs the unexpected failures as they occur and collects data for use in determining maintenance demand. Maintenance and operating data sheets should be prepared for each piece of equipment.

**Waste Stream Segregation.** Hazardous waste hauled off-site is often a mixture of two or more waste streams. Waste stream segregation involves separating hazardous materials from nonhazardous materials; sorting hazardous waste by contaminant; and separating liquid from solid waste. This segregation reduces waste haulage volumes, simplifies disposal, and facilitates recovery and recycle.

Recovery and Recycle

Recovering and recycling includes direct reuse of waste material, recovering used materials for a separate use, and removing impurities from waste to obtain relatively pure substances. The goal is to recover materials for reuse in the
process or for reuse in a different application. The strict quality control requirements of the pharmaceutical industry often restrict reuse opportunities, though some do exist. After a high degree of purification, materials recovered from manufacturing processes may be reused. Recycling can be performed either on-site or off-site. On-site recycling can be either integral to an operation or in a separate operating area.

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; and
- lower unit costs for raw materials use.

Disadvantages include:
- capital expenditure for recycling equipment;
- additional operating and maintenance costs;
- potential additional permitting requirements;
- increased operator training; and
- increased risks to workers.

The last three disadvantages do not apply when recycling is included in the initial design of a process.

Off-site recycling, performed at commercial recycling facilities, is well suited for small quantity generators and firms which cannot accept the technical, economic, and managerial requirements of on-site recycling. The recycler may charge the generator a straight fee or may base fees on waste volumes and in some instances, may credit the generator for the value of saleable wastes. The value of a waste depends on the type, market, purity, quantity and frequency of generation, and distance between the generator and the recycling operation.

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 recycling is more likely to be the alternative chosen (Calif. DHS 1986). Because generators can be held liable for future clean-up cost of wastes leaving their plants, it is important to select a recycler that is reliable.

Table 5. Solvents Commonly Used in Pharmaceutical Manufacturing

<table>
<thead>
<tr>
<th>Solvent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
</tr>
<tr>
<td>Cyclohexane</td>
</tr>
<tr>
<td>Methylene Chloride</td>
</tr>
<tr>
<td>Ethyl Acetate</td>
</tr>
<tr>
<td>Butyl Acetate</td>
</tr>
<tr>
<td>Methanol</td>
</tr>
<tr>
<td>Ethanol</td>
</tr>
<tr>
<td>Isopropanol</td>
</tr>
<tr>
<td>Butanol</td>
</tr>
<tr>
<td>Pyridine</td>
</tr>
<tr>
<td>Methyl Ethyl Ketone</td>
</tr>
<tr>
<td>Methyl Isobutyl Ketone</td>
</tr>
<tr>
<td>Tetrahydrofuran</td>
</tr>
</tbody>
</table>

Source: Calif. DHS 1986.

chlorofluorocarbons 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.

Waste Exchanges

An alternative to recycling is waste exchange, which involves the transfer of a waste to another company for use as is or for reuse after treatment. Waste exchanges are private or government-subsidized organizations that help to identify the supply and demand of various wastes. Appendix B lists exchanges currently in operation.

Three types of waste exchanges are available: information exchanges, material exchanges, and waste brokers. Information exchanges are clearing houses for information on supply and demand, and typically publish a newsletter or catalog. Material exchanges take temporary possession of a waste for transfer to a third party, in contrast to waste brokers, who do not take possession of the waste but charge a fee to locate buyers or sellers.

Because of their high recovery value, metals and solvents are the most frequently recycled materials via waste exchange. Other wastes commonly recycled through waste exchanges include acids, alkalis, salts and other inorganic chemicals, organic chemicals, and metal sludges. Of the total materials listed with waste exchanges, approximately 20 to 30 percent are actually exchanged (Calif. DHS 1989).

References


Section 4
Waste Minimization
Assessment Worksheets

The worksheets provided in this section are intended to assist pharmaceutical manufacturers in systematically evaluating waste generation processes and in identifying waste minimization opportunities. These worksheets include only the waste minimization assessment phase of the procedure described in the Waste Minimization Opportunity Assessment Manual. A comprehensive waste minimization assessment includes planning and organization, gathering background data and information, a feasibility study of specific waste minimization options, and an implementation phase.

In addition, performance of a material balance on each major waste generating process is recommended. For a full description of waste minimization assessment procedures, refer to the manual.

Table 6 lists the worksheets that are provided in this section. After completing the worksheets, the assessment team should evaluate the applicable waste minimization options and develop an implementation plan.

<table>
<thead>
<tr>
<th>NO.</th>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Waste Sources</td>
<td>Checklist of significant wastes</td>
</tr>
<tr>
<td>2a.</td>
<td>Waste Minimization: Material Handling</td>
<td>Questionnaire for material handling techniques</td>
</tr>
<tr>
<td>2b.</td>
<td>Waste Minimization: Material Handling</td>
<td>Questionnaire on bulk liquids handling</td>
</tr>
<tr>
<td>2c.</td>
<td>Waste Minimization: Material Handling</td>
<td>Questionnaire on drums, containers and packages</td>
</tr>
<tr>
<td>3.</td>
<td>Input Materials Summary</td>
<td>Questionnaire on raw materials and supplies</td>
</tr>
<tr>
<td>4.</td>
<td>Products Summary</td>
<td>Questionnaire on products manufactured</td>
</tr>
<tr>
<td>5.</td>
<td>Option Generation: Material Handling</td>
<td>Waste minimization options checklist</td>
</tr>
<tr>
<td>6a.</td>
<td>Process Description</td>
<td>Questionnaire on processing operations</td>
</tr>
<tr>
<td>6b.</td>
<td>Process Description</td>
<td>Questionnaire on processing operations</td>
</tr>
<tr>
<td>6c.</td>
<td>Process Description</td>
<td>Questionnaire on processing operations</td>
</tr>
<tr>
<td>6d.</td>
<td>Process Description</td>
<td>Questionnaire on processing operations</td>
</tr>
<tr>
<td>6e.</td>
<td>Process Description</td>
<td>Questionnaire on processing operations</td>
</tr>
<tr>
<td>7a.</td>
<td>Waste Stream Summary</td>
<td>Relative importance of sources</td>
</tr>
<tr>
<td>7b.</td>
<td>Waste Description</td>
<td>Questionnaire on waste stream characteristics</td>
</tr>
<tr>
<td>6.</td>
<td>Waste Minimization: Reuse and Recovery</td>
<td>Checklist of waste reuse and recovery techniques</td>
</tr>
<tr>
<td>10.</td>
<td>Waste Minimization: Good Operating Practices</td>
<td>Checklist for waste minimization techniques</td>
</tr>
<tr>
<td>11.</td>
<td>Option Generation: Good Operating Practices</td>
<td>Waste minimization options for good operating practices</td>
</tr>
</tbody>
</table>
## WASTE SOURCES

### Waste Source: Material Handling

<table>
<thead>
<tr>
<th>Waste Source</th>
<th>Significance at Plant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low</td>
</tr>
<tr>
<td>Off-spec materials</td>
<td></td>
</tr>
<tr>
<td>Obsolete raw materials</td>
<td></td>
</tr>
<tr>
<td>Obsolete products</td>
<td></td>
</tr>
<tr>
<td>Spills &amp; leaks (liquids)</td>
<td></td>
</tr>
<tr>
<td>Spills (powders)</td>
<td></td>
</tr>
<tr>
<td>Empty container cleaning</td>
<td></td>
</tr>
<tr>
<td>Container disposal (metal)</td>
<td></td>
</tr>
<tr>
<td>Container disposal (paper, plastic)</td>
<td></td>
</tr>
<tr>
<td>Pipeline/tank drainage</td>
<td></td>
</tr>
<tr>
<td>Laboratory wastes</td>
<td></td>
</tr>
<tr>
<td>Evaporative losses</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

### Waste Source: Process Operations

<table>
<thead>
<tr>
<th>Waste Source</th>
<th>Significance at Plant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low</td>
</tr>
<tr>
<td>Tank cleaning</td>
<td></td>
</tr>
<tr>
<td>Container cleaning</td>
<td></td>
</tr>
<tr>
<td>Blender cleaning</td>
<td></td>
</tr>
<tr>
<td>Process equipment cleaning</td>
<td></td>
</tr>
</tbody>
</table>

---

*htm/par/ws1*
## WASTE MINIMIZATION: Material Handling

### A. GENERAL HANDLING TECHNIQUES

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are all raw materials tested for quality before being accepted from suppliers?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Describe safeguards to prevent the use of materials that may generate off-spec product:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is obsolete raw material returned to the supplier?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is inventory used in first-in first-out order?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the inventory system computerized?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the current inventory control system adequately prevent waste generation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What information does the system track?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there a formal personnel training program on raw material handling, spill prevention, proper storage techniques, and waste handling procedures?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the program include information on the safe handling of the types of drums, containers and packages received?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How often is training given and by whom?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is dust generated in the storage area during the handling of raw materials?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes, is there a dedicated dust recovery system in place?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are methods employed to suppress dust or capture and recycle dust?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explain:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
WORKSHEET

WASTE MINIMIZATION:
Material Handling

B. BULK LIQUIDS HANDLING

What safeguards are in place to prevent spills and avoid ground contamination during the transfer and filling of storage and blending tanks?

- High level shutdown/alarms
- Flow totalizers with cutoff
- Secondary containment
- Other

Describe the system:

Are air emissions from solvent storage tanks controlled by means of:

- Conservation vents
- Nitrogen blanketing
- Absorber/Condenser
- Other vapor loss control system

Describe the system:

Are all storage tanks routinely monitored for leaks? If yes, describe procedure and monitoring frequency for above-ground/vaulted tanks:

Underground tanks:

How are the liquids in these tanks dispensed to the users? (i.e., in small containers or hard-piped.)

What measures are employed to prevent the spillage of liquids being dispensed?

Are pipes cleaned regularly? Also discuss the way pipes are cleaned and how the resulting waste is handled:

When a spill of liquid occurs in the plant, what cleanup methods are employed (e.g., wet or dry)? Also discuss the way in which the resulting wastes are handled:

Would different cleaning methods allow for direct reuse or recycling of the waste? (explain)
<table>
<thead>
<tr>
<th>Attribute</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material Name/ID</td>
<td></td>
</tr>
<tr>
<td>Source/Supplier</td>
<td></td>
</tr>
<tr>
<td>Hazardous Component</td>
<td></td>
</tr>
<tr>
<td>Annual Consumption Rate</td>
<td></td>
</tr>
<tr>
<td>Purchase Price, $ per</td>
<td></td>
</tr>
<tr>
<td>Overall Annual Cost</td>
<td></td>
</tr>
<tr>
<td>Material Flow Diagram available (Y/N)</td>
<td></td>
</tr>
<tr>
<td>Delivery Mode 1</td>
<td></td>
</tr>
<tr>
<td>Shipping Container Size &amp; Type 2</td>
<td></td>
</tr>
<tr>
<td>Storage Mode 3</td>
<td></td>
</tr>
<tr>
<td>Transfer Mode 4</td>
<td></td>
</tr>
<tr>
<td>Control Mode 5</td>
<td></td>
</tr>
<tr>
<td>Empty Container Disposal/Management 6</td>
<td></td>
</tr>
<tr>
<td>Shelf Life</td>
<td></td>
</tr>
<tr>
<td>Supplier Would</td>
<td></td>
</tr>
<tr>
<td>• accept expired material (Y/N)</td>
<td></td>
</tr>
<tr>
<td>• accept shipping containers (Y/N)</td>
<td></td>
</tr>
<tr>
<td>• revise expiration date (Y/N)</td>
<td></td>
</tr>
<tr>
<td>Acceptable Substitute(s), If any</td>
<td></td>
</tr>
<tr>
<td>Alternate Supplier(s)</td>
<td></td>
</tr>
</tbody>
</table>

1 e.g., pipeline, tank car, 100 bbl. tank truck, truck, etc.
2 e.g., 55 gal. drum, 100 lb. paper bag, tank, etc.
3 e.g., outdoor, warehouse, underground, aboveground, etc.
4 e.g., pump, forklift, pneumatic transport, conveyor, etc.
5 e.g., on-demand to all, select people only, sign out.
6 e.g., crush and landfill, clean and recycle, return to supplier, etc.
# PRODUCTS SUMMARY

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Stream No.</td>
</tr>
<tr>
<td>Name/ID</td>
<td></td>
</tr>
<tr>
<td>Hazardous Component</td>
<td></td>
</tr>
<tr>
<td>Annual Production Rate</td>
<td></td>
</tr>
<tr>
<td>Annual Revenues, $</td>
<td></td>
</tr>
<tr>
<td>Shipping Mode</td>
<td></td>
</tr>
<tr>
<td>Shipping Container Size and Type</td>
<td></td>
</tr>
<tr>
<td>On-site Storage Mode</td>
<td></td>
</tr>
<tr>
<td>Containers Returnable (Y/N)</td>
<td></td>
</tr>
<tr>
<td>Shelf Life</td>
<td></td>
</tr>
<tr>
<td>Re-work Possible (Y/N)</td>
<td></td>
</tr>
<tr>
<td>Customer would:</td>
<td></td>
</tr>
<tr>
<td>• Relax specification (Y/N)</td>
<td></td>
</tr>
<tr>
<td>• Accept larger containers (Y/N)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**WORKSHEET 5**

**OPTION GENERATION:**
Material Handling

Meeting Format (e.g., brainstorming, nominal group technique) ____________________
Meeting Coordinator ____________________
Meeting Participants ____________________

<table>
<thead>
<tr>
<th>Suggested Waste Minimization Options</th>
<th>Currently Done Y/N?</th>
<th>Rationale/Remarks on Option</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. General Handling Techniques</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality Control Check</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Return Obsolete Material to Supplier</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minimize Inventory</td>
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<tr>
<td>Computerize Inventory</td>
<td></td>
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<tr>
<td>Formal Training</td>
<td></td>
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<tr>
<td><strong>B. Bulk Liquids Handling</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Level Shutdown/Alarm</td>
<td></td>
<td></td>
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<tr>
<td>Flow Totalizers with Cutoff</td>
<td></td>
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<tr>
<td>Secondary Containment</td>
<td></td>
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<tr>
<td>Air Emission Control</td>
<td></td>
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<tr>
<td>Leak Monitoring</td>
<td></td>
<td></td>
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<tr>
<td>Spilled Material Reuse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cleanup Methods to Promote Recycling</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>C. Drums, Containers, and Packages</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raw Material Inspection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper Storage/Handling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prewheighed Containers</td>
<td></td>
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<tr>
<td>Soluble Bags</td>
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<td></td>
</tr>
<tr>
<td>Reusable Drums</td>
<td></td>
<td></td>
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<tr>
<td>Bulk Delivery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waste Segregation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reformulate Cleaning Waste</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# WORKSHEET 6a
## PROCESS DESCRIPTION

### 1. GENERAL

**Aqueous Cleaning**

<table>
<thead>
<tr>
<th>Type of Aqueous Cleaner</th>
<th>Cleaning Procedure (CIP, manual wash)</th>
<th>Hazardous or Active Ingredient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alkaline Surfactant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alkaline Cleaner</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acid Cleaner</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acid Sanitizer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

How are spent cleaning solutions managed:

- Biodegradable; disposed of in sewer [ ] yes [ ] no
- Treated on site; disposed of in sewer [ ] yes [ ] no
- Transported off site [ ] yes [ ] no
- Other [ ] yes [ ] no

If yes, explain:

List waste streams generated by aqueous cleaning:

**Solvent Cleaning**

<table>
<thead>
<tr>
<th>Type of Solvent Used</th>
<th>Cleaning Procedure</th>
<th>Hazardous or Active Ingredient</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

How are spent cleaning solutions managed:

- Biodegradable; disposed of in sewer [ ] yes [ ] no
- Treated on site; disposed of in sewer [ ] yes [ ] no
- Transported off site [ ] yes [ ] no
- Other [ ] yes [ ] no

If yes, explain:

List waste streams generated by solvent cleaning:
### PROCESS DESCRIPTION

#### 1. GENERAL (continued)

*Disinfecting/Sterilizing*

<table>
<thead>
<tr>
<th>Type of Disinfectant Used</th>
<th>Disinfecting Procedure (Spray, wipedown, etc.)</th>
<th>Hazardous or Active Ingredient</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

How are spent disinfectants managed:
- Biodegradable; disposed of in sewer  
  - Yes  
  - No
- Treated on site; disposed of in sewer  
  - Yes  
  - No
- Transported off site  
  - Yes  
  - No
- Other  
  - Yes  
  - No

If yes, explain: _____________________________________________________________

Is ethylene oxide used for sterilization?  
  - Yes  
  - No

What type of pollution control equipment is used? ___________________________

What is the percent (%) ethylene oxide captured? ______

What is the percent (%) chlorofluorocarbon captured? ______

List waste streams generated by disinfecting/sterilizing: ____________________

**Venting**

What large-volume liquid chemicals are stored on-site? _______________________

Are storage tanks with breathing vents used? _______________________________

Do process vessels release vapors? __________________________________________

What chemicals are released through vessel vents? __________________________

What type of pollution control equipment is in place? _________________________

What percent (%) of vent gases generated are captured? _______________________

List waste streams generated by venting: ____________________________
WORKSHEET

PROCESS DESCRIPTION

1. GENERAL (continued)

*Disposables*

List the disposable items used in manufacturing: ____________________________

*Off-Spec Materials*

List the production raw materials that have been disposed of due to being out-dated or off-spec: ____________________________

List the products you manufacture that have been destroyed and disposed of due to being out-dated or off-spec: ____________________________

How are these items managed? ____________________________

2. FERMENTATION

*Fermenter Information*

Description of fermenter: ____________________________

Identification number: ____________________________

Type of growth media used: ____________________________

Size of sump: ____________________________

Frequency of sump cleanout: ____________________________

Does sump fluid go to waste treatment tank? ____________________________

How often is fermenter inspected for the following:

- Heat transfer fluid leakage: ____________________________
- Agitator seal fluid leakage: ____________________________
- Integrity of process connections: ____________________________
- Integrity of sterile barriers: ____________________________

What is the length of the fermentation cycle? ____________________________

*Process Information*

How is culture removed from fermenter? ____________________________
2. **FERMENTATION (continued)**

Where does it go?
________________________________________________________________________
________________________________________________________________________
How are cells removed?
________________________________________________________________________
Is used media sterilized? If so, How:
________________________________________________________________________
Are media, cell debris, or vent gas waste streams hazardous?
________________________________________________________________________
If yes, list hazardous components:
________________________________________________________________________
How are contaminated fermentation batches handled:
________________________________________________________________________
What is the fermentation yield percentage?
________________________________________________________________________
List the waste streams that are generated by fermentation:
________________________________________________________________________

3. **CHEMICAL SYNTHESIS, NATURAL PRODUCT EXTRACTION, FORMULATION**

**Solvent-Based Processes**

<table>
<thead>
<tr>
<th>Solvent</th>
<th>Operation</th>
<th>Annual Usage</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

How are spent solvents managed:
________________________________________________________________________
List waste streams generated by solvent-based processes:
________________________________________________________________________
WORKSHEET 6e

PROCESS DESCRIPTION

CHEMICAL SYNTHESIS, NATURAL PRODUCT EXTRACTION, FORMULATION (continued)

Aqueous-Based Processes

What types of water are used in your plant?
- Water for injection
- Distilled water
- Softened water
- Municipal water
- Reverse osmosis/Deionized water

What aqueous process solutions are generated or used?

<table>
<thead>
<tr>
<th>Aqueous Solution</th>
<th>Type of Water</th>
<th>Operation</th>
<th>Annual Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

How are spent aqueous solutions managed:
- Biodegradable, disposed of in sewer
- Recycled on-site
- Recycled off-site
- Treated on-site
- Treated off-site
- Other

If yes, explain:

List waste streams generated by aqueous-based processes:

4. RESEARCH AND DEVELOPMENT

List disposable items used in R&D processes:

List other R&D wastes:

<table>
<thead>
<tr>
<th>Process</th>
<th>Type of Waste</th>
<th>Current Waste Management Method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
**WORKSHEET 7a**

**WASTE STREAM SUMMARY**

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Waste ID/Name</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Source/Origin</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Annual Generation Rate (units/year)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Hazardous Component Name</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Annual Rate of Component(s) of Concern</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Annual Cost of Disposal</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Unit Cost ($__)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Method of Management</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Priority Rating Criteria</strong></td>
<td>Relative 3 Wi/(W)</td>
</tr>
<tr>
<td>Regulatory Compliance</td>
<td></td>
</tr>
<tr>
<td>Treatment/Disposal Cost</td>
<td></td>
</tr>
<tr>
<td>Potential Liability</td>
<td></td>
</tr>
<tr>
<td>Waste Quantity Generated</td>
<td></td>
</tr>
<tr>
<td>Waste Hazard</td>
<td></td>
</tr>
<tr>
<td>Safety Hazard</td>
<td></td>
</tr>
<tr>
<td>Minimization Potential</td>
<td></td>
</tr>
<tr>
<td>Potential to Remove Bottleneck</td>
<td></td>
</tr>
<tr>
<td>Potential By-product Recovery</td>
<td></td>
</tr>
<tr>
<td><strong>Sum of Priority Rating Scores</strong></td>
<td>$\sum_{i=1}^{n} R_i w_i$</td>
</tr>
<tr>
<td><strong>Priority Rank</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**
1. For example, sanitary landfill, hazardous waste landfill, onsite recycle, incineration, combustion with heat recovery, distillation, dewatering, etc.
2. Rate each stream in each category on a scale from 0 (none) to 10 (high).
3. Very important criteria for your plant would receive a weight of 10; relatively unimportant criteria might be given a weight of 2 or 3.
### WASTE DESCRIPTION

1. **Waste Stream Name/ID:**
   - Stream # ______

2. **Waste Characteristics (Attach additional sheet with composition data, as necessary):**
   - ☐ gas
   - ☐ liquid
   - ☐ solid
   - ☐ mixed phase
   - Density, lb/cu. ft. ________________
   - High Heating Value, Btu/lb ________________
   - Viscosity/Consistency ________________
   - pH ________________ flash point ________________ % water ________________

3. **Waste leaves process as:**
   - ☐ air emission
   - ☐ waste water
   - ☐ solid waste
   - ☐ hazardous waste
   - ☐ other

4. **Waste Generation is:**
   - ☐ continuous
   - ☐ discrete
   - discharge triggered by:
     - ☐ chemical analysis
     - ☐ other (describe) ________________
   - Type:
     - ☐ periodic ___ length of period:
     - ☐ sporadic (irregular occurrence)
     - ☐ non-recurrent ________________

5. **Generation Rate**
   - Annual ________________ lbs per year
   - Maximum ________________ lbs per year
   - Average ________________ lbs per year
   - Frequency ________________ batches per
   - Batch Size ___ Average ___ Range ________________

6. **Waste Origins/Sources**

   *(Fill out this worksheet to identify the origin of the waste. If the waste is a mixture of waste streams, fill out a sheet for each of the individual wastes).*

   Is waste mixed with other wastes? ☐ yes ☐ no
   If yes, what can be segregated from it?

   Is waste segregation possible? ☐ yes ☐ no

   If no, why not?

   Input material source of this waste

---

*htm/phar/ws7b*
WASTE MINIMIZATION: Reuse and Recovery

A. SEGREGATION

Segregation of wastes reduces the amount of unknown material in waste and improves prospects for reuse and recovery.

Are different solvent wastes due to equipment clean-up segregated? [ ] yes [ ] no
Are aqueous wastes from equipment clean-up segregated from solvent wastes? [ ] yes [ ] no
Are spent alkaline solutions segregated from the rinse water streams? [ ] yes [ ] no

If no, explain: ________________________________________________________________

B. ON-SITE RECOVERY

On-site recovery of solvents by distillation is economically feasible for as little as 8 gallons of solvent waste per day.

Has on-site distillation of the spent solvent ever been attempted? [ ] yes [ ] no
If yes, is distillation still being performed? [ ] yes [ ] no

If no, explain: ________________________________________________________________

C. CONSOLIDATION/REUSE

Are many different solvents used for cleaning? [ ] yes [ ] no

If too many small-volume solvent waste streams are generated to justify on-site distillation, can the solvent used for equipment cleaning be standardized? [ ] yes [ ] no

Is spent cleaning solvent reused? [ ] yes [ ] no

Are there any attempts at making the rinse solvent part of a batch formulation (rework)? [ ] yes [ ] no

Are any attempts made to blend various waste streams to produce marketable products? [ ] yes [ ] no

Are spills collected and reworked? [ ] yes [ ] no

Describe which measures were successful: ____________________________________________

Is your solvent waste segregated from other wastes? [ ] yes [ ] no

Has off-site reuse of wastes through waste exchange services been considered? [ ] yes [ ] no

Or reuse through commercial brokerage firms? [ ] yes [ ] no

If yes, results: ________________________________________________________________
# WORKSHEET 9

## OPTION GENERATION:
Process Operation

### Meeting Format (e.g., brainstorming, nominal group technique)

### Meeting Coordinator

### Meeting Participants

<table>
<thead>
<tr>
<th>Suggested Waste Minimization Options</th>
<th>Currently Done Y/N?</th>
<th>Rationale/Remarks on Option</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Substitution/Reformulation Techniques</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solvent Substitution</td>
<td></td>
<td></td>
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<tr>
<td>Product Reformulation</td>
<td></td>
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<tr>
<td>Other Raw Material Substitution</td>
<td></td>
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<tr>
<td><strong>B. Cleaning</strong></td>
<td></td>
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<tr>
<td>Vapor Recovery</td>
<td></td>
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<tr>
<td>Tank Wipers</td>
<td></td>
<td></td>
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<tr>
<td>Pressure Washers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reuse Cleaning Solutions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spray Nozzles on Hoses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mop and Squeegees</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reuse Rinsewater</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reuse Cleaning Solvent</td>
<td></td>
<td></td>
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<tr>
<td>Dedicated Equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clean with Part of Batch</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Segregate Wastes for Reuse</td>
<td></td>
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</tr>
</tbody>
</table>
A. PRODUCTION SCHEDULING TECHNIQUES

Is the production schedule varied to decrease waste generation? (For example, do you attempt to increase size of production runs and minimize cleaning by accumulating orders or production for inventory?)

Describe:

______________________________________________________________________________

Does the production schedule include sequential formulations that do not require cleaning between batches?

If yes, indicate results:

______________________________________________________________________________

Are there any other attempts at eliminating cleanup steps between subsequent batches? If yes, results:

______________________________________________________________________________

B. AVOID OFF-SPEC PRODUCTS

Is the batch formulation attempted in the lab before large scale production?  □ yes  □ no

Are laboratory QA/QC procedures performed on a regular basis?  □ yes  □ no

C. OTHER OPERATING PRACTICES

Are plant material balances routinely performed?  □ yes  □ no

Are they performed for each material of concern (e.g. solvent) separately?  □ yes  □ no

Are records kept of individual wastes with their sources of origin and eventual disposal? (This can aid in pinpointing large waste streams and focusing reuse efforts.)  □ yes  □ no

Are the operators provided with detailed operating manuals or instruction cote?  □ yes  □ no

Are all operator job functions well defined?  □ yes  □ no

Are regularly scheduled training programs offered to operators?  □ yes  □ no

Are there employee incentive programs related to waste minimization?  □ yes  □ no

Does the plant have an established waste minimization program in place?  □ yes  □ no

If yes, is a specific person assigned to oversee the success of the program?  □ yes  □ no

Discuss goals of the program and results:

______________________________________________________________________________

Has a waste minimization assessment been performed at this plant in the past? If yes, discuss:

______________________________________________________________________________
### OPTION GENERATION: Good Operating Practices

**Meeting Format (e.g., brainstorming, nominal group technique):**

**Meeting Coordinator:**

**Meeting Participants:**

<table>
<thead>
<tr>
<th>Suggested Waste Minimization Options</th>
<th>Currently Done Y/N?</th>
<th>Rationale/Remarks on Option</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Production Scheduling Techniques</strong></td>
<td></td>
<td></td>
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<tr>
<td>Increase Size of Production Run</td>
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<td></td>
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<tr>
<td>Sequential Formulating</td>
<td></td>
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<tr>
<td>Avoid Unnecessary Cleaning</td>
<td></td>
<td></td>
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<tr>
<td>Maximize Equipment Dedication</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>B. Avoid Off-Spec Products</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Batch Formulation in Lab</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular QA/QC</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>C. Good Operating Practices</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perform Material Balances</td>
<td></td>
<td></td>
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<tr>
<td>Keep Records of Waste Sources &amp; Disposition</td>
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<td></td>
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<tr>
<td>Waste/Materials Documentation</td>
<td></td>
<td></td>
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<tr>
<td>Provide Operating Manuals/Instruction</td>
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<tr>
<td>Employee Training</td>
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<tr>
<td>Increased Supervision</td>
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<tr>
<td>Provide Employee Incentives</td>
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<tr>
<td>Increase Plant Sanitation</td>
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<tr>
<td>Establish Waste Minimization Policy</td>
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<td></td>
</tr>
<tr>
<td>Set Goals for Source Reduction</td>
<td></td>
<td></td>
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<tr>
<td>Set Goals for Recycling</td>
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<td></td>
</tr>
<tr>
<td>Conduct Annual Assessments</td>
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</tbody>
</table>
Appendix A
Pharmaceutical Manufacturing Plant Assessments
Case Studies of Plants A, B, and C

In 1989 the California Department of Health Services commissioned a waste minimization study of three pharmaceutical manufacturers. The objectives of the waste minimization assessments were to:

- Gather site-specific information concerning the generation, handling, storage, treatment, and disposal of hazardous wastes;
- Evaluate existing waste reduction practices;
- Develop recommendations for waste reduction through source reduction and recycling techniques; and
- Assess costs/benefits of existing and recommended waste reduction techniques.

The first steps in conducting the assessments were selecting and contacting the plants to solicit voluntary participation in the assessment study. Plant selection emphasized small businesses which generally lack the financial and/or internal technical resources to perform a waste reduction assessment. One relatively large plant was also selected for study because it offered the opportunity to evaluate a wide variety of manufacturing operations, as well as a number of in-place waste reduction measures.

During each of the plant visits, the team observed manufacturing processes; inspected waste management facilities; interviewed the plant manager, environmental compliance personnel, and operations supervisors; and reviewed and copied records pertinent to waste generation and management. From the three assessments that were conducted, it was evident that employee knowledge of waste streams, waste minimization approaches and the hazardous waste regulatory structure varied greatly. Most of their technical expertise came from on-the-job experience or vendor contacts. Records of hazardous waste generation were sketchy, and there was little understanding of the importance of waste minimization. In all three plants, accurate material balances often could not be prepared because of inadequate record-keeping.

It should be noted that the information presented here represents procedures which are being conducted by the three pharmaceutical manufacturing companies. These procedures and the suggested waste minimization options should not be construed to represent recommendations of the U.S. Environmental Protection Agency. In addition, these waste management techniques are specific to the California firms. State regulations vary and alternate techniques may be required elsewhere.

This Appendix presents both the results of the assessments of the plants (here identified as A, B, and C) and the potentially useful waste minimization options identified through the assessments. Also included are the practices already in use at the plants that have successfully reduced waste generation from past levels. The original assessments may be obtained from:

Mr. Benjamin Fries
California Department of Health Services
Alternative Technology Division
Toxic Substances Control Program
714/744 P Street
Sacramento, CA 94234-7320
(916) 324-1807

In addition, the results of the waste assessments were used to prepare waste minimization assessment worksheets to be completed by other pharmaceutical manufacturers in a &f-assessment process. Examples of the worksheets are included at the end of this Appendix.
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 industry for further processing. At the time of the waste assessment, Plant A was producing erythromycin thiocyanate. Erythromycin thiocyanate is used as a growth promoter and disease preventative in animal feed or can be sold for further processing.

The plant recently changed ownership and full scale production had not yet been implemented. At the time of the waste assessment, Plant A was operating at approximately 50 percent of full production capacity.

Raw Materials

The raw materials used by Plant A include the inoculum organisms and nutrients for fermentation; solvents for product recovery; ammonium thiocyanate and acetic acid for processing; a diatomaceous earth filter aid 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 current Good Manufacturing Practices as detailed in 21 CFR 211.

Powdered nutrient materials (e.g., sugar, flour, and fillers) are purchased in bulk and arrive in bags on pallets. Upon delivery, nutrient materials are kept segregated and are stored in an on-site warehouse. The identity of each component is verified by quality control inspection and materials are kept in quarantine before they are released for production.

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 distillation units for recovery, then placed in storage tanks prior to release and reuse.

Process Description

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

A lab culture of inoculum is delivered to a sterile 2,000-gallon seed tank containing nutrients in an aqueous media. After an initial fermentation period, seed tank components are transferred to a 67,000-gallon fermentation vessel. Solution transfer lines are steam-sterilized prior to transfer. The fermentation cycle runs for seven days with nutrients being added over the course of the fermentation. During the cycle, the vessel contents are aerated and mechanically stirred while sterility is monitored and fermentation off-gases are vented to the atmosphere via a sub-micron filter. Upon maturation, harvest solution containing erythromycin base is transferred to a holding tank for further processing. Under current scheduling, an average of five batches is harvested each week. This rate will approximately double when full scale operations commence.

To separate erythromycin base from the fermentation broth, rotary vacuum filtration is used. Filtration units are precoated with an aqueous slurry of filter aid and the aqueous filtrate from the filter aid application step is discharged to the sewer. After the filtration is complete, the solid cake is scraped from the filter drum, dropped onto conveyor belts, and collected in a large disposal bin for removal from the plant by a waste hauler. Filtrate containing the erythromycin base, free of any suspended solids, is sent to the solvent extraction process.

Erythromycin base is removed from the filtrate using a multistage countercurrent liquid-liquid extraction process. The rich organic solvent layer and the raffinate, a water layer containing some solvent, are sent to their respective recovery units for recovery and recycle of the solvent.

The erythromycin-rich extract is then sent to a crystallizing unit for product recovery. Crystallized erythromycin base is then separated by centrifugation and the resulting centrifuge cake is sent to a fluid bed dryer. The centrate or spent solvent is again recovered and recycled. Dried product is drummed and sent to the warehouse for storage and quality control inspection with dryer off-gases being vented to the atmosphere. Approximately one-half of one percent of all dried product fails to meet the required product specifications. This off-spec product is stored on-site and saved for subsequent reworking.

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 the warehouse.

Waste Streams and Waste Management

The principal waste streams generated at Plant A include the following:
Filtration Process Wastes

To remove erythromycin base from the fermentation broth, harvests are filtered using rotary vacuum filters coated with diatomaceous earth. Waste streams from this process consist of the aqueous precoat filtrate and the wet filter cake. The precoat material is applied continuously at a rate of approximately 1,100 kg/hr during the precoat operation and the filtrate is discharged into the local sewer. During filtration, each rotary vacuum unit generates solid filter cake waste continuously at a rate of 1,243 kg/hr. The filter cake, consisting of mycelia and filter aid, is mechanically scraped off the filter drum and dropped onto a conveyor belt system. The wet waste cake is directed into large waste bins for disposal in shipments ranging from five to 10 tons per load, with an average weight of nine tons per load. The filter cake material is a nonhazardous waste and is disposed of in a municipal landfill.

Because of the volume of material produced, the wet filter cake is the major waste stream generated by Plant A. Filter cake disposal is contracted out to a waste hauler at a price of $160 for the first six tons plus $16 per ton for each ton thereafter. Seven to 10 loads (five to 10 tons each) are disposed of each week, with the amount of filter cake waste expected to increase significantly as Plant A reaches full scale production. To reduce the amount of filter cake waste generated, Plant A is investigating replacing the rotary vacuum filters currently in use with an ultrafiltration process. Volume reduction will be accomplished by elimination of the requirement for diatomaceous earth filter aid.

Solvents

Spent solvents are generated from recovery and purification operations. Two to three thousand gallons of solvent are used in processing a single fermentation harvest. Under current management practices, spent solvent solutions are transferred to storage tanks, then recovered and recycled back into the production process. This solvent recovery process generates 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 section.

Equipment Cleaning Wastes

Process equipment is thoroughly cleaned between manufacturing campaigns to ensure product purity and maintain operating efficiency. Washwaters are generated intermittently around these campaigns depending upon product scheduling. Periodically, a caustic solution is used to clean out the fermentation vessels. Washwaters are routinely discharged into the local sewer system but the quantity of washwater being discharged is undetermined.
Spills

Spills are the result of inadvertent material discharge during operations. Two types of spills were noted during the plant visits: spillage of dry filter aid material and wet filter cake waste. Prior to filtration, the aqueous filter aid slurry is made by mixing a powdered filter aid material with water. The filter aid material is purchased in bags, and spills can occur as a result of the bags being handled. During the assessment, it was noticed that a small amount of the filter aid material was falling onto the ground and onto adjacent equipment in the filtration area. The amount of spilled filter aid was not quantified.

As noted earlier, wet 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 up for disposal.

Waste Minimization and Management Alternatives

This section presents waste minimization and management alternatives developed for Plant A. The alternatives presented apply to specific waste streams identified during the waste assessment. Waste minimization and management alternatives for each of these waste streams are presented below along with a summary of the generation rate, current disposal practice and disposal cost.

Alternatives for Filtration Process Wastes

Filtration process wastes consist of the liquid precoat carrier and waste filter cake. As discussed earlier, the liquid material is not a hazardous waste and no pretreatment is required prior to sewer discharge. Because of this, the liquid was not considered a high priority for waste minimization and alternatives are not presented for this waste stream. (Editor’s note: While early waste minimization assessments focused on hazardous waste reduction, EPA now encourages attention to all wastes generated using a multi-media approach.)

Alternate uses for waste filter cake could result in significant reductions of waste quantities. At current production rates, the average quantity of waste is seven to 10 loads per week, or 364 to 520 loads per year. Assuming an average load weight of nine tons, this results in 3,276 to 4,680 tons per year of filter cake waste being disposed of in landfills. According to plant personnel, filter cake waste generation will increase significantly when full scale production is achieved.

Using the waste quantities specified above and a disposal cost of $208 per nine-ton load, the current yearly disposal cost for filter cake waste is between $76,000 and $108,000. The estimated disposal cost for filter cake during full scale production is approximately $250,000 per year. To reduce the amount of material disposed of via landfiling and the associated disposal cost, byproduct uses of filter cake material should be examined. These savings would be augmented by the additional revenue generated from the sale of the filter cake material.

Potential uses include:

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. 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 at Plant A is directly usable as a fertilizer.

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 cakes showed that the material 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, California, 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 KC Mattson Company to fully evaluate this alternative.

Alternatives for Solvents

Under current waste management practices, spent solvent solutions of amyl acetate and acetone are recycled. In addition, small quantities of spent solvent which remain after product recovery are also recycled. Solvent recovery processes include the use of 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 operating costs of the recovery units, still bottoms disposal, and makeup for non-recovered solvent. Solvent recovery operations on average generate two 55-gallon drums per week of still bottoms. Solvent recovery wastes are disposed of 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 new waste minimization alternative.

Alternatives for Equipment Cleaning Washwaters

Washwaters generated during equipment cleaning are nonhazardous and require no treatment prior to sewer dis-
charge. Therefore, washwaters are not considered a high priority for waste minimization, and alternatives are not developed for this waste stream. (Editor’s note: As previously stated, EPA now encourages attention to all wastes generated.)

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 the 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 filter cake may have value as a byproduct, it would be beneficial to prevent the filter cake from falling on the ground. Spillage could 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 little capital investment, no operating cost, and could be accomplished between filtration batches.

Another source of spilled material at Plant A is the dry filter aid used to prepare the rotary vacuum filters. Good operating practices will keep filter aid spillage to a minimum.

Recommendations

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

- Provide 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 additive. Identify any subsequent treatment required and the potential value of the material as a byproduct.
- Investigate methods for reducing water content and odor levels in filter cake wastes.
- Install guides beneath each rotary vacuum filter to prevent filter cake materials from missing the conveyor belts and falling onto the ground.
Plant B
Waste Minimization Assessment

Plant Description

Plant B produces a wide range of dermatologic and ophthalmic products. These pharmaceutical compounds are formulated in the production section after having been thoroughly researched by the R & D section. The R & D section is divided into two major groups, the synthetic chemistry division, and the product development division.

Raw Materials

Production

The raw materials used by Plant B in the production section consist of a large variety of active ingredients and fillers. Fillers include oils, fatty acids, surfactants, alcohols, and water used to prepare the various ointments and liquid bases. Raw material storage and management procedures are designed to be in compliance with Good Manufacturing Practices.

R & D

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 such as chloroform, methylene chloride, methanol, acetonitrile, acetone, ethyl ether, xylene and hexane are commonly used for extraction and analyses. Acetonitrile and methanol are extensively used as carrier liquid in high performance liquid chromatography (HPLC) with annual consumptions of 400 gallons of acetonitrile and 991 gallons of methanol. Sulfuric acid is the most widely used acid at an annual consumption of 450 gallons. In addition, a large quantity of sulfuric acid is used during glassware washing at an annual acid consumption of approximately 1,080 gallons.

Process Description

Production

The following categories of products are formulated by the ophthalmic section:

- Contact lens cleaners;
- saline solutions;
- ophthalmic ointments;
- eye drops; and
- disinfecting solutions.

The following categories of products are formulated by the dermatologic section:

- Shampoos, including dandruff shampoos;
- creams;
- suntan lotions;
- acne medications; and
- itch soothing preparations.

Ophthalmic and dermatologic compounds are produced in batches where the raw materials are mixed in 1,000-gallon vessels according to detailed batch records. To avoid spoilage, raw materials are carefully poured into the vessels during formulation. The finished compounds are sampled and analyzed by the QA/QC laboratory where the dermatologic section has found that none of the batches were rejected in the previous 15 months as a result of tight QA/QC during the formulation stage.

After satisfactory analysis results have been obtained, the formulated compounds are released for packaging into the finished product containers where they are again sampled by QA/QC personnel. A minimal amount of rejects is generated during packaging operations and, in fact, less than 0.3 percent of finished products from the dermatologic section is rejected, which corresponds to approximately 12,000 units per year.

R & D

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 stability tests and scales-up operations for new products discovered by the synthetic chemistry division. Compared to the synthetic chemistry division, product development activities are more homogenous, with single processes being tested for several months until the optimal performance is achieved.

In both R & D divisions, synthesized products are analyzed using HPLC. The HPLC uses mixtures of solvents and water as carriers for these separations.

Waste Streams and Waste Management

Production

The principal waste streams generated by the production section include equipment and floor cleaning washwater and reject products. After use, process equipment (i.e. vessels and filling apparatus) is thoroughly cleaned with water. This washwater, which is generated intermittently, typically includes residues from the formulated batch and is discharged to the local sewer system. Depending on the manufactured products, the waste water will have low to medium BOD, COD, TSS and total dissolved solids (TDS) concentrations. Floor cleaning washwater also typically includes traces of
the manufactured products and is discharged according to an industrial sewer discharge permit. The quantity of washwater generated was not determined.

At the dermatologic production section, rejected items constitute only 0.3 percent of the total number of finished products, equating to approximately 12,000 reject containers per year. Currently, 25 percent of these items is disposed of by washing the finished product from the packaging into the sewer and sending the used packaging to a municipal landfill. This manual operation disposes of 50 finished product rejects hourly per person. The remaining 75 percent of rejected finished products is disposed of in a Class I landfill. These items are not accepted by municipal landfills due to the excessively liquid nature of the semi-solid materials (i.e., materials which failed the compression test), high alcohol content, or, for one product, high selenium concentration.

R & D

The principal waste streams generated by the R & D section are solvent wastes, sulfuric acid wastes and expired chemicals. Descriptions of the waste source, waste characteristics, and current waste management techniques for these streams are described below.

Solvent Wastes

Two different procedures have been implemented for collecting solvent waste in the R & D section. In one procedure, each chemist collects the generated waste in a 5-gallon closed safety can. In this method, different types of solvents are collected and mixed in a single container. In the second procedure, waste solvents are segregated by type (i.e., halogenated, non-halogenated and methylene chloride), into 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 where they are emptied into appropriate containers for disposal by a contractor.

Off-site methods used for handling solvent wastes include recycling and regeneration of fresh solvent, burning of waste solvents as fuel supplements, and incineration. Currently, only methylene chloride wastes with a minimum purity of 75 percent are recycled. The majority of solvent wastes generated consists of non-halogenated solvents that are sent to cement kilns for use as fuel supplements. The remaining wastes, halogenated solvents and solvent mixtures containing heavy metals, are sent to a hazardous waste incinerator.

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

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 stainless 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 being 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 a production raw material.

Expired Chemicals

Expired chemicals are discarded periodically by transferring them to the storage area where a waste disposal contractor consolidates them into lab-packs prior to disposal at a hazardous waste landfill.

Waste Minimization and Management Alternatives

Alternatives for Production Section Wastes

As discussed earlier, the production section wastes include equipment and floor washwaters and rejected products. Waste minimization methods for these streams largely depend on careful operator actions. Minimizing spills will decrease the water required for floor cleaning. A weekly cleaning may still be necessary, but in between cleanings can be reduced if spills are prevented.

Equipment used in the pharmaceutical industry is also subject to frequent cleaning. Careful use of water can help decrease this waste stream. If equipment is being manually cleaned, hoses should only be on when equipment is being rinsed. A second operator may be needed for assistance with this effort. If equipment cleaning is automated cleaning cycles should be optimized and validated which use minimal amounts of water.

Careful attention to batch records and frequent QA/QC checks can help reduce the incidence of reject batches. Testing raw materials prior to use can also decrease rejects. When rejected batches have been identified, they should be analyzed to determine if they are suitable for rework. This would be preferable to keep these rejects and rework the product, rather than discard entire batches.

Alternatives for R & D Section Wastes

General Procedures

Currently, two different methods for solvent waste collection are used in the R & D section as described above. In order to establish and maintain an effective waste minimization program, a formalized waste collection system accessible to all concerned employees should be implemented in a standard operating procedure. Solvent collection in non-reusable containers such as the glass four-liter bottles should be discouraged since disposing of glass containers can easily be avoided by employing reusable safety cans.

To minimize waste generated by expired chemicals, Plant B should consider installation of a computerized inventory and material tracking system, implementation of a centralized purchasing department, and creation of a chemical stock room.

A computerized inventory and material tracking system can provide R & D personnel with an up-to-date listing of currently available chemicals which 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 caused by dupli-
cation of orders. Furthermore, by grouping orders, chemi-
cicals will be purchased in the most efficient quantities for R
& D needs. A chemical stock room could serve as a central-
ized purchasing location to handle all orders for new chemi-
cals. Individuals would be required to check out chemicals
from the stock room so that the location of chemicals and
usage requirements could be closely monitored. Commonly
used chemicals would be routinely kept in stock while spe-
cialty chemicals could be ordered as needed. Maintaining
one large stock of certain chemicals, rather than several
small supplies, could result in volume price discounts.

Alternatives for Solvent Waste Management

More than 19 different solvents are used by the R & D
section, several of them in quantities large enough to con-
sider recycling. Currently, only spent methylene chloride
with a minimum 75 percent purity is recycled at an off-site
facility at a cost of $120/drum. By recycling, as opposed to
incineration, Plant B minimizes waste and saves on disposal
costs. Incineration costs at a hazardous waste incinerator
versus a cement kiln are $320/drum (excluding packing and
transportation costs) for the incinerator and $200-270/drum
(including packing and transportation costs) for the cement
kiln.

On-site small scale recycling can be performed using a
reflux apparatus. Implementation of this process will require
laboratory space to set up the equipment and minimum su-
pervision. The recovered product would be analyzed to
verify its purity. On-site recycling will reduce both new
material purchases and disposal costs. Then, only the distil-
lation bottoms will require disposal.

Alternatives for Spent Sulfuric Acid

The spent sulfuric acid generated from washing proce-
dures is currently sent off-site for treatment and disposal at a
cost of $380/drum excluding transportation fees. The pro-
posed waste management option of providing spent acid to a
battery manufacturer will eliminate the cost of off-site treat-
ment and disposal. Reuse will generate savings by eliminat-
ing the cost of hazardous waste disposal.

As the purpose of sulfuric acid is to remove ink mark-
ings from glass, it is recommended that small amounts of
acid be used to wipe off the indelible ink. This may be
slightly more labor-intensive, but the need for sulfuric acid
will be greatly reduced. The estimated cost of sulfuric acid
is $7,700/year and the estimated cost of removal and treat-
ment of this acid is $7,600/year. Assuming acid is already
available in the lab, the resulting annual savings from elimi-
nating the sulfuric acid soaking will be approximately $15,300.

Recommendations

Based on the waste assessment and the discussion
of alternatives presented above, the following
recommendations are given:
- Evaluate manual versus automated destroying
  of the finished product rejects.
- Prepare a standard operating procedure manual
  for R & D waste management.
- Implement on-site recycling of solvents.
- Implement the sale of spent sulfuric acid.
- Investigate changing glassware labelling as a
  means of reducing sulfuric acid usage.
- Review and revise the purchasing and inventory
  tracking procedures of the R & D section to
  reduce waste generated from expired chemicals.
Plant C
Waste Minimization Assessment

Plant Description

Plant C produces sophisticated biochemicals, bulk pharmaceutical compounds, and immunochemicals by batch processing methods. In this assessment, the production processes for a pharmaceutical raw material, an anti-convulsive drug, and a livestock antibiotic—referred to here as Product A, Product B and Product C, respectively—and a pH buffer, Tris-HCl, are examined. At the time of this assessment, products B and C were awaiting FDA approval.

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

Raw Materials

Raw materials used by Plant C include solvents for product processing and recovery; sulfuric and hydrochloric acids for pH control and product processing; sodium hydroxide and ammonia for pH control; and a filter aid (Celite) for use in product filtrations. Solvents used include methanol, butyl acetate, chloroform, acetone, and isopropanol. Raw materials are purchased in 55-gallon drums and are stored outdoors in a fenced-off storage area approximately 100 feet 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 quantities, especially reagents for the small quantity sophisticated biochemicals. These raw materials are stored where the products are made.

Process Descriptions

Product A

Product A is made via chemical synthesis (see Figure C-1). Potassium permanganate, Product A precursor, and water are mixed in a 3,000-gallon reactor. A manganese dioxide precipitate is formed and is removed from the solution by a rotary drum filter coated with Celite. The wet 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. Overhead water is collected and discharged into the sewer. The enriched Product A solution is then sent to an 800-gallon Pfaudler vessel where the final pH adjustment is made with sulfuric acid. As the mixture is agitated and cooled, potassium sulfate crystallizes. The potassium sulfate crystals are removed from the reaction mixture by centrifugation, dissolved in water and then discharged to the sewer. Butyl acetate is added to the centrate and the mixture is azeotropically dehydrated. In a continuous process, the overhead azeotropic mixture is condensed and sent to a decanter where the lower water layer is discharged to the sewer and the butyl acetate is taken off the top and returned to the product mixture. This is continued until all of the water (which contains some butyl acetate) is removed. The butyl acetate product mixture is then filtered to remove any remaining salt.

The filtered solution is then cooled, allowing Product A to crystallize and be separated by centrifugation. Butyl acetate is recovered and stored for reuse. The product is sent to a tumble dryer prior to packaging. Butyl acetate vapor is vented from the dryer, condensed and recovered for reuse. This year Plant C estimates it will produce six batches of Product A yielding approximately 250 kg per batch.

Product B

Product B is also made via chemical synthesis (see Figure C-2). A mixture of valproic acid and sodium 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 one to two days with the methanol vapor being vented to a scrubber system where it is collected in an aqueous scrubber liquor for subsequent recovery. 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.

Product C

Product C is an intracellular bacterial fermentation product (see Figure C-3). The cells are harvested and separated from the fermentation broth by centrifugation and sent offsite for lyophilization. The spent broth centrate is discharged to the sewer without any treatment. The fermenters are cleaned with a caustic solution (NaOH) which 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:chloroform solution. After one day of stirring, 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. This liquid is then sent to a climbing film evaporator to be concentrated and then to a cooler where the product crystallizes. The methanol and chloroform from the evaporator and crystallizing unit are recycled to the filter unit for further extraction of the cells with fresh chloroform or methanol added to adjust the methanol:chloroform ratio. After the third extraction, the
Figure C-1: Process Flow Diagram for Product A

Figure C-2. Process Flow Diagram for Product B
Figure C-3. Process Flow Diagram for Product C.

Figure C-4. Process Flow Diagram for Tris-HCl Buffer
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 prior to being dried in a vacuum shelf dryer and packaged. The spent methanol is put into storage tanks for disposal and the dryer off-gas is vented to the scrubber system. Two batches of Product C will be produced this year, yielding 10 kg per batch.

**Tris-HCl Buffer**

Tris-HCl is produced via chemical synthesis (see Figure C-4). Crude tris amino and hydrochloric acid are mixed in a 200-gallon tank and agitated until the reaction is complete. The mixture is then filtered to remove any residual insolubles and is sent to a crystallization unit. Cold filtered methanol is added slowly and the product is crystallized. The crystals are washed with two smaller aliquots of methanol and are then vacuum dried, sieved and packaged to produce three 300-kg batches of Tris-HCl. The methanol is collected and stored for disposal and the dryer off-gas is sent to the scrubber system.

**Waste Stream and Waste Management**

The principal waste streams generated at Plant C include spent solvents, acid and solvent vapors, acidic and caustic solutions and non-hazardous solid waste. The sources, components, and waste management techniques for each of these waste streams are discussed in the following sections.

**Spent Solvents**

Solvents such as methanol, chloroform, and butyl acetate, are used for product processing and recovery. The butyl acetate used in Product A processing is recovered and recycled, while the methanol/chloroform solution used to extract Product C from the cell cake is used for three extractions and then stored for reuse in subsequent batches. Methanol used for the crystallization of Tris-HCl buffer is not recovered or recycled.

Spent solvent is temporarily stored in 200-gallon tanks, then is eventually transferred to 1,100-gallon storage tanks to await disposal. The spent solvent is burned as supplemental fuel in cement kilns where it must meet a minimum heating value (BTU) content requirement, and not exceed 1 percent chlorine content. The solvent is transported in 6,800- to 7,000-gallon loads at a cost of $600 per load. The cost of reuse is $0.35 per gallon.

In 1987, 30,409 gallons were sent to the cement kiln via commercial recycler at a total cost (including transportation) of $13,351. If this solvent had been incinerated instead of used as supplementary fuel, the disposal cost, including transportation, would have been approximately $110,000, based
on a disposal cost of $200 per 55-gallon drum. Thus, reuse for energy is much more economical than incineration.

**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 four-stage scrubber system containing either a caustic solution or water. Water is continuously passed through all four stages and is sent to the sewer. The volatiles that are not neutralized by the caustic solution or entrained by the water are vented to the atmosphere.

The tumble dryer used for Product A processing utilizes a liquid ring vacuum pump 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 that is not recovered is sent to the scrubber system described above.

**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 is passed through tanks containing baffles used to decrease the flow velocity and allow suspended solids to settle. In 1987, approximately 33,000 gallons of 5 percent HCl and 6,500 gallons of 5 percent NaOH were consumed at the plant. The spent acidic and caustic solutions are neutralized with fresh caustic and acidic solutions.

**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 into the sewer. The quantities produced per year are 24,000 kg of wet manganese dioxide/Celite, 10,200 kg of wet potassium sulfate, and 600 kg of cell cake.

**Waste Minimization**

Plant C has considered waste minimization and management as a high priority. The processes have been designed to minimize the waste generated, and solvents have been recycled or recovered whenever possible. Plant C is also planning to employ a staff person, who would be devoted to waste minimization and management. The following sections outline the current practices and future plans for this waste minimization and waste management.

**Alternatives for Spent Solvents**

Plant C currently disposes of spent solvent at a location where it is burned as supplemental fuel in cement kilns. The cost of removing the 30,409 gallons of spent solvent generated in 1987, including transportation, was $13,351. Wherever possible, however, the solvents are recovered and recycled, especially chlorinated solvents because of the difficulties encountered in their disposal. During Product A processing, 1,500 liters of butyl acetate are used per batch. Approximately 1,350 liters are recovered when recovering the Product A crystals.

Based on a purchase price of $0.22/liter for fresh butyl acetate, the savings from this recovery are approximately $292 per batch of Product A made. (Editor’s note: Recycling is preferred, as incineration is treatment, not waste minimization).

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 solvents 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.

Recovering 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 an aqueous 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.

**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 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 and condensed. The 30 to 50 liters not recovered are sent to the scrubber system on the house vacuum line. Based on a purchase price of $0.22/liter for fresh butyl acetate, the savings from this recovery are an additional $26 per batch. This increases the savings due to butyl acetate recovery to $318 per batch of Product A made.
Alternatives for Acidic and Caustic Solutions

In 1987, 33,000 gallons of 5 percent HCl and 6,500 gallons of 5 percent NaOH were generated by manufacturing operations which required neutralization with fresh solutions of NaOH or HCl. The cost of the fresh acid and caustic solutions used to neutralize the spent solutions generated in 1987 was approximately $470 and $155, respectively. If the NaOH could be saved and used to neutralize some of the HCl, the requirement for fresh acid and base could be reduced.

Future plans for this plant include a new industrial waste treatment system in above-ground tanks. Above-ground tanks can be monitored more closely than underground tanks, thereby reducing the potential for leaks and spillage. Treatment will include batch clarification and automated pH control of the waste before discharge into the sewer. The automation of pH adjustment will decrease labor costs and increase efficiency by reducing the amount of chemicals needed. An additional cost savings would result from this decreased use of acid and base.

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. (Editor’s note: EPA suggests that these wastes be further examined for waste minimization opportunities.)

Recommendations

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

- Examine implementation of solvent segregation.
- Use existing NaOH waste to neutralize waste HCl.

References

# WASTE SOURCES

## Waste Source: Material Handling

<table>
<thead>
<tr>
<th>Waste Source</th>
<th>Significance at Plant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Off-spec materials</td>
<td>X</td>
</tr>
<tr>
<td>Obsolete raw materials</td>
<td>X</td>
</tr>
<tr>
<td>Obsolete products</td>
<td></td>
</tr>
<tr>
<td>Spills &amp; leaks (liquids)</td>
<td>X</td>
</tr>
<tr>
<td>Spills (powders)</td>
<td>X</td>
</tr>
<tr>
<td>Empty container cleaning</td>
<td>X</td>
</tr>
<tr>
<td>Container disposal (metal)</td>
<td>X</td>
</tr>
<tr>
<td>Container disposal (paper, plastic)</td>
<td></td>
</tr>
<tr>
<td>Pipeline/tank drainage</td>
<td>X</td>
</tr>
<tr>
<td>Laboratory wastes</td>
<td></td>
</tr>
<tr>
<td>Evaporative losses</td>
<td>X</td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

## Waste Source: Process Operations

<table>
<thead>
<tr>
<th>Waste Source</th>
<th>Significance at Plant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tank cleaning</td>
<td>X</td>
</tr>
<tr>
<td>Container cleaning</td>
<td>X</td>
</tr>
<tr>
<td>Blender cleaning</td>
<td>X</td>
</tr>
<tr>
<td>Process equipment cleaning</td>
<td>X</td>
</tr>
</tbody>
</table>
A. GENERAL HANDLING TECHNIQUES

Are all raw materials tested for quality before being accepted from suppliers?  ☑ yes  ☐ no

Describe safeguards to prevent the use of materials that may generate off-spec product: Require vendor to provide certificate of analysis before use.

Is obsolete raw material returned to the supplier?  ☐ yes  ☐ no

Is inventory used in first-in first-out order?  ☑ yes  ☐ no

Is the inventory system computerized?  ☑ yes  ☐ no

Does the current inventory control system adequately prevent waste generation?  ☑ yes  ☐ no

What information does the system track?  Product/material name, lot number, control number, date received, expiration date.

Is there a formal personnel training program on raw material handling, spill prevention, proper storage techniques, and waste handling procedures?  ☑ yes  ☐ no

Does the program include information on the safe handling of the types of drums, containers and packages received?  ☑ yes  ☐ no

How often is training given and by whom?  N/A

Is dust generated in the storage area during the handling of raw materials?  ☑ yes  ☐ no

If yes, is there a dedicated dust recovery system in place?  ☑ yes  ☐ no

Are methods employed to suppress dust or capture and recycle dust?  ☑ yes  ☐ no

Explain: N/A
B. BULK LIQUIDS HANDLING

What safeguards are in place to prevent spills and avoid ground contamination during the transfer and filling of storage and blending tanks?

- High level shutdown/alarms □
- Secondary containment □
- Flow totalizers with cutoff □
- Other □

Describe the system: **Underground tanks are located in concrete pits; above ground tanks are surrounded with berms.**

Are air emissions from solvent storage tanks controlled by means of:

- Conservation vents □
- Absorber/Condenser □
- Adsorber □
- Other vapor loss control system □

Describe the system: **NO SYSTEM**

Are all storage tanks routinely monitored for leaks? If yes, describe procedure and monitoring frequency for above-ground/vaulted tanks: **Visual inspection weekly**

Underground tanks: **Visual inspection weekly**

How are the liquids in these tanks dispensed to the users? (i.e., in small containers or hard-piped.) **Hard-piped to manufacturing areas.**

What measures are employed to prevent the spillage of liquids being dispensed? **Employee training**

Are pipes cleaned regularly? Also discuss the way pipes are cleaned and how the resulting waste is handled: **N/A**

When a spill of liquid occurs in the plant, what cleanup methods are employed (e.g., wet or dry)? Also discuss the way in which the resulting wastes are handled: **Wet method for large spills - squeegee to drain; Dry method for small spills - towels to trash.**

Would different cleaning methods allow for direct reuse or recycling of the waste? (explain) **Reuse not allowed per GMP's; volume too small for recycling.**
C. DRUMS, CONTAINERS, AND PACKAGES

Are drums, containers, and packages inspected for damage before being accepted?  □ yes □ no

Are employees trained in ways to safely handle the types of drums & packages received?  □ yes □ no

Are they properly trained in handling of spilled materials?  □ yes □ no

Are stored items protected from damage, contamination, or exposure to rain, snow, sun & heat?  □ yes □ no

Describe handling procedures for damaged items: **Place in large plastic bag, return to distributor**

Does the layout of the facility result in heavy traffic through the raw material storage area?  □ yes □ no

(Heavy traffic increases the potential for contaminating raw materials with dirt or dust and for causing spilled materials to become dispersed throughout the facility.)

Can traffic through the storage area be reduced?  □ yes □ no

To reduce the generation of empty bag & packages, dust from dry material handling and liquid wastes due to cleaning, empty drums, has the plant attempted to:

- Purchase hazardous materials in preweighed containers to avoid the need for weighing?  □ yes □ no
- Use reusable/recyclable drums with liners instead of paper bags?  □ yes □ no
- Use larger containers or bulk delivery systems that can be returned to supplier for cleaning?  □ yes □ no
- Dedicate systems in the loading area so as to segregate hazardous from non-hazardous wastes?  □ yes □ no
- Recycle the cleaning waste into a product?  □ yes □ no

Describe the results of these attempts: **Drums with liners OK**

Are all empty bags, packages, and containers that contained hazardous materials segregated from those that contained non-hazardous wastes?  **NO**

 hazardous wastes generated by plant, lab hazardous wastes put in lab packs and removed from facility
### Worksheet 3

**Input Materials Summary**

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Material Name/ID</strong></td>
<td>Sodium Chloride, Water (sub)</td>
</tr>
<tr>
<td><strong>Source/Supplier</strong></td>
<td>JT Baker, made in USA</td>
</tr>
<tr>
<td><strong>Hazardous Component</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Annual Consumption Rate</strong></td>
<td>50,000 kg, 1,000,000 L</td>
</tr>
<tr>
<td><strong>Purchase Price, $ per</strong></td>
<td>$5/lb, $4/L</td>
</tr>
<tr>
<td><strong>Overall Annual Cost</strong></td>
<td>$250,000, $4,000,000</td>
</tr>
<tr>
<td><strong>Material Flow Diagram available (Y/N)</strong></td>
<td>N, Y</td>
</tr>
<tr>
<td><strong>Delivery Mode</strong></td>
<td>Truck, pipeline</td>
</tr>
<tr>
<td><strong>Shipping Container Size &amp; Type</strong></td>
<td>25 lb drum, N/A</td>
</tr>
<tr>
<td><strong>Storage Mode</strong></td>
<td>Warehouse, N/A</td>
</tr>
<tr>
<td><strong>Transfer Mode</strong></td>
<td>Hand truck, Pump</td>
</tr>
<tr>
<td><strong>Control Mode</strong></td>
<td>Sign out, available to all</td>
</tr>
<tr>
<td><strong>Empty Container Disposal/Management</strong></td>
<td>Crush &amp; landfill, N/A</td>
</tr>
<tr>
<td><strong>Shelf Life</strong></td>
<td>2 yr, N/A</td>
</tr>
<tr>
<td><strong>Supplier Would</strong></td>
<td>Y, N/A</td>
</tr>
<tr>
<td>- accept expired material (Y/N)</td>
<td>Y, N/A</td>
</tr>
<tr>
<td>- accept shipping containers (Y/N)</td>
<td>Y, N/A</td>
</tr>
<tr>
<td>- revise expiration date (Y/N)</td>
<td>Y, do not, N/A</td>
</tr>
<tr>
<td><strong>Acceptable Substitute(s), if any</strong></td>
<td>None, None</td>
</tr>
<tr>
<td><strong>Alternate Supplier(s)</strong></td>
<td>Several</td>
</tr>
</tbody>
</table>

1. e.g., pipeline, tank car, 100 bbl. tank truck, truck, etc.
2. e.g., 55 gal. drum, 100 lb. paper bag, tank, etc.
3. e.g., outdoor, warehouse, underground, aboveground, etc.
4. e.g., pump, forklift, pneumatic transport, conveyor, etc.
5. e.g., on-demand to site, select people only, sign out.
6. e.g., crush and landfill, clean and recycle, return to supplier, etc.
<table>
<thead>
<tr>
<th>Attribute</th>
<th>Description</th>
<th>Stream No. 1</th>
<th>Stream No. 2</th>
<th>Stream No. 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name/ID</td>
<td>Saline solution, Protein solution</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hazardous Component</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annual Production Rate</td>
<td>1,000,000 L</td>
<td>2,000 L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annual Revenues, $</td>
<td>$2.5 million</td>
<td>$2.5 million</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shipping Mode</td>
<td>TRUCK</td>
<td>TRUCK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shipping Container Size and Type</td>
<td>CARDBOARD BOX 3' X 2' X 1'</td>
<td>CARDBOARD BOX 3' X 2' X 1'</td>
<td></td>
<td></td>
</tr>
<tr>
<td>On-site Storage Mode</td>
<td>Warehouse</td>
<td>Cold storage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Containers Returnable (Y/N)</td>
<td>Y</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shelf Life</td>
<td>1 year</td>
<td>6 mos.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Re-work Possible (Y/N)</td>
<td>Y</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Customer would:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Relax specification (Y/N)</td>
<td>N</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Accept larger containers (Y/N)</td>
<td>Y</td>
<td>N</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### OPTION GENERATION: Material Handling

**Meeting Format (e.g., brainstorming, nominal group technique):** Brainstorming

**Meeting Coordinator:** DGL

**Meeting Participants:** MAT, PEP, DLS

#### Suggested Waste Minimization Options

<table>
<thead>
<tr>
<th>A. General Handling Techniques</th>
<th>Currently Done Y/N?</th>
<th>Rationale/Remarks on Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality Control Check</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Return Obsolete Material to Supplier</td>
<td>N</td>
<td>Supplier would take back</td>
</tr>
<tr>
<td>Minimize Inventory</td>
<td>Y</td>
<td>Not cost effective</td>
</tr>
<tr>
<td>Computerize Inventory</td>
<td>N</td>
<td>To estimate cost/benefit</td>
</tr>
<tr>
<td>Formal Training</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B. Bulk Liquids Handling</th>
<th>Currently Done Y/N?</th>
<th>Rationale/Remarks on Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Level Shutdown/Alarm</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Flow Totalizers with Cutoff</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Secondary Containment</td>
<td>Y</td>
<td>Look into this</td>
</tr>
<tr>
<td>Air Emission Control</td>
<td>N</td>
<td>Cost ??</td>
</tr>
<tr>
<td>Leak Monitoring</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spilled Material Reuse</td>
<td>N</td>
<td>Against GMP</td>
</tr>
<tr>
<td>Cleanup Methods to Promote Recycling</td>
<td>N</td>
<td>Examine spill types</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C. Drums, Containers, and Packages</th>
<th>Currently Done Y/N?</th>
<th>Rationale/Remarks on Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw Material Inspection</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Proper Storage/Handling</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Preweighed Containers</td>
<td>N</td>
<td>Need to weigh or verify in house</td>
</tr>
<tr>
<td>Soluble Bags</td>
<td>N</td>
<td>No</td>
</tr>
<tr>
<td>Reusable Drums</td>
<td>Y</td>
<td>To be considered</td>
</tr>
<tr>
<td>Bulk Delivery</td>
<td>N</td>
<td>No hazardous mfg. waste</td>
</tr>
<tr>
<td>Waste Segregation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reformulate Cleaning Waste</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
WORKSHEET

PROCESS DESCRIPTION

1. GENERAL

Aqueous Cleaning

Type of Aqueous Cleaner
- Alkaline Surfactant
- Alkaline Cleaner
- Acid Cleaner
- Acid Sanitizer
- Other

Cleaning Procedure
- MANUAL
- CIP

Hazardous or Active Ingredient
- KOH, phosphates
- NaOH
- H₃PO₄

How are spent cleaning solutions managed:
- Biodegradable, disposed of in sewer
- Treated on site, disposed of in sewer
- Transported off site
- Other

If yes, explain: MANUAL wash solution to sewer, CIP solution neutralized then to sewer

List waste streams generated by aqueous cleaning: Tank + equipment cleaning

Solvent Cleaning
- N/A

Type of Solvent Used

Cleaning Procedure

Hazardous or Active Ingredient

How are spent cleaning solutions managed:
- Biodegradable, disposed of in sewer
- Treated on site, disposed of in sewer
- Transported off site
- Other

If yes, explain:

List waste streams generated by solvent cleaning:
**WORKSHEET 6b**

**PROCESS DESCRIPTION**

1. **GENERAL (continued)**  
   *Disinfecting/Sterilizing*

<table>
<thead>
<tr>
<th>Type of Disinfectant Used</th>
<th>Disinfecting Procedure (Spray, wipedown, etc.)</th>
<th>Hazardous or Active Ingredient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue Chip</td>
<td>wipedown</td>
<td>guaethamine</td>
</tr>
</tbody>
</table>

   How are spent disinfectants managed:  
   - Biodegradable; disposed of in sewer: yes  
   - Treated on site; disposed of in sewer: no  
   - Transported off site: yes  
   - Other: no

   If yes, explain: excess solution dumped to drain

   Is ethylene oxide used for sterilization? yes  

   What type of pollution control equipment is used?  

   What is the percent (%) ethylene oxide captured?  

   What is the percent (%) chlorofluorocarbon captured?  

   List waste streams generated by disinfecting/sterilizing: *Excess solution from daily fill area wiped down*

   **Venting**

   What large-volume liquid chemicals are stored on-site? ethanol  

   Are storage tanks with breathing vents used? yes  

   Do process vessels release vapors? yes  

   What chemicals are released through vessel vents? ethanol  

   What type of pollution control equipment is in place? NONE  

   What percent (%) of vent gases generated are captured?  

   List waste streams generated by venting: ethanol vapor
WORKSHEET 6c

PROCESS DESCRIPTION

1. GENERAL (continued)

Disposables
List the disposable items used in manufacturing: plastic pipets, beakers, etc.

Off-Spec Materials
List the production raw materials that have been disposed of due to being out-dated or off-spec: sodium chloride
List the products you manufacture that have been destroyed and disposed of due to being out-dated or off-spec: saline solution
How are these items managed? NaCl to manufacturer, sometimes trash. Solutions are reworked

2. FERMENTATION

Fermenter Information
Description of fermenter: 
Identification number: 
Type of growth media used: 
Size of sump: 
Frequency of sump cleanout: 
Does sump fluid go to waste treatment tank? 
How often is fermenter inspected for the following:
  Heat transfer fluid leakage: 
  Agitator seal fluid leakage: 
  Integrity of process connections: 
  Integrity of sterile barriers:

What is the length of the fermentation cycle? 

Process Information
How is culture removed from fermenter? 

2. **FERMENTATION (continued)**

Where does it go? 

__________________________________________________________________________________

How are cells removed? 

__________________________________________________________________________________

Is used media sterilized? If so, How: 

__________________________________________________________________________________

Are media, cell debris, or vent gas waste streams hazardous? 

__________________________________________________________________________________

If yes, list hazardous components: 

__________________________________________________________________________________

How are contaminated fermentation batches handled? 

__________________________________________________________________________________

What is the fermentation yield percentage? 

__________________________________________________________________________________

List the waste streams that are generated by fermentation: 

__________________________________________________________________________________

3. **CHEMICAL SYNTHESIS, NATURAL PRODUCT EXTRACTION, FORMULATION**

**Solvent-Based Processes**

<table>
<thead>
<tr>
<th>Solvent</th>
<th>Operation</th>
<th>Annual Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>ethanol</td>
<td>protein separations</td>
<td>4,600,000 gal</td>
</tr>
</tbody>
</table>

How are spent solvents managed: recover and reclaim by distillation for reuse

List waste streams generated by solvent-based processes: spent ethanol solution containing denatured proteins
### Aqueous-Based Processes

What types of water are used in your plant?
- Water for injection: Yes
- Distilled water: Yes
- Softened water: No
- Municipal water: Yes
- Reverse osmosis/Deionized water: Yes

What aqueous process solutions are generated or used?

<table>
<thead>
<tr>
<th>Aqueous Solution</th>
<th>Type of Water</th>
<th>Operation</th>
<th>Annual Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>WFE</td>
<td>Formulation</td>
<td>1,000,000 L</td>
</tr>
<tr>
<td>lab reagents</td>
<td>distilled H2O</td>
<td>lab operations</td>
<td>known</td>
</tr>
</tbody>
</table>

How are spent aqueous solutions managed:
- Biodegradable, disposed of in sewer: Yes
- Recycled on-site: Yes
- Recycled off-site: Yes
- Treated on-site: Yes
- Treated off-site: Yes
- Other: Yes, explain: Saline solutions recycled on-site, if out of spec, lab solutions are put down the drain

List waste streams generated by aqueous-based processes: Spent laboratory reagents

### Research and Development

List disposable items used in R&D processes: Misc plastic labware

List other R&D wastes:

<table>
<thead>
<tr>
<th>Process</th>
<th>Type of Waste</th>
<th>Current Waste Management Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filtration</td>
<td>Filter media</td>
<td>trash/landfill</td>
</tr>
<tr>
<td>packaging waste</td>
<td>paper, plastics</td>
<td>trash/landfill</td>
</tr>
</tbody>
</table>
## WASTE STREAM SUMMARY

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Description</th>
<th>Stream No. 1</th>
<th>Stream No. 2</th>
<th>Stream No. 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waste ID/Name</td>
<td>cleaning wastes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ETCH vortex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PKy. waste</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Source/Origin</td>
<td>tank and equipment cleaning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>storage tank vents packaging</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>packaging materials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annual Generation Rate (units/year)</td>
<td>150,000 gal/yr</td>
<td></td>
<td>1000 gal/yr</td>
<td>25,000 gal/yr</td>
</tr>
<tr>
<td>Hazardous Component Name</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annual Rate of Component(s) of Concern</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annual Cost of Disposal</td>
<td>$1,000,000</td>
<td>$1,000,000</td>
<td>$5,000,000</td>
<td></td>
</tr>
<tr>
<td>Unit Cost ($____)</td>
<td>$0.009/gal</td>
<td>$0.001/gal</td>
<td>$0.06/gal</td>
<td></td>
</tr>
<tr>
<td>Method of Management ¹</td>
<td>sewer</td>
<td>air emission</td>
<td>sanitation</td>
<td>landfill</td>
</tr>
<tr>
<td>Priority Rating Criteria ²</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulatory Compliance</td>
<td>9</td>
<td>5</td>
<td>7</td>
<td>32</td>
</tr>
<tr>
<td>Treatment/Disposal Cost</td>
<td>4</td>
<td>3</td>
<td>7</td>
<td>28</td>
</tr>
<tr>
<td>Potential Liability</td>
<td>7</td>
<td>5</td>
<td>35</td>
<td>35</td>
</tr>
<tr>
<td>Waste Quantity Generated</td>
<td>6</td>
<td>9</td>
<td>54</td>
<td>24</td>
</tr>
<tr>
<td>Waste Hazard</td>
<td>2</td>
<td>2</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>Safety Hazard</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Minimization Potential</td>
<td>5</td>
<td>8</td>
<td>40</td>
<td>8</td>
</tr>
<tr>
<td>Potential to Remove Bottleneck</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Potential By-product Recovery</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Sum of Priority Rating Scores</td>
<td>( \Sigma \text{R x W} ) 192</td>
<td>( \Sigma \text{R x W} ) 197</td>
<td>( \Sigma \text{R x W} ) 192</td>
<td></td>
</tr>
</tbody>
</table>

### Notes:
1. For example, sanitary landfill, hazardous waste landfill, onsite recycle, incineration, combustion with heat recovery, distillation, dewatering, etc.
2. Rate each stream in each category on a scale from 0 (none) to 10 (high).
3. Very important criteria for your plant would receive a weight of 10; relatively unimportant criteria might be given a weight of 2 or 3.
WORKSHEET
7b

1. Waste Stream Name/ID: **Ethanol vapor**
   Process Unit/Operation: **storage tank emissions**
   Stream # 2

2. Waste Characteristics (Attach additional sheet with composition data, as necessary)
   - gas
   - liquid
   - solid
   - mixed phase
   Density, lb/cu. ft. ____________________________ High Heating Value, Btu/lb ____________________________
   Viscosity/Consistency ____________________________
   pH ____________________________ % water ____________________________

3. Waste leaves process as:
   - air emission
   - waste water
   - solid waste
   - hazardous waste
   - other ____________________________

4. Waste Generation is:
   - continuous ____________________________
   - discrete ____________________________
   - discharge triggered by:
     - chemical analysis
     - other (describe) tank venting ____________________________
   Type:
   - periodic _____ length of period: ____________________________
   - sporadic (irregular occurrence) ____________________________
   - non-recurrent ____________________________

5. Generation Rate
   Annual ____________________________ 30l per year
   Maximum ____________________________ lbs per year ____________________________
   Average ____________________________ lbs per year ____________________________
   Frequency ____________________________ batches per ____________________________
   Batch Size __________________ Average __________________ Range __________________

6. Waste Origins/Sources

   (Fill out this worksheet to identify the origin of the waste. If the waste is a mixture of waste streams, fill out a sheet for each of the individual wastes).
   Is waste mixed with other wastes?  □ yes  □ no
   Is waste segregation possible?  □ yes  □ no

   If yes, what can be segregated from it? ____________________________
   If no, why not? Pure vapor ____________________________
   Input material source of this waste ethanol storage ____________________________
A. SEGREGATION

Segregation of wastes reduces the amount of unknown material in waste and improves prospects for reuse and recovery.

Are different solvent wastes due to equipment clean-up segregated?  □ yes □ no
Are aqueous wastes from equipment clean-up segregated from solvent wastes?  □ yes □ no
Are spent alkaline solutions segregated from the rinse water streams?  □ yes □ no
If no, explain: ____________________________________________________________

B. ON-SITE RECOVERY

On-site recovery of solvents by distillation is economically feasible for as little as 8 gallons of solvent waste per day.

Has on-site distillation of the spent solvent ever been attempted?  □ yes □ no
If yes, is distillation still being performed?  □ yes □ no
If no, explain: ____________________________________________________________

C. CONSOLIDATION/REUSE

Are many different solvents used for cleaning?  □ yes □ no
If too many small-volume solvent waste streams are generated to justify on-site distillation, can the solvent used for equipment cleaning be standardized?  □ yes □ no
Is spent cleaning solvent reused?  □ yes □ no
Are there any attempts at making the rinse solvent part of a batch formulation (rework)?  □ yes □ no
Are any attempts made to blend various waste streams to produce marketable products?  □ yes □ no
Are spills collected and reworked?  □ yes □ no
Describe which measures were successful: _______________________________________

Is your solvent waste segregated from other wastes?  □ yes □ no
Has off-site reuse of wastes through waste exchange services been considered?  □ yes □ no
Or reuse through commercial brokerage firms?  □ yes □ no
If yes, results: ___________________________________________________________
**WORKSHEET 9**

**OPTION GENERATION:**
Process Operation

Meeting Format (e.g., brainstorming, nominal group technique) **BRAINSTORMING**
Meeting Coordinator **DGL**
Meeting Participants **MAT, PEP, DLS, MJS**

<table>
<thead>
<tr>
<th>Suggested Waste Minimization Options</th>
<th>Currently Done Y/N?</th>
<th>Rationale/Remarks on Option</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Substitution/Reformulation Techniques</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solvent Substitution</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Product Reformulation</td>
<td>N</td>
<td><strong>Not feasible</strong></td>
</tr>
<tr>
<td>Other Raw Material Substitution</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td><strong>B. Cleaning</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vapor Recovery</td>
<td>N</td>
<td>To study this for ETCH</td>
</tr>
<tr>
<td>Tank Wipers</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Pressure Washers</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Reuse Cleaning Solutions</td>
<td>Y</td>
<td>for CIP only</td>
</tr>
<tr>
<td>Spray Nozzles on Hoses</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Mop and Squeegees</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Reuse Rinsewater</td>
<td>Y</td>
<td>CIP only - final rinse</td>
</tr>
<tr>
<td>Reuse Cleaning Solvent</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Dedicated Equipment</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Clean with Part of Batch</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Segregate Wastes for Reuse</td>
<td>N</td>
<td></td>
</tr>
</tbody>
</table>
WORKSHEET

10

WASTE MINIMIZATION:
Good Operating Practices

A. PRODUCTION SCHEDULING TECHNIQUES

Is the production schedule varied to decrease waste generation? (For example, do you attempt to increase size of production runs and minimize cleaning by accumulating orders or production for inventory?)

Describe: Yes - sometimes Equipment is rinsed only (not washed) between runs that will go to one batch.

Does the production include sequential formulations that do not require cleaning between batches?
If yes, indicate results: see above

Are there any other attempts at eliminating cleanup steps between subsequent batches? If yes, results:

B. AVOID OFF-SPEC PRODUCTS

Is the batch formulation attempted in the lab before large scale production? ☑ yes ☐ no

Are laboratory QA/QC procedures performed on a regular basis? ☑ yes ☐ no

C. CONSOLIDATION/REUSE

Are plant material balances routinely performed? ☐ yes ☑ no

Are they performed for each material of concern (e.g. solvent) separately? ☐ yes ☑ no

Are records kept of individual wastes with their sources of origin and eventual disposal? ☑ yes ☐ no
(This can aid in pinpointing large waste streams and focusing reuse efforts.)

Are the operators provided with detailed operating manuals or instruction sets? ☑ yes ☐ no

Are all operator job functions well defined? ☑ yes ☐ no

Are regularly scheduled training programs offered to operators? ☑ yes ☐ no

Are there employee incentive programs related to waste minimization? ☐ yes ☑ no

Does the facility have an established waste minimization program in place? ☐ yes ☑ no

If yes, is a specific person assigned to oversee the success of the program? ☐ yes ☑ no

Discuss goals of the program and results:

Has a waste minimization assessment been performed at this plant in the past? If yes, discuss:

No
**Waste Minimization Assessment**

**Firm:** ABC CORP  
**Site:** LOS ANGELES  
**Date:** MARCH 1971  
**Proj. No.:** 1  
**Prepared By:** DGL  
**Checked By:** PEP  
**Sheet:** 1 of 1  
**Page:** 13 of 13

---

**WORKSHEET 11**

**OPTION GENERATION:**

**Good Operating Practices**

---

**Meeting Format (e.g., brainstorming, nominal group technique):** BRAINSTORMING

**Meeting Coordinator:** DGL  
**Meeting Participants:** MAT, PEP, HIM, JEG, DLS

---

**Suggested Waste Minimization Options**

<table>
<thead>
<tr>
<th>A. Production Scheduling Techniques</th>
<th>Currently Done Y/N?</th>
<th>Rationale/Remarks on Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase Size of Production Run</td>
<td>Y</td>
<td>Could go larger</td>
</tr>
<tr>
<td>Sequential Formulating</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Avoid Unnecessary Cleaning</td>
<td>Y</td>
<td>Cleaning usually necessary</td>
</tr>
<tr>
<td>Maximize Equipment Dedication</td>
<td>Y</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B. Avoid Off-Spec Products</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Batch Formulation in Lab</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular QA/QC</td>
<td>Y</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C. Good Operating Practices</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Perform Material Balances</td>
<td>N</td>
<td>Engr. to do this</td>
</tr>
<tr>
<td>Keep Records of Waste Sources &amp; Disposition</td>
<td>N</td>
<td>Prod's to do this</td>
</tr>
<tr>
<td>Waste/Materials Documentation</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Provide Operating Manuals/Instructions</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Employee Training</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Increased Supervision</td>
<td>Y</td>
<td>To be considered</td>
</tr>
<tr>
<td>Provide Employee Incentives</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Increase Plant Sanitation</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Establish Waste Minimization Policy</td>
<td>Y</td>
<td>Engr/Prod's to do this</td>
</tr>
<tr>
<td>Set Goals for Source Reduction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Set Goals for Recycling</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Conduct Annual Assessments</td>
<td>Y</td>
<td>Form WM team</td>
</tr>
</tbody>
</table>

---

**himi/pmar/ws11**

**68**
Additional information on source reduction, reuse and recycling approaches to pollution prevention is available in EPA reports listed in this section, and through state programs and regional EPA offices (listed below) that offer technical and/or financial assistance in the areas of pollution prevention and treatment. An industry association that can make referrals for waste minimization information is also listed.

Waste exchanges have been established in some areas of the U.S. to put waste generators in contact with potential users of the waste. Twenty-four exchanges operating in the U.S. and Canada are listed.

**U.S. EPA Reports on Waste Minimization**


Waste Minimization Audit Report: Case Studies of Corrosive and Heavy Metal Waste Minimization Audit at a Specialty Steel Manufacturing Complex. Executive Summary. NTIS No. PB88 - 107180

Waste Minimization Audit Report: Case Studies of Minimization of Solvent Waste for Parts Cleaning and from Electronic Capacitor Manufacturing Operation. Executive Summary. NTIS No. PB87 - 229662


The Guides to Pollution Prevention manuals* describe waste minimization options for specific industries. This is a continuing series which currently includes the following titles:

Guides to Pollution Prevention Paint Manufacturing Industry. EPA/625/7-90/005

Guides to Pollution Prevention The Pesticide Formulating Industry. EPAJ625/7-901004

Guides to Pollution Prevention The Commercial Printing Industry. EPA/625/7-90/008

Guides to Pollution Prevention The Fabricated Metal Industry. EPA/625/7-90/006

Guides to Pollution Prevention For Selected Hospital Waste Streams. EPA/625/7-90/009

Guides to Pollution Prevention Research and Educational Institutions. EPA/625/7-90/010

Guides to Pollution Prevention The Printed Circuit Board Manufacturing Industry. EPA/625/7-90/007

Guides to Pollution Prevention The Photoprocessing Industry. EPA/625/7-91/012

Guides to Pollution Prevention The Fiberglass Reinforced and Composite Plastic Industry. EPA/625/7-91/014

Guides to Pollution Prevention The Automotive Repair Industry. EPA/625/7-91/013

Guides to Pollution Prevention The Automotive Refinishing Industry. EPA/625/7-91/016

Guides to Pollution Prevention The Marine Repair Industry. EPA/625/7-91/015


Waste Reduction Technical/Financial Assistance Programs

The EPA Pollution Prevention Information Clearinghouse (PPIC) was established to encourage waste reduction through technology transfer, education, and public awareness. PPIC collects and disseminates technical and other information about pollution prevention through a telephone hotline and an electronic information exchange network. Indexed bibliographies and abstracts of reports, publications, and case studies about pollution prevention are available. PPIC also lists a calendar of pertinent conferences and seminars; information about activities abroad and a directory of waste exchanges. Its Pollution Prevention Information Exchange System (PIES) can be accessed electronically 24 hours a day without fees.

**For more information contact:**

PIES Technical Assistance
Science Applications International Corp.
8400 Westpark Drive
McLean, VA 22102
(703) 821-4800

or

U.S. Environmental Protection Agency
401 M Street S. W.
Washington, D. C. 20460
The EPA’s Office of Solid Waste and Emergency Response has a telephone call-in service to answer questions regarding RCRA and Superfund (CERCLA). The telephone numbers are:

- (800) 424-9346 (outside the District of Columbia)
- (202) 382-3000 (in the District of Columbia)

The following state programs offer technical and/or financial assistance for waste minimization and treatment.

**Alabama**
- Hazardous Material Management and Resources Recovery Program
  - University of Alabama
  - P.O. Box 6373
  - Tuscaloosa, AL 35487-6373
  - (205) 348-8401

**Alaska**
- Alaska Health Project
  - Waste Reduction Assistance Program
  - 431 West Seventh Avenue, Suite 101
  - Anchorage, AK 99501
  - (907) 276-2864

**Arkansas**
- Arkansas Industrial Development Commission
  - One State Capitol Mall
  - Little Rock, AR 72201
  - (501) 371-1370

**California**
- Alternative Technology Division
  - Toxic Substances Control Program
  - California State Department of Health Services
  - 714/744 P Street
  - Sacramento, CA 94234-7320
  - (916) 324-1807

**Connecticut**
- Connecticut Hazardous Waste Management Service
  - Suite 360
  - 900 Asylum Avenue
  - Hartford, CT 06105
  - (203) 244-2007

**Florida**
- Waste Reduction Assistance Program
  - Florida Department of Environmental Regulation
  - 2600 Blair Stone Road
  - Tallahassee, FL 32399-2400
  - (904) 488-0300

**Georgia**
- Hazardous Waste Technical Assistance Program
  - Georgia Institute of Technology
  - Georgia Technical Research Institute
  - Environmental Health and Safety Division
  - O’Keeffe Building, Room 027
  - Atlanta, GA 30332
  - (404) 894-3806

- Environmental Protection Division
  - Georgia Department of Natural Resources
  - Floyd Towers East, Suite 1154
  - 205 Butler Street
  - Atlanta, GA 30334
  - (404) 656-2833

- Guam
  - Solid and Hazardous Waste Management Program
  - Guam Environmental Protection Agency
  - IT & E Harmon Plaza, Complex Unit D-107
  - 130 Rojos Street
  - Harmon, Guam 96911
  - (671) 646-8863

**Illinois**
- Hazardous Waste Research and Information Center
  - Illinois Department of Energy and Natural Resources
  - One East Hazelwood Dr.
  - Champaign, IL 61820
  - (217) 333-8940

- Illinois Waste Elimination Research Center
  - Pritzker Department of Environmental Engineering
  - Alumni Building, Room 102
  - Illinois Institute of Technology
  - 3200 South Federal Street
  - Chicago, IL 60616
  - (312) 567-3535

**Indiana**
- Environmental Management and Education Program
  - Young Graduate House, Room 120
  - Purdue University
  - West Lafayette, IN 47907
  - (317) 494-5036

- Indiana Department of Environmental Management
  - Office of Technical Assistance P.O. Box 6015
  - 105 South Meridian Street
  - Indianapolis, IN 46206-6015
  - (317) 232-8172

**Iowa**
- Center for Industrial Research and Service
  - 205 Engineering Annex
  - Iowa State University
  - Ames, IA 50011
  - (515) 294-3420

- Iowa Department of Natural Resources
  - Air Quality and Solid Waste Protection Bureau
  - Wallace State Office Building
  - 900 East Grand Avenue
  - Des Moines, IA 50319-0034
  - (515) 281-8690
Kansas
Bureau of Waste Management
Department of Health and Environment
Forbesfield, Building 730
Topeka, KS 66620
(913) 269-1607

Kentucky
Division of Waste Management
Natural Resources and Environmental Protection Cabinet
18 Reilly Road
Frankfort, KY 40601
(502) 564-6716

Louisiana
Department of Environmental Quality
Office of Solid and Hazardous Waste
P.O. Box 44307
Baton Rouge, LA 70804
(504) 342-1354

Maryland
Maryland Hazardous Waste Facilities Siting Board
60 West Street, Suite 200 A
Annapolis, MD 21401
(301) 974-3432

Maryland Environmental Service
2020 Industrial Drive
Annapolis, MD 21401
(301) 269-3291
(800) 492-9188 (in Maryland)

Massachusetts
Office of Technical Assistance
Executive Office of Environmental Affairs
100 Cambridge Street, Room 1094
Boston, MA 02202
(617) 727-3260

Source Reduction Program
Massachusetts Department of Environmental Protection
1 Winter Street
Boston, MA 02108
(617) 292-5982

Michigan
Resource Recovery Section
Department of Natural Resources
P.O. Box 30028
Lansing, MI 48909
(517) 373-0540

Minnesota
Minnesota Pollution Control Agency
Solid and Hazardous Waste Division
520 Lafayette Road
St. Paul, MN 55155
(612) 296-6300

Minnesota Technical Assistance Program
Box 197 Mayo
420 Delaware Street S.E.

University of Minnesota
Minneapolis, MN 55455
(612) 625-9677
(800) 247-0015 (in Minnesota)

Missouri
State Environmental Improvement and Energy Resources Agency
P.O. Box 744
Jefferson City, MO 65102
(314) 751-4919

New Hampshire
New Hampshire Department of Environmental Sciences
Waste Management Division
6 Hazen Drive
Concord, New Hampshire 03301-6509
(603) 271-2901

New Jersey
New Jersey Hazardous Waste Facilities Siting Commission
Room 614
28 West State Street
Trenton, NJ 08608
(609) 292-1459
(609) 292-1026

Hazardous Waste Advisement Program
Bureau of Regulation and Classification
New Jersey Department of Environmental Protection
401 East State Street
Trenton, NJ 08625
(609) 292-8341

Risk Reduction Unit
Office of Science and Research
New Jersey Department of Environmental Protection
401 East State Street
Trenton, NJ 08625
(609) 984-6070

New York
New York State Environmental Facilities Corporation
50 Wolf Road
Albany, NY 12205
(518) 457-3273

North Carolina
Pollution Prevention Pays Program
Department of Natural Resources and Community Development
P.O. Box 27687
512 North Salisbury Street
Raleigh, NC 27611
(919) 733-7015

Governor’s Waste Management Board
325 North Salisbury Street
Raleigh, NC 27611
(919) 733-9020

Technical Assistance Unit
Solid and Hazardous Waste Management Branch
North Carolina Department of Human Resources  
P.O. Box 2091  
306 North Wilmington Street  
Raleigh, NC 27602  
(919) 733-2178

Ohio  
Division of Solid and Hazardous Waste Management  
Ohio Environmental Protection Agency  
P.O. Box 1049  
1800 WaterMark Drive  
Columbus, OH 43266-1049  
(614) 481-7200

Oklahoma  
Industrial Waste Elimination Program  
Oklahoma State Department of Health  
P.O. Box 53551  
Oklahoma City, OK 73152  
(405) 271-7353

Oregon  
Oregon Hazardous Waste Reduction Program  
Department of Environmental Quality  
811 Southwest Sixth Avenue  
Portland, OR 97204  
(503) 229-5913

Pennsylvania  
Pennsylvania Technical Assistance Program  
501 F. Orvis Keller Building  
University Park, PA 16802  
(814) 865-0427

Center of Hazardous Material Research  
320 William Pitt Way  
Pittsburgh, PA 15238  
(412) 826-5320

Bureau of Waste Management  
Pennsylvania Department of Environmental Resources  
P.O. Box 2063  
Fulton Building  
3rd and Locust Streets  
Harrisburg, PA 17120  
(717) 787-6239

Rhode Island  
Office of Environmental Coordination  
Department of Environmental Management  
83r Park Street  
Providence, RI 02903  
(401) 277-3434  
(800) 253-2674 (in Rhode Island)

Ocean State Cleanup and Recycling Program  
Rhode Island Department of Environmental Management  
9 Hayes Street  
Providence, RI 02908-5003  
(401) 277-3434  
(800) 253-2674 (in Rhode Island)

Center for Environmental Studies  
Brown University  
P.O. Box 1943  
135 Angell Street  
Providence, RI 02912  
(401) 863-3449

Tennessee  
Center for Industrial Services  
102 Alumni Hall  
University of Tennessee  
Knoxville, TN 37996  
(615) 974-2456

Virginia  
Office of Policy and Planning  
Virginia Department of Waste Management  
11th Floor, Monroe Building  
101 North 14th Street  
Richmond, VA 23219  
(804) 225-2667

Washington  
Hazardous Waste Section  
Mail Stop PV-11  
Washington Department of Ecology  
Olympia, WA 98504-8711  
(206) 459-6322

Wisconsin  
Bureau of Solid Waste Management  
Wisconsin Department of Natural Resources  
P.O. Box 7921  
101 South Webster Street  
Madison, WI 53707  
(608) 267-3763

Wyoming  
Solid Waste Management Program  
Wyoming Department of Environmental Quality  
Horchler Building, 4th Floor, West Wing  
122 West 25th Street  
Cheyenne, WY 82002  
(307) 777-7752

Waste Exchanges  
Alberta Waste Materials Exchange  
Mr. William C. Kay  
Alberta Research Council  
Post Office Box 8330  
Postal Station F  
Edmonton, Alberta  
CANADA T6H 5X2  
(403) 450-5408

British Columbia Waste Exchange  
Ms. Judy Toth  
2150 Maple Street  
Vancouver, B.C.  
CANADA V6J 3T3  
(604) 731-7222

California Waste Exchange  
Mr. Robert McCormick
Southeast Waste Exchange  
Ms. Maxie L. May  
Urban Institute  
UNCC Station  
Charlotte, NC 28223  
(704) 547-2307

Southern Waste Information Exchange  
Mr. Eugene B. Jones  
Post Office Box 960  
Tallahassee, FL 32302  
(800) 441-SWIX (7949)  
(904) 644-5516  
FAX: (904) 574-6704

Tennessee Waste Exchange  
Ms. Patti Christian  
226 Capital Blvd., Suite 800  
Nashville, TN 37202  
(615) 256-5141  
FAX: (615) 256-6726

Wastelink, Division of Tencon, Inc  
Ms. Mary E. Malotke  
140 Wooster Pike  
Milford, OH 45150  
(513) 248-0012  
FAX: (513) 248-1094

U.S. EPA Regional Offices
Region 1 (VT, NH, ME, MA, CT, RI)  
John F. Kennedy Federal Building  
Boston, MA 02203  
(617) 565-3715

Region 2 (NY, NJ)  
26 Federal Plaza  
New York, NY 10278  
(212) 264-2525

Region 3 (PA, DE, MD, WV, VA)  
841 Chestnut Street  
Philadelphia, PA 19107  
(215) 597-9800

Region 4 (KY, TN, NC, SC, GA, FL, AL, MS)  
345 Courtland Street, NE  
Atlanta, GA 30365  
(404) 347-4727

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