Basis and Purpose Document

PHARMACEUTICAL PRODUCTION NESHAP

Emission Standards Division

U.S. ENVIRONMENTAL PROTECTION AGENCY
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BASIS AND PURPOSE DOCUMENT

PHARMACEUTICAL PRODUCTION NESHAP

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1.0 PURPOSE OF DOCUMENT

The Basis and Purpose Document provides background information on, and the rationale for, decisions made by the U. S. Environmental Protection Agency (EPA) related to the proposed standards for the reduction of hazardous air pollutants (HAP) emitted through the manufacture of pharmaceutical products covered by the source category. The source category includes processes used in chemical synthesis, formulation, fermentation, and extraction manufacturing operations. This document is intended to supplement the preamble for the proposed standards.

This document is separated into eight chapters providing a combination of background information and rationale for decisions made in the standards development process. Chapters 2, 3, 5, and 7 provide background information; Chapter 2 is an introduction, Chapter 3 describes the affected industry, Chapter 5 presents the baseline organic HAP emissions, and Chapter 7 presents the predicted impacts associated with the selected regulatory alternatives. Chapters 4, 6, and 8 provide rationale for determination of MACT "floors" and development of regulatory alternatives, and rationale for the selection of the proposed standards, respectively.

Supporting information and more detailed descriptions of certain analyses are contained in the memoranda referenced in this document, the Supplementary Information Document (SID), the preamble, and the project docket.

2.0 INTRODUCTION

Section 112 of the Clean Air Act, as amended in 1990, gives the EPA the authority to establish national standards to reduce air emissions from sources that emit one or more HAP. Section 112(b) contains a list of HAP's to be regulated by national emission standards for hazardous air pollutants (NESHAP), and section 112(c) directs the EPA to use this pollutant list to develop and publish a list of source categories for which NESHAP will be developed. The EPA must list all known source categories and subcategories of "major sources" that emit one or more of the listed HAP's. A major source is defined in section 112(a) as any stationary source or group of stationary sources located within a contiguous area under common control that emits, or has the potential to emit, in aggregate, considering controls, 10 tons per year or more of any one HAP or 25 tons per year or more of any combination of HAP's. This list of source categories was published in the Federal Register on July 16, 1992 (57 FR 31576), and includes the pharmaceuticals production source category.

3.0 DESCRIPTION OF THE AFFECTED INDUSTRY

The source category covered under the proposed rule includes those facilities with process operations that are manufacturing, extracting, processing, purifying, or packaging chemical materials to be used as medication for humans and animals. The source category is defined as those processes and activities covered by the general standard industrial classification code 283. Additionally, any other fermentation, biological and natural extraction, chemical synthesis, and formulation products regulated by the Food and Drug Administration, including components (excluding excipients) of pharmaceutical formulations, or intermediates used in the production of a pharmaceutical product are covered.

The EPA collected information on HAP emissions from all facilities thought to be engaging in the production of pharmaceuticals. Based on this survey, which was conducted in 1992, EPA identified a total of 101 facilities producing one or more pharmaceutical products covered by the source category definition. All of these facilities are believed to be major sources due either to the hazardous air pollutant (HAP) emissions generated by pharmaceutical operations or the pharmaceutical operations being located at facilities whose entire plant site is a major source. Table 3-1 presents a list of the major sources identified for this source category.

3.1 DESCRIPTION OF PROCESSES AND SOURCES OF ORGANIC HAP EMISSIONS

This section contains information on the sources of HAP emissions from process vents, equipment leaks, storage tanks, and wastewater for the pharmaceuticals production source category.

TABLE 3-1. MAJOR SOURCES AFFECTED BY THE PHARMACEUTICALS PRODUCTION NESHAP

No.	Plant Name	City	State
1	3M PHARMACEUTICALS	NORTHRIDGE	CA
2	3M BROOKINGS	BROOKINGS	SD
3	3M PHARMACEUTICALS DIV. PILOT PLANT	MAPLEWOOD	MN
4	ABBOTT LABORATORIES	ROCKY MOUNT	NC
5	ABBOTT LABORATORIES, INC.	ABBOTT PARK	IL
6	ABBOTT LABORATORIES, INC.	BARCELONETA	PR
7	ABBOTT LABORATORIES - N. CHICAGO	NORTH CHICAGO	IL
8	ALTANA INC.	MELVILLE	NY
9	ALZA CORP.	VUCAVILLE	CA
10	AMERICAN CYANAMID CO. LEDERLE LAB DIV.	BOUND BROOK	NJ
11	ANAQUEST CARIBE, INC	GUAYAMA	PR
12	ARMOUR PHARMACEUTICAL COMPANY	BRADLEY	IL
13	AYERST LABORATORIES. INC.	ROUSES POINT	NY
14	B.L. CHEMICALS, INC.	PETERSBURG	VA
15	BASF CORP. VITAMINS COMPLEX	WYANDOTTE	Ml
16	BAXTER HEALTHCARE CORP. OF PR-I.V. SYSTEMS	JAYUYA	PR
17	BILCHEM, LTD.	PONCE	PR
18	BIOKYOWA, INC.	CAPE GIRADEAU	MO
19	BOOTS PHARMACEUTICALS, INC	KINGSTREE	SC
20	BRISTOL-MYERS BARCELONETA, INC.	BARCELONETA	PR
21	BRISTOL-MYERS SQUIBB COMPANY	SYRACUSE	NY
22	BURROUGHS WELLCOME CO.	GREENVILLE	NC
23	CHATTEM, INCORPORATED	CHATTANOOGA	TN
24	CIBA-GEIGY CORPORATION	SUMMIT	NJ
25	CYCLO PRODUCTS, INC.	LOS ANGELES	CA
26	DANBURY PHARMACAL INC.	DANBURY	CT
27	DIOSYNTH INC.	SIOUX CITY	IA
28	DOW CHEMICAL COMPANY LA PLANT	MIDLAND	Ml
29	ELI LILLY INDUSTRIES INC.	MAYAGUEZ	PR
30	ELI LILLY AND COMPANY, TIPPECANOE LABS	SHADELAND	IN
31	ELI LILLY AND COMPANY-LILLY TECH CTR NORTH	INDIANAPOLIS	IN
32	ELI LILLY AND COMPANY-LILLY CORPORATE CENTER	INDIANAPOLIS	IN
33	ELI LILLY AND COMPANY-LILLYTECH CTR SOUTH	INDIANAPOLIS	IN
34	ELI LILLY - CLINTON LABS.	CLINTON	IN
35	ETHYL CORP, ORANGEBURG PLANT	ORANGEBURG	SC
36	FISONS CORPORATION	ROCHESTER	NY
37	G.D. SEARLE & CO.	AUGUSTA	GA
38	GANES CHEMICALS, INC.	PENNSVILLE	NJ
39	GEL-TECH	WESTBURY	NY
40	GRANUTEC INC.	WILSON	NC
41	HAUSER CHEMICALS RESEARCH-AIRPORT FACILITY	BOULDER	CO
42	HOECHST CELANESE CORP.	COVENTRY	Rl
43	HOFFMANN-LAROCHE, INC.	NUTLEY	NJ
44	KABI PHARMACIA HEPAR, INC.	FRANKLIN	OH
45	KV PHARMACEUTICAL COMPANY	ST. LOUIS	MO
46	LEDERLE LABORATORIES DIVISION	PEARL RIVER	NY
47	MALLINCKRODT SPECIALTY CHEMICALS CO.	BELLEVILLE	NJ
48	MALLINCKRODT SPECIALTY CHEMICALS CO.	ST. LOUIS	MO
49	MEAD JOHNSON & COMPANY	EVANSVILLE	IN

TABLE 3-1. (continued)

No.	Plant Name	City	State
50	MENTHOLATUM CO. INC.	BUFFALO	NY
51	MERCK SHARP & DOHME QUIMICA DE PR INC	BARCELONETA	PR
52	MERCK AND CO., INC. RAHWAY SITE	RAHWAY	NJ
53	MERCK & CO. INC.	RIVERSIDE	PA
54	MERCK AND CO., INC. FLINT RIVER PLANT	ALBANY	GA
55	MERCK AND CO., INC. - STONEWALL	ELKTON	VA
56	MERRELL DOW PHARMACEUTICALS INC.	CINCINNATI	OH
57	NAPP CHEMICALS INC.	LODI	NJ
58	NATURALLY VITAMIN SUPPLEMENTS INC.	SCOTTSDALE	AZ
59	NORAMCO, INC.	ATHENS	GA
60	NORAMCO, INC. OF DELAWARE	WILMINGTON	DE
61	ORTHO-MCNEIL RARITAN	RARITAN	NJ
62	OXFORD LABORATORIES INC.	GUTTENBERG	NJ
63	PENCO OF LYNDHURST	LYNDHURST	NJ
64	PENICK CORPORATION	NEWARK	NJ
65	PENNEX PRODUCTS CO. INC.	VERONA	PA
66	PFIZER PHARMACEUTICALS, INC.	BARCELONETA	PR
67	PFIZER-US PHARMACEUTICALS GROTON FACILITY	GROTON	CT
68	PROCTER & GAMBLE (PUERTO RICO)	MANATI	PR
69	PROCTER & GAMBLE PHARM.	NORWICH	NY
70	R. P. SCHERER NORTH AMERICA	SAINT PETERSBURG	FL
71	RHONE-POULENC INC.	SAINT LOUIS	MO
72	RHONE-POULENC RORER PHARM, INC.	FORT WASHINGTON	PA
73	ROCHE VITAMINS & FINE CHEMICALS-BELVIDERE	BELVIDERE	NJ
74	ROCHE PRODUCTS INC.	MANATI	PR
75	SANDOZ PHARMACEUTICALS CORPORATION	EAST HANOVER	NJ
76	SCHERING PLOUGH PRODUCTS INC.	LAS PIEDRAS	PR
77	SCHERING CORPORATION,	UNION	NJ
78	SCHERING-PLOUGH PRODUCTS, INC.	MANATI	PR
79	SIDMAK LABS, INC.	EAST HANOVER	NJ
80	SMITHKLINE BEECHAM PHARMACEUTICALS CO.	GUAYAMA	PR
81	SMITHKLINE BEECHAM PHARM.-ANTIBIOTICS PLANT	BRISTOL	TN
82	SMITHKLINE BEECHAM ANIMAL HEALTH	LINCOLN	NE
83	SMITHKLINE BEECHAM PHARMACEUTICALS	CIDRA	PR
84	SMITHKLINE BEECHAM PHARMACEUTICALS, CO	CONSHOHOCKEN	pa
85	SMITHKLINE BEECHAM PHARMACEUTICALS, CO.	PHILADELPHIA	PA
86	SMITHKLINE BEECHAM PHARMACEUTICALS, CO	PISCATAWAY	NJ
87	SOLVAY PHARMACEUTICALS, INC.	BAUDETTE	MN
88	SOLVAY ANIMAL HEALTH, INC.	CHARLES CITY	IA
89	SQUIBB MANUFACTURING, INC.	HUMACAO	PR
90	STERLING ORGANICS	RENSSELAER	NY
91	STERLING PHARMACEUTICALS INC.	BARCELONETA	PR
92	SYNTEX AGRIBUSINESS INC.	VERONA	MO
93	SYNTEX AGRIBUSINESS, INC.	SPRINGFIELD	MO
94	SYNTEX CHEMICALS INC.	BOULDER	CO
95	TAKEDA CHEMICAL PRODUCTS USA, INC.	WILMINGTON	NC
96	THE UPJOHN COMPANY	PORTAGE	Ml
97	THE UPJOHN MANUFACTURING COMPANY	ARECIBO	PR
98	UPSHER-SMITH LABORATORIES INC.	MINNEAPOLIS	MN

No.	Plant Name	City	State
99	WARNER-LAMBERT CO. PARKE-DAVIS DIV.	HOLLAND	Ml
100	WYCKOFF CHEMICAL CO., INC.	SOUTH HAVEN	Ml
101	WYETH-AYERST LABORATORIES	WEST CHESTER	PA

The information below was compiled from a section 114 information request for the pharmaceuticals industry that was conducted in July 1993. The section 114 information requests were sent to 397 facilities, and 165 completed responses were received from these facilities. Facilities not completing the section 114 information request returned an explanation as to why they did not. These reasons included: outside the source category, below the de minimis level (i.e., 100 lb HAP uncontrolled, from the entire facility), or no HAP's emitted. The information requested in the section 114 information request included production information, uncontrolled and controlled HAP emissions per process, control devices used, and for dedicated processes, detailed unit operation emission information. This included flowcharts, duration of emission events, HAP constituents, and HAP mass of individual steams. The unit operation emission stream characteristics for dedicated processes, in combination with trip reports conducted at the onset of the project, were the primary sources of information for the source category information presented below for process vents, storage, and equipment leaks. A similar data gathering effort conducted by the Office of Water (OW) for this industry was the primary data source for wastewater.

3.1.1 Process Vents

There are four manufacturing operations commonly found in the pharmaceuticals production industry. These manufacturing operations are: (1) chemical synthesis, (2) formulation, (3) fermentation, and (4) extraction. Each of these manufacturing techniques contains an equipment train with unit operations unique to the type of operation being conducted. These unit operations are often vented to the atmosphere; these events are termed process vent emissions. A review of individual emission stream data received from the pharmaceuticals section 114 responses provides some information relative to characteristics of emission streams from the four manufacturing operations listed above. The following paragraphs detail this emission stream data.

Flowrate data were requested in terms of four groups for each dedicated emission source. These flowrate groups were 0 to 1.42 scmm (50 scfm), 1.42 to 14.2 scmm (50 to 500 scfm), 14.2 to 56.6 scmm (500 to 2,000 scfm), and >56.6 scmm (>2,000 scfm). The vast majority of dedicated unit operations included in the section 114 data base had flowrates that fell into the 0 to 50 scfm range (i.e., 1,795 unit operations). The specific pieces of equipment having flowrates in this range were process tanks (310), reactors (120), distillation operations (65), centrifuges (50), crystallizers (29), and dryers (21). There were significantly fewer dedicated unit operations (190) reporting flowrates in the range of 50 to 500 scfm. The unit operations falling in this flow rate were process tanks (15) reactors (13), dryers (5), and distillation (4). Eighty-three dedicated unit operations were found in the 14.2 to 56.6 scmm (500 to 2,000 scfm) range. In this group dryers were most prevalent making up 20 percent of the total unit operations. Reactors (6), centrifuges (5) and coating operations (4) were also noted. In the >56.6 scmm (>2,000 scfm) range, coating operations were most prevalent making up 31 percent of the 119 unit operations reporting flowrates in this range. Dryers (9), fermentation tanks (8), and reactors (5) were also found.

Two regulatory options (including the MACT floor) were evaluated. The regulatory alternative above the floor includes a control requirement for large individual streams to a level of 98 percent, in addition to process control level of 93 percent, which represents the MACT floor. In order to cost out both regulatory alternatives, model emissions from processes were developed. Two model streams were developed based on industry information. The two model process streams are shown on the following page.

Model emission stream No. 1 (concentration ≤3,500 ppmv)[a]	Model emission stream No. 2 (concentration >3,500 ppmv)[a]
Flow rate = 184 acmm (6,500 scfm)	Flowrate = 19.1 acmm (675 scfm)
Uncontrolled HAP emissions = 24.3 Mg/yr (53,500 lb HAP/yr)	Uncontrolled HAP emissions = 206.1 Mg/yr (454,000 lb HAP/yr)
Operating schedule = 22 hr/d 240 d/yr	Operating schedule = 21 hr/d 213 d/yr
Calculated concentration = 320 ppmv	Calculated concentration = 31,000 ppmv

[a] Two types of streams were developed because a concentration of 3,500 ppmv was found to be the "breakpoint" for cost effectiveness in the national impacts analysis for control devices evaluated (i.e., thermal incineration and condensation). Thermal incineration was used for streams ≤3,500 ppmv and condensation for streams with a concentration >3,500 ppmv.

More information on the MACT floor for process vents can be found in the supplementary information document (SID) in a memorandum dated October 13, 1995.[1] The following paragraphs include a general description of the equipment trains and unit operations typical of each manufacturing operation, the types of emission streams released to the atmosphere, and the characteristics of these emission streams.

Equipment trains in pharmaceutical processes can be operated in both batch and continuous modes, although batch processing accounts for 90 percent of all processes reported in the pharmaceuticals section 114 information request. Batch processes are characterized by nonsteady-state conditions which result in finite emission periods during which the concentration, flowrate, and stream conditions (temperature and pressure) fluctuate. Batch manufacturing in this industry can be broken down further into equipment trains that are dedicated to the manufacture of one product, and equipment trains that are not dedicated to the manufacture of any one product. Nondedicated batch processes are made up of unit operations that are easily moved, typically on wheels and equipped with flexible piping, and can be reconfigured with relative ease to accommodate fluctuations in market demand. Dedicated batch processes, conversely, are operated with the same equipment for considerably longer periods of time.

A summary of emission characteristics for the entire industry (major and area sources) is presented in Table 3-2. This information was compiled from data reported in the 1992 pharmaceuticals section 114 information request.

TABLE 3-2. SUMMARY OF PROCESS AND EMISSION CHARACTERISTICS

	MANUFACTURING CATEGORIES				
	Formulation	Fermentation	Extraction	Chemical synthesis	Total
PROCESS VENTS - ALL					
No. of processes reported	196	20	43	679	938
OP. days/yr	19,912	3,954	4,947	68,410	97,233
Uncontrolled HAP emissions, lb/yr	7,809,292	8,387,329	1,445,953	61,737,559	79,380,133
Baseline HAP emissions, lb/yr	2,479,339	1,608,065	332,030	8,646,871	13,066,305
Average HAP emissions, lb/batch	125	407	67	126	149
Average HAP reduction, %	68	81	77	86	84
*Average lb HAP/lb product	0.44	43.19	13.75	0.23	NA
PROCESS VENTS - NONDEDICATED PROCESSES					
No. of process reported	135	11	16	480	642
OP. days/yr	10,018	1,364	1,492	34,463	47,337
Uncontrolled HAP emissions, lb/yr	1,030,946	1,317,968	531,442	18,403,433	21,283,789
Baseline HAP emissions, lb/yr	847,140	736,868	122,838	2,984,138	4,690,984
Average HAP emissions, lb/batch	84	540	82	87	99
Average HAP reduction, %	18	44	77	84	78
PROCESS VENTS - DEDICATED PROCESS					
No. of processes reported	61	9	27	199	296
OP. days/yr	9,894	2,590	3,455	33,947	49,886
Uncontrolled HAP emissions, lb/yr	6,802,516	7,069,361	914,510	43,336,601	58,122,988
Baseline HAP emissions, lb/yr	1,656,369	871,197	209,192	5,664,804	8,401,562
Average HAP emission, lb/batch	167	336	61	167	168
Average HAP reduction, %	76	88	77	87	86PROCESS VENTS - BATCH
No. of processes reported	181	17	39	613	850
Batches/yr	16,675	2,553	4,233	59,773	83,234
Uncontrolled HAP emissions, lb/yr	7,160,546	6,365,364	832,998	52,513,671	66,872,579
Baseline HAP emissions, lb/yr	2,149,151	1,194,771	129,940	8,075,164	11,549,026
Average HAP emission, lb/batch	129	468	31	135	139
Average HAP reduction, %	70	81	84	84	83
PROCESS VENTS - NONBATCH					
No. of processes	21	4	4	66	95
OP. days/yr	3,302	1,385	714	8,560	13,961

TABLE 3-2. (continued)

MANUFACTURING CATEGORIES					
	Formulation	Fermentation	Extraction	Chemical synthesis	Total
Uncontrolled emissions lb/yr	673,986	2,021,964	612,954	9,226,728	12,535,632
Baseline emissions, lb/yr	335,428	413,294	202,090	573,785	1,544,597
Average HAP emissions, lb/d	108	298	283	67	111
Average HAP reduction, %	47	80	67	94	88

*Based on a subset of data points.

Notes

1. OP. days/yr corresponds to sum of batches/yr for batch processes and days/yr of operation for continuous processes.
2. Average lb HAP/lb product was calculated only with non-zero data points.
3. 81 percent of emissions are from batch processes.

3.1.1.1 Chemical Synthesis. Most of the active ingredients manufactured in this industry are synthesized chemicals. Chemical synthesis is the process of manufacturing pharmaceuticals using organic and inorganic chemical reactions. Unit operations generally found in chemical synthesis equipment trains include reactors, centrifuges, dryers, distillation columns, and process tanks. Figure 3-1 contains a simple process flow diagram for a typical chemical synthesis manufacturing equipment train.

Emissions of HAP's can occur from any of these unit operations, resulting from events such as vapor space displacement during vessel charging, purging of vessel headspace, vessel heatup, gas evolution from reaction and processing, and vessel emptying. Detailed descriptions of processing characteristics, equipment, and emission estimation methodologies are contained in the EPA draft document, EPA-453/R-93-017, Control of Volatile Organic Compound Emissions from Batch Processes.[2]

Data extracted from the information collection effort conducted in the development of the proposed rule indicate that chemical synthesis operations make up 70 and 75 percent of

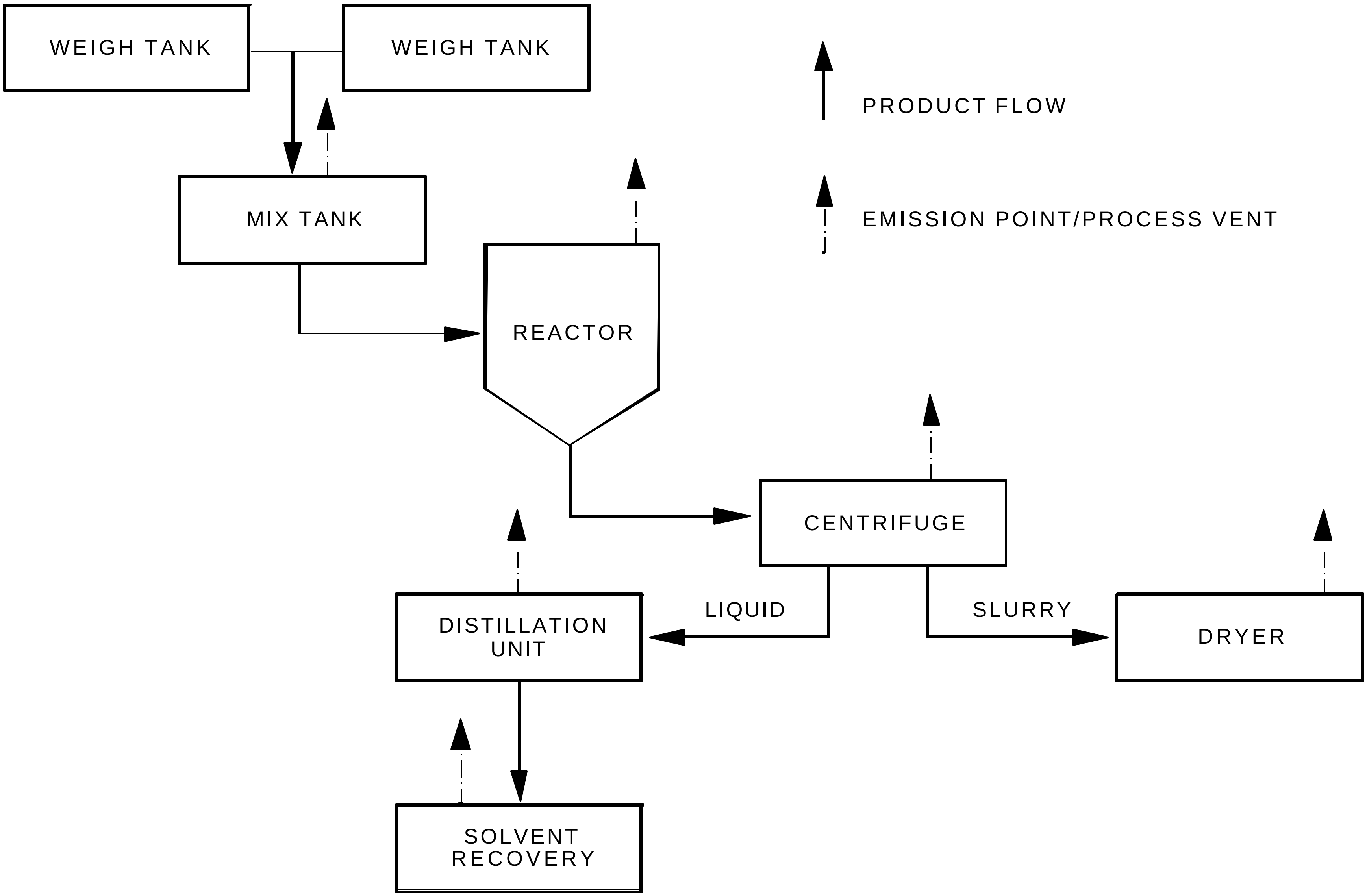

Figure 3-1. Chemical synthesis process flow diagram.

processes and HAP emissions, respectively. This accounts for nearly 500 processes at major sources. The predominant HAP's emitted to the atmosphere are methylene chloride, toluene and methanol.

3.1.1.2 Formulation. Active ingredients produced by the pharmaceutical industry are generally produced in bulk form and must be formulated to dosage form for consumer use. Common dosage forms include tablets, capsules, liquids, and ointments. A variety of equipment is used to convert the bulk products into these dosage forms. Figure 3-2 presents a process flow diagram for a tablet coating/formulation operation.

The largest source of HAP emissions from formulation activities is tablet coating. Tablets are formed in a tablet press machine by blending active ingredients, filler, and binder. The filler's purpose is to dilute the active ingredient to the proper concentration, and the binder is used to hold the tablet's contents together. Tablets are coated with a coating material and dried. The coating material may either be water or solvent based. Further, the coating may be applied either in a coating pan, where the coating is sprayed on the tablets, or in a fluidized bed where the tablets remain suspended while the coating is applied.[3] Emissions of HAP's can occur from coating pans and dryers if the coating material contains HAP solvents. Note that coating pans often have warm air blowing across them as the coating is being applied. The coating and drying operations in this case occur in the same equipment. Because dryers are typically operated at elevated temperatures (30° to 80°C) there is potential for more HAP to be emitted from these unit operations. Information received from the pharmaceuticals section 114 information request shows that the typical HAP solvents used in tablet coating operations are methanol and methylene chloride. Aqueous-based coatings are available for most applications, including some of the functional coating applications such as time-release and enteric-release that have traditionally warranted the use of solvent-based coatings.

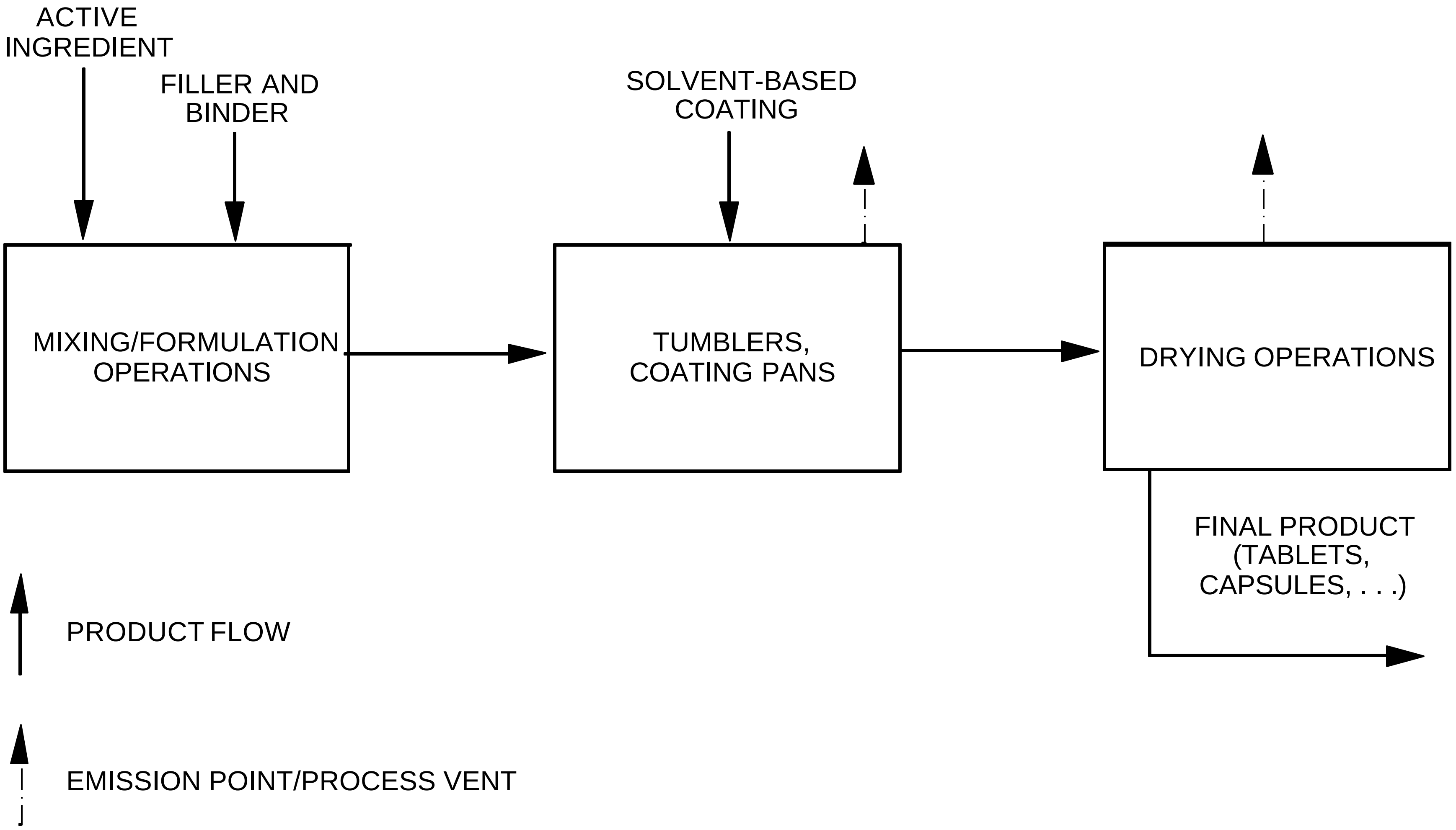

Figure 3-2. Formulation (tablet coating) process flow diagram.

A total of 92 processes were reported in the pharmaceuticals section 114 information request as performing formulation operations. These processes accounted for approximately 15 percent of the total number of processes in the industry and 13 percent of the HAP's emitted. The HAP's emitted to the atmosphere include methylene chloride, methanol, chloroform, and toluene.

3.1.1.3 Fermentation. Most antibiotics and steroids are produced by fermentation, which involves three basic steps: inoculum and seed preparation, fermentation, and product recovery. Figure 3-3 is a process flow diagram for a fermentation process.

Production of a fermentation product begins in the seed preparation step with spores from the master stock. These spores are activated with water, nutrients, and warmth until they are large enough for transfer to the seed tank. The fermentation process begins with the sterilization of the fermenter vessel. Data received from the pharmaceuticals section 114 information request suggests that the fermenter vessels are between 10,000 and 50,000 gallons. This volume is considered quite large in an industry that typically uses vessels that range from 500 to 5,000 gallons to produce essentially "specialty" organic chemicals.

After sterilizing the fermenter vessel, nutrient raw materials are charged to the fermenter. The microorganisms grown in the seed preparation step are then added to the fermenter and fermentation begins. Air is commonly sparged through the fermenter during the process which typically takes anywhere from 12 hours to 1 week. After the broth has fermented for the given time period it is ready for filtration. Filtration removes the dead microorganisms, leaving behind a filtered broth containing product and residual nutrients that are next sent to product recovery.

There are three common methods of product recovery: solvent extraction, direct precipitation, and ion exchange or adsorption. For purposes of this document the only method that will be

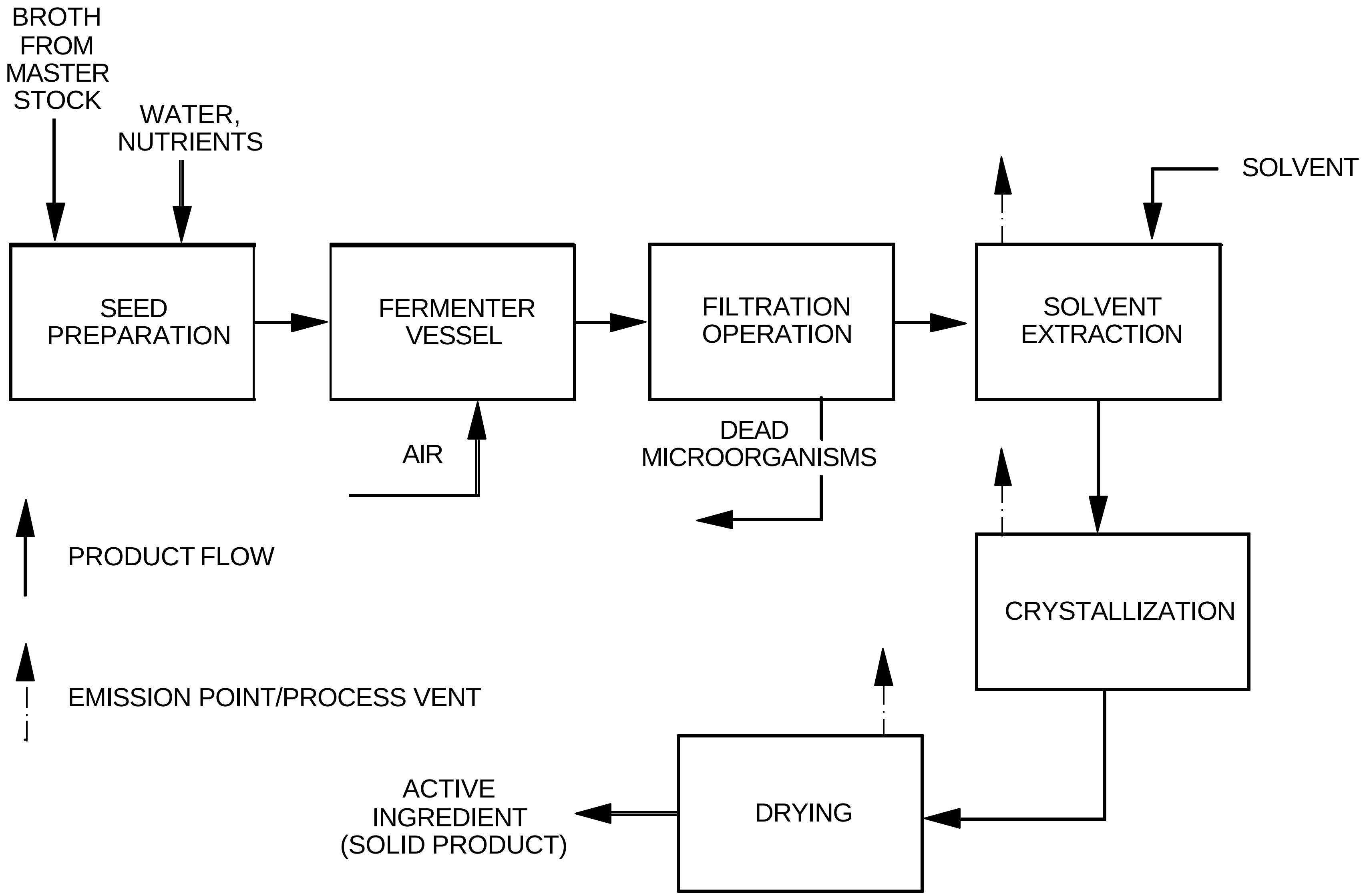

Figure 3-3. Fermentation process flow diagram.

described in detail is solvent extraction because this is the only method of product recovery in which HAP's may be emitted. In solvent extraction an organic solvent is used to remove pharmaceutical product from the broth and form a more concentrated solution.

Often, the solvent extraction process involves removing the active ingredient by allowing it to adhere to a solid (e.g., diatomaceous earth) then filtering to remove the excess liquid. Further extraction of the active ingredient by adding a solvent such as methanol, in many cases, brings the active ingredient back into the liquid phase with the solvent. At this point, a final filtration or drying step removes the excess solvent. Emissions occur as a result of displacement (charging) of large volumes of solvent from one vessel to another, and recovery of product from the concentrated solvent by crystallization, filtration and drying for solid product. The HAP solvents most commonly used based on data received from the pharmaceuticals section 114 information request are methanol and methyl isobutyl ketone. Also, only 20 fermentation processes were reported in the pharmaceuticals section 114 information requests. In turn, these 20 processes emit 14 percent of the total HAP lost to the atmosphere from the entire source category.

3.1.1.4 Extraction. Many pharmaceutical active ingredients are derived from natural sources such as plants, animal glands, or parasitic fungi. Because these active ingredients are too complex to synthesize commercially (i.e., they may be extremely large molecules or produce several stereoisomers, only one of which has pharmacological value) they are isolated through extraction. The following paragraphs describe extraction operations found in the pharmaceuticals production industry.

The extraction process consists of a series of steps beginning with the processing of a large quantity of natural material that contains the active ingredient. The volume of active ingredient acquired from the volume of natural material is sometimes several orders of magnitude smaller. An assembly-line, small-scale batch processing method is typically used to carry out the extraction process. Materials are transported in 75 to 100 gallon batches throughout the plant. The containers are sent through a series of stations where operators perform specific steps on each batch. As the volume of the material decreases the contents are combined to maintain a reasonable size.

Solvents are used in two ways in extraction. Some solvents are used to remove fats and oils that would contaminate the product. These extractions use an organic liquid that dissolves the fat but not the product. Solvents are also used to extract the product itself. As in the extractive steps in fermentation operations, product is then isolated from the solvent in vacuum distillation, crystallization and drying operations. Once the solvents have been added to the process they are lost to the atmosphere by evaporation in filters, crystallizers, or dryers.

Data in the pharmaceuticals section 114 information request suggests that the HAP's most commonly used in extraction operations are toluene, methylene chloride, and chloroform. The responses to the pharmaceuticals section 114 information request also indicate that extraction operations make up 7 percent (40 processes) of the total number of manufacturing processes found in this industry.

3.1.2 Storage Tanks

Storage tanks used by facilities in this source category are typically fixed roof tanks. The significant portion of tanks are between 38 m^3 and 150 m^3.

Data submitted to the EPA in response to the pharmaceuticals section 114 information request indicates that there were 623 storage tanks at 66 facilities that stored a wide variety of organic HAP solvents, including toluene, methylene chloride, methanol, hexane, and methyl ethyl ketone.

Also, many facilities store hydrochloric acid. Emissions of HAP's occur during vapor expansion and contraction due to diurnal temperature changes (breathing losses) and refilling the tanks with virgin solvent (working losses). Many responses did not indicate tank size or liquid stored.

3.1.3 Equipment Leaks

Emissions of HAP occur from piping components such as valves, pump seals, flanges, open-ended lines, pressure relief devices, and sampling connections.

The information received from the pharmaceuticals section 114 information request shows that there were few formal leak detection and repair (LDAR) programs in existence for this source category in 1992. However, since the pharmaceuticals section 114 information request was received, subpart I of 40 CFR part 63, The Equipment Leaks Negotiated Regulation, has been implemented which contains equipment leaks standards for components in methylene chloride and carbon tetrachloride service in chemical synthesis operations. Therefore, formal LDAR programs are currently in place for these processes. Components subject to subpart I are not considered part of this source category. Data reported in the pharmaceuticals section 114 information request suggests that this subset makes up nearly one third of the total processes located at major sources in the source category.

3.1.4 Wastewater

Air emissions from evaporative losses of HAP in wastewater are a significant source of HAP emissions in this industry. Pharmaceutical manufacturing facilities are divided into those that directly discharge wastewater to surface water and those that discharge wastewater to publicly-owned treatment works (POTW). Further, nearly 93 percent of all the wastewater generated by pharmaceutical manufacturing was generated by chemical synthesis and fermentation processes. The following paragraphs discuss emission mechanisms from collection systems used to route the individual wastewater streams to the treatment systems, and from the types of wastewater treatment system components associated with both direct and indirect discharging facilities.

3.1.4.1 Point of Determination. The point at which wastewater exits a process (and after the decanter for separation operations) is considered the point of determination (POD) for wastewater. In determining the characteristics of POD's for this industry data submitted by an industry trade association was evaluated and four general POD's were developed. The characteristics of these POD's is presented below.

	Percent flow	Percent load
POD 1	44	1
POD 2	9	2
POD 3	19	6
POD 4	28	91

The POD data submitted to the EPA was compiled by the affected industry and thus considered representative of POD's expected to be found at facilities in the source category.

3.1.4.2 Collection Systems. Prior to entering the onsite treatment system, the wastewater must be routed to the treatment system. The collection systems used to route the wastewater can be hard piped, therefore not allowing evaporative losses, or can be composed of covered or grated sewers; additionally open sumps and drop structures may be encountered. The evaporation of HAP's to the atmosphere occur most readily from open or uncovered collection components where the wind retards the saturation of the ambient air thus allowing volatile organic HAP's to evaporate.

Information on HAP emissions from wastewater treatment systems was obtained from data gathered by the EPA Office of Water (OW) 308 questionnaire to the industry in 1990. Emissions from collection systems were not quantified during the estimation of HAP emissions.

3.1.4.3 Indirect Dischargers. Facilities that route their wastewater streams to a POTW usually have treatment systems that are not designed to fully destroy wastes, since this is accomplished in the POTW. Indirect discharge treatment systems usually comprise one to two open equalization basins, an open neutralization basin, and one or more open aerated stabilization basins. Figure 3-4 contains a generalized process flow diagram for an indirect discharge facility. Evaporation of HAP compounds to the atmosphere occurs in these treatment components. However, both equalization and neutralization generally have less HAP air emissions than aerated basins because they are typically not sparged.

The sizes of these basins are quite large, on the order of 189 to 3,785 m^3 (50,000 to 1,000,000 gallons) depending on the wastewater flowrate. The daily wastewater flow also spans a huge range from a few thousand gallons per day (gal/d) to several million gal/d. The load of HAP's to POTW's from the 43 indirect discharge facilities that are major sources for which data was available was reported to be 21,000 Megagrams per year (Mg/yr) (50 percent of the total HAP load to wastewater).

3.1.4.4 Direct Dischargers. Facilities that allow the treated wastewater exiting the plant to flow directly to a source of surface water are referred to as direct discharging facilities. These treatment components are generally similar in size to treatment components and gal/d wastewater flow from indirect dischargers. However, these facilities generally provide more thorough treatment of the wastewater streams generated at the plant than do indirect dischargers. Figure 3-5 contains a wastewater flow schematic for a direct discharge facility.

Direct discharging facilities typically have equalization and neutralization, but the aerated basins contain higher quantities of active biomass (i.e., 4 to 8 g/L) which provides for more degradation of the organic pollutants in the wastewater. Additionally, primary and secondary clarification may be present as well as liquid incineration or steamstripping of specific, high concentration wastewater streams. The HAP load to the treatment system for the 10 direct treatment systems located at major sources for which data was available was reported to be 20,500 Mg/yr (50 percent of the total HAP load to wastewater), and the baseline emissions of HAP's emitted to the air was 2,000 Mg/yr (10 percent of total HAP emissions to the air from

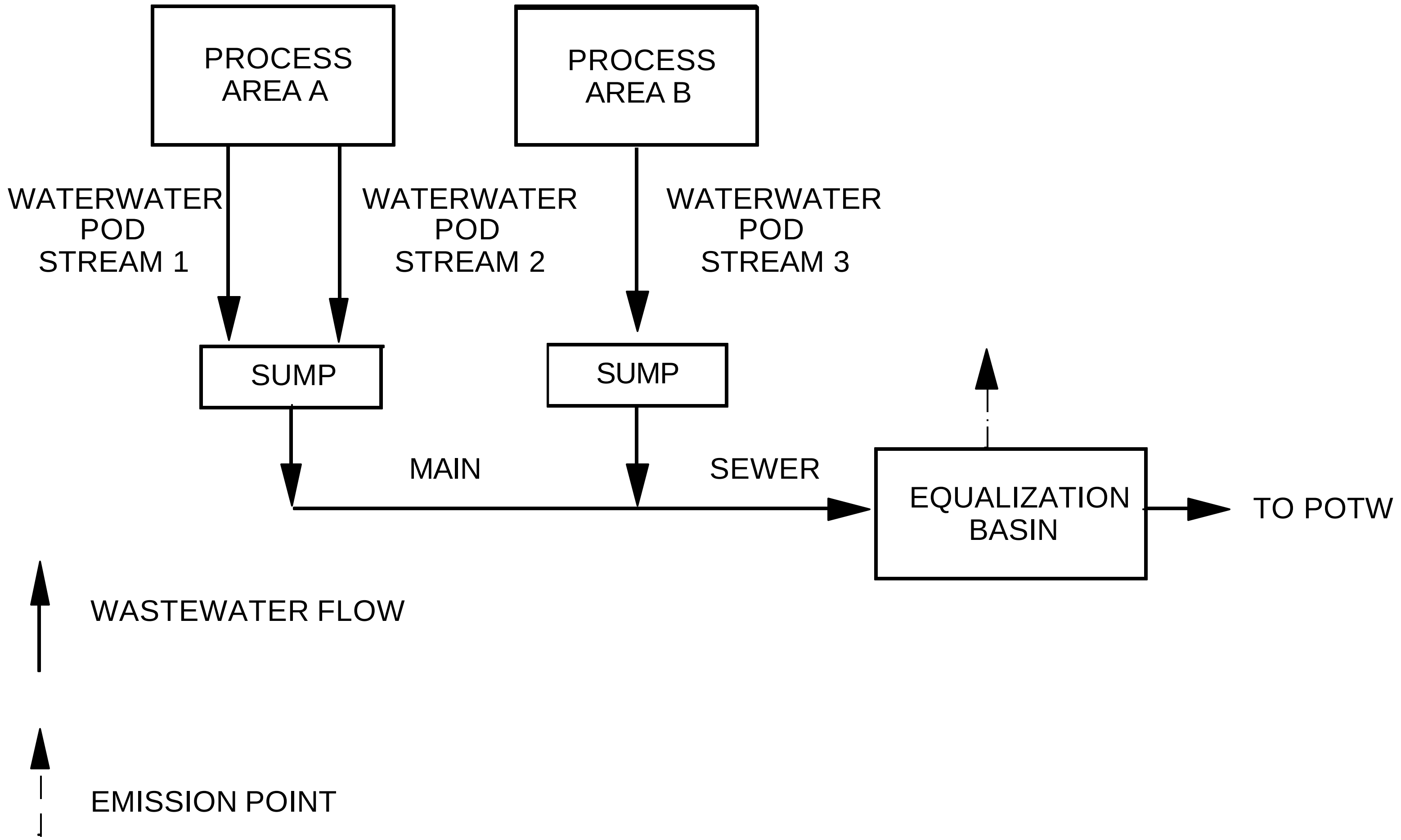

Figure 3-4. Indirect discharge facility.

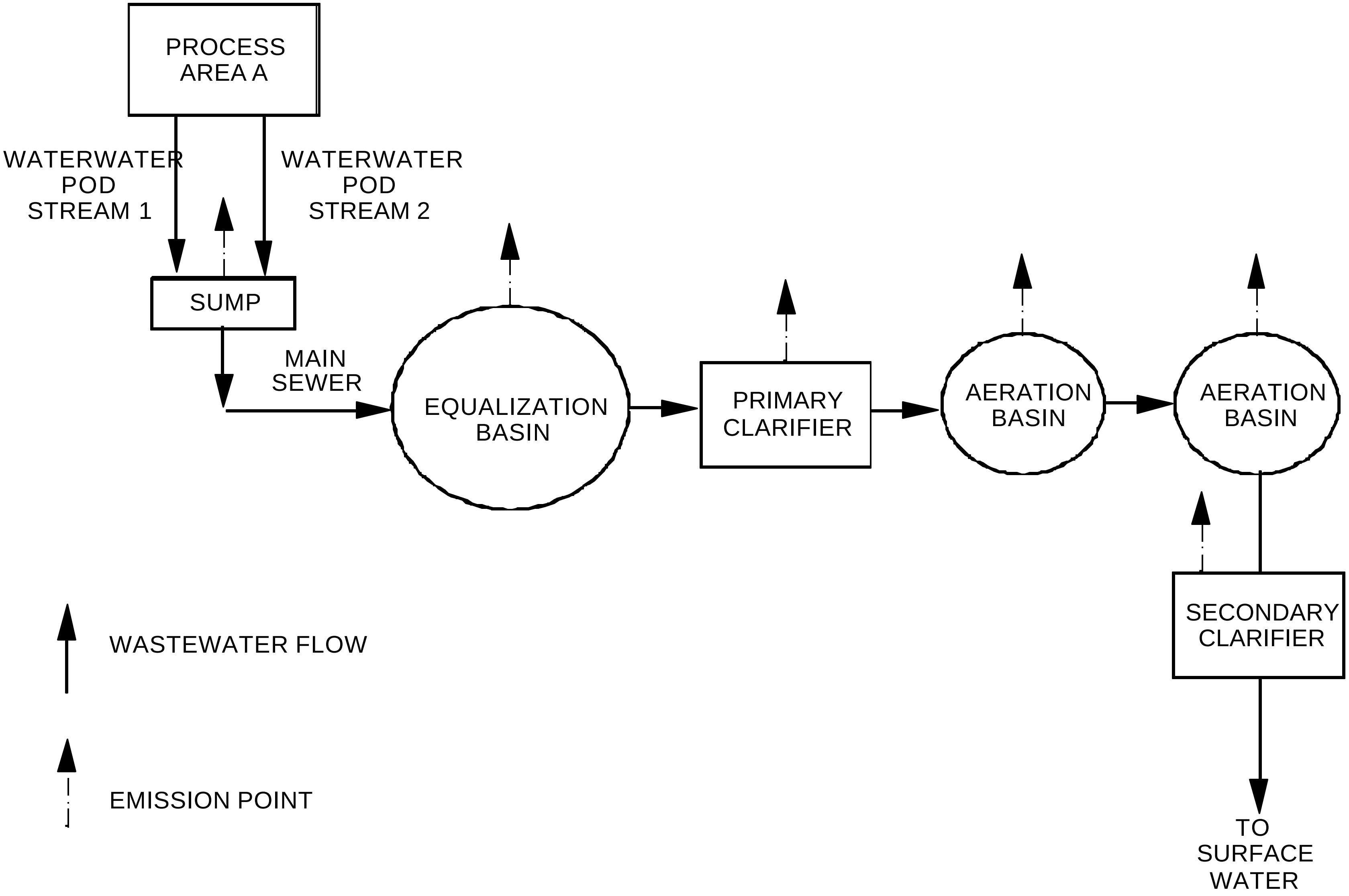

Figure 3-5. Direct discharge facility.

wastewater). The three HAP's emitted in the largest mass from direct discharging facilities were methanol, methylene chloride, and n,n-dimethylformamide.

3.1.5 Information on VOC and HAP Emissions from Waste Treatment and Collection Systems

The following summaries describe studies conducted on wastewater management units in this industry.

3.1.5.1 PhRMA Sewer Study. [5] The sewer study submitted to the EPA by the Pharmaceutical Research and Manufacturer's Association (PhRMA) was conducted on two POTW's. One of the POTW's was in Puerto Rico and the other in New York. These sites were chosen because they have a high methanol loading from industrial sources, in particular pharmaceutical operations.

In this study, parameters gathered from an earlier pass-through study on the same two POTW's were used to estimate methanol emissions using EPA's WATER8 model. The first-order biodegradation coefficient used was 37 L/gm VSS-hr. This was obtained from the serum-bottle testing, but it lies in the middle of the range of the first order constants measured in the PhRMA study (see below).

Results of the study indicate that volatilization emissions of methanol from these two POTW's was small. Approximately 2.64 percent of the methanol was volatilized at the POTW that receives the highest methanol concentration in its wastewater (Barceloneta), with 84 percent of this amount being lost from primary clarifiers and 15.4 percent from the aerated grit chamber. The volatilization from the aerated activated sludge units at both POTW's were negligible, on the order of 0.01 percent.

3.1.5.2 PhRMA Biorate Study and Results. [6] The Pharmaceuticals Research and Manufacturers Association conducted a modified EPA Method 304 test for wastewater to determine specific first-order biodegradation coefficients for methanol. Three campaigns were conducted each with varying concentrations of methanol in the wastewater. Campaign 1 had a methanol concentration of 211 mg/L (typical full-strength concentration at the plant where the tests were conducted), campaign 2 had a methanol concentration of 330 mg/L (upset conditions, 50 percent increase in concentration), and campaign 3 had a methanol concentration of 105 mg/L (50 percent decrease in concentration).

The results of these tests were compared to a study conducted on wastewater in the pulp and paper industry and the EPA WATER8 wastewater emission estimation model. The first-order biodegradation coefficients calculated from campaigns 1 and 3 of the tests were deemed not statistically different. The coefficients calculated for these campaigns were 43.4 and 66.7 L/g VSS-h for campaigns 1 and 3, respectively. The coefficient calculated in campaign 2 (upset) was statistically different and lower, 23.1 L/g VSS-h. The primary reason given for the deterioration in performance for campaign 2 was the upset conditions (increased methanol concentration) of the reactor. Comparisons to the pulp and paper wastewater study and WATER8 showed that the first-order biodegradation coefficients for the PhMRA tests were higher than those calculated for the pulp and paper tests, but on the same order of magnitude, and nearly two orders of magnitude higher than the biodegradation coefficients used in WATER8.

3.1.5.3 PhRMA Waste Treatment Plant Oxygenated Study.[7]

A study on the biodegradability of oxygenated solvents and their volatility was conducted at industrial wastewater treatment facility. Sampling of influent and effluent from various wastewater management units was conducted to provide data with which to base a mass balance on. The results of the mass balance indicate that, of the total influent mass to treatment, <0.1 to <2.0 percent was emitted to the atmosphere, <1 percent to <8 percent was released in the wastewater, and biodegradation was estimated to account for 92 percent to 98 percent. No material was detected in the sludge.

3.1.5.4 PhRMA Study on Emissions from High Solubility VOC's from Municipal Sewers.[8] A study on the potential for volatilization of methanol and similar soluble compounds from sewers was commissioned by PhRMA. This study was intended to support their position that MACT should allow for discharge of soluble compounds to the POTW. Researchers employed the use of mass transfer emissions models to identify conditions in sewer reaches and drop structures that would lead to "worst-case" stripping efficiencies. The results of the study were that, at worst case (which was a totally open system), only 6 percent of the total load of methanol could be emitted to the atmosphere prior to entering a downstream treatment facility. Worst case stripping efficiencies for acetone and ethanol at these conditions was 20 percent and 25 percent, respectively. For closed reaches and drop systems, stripping efficiencies were considerably lower, and typically less than 0.5 percent.

3.2 REFERENCES FOR CHAPTER 3

1. Supplementary Information Document, Process vents MACT floor memorandum. October 13, 1995.
2. Control of Volatile Organic Compound Emissions from Batch Processes. EPA-453/R-93-017, Draft. February 1994.
3. Volatile Organic Compound Emission Controls for Tablet Coating at Pharmaceutical Plants, U. S. EPA--Region III. January 1984.
4. Supplementary Information Document, Storage Tanks MACT floor memorandum. August 10, 1995.
5. Methanol Emissions from POTWs; Report on Calculated Methanol Emission for the Barceloneta, PR, and Rensselaar County, NY POTW's. Submitted by T. White, PhrMA to R. McDonald, ESD. January 30, 1996.
6. Investigation of Biodegradation Rate Coefficients for Methanol and Other Oxygenated Solvents in a Pharmaceutical Wastewater. Dated November 8, 1993. Submitted by T. White, PhRMA, to R. McDonald, ESD. November 13, 1995.

7. Oxygenated Solvent Biodegradation and Volatilization Study. Prepared for Abbott Labs by Tischler-Kocurek, Round Rock, Texas. Submitted by J. Kravcisin-McClain, Abbott Labs, to R. McDonald, ESD. March 7, 1996.

8. Emissions of High-Solubility VOC's from Municipal Sewers, prepared for PhRMA by Richard L. Corsi, PhD. University of Texas. Submitted by T. White, PhRMA, to R. McDonald, ESD. February 9, 1996.

4.0 RATIONALE FOR THE SELECTION OF SOURCE CATEGORIES, SUBCATEGORIZATION, AND EMISSIONS AVERAGING

The source category for this standard is pharmaceuticals production. Subcategories were considered by the Office of Water (OW) in developing effluent guidelines. However, the industry was not subcategorized in the MACT development process because of the difficulty associated with setting separate floors for numerous production types. The MACT floors nonetheless are representative of all types of production associated with this source category.

Emissions averaging will be part of this rule. The emissions averaging provisions in this rule are based on discussions with PhRMA. The emissions averaging incorporates several ideas proposed by PhRMA, but maintains the emissions averaging constraints included in the HON rule. These constraints are discussed in a supplementary Federal Register notice published on October 15, 1993; 58 FR 53479, and include consideration of: (1) state discretion on the use of emissions averaging, (2) inclusion of risk in averaging determinations, (3) compliance period for emissions averaging, and (4) limit on the number of emission points allowed in an average. Another constraint is to not allow controls to be used for averaging if those controls were required to meet other state or Federal regulatory requirements. This constraint is discussed in Federal Register notice published on April 22, 1994; 59 FR 19402.

One of PhRMA's concerns with regard to emissions averaging as allowed in the HON was the complexity of the requirements. To reduce much of this complexity, PhRMA suggested limiting the averaging to within the process vent and the storage tank planks. The other fundamental change to the HON averaging provisions is to allow owners and operators to make changes to the initial averaging plan over time and to demonstrate that the required annual emissions reductions have been met in the quarterly reports. Because of the nature of this industry, EPA agreed that flexibility with regard to changing process operations was warranted.

As in the HON rule, for this proposed rule, emissions averaging is not allowed as a compliance option for new sources. The decision to limit emissions averaging to only existing sources is based on the fact that new sources have historically been held to stricter standards than existing sources. It is most cost effective to integrate state-of-the-art controls into equipment design and to install the technology during construction of new sources. By allowing emissions averaging, existing sources have the flexibility to achieve compliance at diverse points with varying degrees of control already in place in the most economically and technically reasonable fashion. This concern does not apply to new sources which can be designed and constructed with compliance in mind. Therefore, emissions averaging is only allowed at existing sources.

5.0 BASELINE EMISSIONS

Baseline organic hazardous air pollutant (HAP) emissions for major sources in the pharmaceuticals production source category as reported in the pharmaceuticals Section 114 information request for the 1992 reporting year are included in Table 5-1. Also included in this table are the uncontrolled HAP emissions for this source category. As shown in the table, the total nationwide estimated HAP emissions is 34,100 Mg/yr.

TABLE 5-1. SUMMARY OF UNCONTROLLED AND BASELINE EMISSION INFORMATION

Emission source type	Uncontrolled emissions, Mg/yr	Baseline emissions, Mg/yr	Average emission reduction, %
Process vents	28,000	7,600	73
Storage tank	900	500	44
Equipment leaks	3,000	3,000	b
Wastewater	NC[a]	23,000	c
Total		34,100	

a NC = not considered.

b The number of facilities instituting LDAR programs on processes other than those subject to Subpart I was negligible.

c The average emissions reduction was not calculated for wastewater.

5.1 DETAILED BASELINE EMISSIONS INFORMATION FROM EACH GENERIC SOURCE TYPE

The following paragraphs detail the basis for the baseline HAP emissions from each of the generic source types (i.e., process vents, storage tanks, equipment leaks, and wastewater). Information is also provided on the magnitude of the emissions, the current average control level, and the HAP emitted from sources affected by the proposed Standard.

5.1.1 Process Vents

Table 5-2 presents a summary of major HAP emitted from process vents. Included in this table is the magnitude of the uncontrolled and baseline emissions and the emission reduction across the entire industry for each HAP. As shown in Table 5-2, methylene chloride, methanol, and toluene are the three HAP emitted in the largest quantities from process manufacturing operations in this source category. These three HAP's constitute nearly 76 percent of the HAP process vent emissions in the pharmaceuticals production source category.

5.1.2 Storage Tanks

Table 5-3 presents a summary of major HAP's emitted from storage tanks. The three HAP with the largest uncontrolled emissions in this industry include hydrochloric acid, methylene chloride, and methanol. These three HAP make up 90 percent of the uncontrolled HAP emissions from storage tanks. As shown in Table 5-1, the uncontrolled and baseline HAP emissions from storage tanks is 900 and 500 Mg/yr, respectively. These numbers were obtained from the pharmaceuticals Section 114 information request and extrapolated to account for facilities that did not report emissions specifically from storage tanks. Only 66 out of 101 major sources reported storage tank HAP emissions.

5.1.3 Equipment Leaks

Equipment leaks are essentially not controlled in this industry. The magnitude of the uncontrolled (and baseline HAP) emissions is 3,000 Mg/yr. The baseline HAP emissions were estimated using the SOCMI average emission factors for light liquid pumps, liquid valves and flanges applied to a model component count. The model component count was developed from data submitted by industry in response to the pharmaceuticals Section 114 information request. The model component count for a single process is composed of 9 pumps, 200 valves, and 1,047 flanges. The model component count was extrapolated to the

TABLE 5-2. PROCESS VENT EMISSIONS/REDUCTIONS BY HAP

HAP	Uncontrolled emissions, lb/yr	Baseline emissions, lb/yr	Emission reduction,%
Methylene chloride	40,489,013	7,128,769	82.39
Methanol	18,270,408	4,200,105	77.01
Toluene	10,559,263	936,502	91.13
Hydrochloric acid	7,306,362	312,489	95.72
Methyl isobutyl ketone	4,213,926	758,045	82.01
Dichloromethane	3,074,265	659,060	78.56
Hexane	2,498,277	332,341	86.70
Dimethylformamide	1,311,981	1,112,153	15.23
Chloroform	742,215	234,990	68.34
Acetonitrile	447,576	136,594	69.48
Methyl chloride	328,752	264,194	19.64
Triethylamine	310,235	42,976	86.15
Methyl ethyl ketone	277,140	139,567	49.64
Ethylene oxide	266,086	21,114	92.06
Carbon disulfide	255,442	18,105	91.97
Methyl chloroform	178,902	85,933	51.97
Chlorine	158,933	5,052	96.82
Trichloroethylene	150,300	150,300	0.00

TABLE 5-3. STORAGE TANK EMISSIONS/REDUCTION BY HAP

HAP	Uncontrolled emissions, lb/yr	Baseline emissions, lb/yr	Emission reduction, %
Hydrochloric acid	995,651	46,163	95.17
Methylene chloride	785,792	496,917	37.00
Methanol	166,020	128,185	22.79
Toluene	42,597	35,216	17.33
Hexane	33,489	29,201	12.80

entire industry (i.e., all processes expected to be affected by the proposed regulation) in order to estimate baseline HAP emissions. Further, the baseline emissions were estimated exempting processes that contained methylene chloride and carbon tetrachloride because these HAP are covered by Subpart I of the Hazardous Organic NESHAP (HON).

5.1.4 Wastewater

Air emissions from wastewater are the largest source of HAP emissions from the pharmaceuticals production source category. The data used in the estimation of HAP emissions was collected by the Office of Water (OW) in 1991 as part of the technical development of their effluent guideline standards for this industry. The OW questionnaire provided detailed information from 244 pharmaceutical manufacturing facilities. The data obtained from OW contained a broad base of information on the treatment systems in use by each facility in the industry including the types of treatment components (e.g., equalization and neutralization basins, clarifiers, aeration basins, etc.), the wastewater flow and load into the treatment system, the biomass present in the aeration basins, and the sizes, including available surface area, of most management units.

Of the 244 facilities surveyed, 178 reported the discharge of HAP into wastewater. Of these 178 facilities, a total of 83 facilities were analyzed in detail using the EPA-WATER8 emission estimation model. The WATER8 model calculates air emissions from wastewater systems by accounting for several pollutant removal mechanisms, including surface volatilization, biodegradation, and adsorption onto solids (i.e., sludge). Physical parameters of the treatment units, such as surface area, aeration and agitation mechanisms, and biomass levels are among the parameters most sensitive to air emissions. The remaining 95 facilities did not report enough information about their treatment system to facilitate a modeling effort. However, the total HAP load to wastewater from these 95 facilities accounts for only 5 percent of the total load from all 178 facilities.

The baseline emissions of HAP in Table 5-4 were assumed to be equal to the HAP load in the wastewater as it entered the treatment system for facilities that had no controls other than biotreatment. This assumption was used to reflect HAP recovery potential with steam stripping. Also, existing biotreatment systems possibly are not operated to achieve the level of HAP destruction indicated by modeling of enhanced biotreatment systems. The magnitude of baseline HAP emissions was estimated to be 23,000 Mg/yr. Table 5-4 contains a list of the HAP's emitted to the air from wastewater.

TABLE 5-4. WASTEWATER EMISSIONS

Compound	Baseline emissions, lb/yr
Methanol (methyl alcohol)	29,136,677
Methylene chloride	8,076,206
N,N-dimethylformamide	4,571,456
Toluene	3,632,402
n-Hexane	1,838,778
Acetonitrile	926,804
Xylenes	724,196
Formaldehyde	702,230
Triethylamine	600,080
1,2-Dichloroethane (ethylene dichloride)	482,499
Chloroform	402,025
Phenol	357,533
Acetophenone	353,492
Hydrazine	216,313
Chloromethane	194,604
Chloroacetic acid	57,790
Ethylene glycol	45,545

TABLE 5-4. (continued)

Compound	Baseline emissions, lb/yr
Carbon disulfide	40,392
Diethylaniline	38,311
Aniline	36,400
Epichlorohydrin	33,493
4-Methyl-2-pentanone (MIBK)	13,900
2-Butanone (MEK)	12,868
Chlorobenzene	10,959
Vinyl acetate	9,029
Chloromethyl methyl ether	4,600
Benzene	1,700
Ethylene oxide	900
Iodomethane (methyl iodide)	540
1,2-Dibromoethane	100

6.0 MACT FLOORS AND REGULATORY ALTERNATIVES

This chapter presents the approach used to determine MACT floors and regulatory alternatives for the pharmaceuticals production source category. The Clean Air Act requirements for the determination of MACT floors are discussed, as well as the general approach used to determine the MACT floors and regulatory alternatives.

6.1 CLEAN AIR ACT REQUIREMENTS

The amended Clean Air Act contains requirements for the development of regulatory alternatives for sources of HAP emissions. The statute requires the standards to reflect the maximum degree of reduction in emissions of HAP that is achievable for new or existing sources. This control level is referred to as MACT. The amended Clean Air Act also provides guidance on determining the least stringent level allowed for a MACT standard; this level is termed the "MACT floor." Consideration of control levels more stringent than the MACT floor must reflect consideration of the cost of achieving the emission reduction, any nonair quality, health, and environmental impacts, and energy requirements.

For new sources, the standards for a source category or subcategory "shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source, as determined by the Administrator" [section 112(d)(3)]. Existing source standards shall be no less stringent than the average emission limitation achieved by the best performing 12 percent of the existing sources for source categories and subcategories with 30 or more sources or the average emission limitation achieved by the best performing 5 sources for source categories or subcategories with fewer than 30 sources [section 112(d)(3) of the Act]. These two minimum levels of control define the MACT floor for new and existing sources.

Two interpretations have been evaluated by the EPA for representing the MACT floor for existing sources. One interpretation is that the MACT floor is represented by the worst performing facility of the best 12 percent performing sources. The second interpretation is that the MACT floor is represented by the "average emission limitation achieved" by the best performing sources, where the "average" is based on a measure of central tendency, such as the arithmetic mean, median, or mode. This latter interpretation is referred to as the "higher floor interpretation." In a June 6, 1994 Federal Register notice (59 FR 29196), the EPA presented its interpretation of the statutory language concerning the MACT floor for existing sources. Based on a review of the statute, legislative history, and public comments, the EPA believes that the "higher floor interpretation" is a better reading of the statutory language. The determination of the MACT floor for existing sources under the proposed rule followed the "higher floor interpretation."

6.2 DETERMINATION OF MACT FLOORS AND REGULATORY ALTERNATIVES

This section describes the general approach taken for determining the MACT floor for existing and new sources and specific details of the analyses for this source category.

6.2.1 General Approach

The EPA developed a general approach for evaluating the MACT floor and determining regulatory alternatives that were equivalent to or more stringent than the MACT floor for existing sources. This approach was applied to each type of emission point within each category.

The first step in the general approach for evaluating the MACT floor and determining regulatory alternatives for existing sources was to identify the potential types of emission points within the source category.

The next step in the general approach was to determine which facilities were the best performing facilities. This was done by examining the types of control and the level of emission reductions being achieved (e.g., percent reductions). For storage vessels, the EPA examined the level of control to determine which facilities were best controlled. A subsequent examination of control among individual tanks was then conducted based on tank capacity and vapor pressure. For process vents and wastewater, the EPA used percent emission reduction as the primary indicator of the best controlled facilities. For equipment leaks, the EPA used percent reduction based on the facility's actual LDAR program to identify the best controlled facilities.

The next step was to determine regulatory alternatives equivalent to or more stringent than the MACT floor as reflected in the existing level of control for the "best performing" facilities. Potential regulatory alternatives were developed based on the HON and the Batch Processes ACT. The HON was selected because (1) the characteristics of the emissions from storage vessels, equipment leaks, and wastewater are similar or identical to those addressed by the HON and (2) the levels of control required under the HON were already determined through extensive analyses to be reasonable from a cost and impact perspective.

The Batch Processes ACT was selected to identify regulatory alternatives for batch process vents, which are not addressed by the HON. The Batch Processes ACT covers VOC emissions and most of the HAP emissions identified for the pharmaceutical facilities are also VOC. Unlike the HON, the Batch Processes ACT is not a regulation and, therefore, does not specify a level of control that must be met. Instead, the Batch Processes ACT provides information on potential levels of control, and their costs. Based on the review of the Batch

Processes ACT, the EPA selected a level of control equivalent to 98 percent reduction for batch process vents that are cost effective to control. This level of control was selected for regulatory analysis purposes because it represents, for the purposes of the proposed rule, a level of control that is achievable for large process vent emissions, considering costs and other impacts.

6.2.2 Determination of Existing Source MACT floors and Regulatory Alternatives

6.2.2.1 Process Vents. The MACT floor was initially calculated to be 93 percent, based on the facility-wide control level achieved by the median facility in the top 12 percent of facilities in the source category. Table 6-1 contains the ranking of the MACT floor plants. The facility-wide control level is the overall control achieved at a site as calculated by summing all the uncontrolled emissions and all the controlled emissions from the multiple processes at the site. As such, the facility-wide control level is a weighted average of all the process control levels. While the facility-wide control level is a useful parameter for evaluating the level of control in the industry, it is difficult to implement a standard on this basis in this industry because of the predominant use of batch processes. Facilities typically run multiple processes at any one time, and can cease and restart operations often. In addition, the emission stream characteristics of batch emission sources are not constant, so that control devices do not yield constant control levels. The application of a facility-wide standard would therefore require an enormous amount of effort to track site-wide uncontrolled and controlled emissions to ensure that a single percent control level would be met over the entire plant site on a yearly basis. Because of these implementation concerns, a decision was made to apply the standard on a per-process basis. In other words, each individual process within a facility would be required to meet some level of control.

TABLE 6-1. PROCESS VENTS MACT FLOOR

Ranking	Plant No.	Plant name	Uncontrolled HAP, lb/yr	Controlled HAP, lb/yr	Percent control
1	334	SmithKline Beecham, Philadelphia, PA	90,459	911	99
2	129	Ethyl Corp., Orangeburg, SC	2,300,557	38,700	98.3
3[c]	350	Syntex, Springfield, MO	715,337	14,307	98
4	135	Fisons Corp., Rochester, NJ	39,999	1,458	96.4
5	79	Bristol-Myers Squibb, Syracuse, NY	7,256,901	340,584	95.3
6	279	Pfizer, Barcelonetta, PR	3,724,683	224,285	94.0
7	354	Takeda Chemicals, Wilmington, NC	468,510	38,844	91.7
8	310	Sandoz, East Hanover, NJ	227,303	20,000	91.2
9	95	Ciba Geigy, Summitt, NJ	41,577.6	3,824	90.8
10	77	Bristol-Myers, Barcelonetta, PR	167,648.4	16,528	90.1
11	8	Abbott Labs, Barcelonetta, PR	2,071,947	311,311	85.0
12	160	Hauser Chem Research, Boulder, CO	487,000	78,400	83.9

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In developing this option, the EPA found that a large number of processes have very low emissions. Many of these small-emitting processes have controls with very low efficiencies, thus the emission reductions are low and the control techniques do not represent the control efficiencies of standard air pollution control technology. The EPA has estimated that approximately half of the processes at the major facilities account for one percent of the emissions from all processes. Over 60 percent of the processes are in manufacturing of product in non-dedicated, multipurpose equipment. Because of these results, the EPA decided to undertake an analysis to compute a floor on a process basis that incorporated an emissions cutoff (below which no additional control would be required) and that was at least equivalent to the facility-wide floor. In addition to enabling the calculation of an equivalent floor, the cutoff would also function in reducing the burden of effort associated with implementing the standard, because, for processes falling below the cutoff, only one set of emissions would require documentation, calculation, or measurement of both uncontrolled and controlled emissions would be unnecessary.

In calculating the cutoff, the project team sorted the processes at the twelve MACT floor facilities by magnitude of emissions and found a logical cutoff that represents the bulk of the emissions. Upon eliminating processes that fall under 2,000 lb/yr, the remaining processes account for 98 percent of the total emissions from process vents at the MACT floor facilities. A comparison of the emission reduction achieved by applying the MACT floor of 93 percent on a facility-wide basis and 93 percent on a process basis with a 2,000 lb/yr cutoff shows that control on a process basis results in more reduction. Because the process basis format requires that all processes be controlled by at least 93 percent, the format achieves greater reduction than a facility-wide format.

A regulatory alternative beyond the floor was also developed. The regulatory alternative beyond the floor requires 98 percent control of emission points not meeting the MACT floor level of control of 93 percent, but meeting certain flow and HAP uncontrolled mass loading criteria, while the combination of all other emission points within a process not meeting the flow and mass loading criteria remain controlled to an overall level of 93 percent. The criteria used for flow and HAP load are based on a linear equation relating flow and load. Emission points currently controlled to levels of less than 93 percent and having actual flowrates (in scfm) less than the flowrate calculated by multiplying uncontrolled HAP emissions, in lb/yr, by 0.02 and subtracting 1,000 would meet the criteria for required control of 98 percent. This equation was developed using a method that approximates boundaries for cost effective control of emission stream characteristics--in this case, flow and load. The cost effectiveness target used in this particular analysis is $3,500/Mg. This value is based on decisions in previously promulgated Part 63 rules where the cost effectiveness was judged to be reasonable. The development and documentation of the equation is described in greater detail below.

The approach used to develop the equation is identical to the approach described in the Batch Processes ACT, except that no volatility ranges were considered. Instead, the properties of methanol only were used to develop cost-effectiveness curves describing control by thermal incineration and condensation. Because of constraints related to the uploading of this document on the TTN, these curves are not presented in this document. However, they are available in the project docket. As described in the Batch ACT, the curves form the basis for setting up control requirements based on annual emissions and flow rate. By developing a number of curves for different annual emission totals, values of flow rate were obtained for an optimum cost- effectiveness range, considered to be $3,500/Mg. These annual emissions, and corresponding flow rates were used as data points for simple regression analysis to define a line that represents the limits of cost effective control to 98 percent.

Technical reasons for going beyond the MACT floor for large emission sources that are currently controlled to less than 93 percent (sources meeting the equation criteria) also exist. Because there are situations in this industry where very large emission streams can dominate overall emissions from processes and facilities, the control levels associated with these streams should be considered separately from the controls allocated to the remaining sources within the processes. Without separate consideration of these sources, it is likely that the control of only these sources would satisfy overall process control requirements of 93 percent, even though the sizes of these emission streams alone would warrant the installation of control systems.

The decision to not require 98 percent control of emission sources meeting the equation that are already controlled to the level of the MACT floor (93 percent) is based on the rationale that the incremental 5 percent control achieved in stepping up control from 93 percent to 98 percent may be difficult for many facilities to achieve without unreasonable expense. Because 98 percent control efficiency in many cases cannot be achieved by retrofitting or modifying existing control systems, there is a possibility that owners and operators that had made a good faith effort to control their emission sources to high levels (93 percent) would be required to scrap existing controls and install completely new control systems.

6.2.2.2 Storage Tanks. The MACT floor for storage tanks was determined using the same procedure that was used to determine the floor for tanks in the HON. The storage tank population was divided into three size ranges. The parameter used in the analysis to determine the storage tank floor was the vapor pressure of the liquid being stored. Vapor pressure is a major factor that influences emissions from storage tanks and is commonly a prime determining factor in whether or not a tank is controlled.

For each segment of the tank population (small, medium, and large), the procedure used to define the floor was to rank storage tanks at the twelve MACT floor facilities by vapor pressure and determine the vapor pressure at which at least one half of the tanks (median) are controlled by the reference control technology in the HON. Thus, this procedure was done at 95 percent control; however, if no floor was found, the procedure was repeated at a lower level. In no case was there a floor at 95 percent. In all cases there was a floor at 90 percent. For all size ranges the vapor pressure representing the floor is 1.9 psia. This vapor pressure covers most of the commonly used solvents, methylene chloride, hexane, and methanol (see Table 5-3). There was no floor at a lower vapor pressure (0.5 psia) which would cover the other common solvent, toluene.

Therefore, the MACT was determined to be 90 percent for tanks with capacities greater than or equal to 38 m^3 (10,000 gallons), storing a material with a vapor pressure of greater than or equal to 13.1 kPa (1.9 psia).

A regulatory alternative beyond the MACT floor was also developed. This alternative requires 95 percent control of tanks storing material with a vapor pressure of greater than or equal to 13.1 kPa for capacities greater than or equal to 75 m^3 (20,000 gallons).

Floating roof technology has been demonstrated to achieve 95 percent control and is considerably less expensive than other technologies, even technologies that achieve control levels of less than 95 percent; therefore, it is the preferred method of control for tanks with capacities of greater than 75 m^3 (20,000 gallons). Regulatory alternative No. 1 takes advantage of this fact for tanks that can be equipped with floating roof technology and merely requires the level of control that has been demonstrated to be cost effective and technically feasible to achieve.

In developing the regulatory alternative for storage tanks, EPA also decided not to include in Regulatory Alternative No. 1 tanks that are currently equipped with control devices achieving 90 percent, because the incremental reductions achieved in moving above the floor from 90 percent to 95 percent would not yield an option with reasonable cost effectiveness.

6.2.2.3 Wastewater. The MACT floor for wastewater was calculated to be 54 percent control of HAP evaporative losses from wastewater collection and treatment systems based on steam stripping technology. Table 6-2 presents a ranking of MACT floor facilities for wastewater. This MACT floor level of control represents the level of control achieved by the sixth-ranked facility in terms of overall control from facilities treating wastewater using methods other than biodegradation. Only eight facilities were actively controlling emissions from wastewater. Therefore, the best 12 facilities included 4 facilities that were uncontrolled. This level of control represents the average control achieved with steam stripping.

TABLE 6-2. WASTEWATER MACT FLOOR

Direct/ indirect	lb/yr HAP load	Total compound load	MAX of W7 or 32D (baseline) emissions	Uncontrolled emissions	Control device	Reduction, %
Direct	843,476	843,476	—	108,476	Incineration	a
Direct	35,856,830	41,383,080	200	b	Incineration	>99
Direct	1,796,007	4,635,852	3,625	1,161,235	Steam stripper, evaporator, incineration	99.7
Direct	431,500	2,815,700	39,191	344,993	Incineration, evaporator	88.6
Indirect	2,354,162	3,412,312	103,045	351,815	Steam stripper	71
Indirect	4,465,451	5,018,351	317,190[c]	689,544	Steam stripper	54
Indirect	866,832	1,290,310	84,176	133,287	Steam stripper	37
Indirect	1,924,779	8,070,757	45,480	71,021	Incineration	36

[a] Not enough data were available to identify the exact portion of wastewater that is incinerated, assumed 99%.

[b] No treatment system other than incineration is in place at the facility; therefore, no estimate of uncontrolled emissions from collection and other treatment could be developed.

[c] No data in OW files or on PFD about this steam stripper; therefore, could not calculate accurate baseline emissions. Used average of plants immediately above and below that also used steam strippers and OW files contained data on these steam strippers.

Applicability is on a point of determination (POD) basis, which is consistent with the HON. This approach allows identification and control of those wastewater streams containing the most significant amount of HAP. Although the industry collected wastewater data at the equipment level (point of generation) the data were not complete enough to perform analysis on the industry 308 data to calculate the nationwide impacts of the control alternatives. Instead, a model stream stripper and a steam stripper with rectification were designed for wastewater flow and characteristics representative of the 308 data and designed to achieve a level of control at least as stringent as the MACT floor (54 percent control). Based on these designs, HAP concentration cutoffs were calculated for reasonable cost-effective control.

No regulatory alternatives above the floor were developed for wastewater because any more stringent regulatory option would exceed the limits of reasonable cost effectiveness.

In developing regulatory requirements based on this MACT floor, the EPA developed applicability requirements on concentration and HAP load cutoffs to be applied at the POD for wastewater streams. The HAP's contained in POD streams meeting these criteria are required to be controlled to varying levels--90 percent for soluble HAP's, 99 percent for partially soluble HAP's, and 95 percent for total organics. Although biodegradation was not considered in setting the MACT floor because it is not a technology available to all facilities, most notably indirect dischargers (which make up the majority of facilities in this industry), it is a technology, either onsite for direct dischargers or offsite at Publicly Owned Treatment Works (POTW's) for indirect dischargers, that can be used to meet the proposed control requirements.

EPA established the load criteria of 1 MG/yr per POD, per process, and per facility, on a mass format as opposed to a volumetric flowrate format (i.e., liter/min) because of the batch nature of the industry. The 1 Mg/yr levels are based on the HON wastewater exemption criteria, and correspond to exemption criteria suggested by the industry.

6.2.2.4 Equipment Leaks. The MACT floor for equipment leaks was found to be negligible. The regulatory alternative above the floor is the implementation of a Leak Detection and Repair Program (LDAR), patterned after the requirements of 40 CFR subpart H, but with some fundamental differences. The LDAR program proposed in this regulation allows for quarterly monitoring of pumps, as opposed to monthly monitoring, and begins at the phase III implementation mark.

Additionally, the LDAR program does not cover receivers and surge control vessels; this equipment will be covered under the process vent planks. The EPA is also considering eliminating the QIP in favor of more frequent monitoring when nominal leakage rates are exceeded.

In developing this proposed LDAR program, industry suggested several changes to the Subpart H LDAR program. Several of these suggestions are described below. In response to industry's suggestion of a de minimis number of components (1,000), EPA believes that the current model process containing approximately 1,000 components serves as an example of a cost effective LDAR program. Therefore, no deminimis has been provided. In response to industry's suggestion to substitute visual/audible/factory detection for Method 21 in some cases, the EPA believes that this type of monitoring may be too subjective for the cases provided.

The industry has also suggested that no case-by-case approval of "leakless" equipment is necessary when documented information exists. However, no such lists of leakless equipment have been submitted to the EPA in support of this suggestion.

6.2.3 New Source MACT Floors and Regulatory Alternatives

For new sources, the MACT floor shall be no less stringent than the level of control achieved by the best performing similar source. The regulatory alternatives chosen represent a high level of control for two of the four planks. A new source MACT floor option is the same as the existing source flor for storage and equipment leaks, but is more stringent for process vents and wastewater. For process vents, the option requires 98 percent control of vents with uncontrolled emissions greater than 0.18 Mg/yr (400 lb/yr). This option is based on a level of control representative of thermal oxidation technology. The cutoff is part of the new source MACT floor because it represents the smallest controlled process considered to be a similar source.

The new source MACT floor for wastewater is based on the practices of a single direct discharger facility that currently incinerates a significant percentage of wastewater containing HAP's in a RCRA incinerator combusting a mixture of wastes. This facility is the best performer, primarily due to the degree and extent to which it is controlling wastewater streams containing soluble HAP compounds. According to 1990 data submitted to EPA's Office of Water, the facility generates three wastewater streams containing HAP's. Two of the streams contain Table 3 (soluble) HAP compounds at low concentrations and are sent directly to either the facility outfall or to "farm operations," (i.e., land application). Neither of these practices constitute air pollution control of HAP's. The remaining stream contains a mixture of soluble (Table 3) and partially soluble (Table 2) compounds and is incinerated. Examination of the concentration of these compounds indicates that the concentration of partially soluble compounds is 68,500 ppmw and for soluble compounds it is 112,862 ppmw. The total HAP concentration of the stream is 181,359 ppmw. These data can be found in the SID in a memorandum dated August 23, 1996

With regard to control device efficiency, no data on the efficiency of the incinerator were reported, and in particular, no data are available on the control level of the specific wastewater stream being evaluated. However, it is reasonable to assume, because this is a RCRA incinerator, that the control efficiency is at least 99 percent, the same level achievable by steam stripping for partially soluble compounds. Data are not available for EPA to conclude that the incinerator is achieving a greater efficiency on this stream alone. Therefore, the floor for control device efficiency was determined to be 99 percent.

The control device efficiency is only one of the factors that needs to be considered in the floor. The other factor is applicability cutoffs; i.e., which wastewater streams need to be treated by the control device. With regard to cutoffs, EPA examined the concentrations of the various compound types that are being incinerated at this facility. For soluble compounds, the concentration being incinerated is 112,862 ppmw. Thus, 112,862 ppmw (rounded to 110,000 ppmw) is the floor cutoff associated with the 99 percent control level for these types of streams.

For partially soluble compounds, the concentration being incinerated is 68,500 ppmw. However, the control device efficiency (99 percent) derived for the floor for new sources is the same as that being required for partially soluble compounds at existing facilities. The concentration cutoff at existing facilities for these compounds (based on the floor) is 1,300 ppmw. By definition, the floor for new sources cannot be less stringent than for existing sources. Therefore, the floor concentration cutoff for partially soluble compounds at new sources is also 1,300 ppmw.

The best performing facility is not controlling soluble compounds in wastewater streams with concentrations lower than 112,862 ppmw. However, the existing source floor MACT requires 90 percent control of these types of compounds in streams greater than 5,200 ppmw. This cutoff also applies to total HAP's.

Therefore, in summary, the MACT floor for wastewater at new sources includes:

1. Ninety-nine percent control of partially soluble HAP's in streams with concentrations of greater than 1,300 ppmw or 5,200 ppmw total HAP's, and 99 percent control of soluble HAP with concentrations of greater than 110,000 ppmw; and
2. Ninety percent control of soluble HAP's in streams containing greater than or equal to 5,200 ppmw and less than 110,000 ppmw total HAP's.

Upon examination, this regulatory alternative is more stringent than the existing source requirement in that it requires 99 percent control of very concentrated soluble HAP-containing water, rather than the 90 percent control requirement in the existing source standard.

The EPA considered alternatives beyond the floor for new sources and concluded there are none with reasonable costs. Therefore, the floor was selected as MACT for new sources.

The MACT floor for new sources for leaks is the same as for existing. No facility is operating above subpart H.

The MACT floor for new sources for tanks is set at the same level as the Regulatory Alternative No. 1 for existing tanks. It has been determined that no facility is controlling tanks beyond Regulatory Alternative No. 1. For example, no facility reduces emissions from tanks containing liquids with vapor pressures less than 1.9 psia by greater than 95 percent in the facility.

6.3 CLEAN WATER ACT

6.3.1 Regulation of the Pharmaceutical Manufacturing Industry Under the Clean Water Act

6.3.1.1 Summary of Prior Regulations. The Clean Water Act (CWA) and a recent settlement agreement (see 59 FR 25869) require the EPA to develop effluent limitations guidelines and standards regulations for certain industrial categories. The Pharmaceutical Manufacturing Industry is one of the categories required to be regulated by this settlement agreement. The EPA's most recent regulatory proposal for the pharmaceutical industry was on May 2, 1995 (60 FR 21592). A summary discussion of this most recent proposal along with the previously promulgated effluent limitations guidelines and standards regulations issued by the EPA for the pharmaceutical industry follows.

The EPA promulgated interim final BPT (Best Practicable Control Technology) regulations for five subcategories of the pharmaceutical manufacturing point source category on November 17, 1976 (41 FR 50676). The subcategories identified in this rulemaking were: A (Fermentation), B (Natural Extraction), C (Chemical Synthesis), D (Mixing, Compounding and Formulating), and E (Pharmaceutical Research). These regulations set monthly limitations for BOD_5 (5-day

Biochemical Oxygen Demand) and COD (Chemical Oxygen Demand) based on percent removals for all subcategories. No daily maximum limitations were established for these pollutants. In addition, monthly limitations on TSS (total suspended solids) were set for subcategories B, D, and E and the pH was set within the range of 6.0 and 9.0 standard units for all subcategories. In the October 27, 1983 regulation (49 FR 49808), the EPA added BPT, BAT (Best Available Technology Economically Achievable), NSPS (New Source Performance Standards), PSES (Pretreatment Standards for Existing Sources) and PSNS (Pretreatment Standards for New Sources) regulations for cyanide, provided monthly TSS BPT limitations for subcategories A and C and established BPT minimum BOD_5 and COD limitations for subcategories B, D, and E. The EPA also indicated that subcategory E would not be regulated beyond BPT. On July 9, 1986 at 51 FR 24974, the EPA set BCT (Best Conventional Pollutant Control Technology) limitations equal to existing BPT limitations for BOD_5 and TSS. No limitations or standards for organic pollutants were promulgated.

6.3.1.2 Summary of May 2, 1995 Proposal. The EPA proposed BAT and NSPS regulations for 54 volatile and semivolatile organic pollutants of which 20 are HAP's. The Agency also proposed PSES and PSNS for 45 volatile organic pollutants of which 19 are HAP's. [Air emissions of HAP's by major sources will be controlled by this MACT rule provided that the wastewater streams containing the HAP's meet concentration criteria for soluble and partially soluble HAP's in today's proposal.]

6.3.1.2.1 Hazardous air pollutants regulated. The proposed BAT end-of-pipe limitations would control the discharge of 20 HAP's at both A and C and B and D manufacturing facilities. The technology basis for the BAT limitations for A and C subcategory facilities was in-plant steam stripping followed by advanced biological treatment while the technology basis of the BAT limitations for B and D facilities was advanced biological treatment. Since these proposed limitations are set at the end-of-pipe, they would not prevent air emissions of these pollutants prior to discharge.

Also proposed in the May 2, 1995 notice (see coproposal A), were PSES for 8 HAP's set in-plant at a point roughly equivalent to the MACT standards point of determination while PSES for 11 other HAP's were proposed at the end-of-pipe discharge point. The technology basis for the HAP and non-HAP pollutants alike was steam stripping. Under coproposal B, only in-plant PSES for the eight HAP's would be established. The Agency decided to establish an in-plant monitoring point for 12 highly volatile pollutants (including the 8 HAP's) because measuring compliance at the end-of-pipe monitoring point was not considered practical for these pollutants due to the high potential for air stripping associated with them and commingling with other process wastewater not containing any of the 12 pollutants. As is the case with the BAT end-of-pipe limitations, the end-of-pipe proposed PSES would not prevent air emissions of HAP's at facilities prior to the discharge point to the municipal sewer systems.

6.3.1.2.2 <u>Nonhazardous air pollutants regulated</u>. The proposed BAT end-of-pipe limitations would also control the discharge of 34 non-HAP volatile organic pollutants at A and C and B and D manufacturing facilities. Under coproposal A, PSES for 4 volatile non-HAP's would be set in-plant while PSES for 22 other non-HAP volatile organic pollutants would be set at the end-of-pipe discharge point. Emissions of non-HAP volatile organic pollutants may be incidentally controlled if they are present in wastewater streams that require control under the MACT regulations being proposed today.

6.3.1.3 <u>Potential Interaction of Final MACT Standards and Final Effluent Limitations Guidelines and Standards</u>.

6.3.1.3.1 <u>Summary of public comment concerning an integrated air-water rule</u>. Some commenters said that the EPA should defer regulation of volatile organic pollutants until after the EPA proposes MACT standards for the pharmaceutical industry. These commenters also added that after implementation of the MACT standards, the EPA can reassess the need for an effluent guideline for the industry and propose regulations at that time, if necessary. Other commenters maintained that regulating air emissions from wastewater is misplaced in light of the Agency's Common Sense Initiative and that the MACT Rule will likely provide a flexible, cost-effective approach for addressing air emissions while the in-plant limitations proposed in the May 2, 1995 proposal of effluent guidelines and standards are very prescriptive. Still other commenters maintained that the EPA in attempting to control emissions of HAP's has circumvented the requirements of the Clean Air Act by establishing technology-based requirements for HAP's. Finally, another group of commenters suggest that any aspects of the final guidelines and standards incorporate the CAA MACT approach with no modifications.

6.3.1.3.2 <u>Potential integrated approach for direct dischargers</u>. As noted earlier, the EPA proposed end-of-pipe BAT limitations for HAP and non-HAP pollutants based on steam stripping and advanced biological treatment for subcategories A and C and advanced biological treatment for subcategories B and D. The MACT standards being proposed today will control HAP emissions (if promulgated) at major source pharmaceutical plants with steam stripping as the reference control technology. The EPA is considering revising the BAT limitations for subcategories A and C based on only advanced biological treatment performance data. This would in effect shift control of HAP air emissions and wastewater pollutant discharges of the HAP's to the MACT standards. With regard to control of non-HAP's at major sources, the Agency believes that the significant reductions in HAP emissions required by the proposed MACT standards will also result in incidental reductions in non-HAP air emissions because many non-HAP's are found in the same wastewater streams as the HAP's, and thus will be steam stripped along with the HAP's. While control of air emissions of HAP and non-HAP VOC's will be addressed to some extent under the CAA, additional control of water discharges of the VOC's from direct dischargers needs to be addressed under the Clean Water Act using as a basis the BAT limitations and NSPS proposed on May 2, 1995.

6.3.1.3.3 Potential integrated approaches for indirect dischargers. The MACT standards being proposed today would apply to select streams at 60, out of a possible 259, pharmaceutical indirect dischargers deemed to be major sources of air emissions. Only those streams which meet the flow and concentration cutoffs established for HAP's would require control. Assuming that the EPA's pass-through analysis does not change and coproposal A is chosen, the EPA estimates that today's proposed MACT rule would reduce the load of VOC's to POTW's from pharmaceutical manufacturing plants by approximately 48 percent. Part or all of the remainder of the pollutant loadings to POTW's may need to be controlled by additional pretreatment requirements. The Agency is considering three options for setting pretreatment standards (PSES and PSNS) to address HAP and non-HAP wastewater pollutant discharges not controlled by today's proposed MACT standard.

Option 1. Under this option (which has been suggested by commenters), compliance with today's MACT standards would constitute compliance with final PSES and PSNS for all manufacturing subcategories. However, since compliance with the MACT regulation requires only one demonstration by the facility, the EPA is considering some form of regular monitoring to verify compliance with wastewater discharge standards. Facilities could either monitor for individual

HAP's or non-HAP's on a regular basis or for some indicator pollutant parameter whose regulatory compliance level would be established at the same time that MACT rule compliance demonstration is performed. This option would result in control of about 48 percent of the VOC pollutant load that is currently being discharged to POTW's by pharmaceutical facilities.

Option 2. In addition to the MACT regulations on selected streams at 60 indirect dischargers, the EPA would establish pretreatment standards for the streams and pollutants not controlled by the MACT regulations. The level of control dictated by these additional standards would be the same level as that of the MACT standards (90 percent reduction for soluble organics and 99 percent for partially soluble organics). The pretreatment standards could either be in the form of percent reduction requirements for individual pollutants or single number standards resulting from the application of the MACT percent reduction requirements. The EPA estimates that this option would reduce the discharge of pollutants to POTW's by an additional 46 percent over Option 1.

Option 3. Option 3 would involve promulgating the coproposal A pretreatment standards for all major sources at the end-of-pipe regulatory point. These pretreatment standards would apply to all streams at facilities designated as major sources regardless of whether the streams were within the concentration cutoffs for HAP's and would be established for all pollutants which pass-through. The level of control dictated by these standards would be the coproposal A level with the exception that standards for 12 pollutants which were established in-plant will now be set at the end-of-pipe and adjusted downward to account for dilution due to mixing with other waste streams. Other changes in parameters or limitations may result from the evaluation of comments and receipt of additional performance data. Using the proposed limitations, the EPA estimates that this option would reduce the discharge of pollutants to POTW's by an additional 29 percent over Option 1.

6.3.2 Possible Revision of the Methodology for Evaluation of Pass-Through of Pollutants

The EPA is considering revising its pass-through analysis for water soluble, biodegradable pollutants such as methanol, acetone, isopropanol and ethanol based on approaches suggested by commenters on the May 2, 1995 pharmaceutical proposal as well as the approaches used in the Pesticide Chemicals Manufacturing and Organic Chemicals, Plastics, and Synthetic Fibers (OCPSF) rulemakings. In general, pollutants are considered to pass-through POTW's if the average percent removal achieved by well operated POTW's is less than that achieved by the BAT model treatment systems. The EPA is considering specifically the methodology modifications employed in the evaluation for phenol, a biodegradable water soluble pollutant as discussed in the Pesticides and OCPSF rulemakings (see 59 FR 50638, 50664-65, September 28, 1993 and 58 FR 36872, 36885-86, July 9,1993.) Among the modifications suggested by the commenters were: (1) using only data from acclimated POTW systems to determine POTW removal; (2) finding no pass-through for pollutants if the differential between the model BAT percent removal and the POTW percent removal for a pollutant is less than 5 percent and; (3) utilizing a higher Henry's Law Constant cutoff when pass through is determined by the volatile override approach (pollutants which have a higher Henry's Law Constant value than the cutoff are presumed to pass-through using this methodology). The Agency is reevaluating its proposed pass-through analysis because of the comments received concerning it and to be more consistent with today's proposed MACT standards for soluble organic HAP's which allows the biodegradation achieved by POTW's to be included in the compliance demonstration for these pollutants. Today's MACT standards require a demonstration of at least a

90 percent reduction in air emissions from wastewater of water soluble biodegradable HAP's. As a result, a finding of pass-through may result in duplicative and somewhat inconsistent control (by water and air regulations) for some pollutants. The EPA solicits comments on possible revisions to its pass-through methodology as applied to water soluble, biodegradable pollutants.

7.0 SUMMARY OF ENVIRONMENTAL, ENERGY, COST, AND ECONOMIC IMPACTS

This section presents air, secondary (air and nonair), energy, cost, and economic impacts resulting from the control of organic HAP emissions under the proposed standards.

7.1 PRIMARY AIR IMPACTS

The proposed standards for the four generic source types (i.e., process vents, storage tanks, equipment leaks, and wastewater) are expected to reduce organic HAP emissions from all existing sources by 22,000 megagrams per year (Mg/yr) from a baseline level of 34,100. This corresponds to an overall reduction of 65 percent for organic HAP's from existing sources. Individually, the control options selected for each of the four generic source types reduce air emissions by 6,000 Mg/yr for process vents, 300 Mg/yr for storage tanks, 2,000 Mg/yr for equipment leaks, and 13,100 Mg/yr for wastewater. These reductions equate to 83 percent, 65 percent, 67 percent, and 57 percent for process vents, storage tanks, equipment leaks, and wastewater, respectively. Table 7-1 contains the air impacts for each of these generic source types. Additionally, Table 7-2 contains the anticipated annualized costs for new sources that will be subject to the proposed regulation over the next 5 years. These costs were derived from the average cost per facility for existing sources subject to the proposed regulation with consideration of any additional new source requirements.

TABLE 7-1. SUMMARY OF AIR IMPACTS FOR EXISTING SOURCES (INCLUDING COST AND ECONOMICS IMPACTS)

MACT Plank	Uncontrolled, Mg/yr	Baseline, Mg/yr	TCI, \$	Annual costs, \$/yr	ER from baseline, Mg/yr	ER from baseline, %	C/E, \$/Mg	Inc. C/E, \$/Mg
<u>Process vents</u>								
Reg. Alt. No. 1 (MACT floor + 98% cutoff)	28,000	7,600	94×10^6	46×10^6	6,000	83	7,500	1,000[a]
<u>Storage tanks</u>								
MACT floor/Reg. Alt. No. 1	900	500	4×10^6	1.5×10^6	300	65	5,000	
<u>Wastewater</u>								
MACT floor	NC	23,000	41×10^6	13×10^6	13,100	57	1,000	
<u>Equipment leaks</u>								
Reg. Alt.	3,000	3,000	0.3×10^6	2×10^6	2,000	67	1,000	
Total for all options		34,100	138×10^6	62×10^6	21,900	65	2,900	

NC = Not considered.

[a] This is the incremental cost effectiveness between the MACT floor regulatory alternative and regulatory alternative 1 included here.

TABLE 7-2. ANNUAL COSTS FOR NEW SOURCES

MACT Plank[a]	Annual Costs, \$/yr
Process Vents	7.9×10^6
Storage	0.2×10^6
Wastewater	3×10^6
Equipment Leaks	0.2×10^6

[a] The costs are based on average costs per facility at expected rate of growth (12 new facilities over a 5 year period).

7.2 SECONDARY ENVIRONMENTAL IMPACTS

The proposed standards are not expected to generate significant increases in secondary environmental concerns (i.e., carbon monoxide (CO), nitrogen oxides (NO_x), solid waste, or water). However, these areas have been addressed and are included in the following paragraphs. This section is arranged in the following subsections: (1) secondary nonair environmental (i.e., water and solid waste); and (2) secondary air environmental impacts (CO and NO_x).

7.2.1 Secondary Nonair Impacts

The proposed standards are not expected to contain adverse water impacts. Note that this control method was not analyzed in the estimation of national impacts for any of the four generic source types.

The proposed standards are expected to increase the generation of solid waste at new facilities that generate rich soluble-containing HAP streams that require 99 percent HAP removal.

7.2.2 Secondary Air Impacts

Secondary air impacts associated with the proposed standards include an increase in CO and NO_x emissions to the atmosphere. Control of all of the generic source types, except equipment leaks, are expected to contribute to the increase in both CO and NO_x emissions. These impacts are also contained is Table 7-3.

TABLE 7-3. SECONDARY ENVIRONMENTAL IMPACTS

Emission source type	Increase in solid waste, Mg/yr[a]	Increase in CO emissions, Mg/yr	Increase in NO_x emissions, Mg/yr
Equipment leaks	0	0	0
Process vents	0	288	155
Storage tanks	0	5	15
Wastewater[b]	2,009		
1		64	106
2		44	72

a Increase in solid waste generated is only projected for new sources of wastewater with a concentration of ≥110,000 ppmw of soluble compounds in the wastewater. An annual growth rate of 2.4 percent was used.

b Options 1 and 2 for wastewater are given to show the difference in the secondary environmental impacts for the industry if: (1) soluble POD streams are steamstripped, and (2) soluble POD streams are not steamstripped and are sent to biotreatment.

Carbon monoxide and NO_x are produced as byproducts of combustion from the add-on control devices analyzed in the proposed standard's national impacts and from the generation of electricity. The increase in CO and NO_x emissions were due to coal combustion for the production of electricity used for the refrigerated condensers in storage tanks and process vents, the pumps used in the steamstripper designs for wastewater, natural gas and HAP combustion used for the thermal incinerators in process vents, and natural gas combustion used in the boilers that supply steam to the steamstrippers.

The amount of CO and NO_x expected to be produced as a result of coal combustion was based on emission factors contained in AP-42. These factors are 5 pounds CO per ton coal (lb CO/ton coal) and 14 lb NO_x/ton coal. For CO and NO_x emissions resulting from combustion of natural gas in thermal incinerators and on-site boilers used to generate the steam for steamstrippers, an outlet concentration of CO and NO_x was assumed. These concentrations were 200 and 50 parts per million for CO and NO_x, respectively. As shown in Table 7-3 the generic source type that produces the largest increase in both CO and NO_x emissions is process vents (288 Mg CO/yr, 155 Mg NO_x/yr). Storage tank add-on control devices are expected to increase CO and NO_x emissions by 5 and 15 Mg/yr for CO and NO_x, respectively. The wastewater options are expected to increase CO emissions by 64 Mg CO/yr and 44 Mg CO/yr for options 1 and 2, and increase NO_x emissions by 106 Mg NO_x/yr and 72 Mg NO_x/yr for options 1 and 2, respectively. Details of the calculations used to estimate CO and NO_x emissions are included in the Sample Calculations at the end of this chapter.

7.3 ENERGY IMPACTS

Energy impacts include the increased raw fuel (natural gas) usage and electricity consumption to operate control devices required by the proposed standards. Table 7-4 contains the energy impacts associated with these standards. The following paragraphs describe the increase in energy that will be required to implement the proposed standards and how these estimates were derived. The calculations used to estimate the energy impacts (i.e., electricity, natural gas, and steam) are included in the Sample Calculations at the end of this chapter.

TABLE 7-4. NATIONAL ENERGY IMPACTS

Emission source type	Increase in electricity consumption, 10^6 Kw-hr/yr	Increase in natural gas consumption, 10^9 Btu/yr	Increase in steam consumption, 10^9 Btu/yr
Equipment leaks	0	0	0
Process vents	20	2,096	0
Storage tanks	7	0	0
Wastewater[a]			
1	0.39	0	494
2	0.34	0	335

[a] Options 1 and 2 for wastewater are given to show the difference in the energy impacts for the industry if: (1) soluble POD streams are steamstripped, and (2) soluble POD streams are not steamstripped and are sent to biotreatment.

7.3.1 Electricity

Increases in electricity are caused by operating treatment devices for process vents, storage tanks, and wastewater. The electricity required by these devices was estimated in Kilowatt-hours per year (Kw-hr/yr). These estimates are strictly the energy provided to the facility by the local power supplier. Process vents are expected to require the most additional electricity (20 million Kw-hr/yr) followed by storage tanks (7 million Kw-hr/yr) and wastewater (0.4 million Kw-hr/yr).

7.3.2 Natural Gas

The increased natural gas usage will be required by the thermal incinerator for process vents and by the boiler supplying steam to the steamstripper. The natural gas needed to operate the thermal incinerators was calculated to be 2,096 billion Btu/yr. For wastewater, the natural gas needed to generate the amount of steam required by the proposed standards was calculated by estimating the energy, in BTU, of the total amount of steam required, and dividing by an assumed boiler efficiency of 80 percent. Two options were estimated for wastewater as discussed earlier, and the increased natural gas for these two options are 494 billion Btu/yr for option 1 and 335 billion Btu/yr for option 2.

7.4 COST AND ECONOMIC IMPACTS

The cost and economic impacts for the proposed standards are included in Table 7-1. As shown in this table, the total capital cost to the industry is expected to be approximately $138 million. The capital cost for each of the individual options was estimated to be $94 million, $4 million, $40 million, and $300,000 for process vents, storage tanks, wastewater, and equipment leaks. The annual cost for the implementation of all the regulatory alternatives selected was estimated to be $62 million. This amount can be broken up into the four generic source types with their individual annual costs being $46 million for process vents, $1.5 million for storage tanks, $13 million for wastewater, and $2 million for equipment leaks.

Sample Calculations

I. Secondary Environmental Impacts

Solid Waste

Existing sources with wastewater containing ≥110,000 ppmw is generated at a rate of 67,329 gpd.

Total quantity of wastewater from existing sources is generated at a rate of 83,206,761 gpd.

So,

The fraction of daily wastewater containing soluble HAPs at a concentration greater than 110,000 ppmw is:

$$\frac{67,329}{83,206,761} = 8.09 \times 10^{-4}$$

Now, the total average amount of wastewater per facility over the year (273,607,605 gallons) was multiplied by the fraction of daily wastewater containing ≥110,000 ppmw of soluble HAPs in order to estimate the yearly quantity of wastewater with ≥110,000 ppmw soluble HAPs.

$$(8.09 \times 10^{-4})\ (273,607,650 \text{ gal/yr})\left(\frac{8.33 \text{ lb}}{\text{gal}}\right)\left(\frac{\text{ton}}{2,000 \text{ lb}}\right)$$

= 921.9 TPY per facility

Now, at \$140/ton disposal cost (from OW)

$$\left.\frac{921.9 \text{ ton}}{\text{yr}}\right|\frac{\$140}{\text{ton}} = 129,080 \text{ per facility}$$

CO, NO_x

Coal combustion emission factors from AP-42

14 lb NO_x/ton coal
5 lb CO/ton coal

Natural gas combustion incinerator outlet concentrations

200 ppm CO
50 ppm NO_x

For process vents,

Electricity supplied to all facilities was estimated to be 20 x 10^6 Kw-hr/yr

So,

$$\frac{20 \times 10^6\ \text{Kw-hr}}{\text{yr}} \Bigg| \frac{3{,}412\ \text{Btu}}{\text{Kw-hr}} \Bigg| \frac{\text{lb coal}}{14{,}000\ \text{Btu}} \Bigg| \frac{\text{ton}}{2{,}000\ \text{lb}} \Bigg| \frac{5\text{lb CO}}{\text{ton coal}} \Bigg| \frac{0.454\ \text{kg}}{\text{lb}} \Bigg| \frac{1}{0.35} \Bigg| \frac{\text{Mg}}{1{,}000\ \text{kg}}$$

= 16 Mg CO/yr

Substituting 14 lb NO_x/ton coal = 44 Mg NO_x/yr

Finally, CO and NO_x emitted from the combustion of natural gas used by incinerators and boilers operated in the national impacts analysis must be added.

First, the stoichiometric equation for combustion was identified:

$$CH_4 + 2O_2 \rightarrow CO_2 + 2H_2O$$

where,

Basis: 100 lbmole CH_4
Theoretical O_2 requirement = 200 lbmole O_2
Theoretical air = 4.76 x 200 lbmole O_2 = 952 lbmole air
Excess air: assume 100% of theoretical air
Assume inlet gas flow = outlet gas flow

So,

Total air = theoretical + excess = 2 x 952 = 1,904 lbmole air
Total gas flow = 100 + 1,904 = 2,000 lbmole gas

$$\text{CO: } \underline{2{,}000\ \text{lbmole gas}} \Bigg| \frac{200\ \text{lbmole CO}}{1{,}000{,}000\ \text{lbmole gas}} = \frac{0.4\ \text{lbmole CO}}{100\ \text{lbmole CH}_4}$$

$$\text{NO}_x\text{: } \underline{2{,}000\ \text{lbmole gas}} \Bigg| \frac{50\ \text{lbmole NO}_x}{1{,}000{,}000\ \text{lbmole gas}} = \frac{0.1\ \text{lbmole NO}_x}{100\ \text{lbmole CH}_4}$$

Now,

$$\frac{42 \times 10^{9}\ \text{Btu}}{\text{yr}} \Big| \frac{\text{scf nat. gas}}{1{,}000\ \text{Btu}} \Big| \frac{\text{lb mole nat. gas}}{392\ \text{scf nat. gas}}$$

$$= 107{,}143\ \text{lb mole nat. gas/yr}$$

$$\text{CO:}\ \frac{107{,}143\ \text{lbmole}\ CH_4}{\text{yr}} \Big| \frac{0.4\ \text{lbmole CO}}{100\ \text{lbmole}\ CH_4} \Big| \frac{28\ \text{lb CO}}{\text{lbmole CO}} = 12{,}000\ \text{lb CO/yr/unit}$$

$$NO_x\text{:}\ \frac{107{,}143\ \text{lbmole}\ CH_4}{\text{yr}} \Big| \frac{0.1\ \text{lbmole}\ NO_x}{100\ \text{lbmole}\ CH_4} \Big| \frac{46\ \text{lb}\ NO_x}{\text{lbmole}\ NO_x} = 493\ \text{lb}\ NO_x\text{/yr/unit}$$

Adding the CO and NO_x emissions from both electricity and natural gas combustion equations and multiplying by the number of impacted units yields an estimate of approximately 288 Mg CO/yr and 155 Mg NO_x/yr. Similarly, using the same calculation methodology for storage tanks and wastewater the amount of CO and NO_x emitted from storage was estimated to be 5 Mg CO/yr and 15 Mg NO_x/yr. For wastewater, the amount of CO and NO_x estimated for options 1 and 2 was 64 Mg CO/yr and 106 Mg NO_x/yr, and 44 Mg CO/yr and 72 Mg NO_x/yr, respectively.

II. Energy Impacts

Energy increase associated with the proposed regulation was split into electricity, natural gas, and steam.

A. Electricity

Electricity increase was estimated as follows for process vents: the total electricity requirement for the refrigeration systems at the plant was estimated for two vents.

93 percent unit → 1.3 x 10^9 Btu/yr/unit
98 percent unit → 1.9 x 10^9 Btu/yr/unit

These were multiplied by the appropriate number of each units (24, 93 percent unit and 20, 98 percent unit) to get a total electricity requirement, and this quantity was converted to Kw-hr/yr.

$$[(1.3 \times 10^{9} \times 24) + (1.9 \times 10^{9} \times 20)]/3{,}412 = 20 \times 10^{6}\ \text{Kw-hr/yr}$$

The same methodology was used for storage tanks and wastewater.

B. Natural Gas

Natural gas increase was estimated for process vents as follows:

The natural gas required for all the thermal incinerators used in the regulatory alternatives was estimated to be (in Btu/yr)

42×10^9 Btu/yr/unit x 50 units = $2{,}096 \times 10^9$ Btu/yr

C. Steam

Steam consumption was estimated for the wastewater regulatory alternative as follows:

The total wastewater feed for both soluble and partially soluble POD streams was found.

Soluble POD streams → 64,765,366 gal/yr
Partially soluble POD streams → 545,125,266 gal/yr

Now, multiplying these amounts by the correct steam to feed ratio (s/f) (0.2 for soluble, 0.05 for partially soluble), a boiler efficiency of 80 percent, and the heat content of steam (1,180 Btu/lb) equates to the Btu/yr needed to produce the needed amount of steam.

8.0 SELECTION OF THE STANDARDS

The purpose of this chapter is to provide the rationale for the selection of the standards for the pharmaceuticals production source category. In order to provide background for the subsequent discussions, the first section of this chapter is a summary of the proposed rule. This is followed by a discussion of the rationale for the selection of the level and format of the standards and the compliance, reporting, and recordkeeping provisions.

8.1 SUMMARY OF THE PROPOSED STANDARDS

This section provides a summary of the proposed standards. The full regulatory text is available in Docket No. A-96-03, directly from the EPA, or from the Technology Transfer Network (TTN) on the EPA's electronic bulletin boards. More information on how to obtain a copy of the proposed standards are provided in the preamble.

The affected source is the facility-wide collection of pharmaceutical manufacturing operations, including pharmaceutical manufacturing process units (PMPU's) and associated storage tanks, wastewater and associated treatment residuals, equipment components (pump, compressors, agitators, pressure relief devices, sampling connection systems, open-end valves or lines, valves, connectors, and instrumentation systems), and heat exchange systems. A PMPU is defined as the processing equipment assembled to process materials and manufacture a pharmaceutical product. The definition of a pharmaceutical product is as follows:

1. Any material described by the Standard Industrial Classification (SIC) Code 283;

2. Any other fermentation, biological or natural extraction, and chemical synthesis products regulated by the Food and Drug Administration, including components (excluding excipients) of pharmaceutical formulations, or intermediates used in the production of a pharmaceutical product.

The proposed standards regulate HAP emissions from pharmaceutical production processes that are located at major sources.

Existing affected sources are those facilities manufacturing a pharmaceutical product as defined above as of the proposal date of this standard. Such existing affected sources will be required to comply with the standards 3 years after the date of promulgation. New affected sources constructed or reconstructed after the effective date of this standard (promulgation date) will be required to comply with the new source standards upon startup. New affected sources constructed or reconstructed after proposal but prior to promulgation are not required to comply with the new source standards until 3 years after the date of promulgation provided:

1. The promulgated standard is more stringent than the proposed standard, and

2. The owner or operator complies with the standard as proposed during the 3-year period following the promulgation date.

Only dedicated pharmaceutical manufacturing process units that are added after the proposal date to an existing facility that is a major source, as defined in Section 112(a) of the Act, will be subject to the new source standards only if they meet the definition of construction in § 63.2 of subpart A of 40 CFR 63 and if the addition(s) has the potential to emit 10 tons per year or more of any HAP or 25 tons per year or more of any combination of HAP.

8.1.1 Relationship to Other Rules

The proposed standard requires that equipment leak emission sources be regulated according to the procedures described in 40 CFR 63 subpart H, with some slight modifications. The requirements proposed in this rule do not affect components regulated under subpart I of 40 CFR 63.

8.1.2 Pollutants to be Regulated

Emissions from pharmaceuticals production occur from the following emission points: storage tanks, process vents, equipment leaks, and wastewater. The proposed standards consider all of these emission points.

8.1.3 Proposed Standards

8.1.3.1 Standards. Table 8-1 summarizes the standards for new and existing pharmaceutical affected sources. Figures 8-1 through 8-4 present logic diagrams of applicability and requirements for the standards. For process vents, each individual pharmaceutical process that generates HAP emissions of greater than 0.91 Megagrams (Mg) per year [2,000 lb/yr] with controls in place (baseline emissions) would be required by the proposed standards for existing sources to reduce uncontrolled emissions from the sum of all vents within a process not meeting the Pharmaceutical equation criteria by 93 percent and to reduce uncontrolled emissions from vents meeting the equation criteria that are not currently controlled to at least 93 percent by 98 percent. For new sources, the proposed standards would require 98 percent control of the sum of all vents within a process that generates HAP emissions of greater than 0.18 Megagrams (Mg) per year [400 lb/yr] with no controls in place.

For storage tanks at new and existing sources, each individual storage tank having a volume greater than or equal to 38 m^3 (10,000 gallons) but less than 75 m^3 (20,000 gallons), storing material with a vapor pressure of greater than or equal to 13.1 kPa (1.9 psi) would be required by the proposed standards to be controlled to a level of 90 percent; tanks greater than or equal to 75 m^3 (20,000 gallons) and storing material meeting the

TABLE 8-1. PROPOSED STANDARDS FOR NEW AND EXISTING SOURCES

		Applicability		Requirement	
Emission source	New or existing?	Applicability level	Cutoff	Control efficiency	Emission limit
Process vent	New	Processes	≥400 lb/yr uncontrolled	98%	
	Existing	Processes	≥2,000 lb/yr controlled	93%; or 98% for individual vents meeting cutoff based on flow and emissions	2,000 lb/yr
Storage tanks	New and existing	≥10,000 gal and <20,000 gal	≥1.9 psia vapor pressure of liquid stored	90%	
		≥20,000 gal	≥1.9 psia vapor pressure of liquid stored	95%	
Waste-water	New and existing	>1 Mg/yr total HAP load from all POD within a process or any single POD	≥1,300 ppm at POD of Table 2 HAP	99% reduction of Table 2 HAP	
			≥5,200 ppmw at POD of total HAP load	99% reduction of Table 2 HAP 90% reduction of Table 3 HAP 95% reduction of total HAP using biotreatment	
		>1 Mg/yr total HAP load from facility	≥10,000 ppmw at POD of total HAP load	99% reduction of Table 2 HAP 90% reduction of Table 3 HAP 95% reduction of total HAP using biotreatment	
	New	>1 Mg/yr total HAP load from all POD within a process or any single POD	≥110,000 ppmw at POD of Table 3 HAP	99% reduction of Table 3 HAP	
Equip-ment leaks	New and existing	All components in HAP service excluding components covered by subpart H		LDAR program	

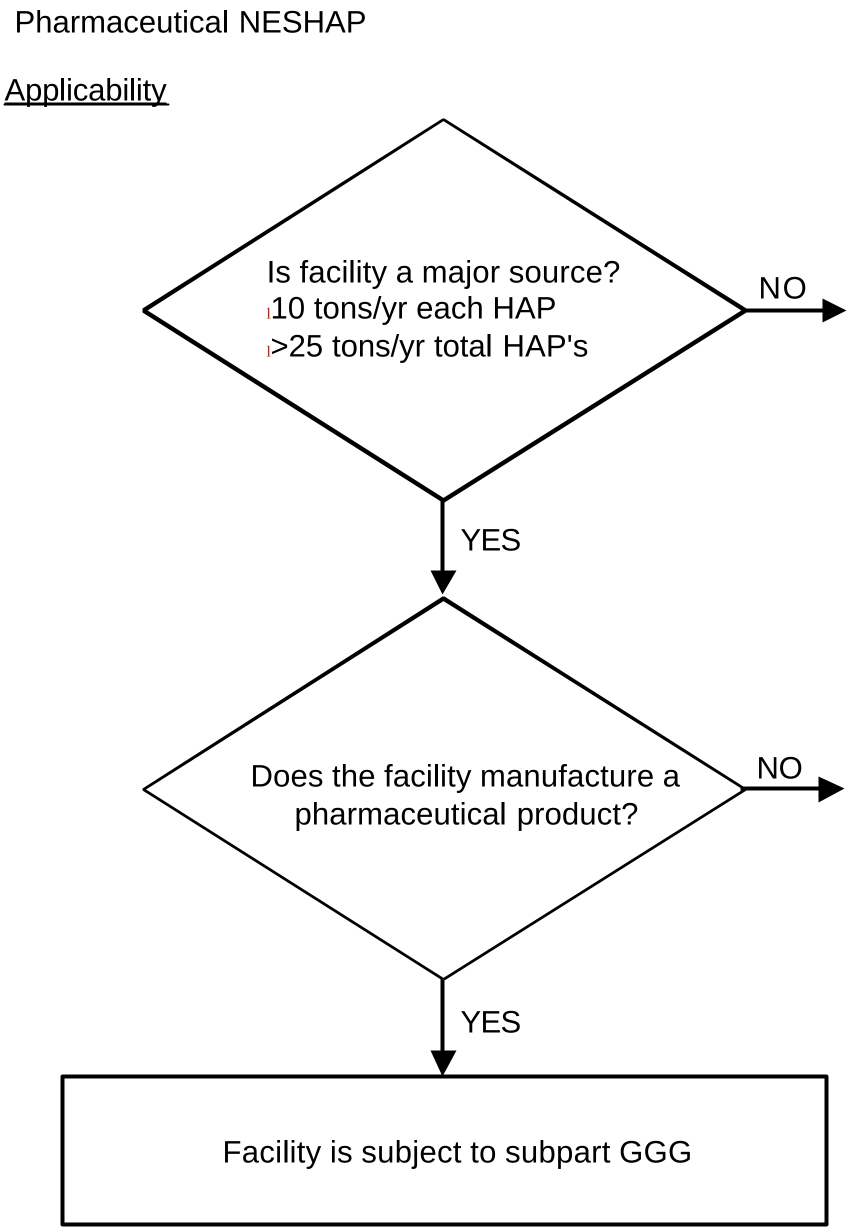

Figure 8-1. General applicability.

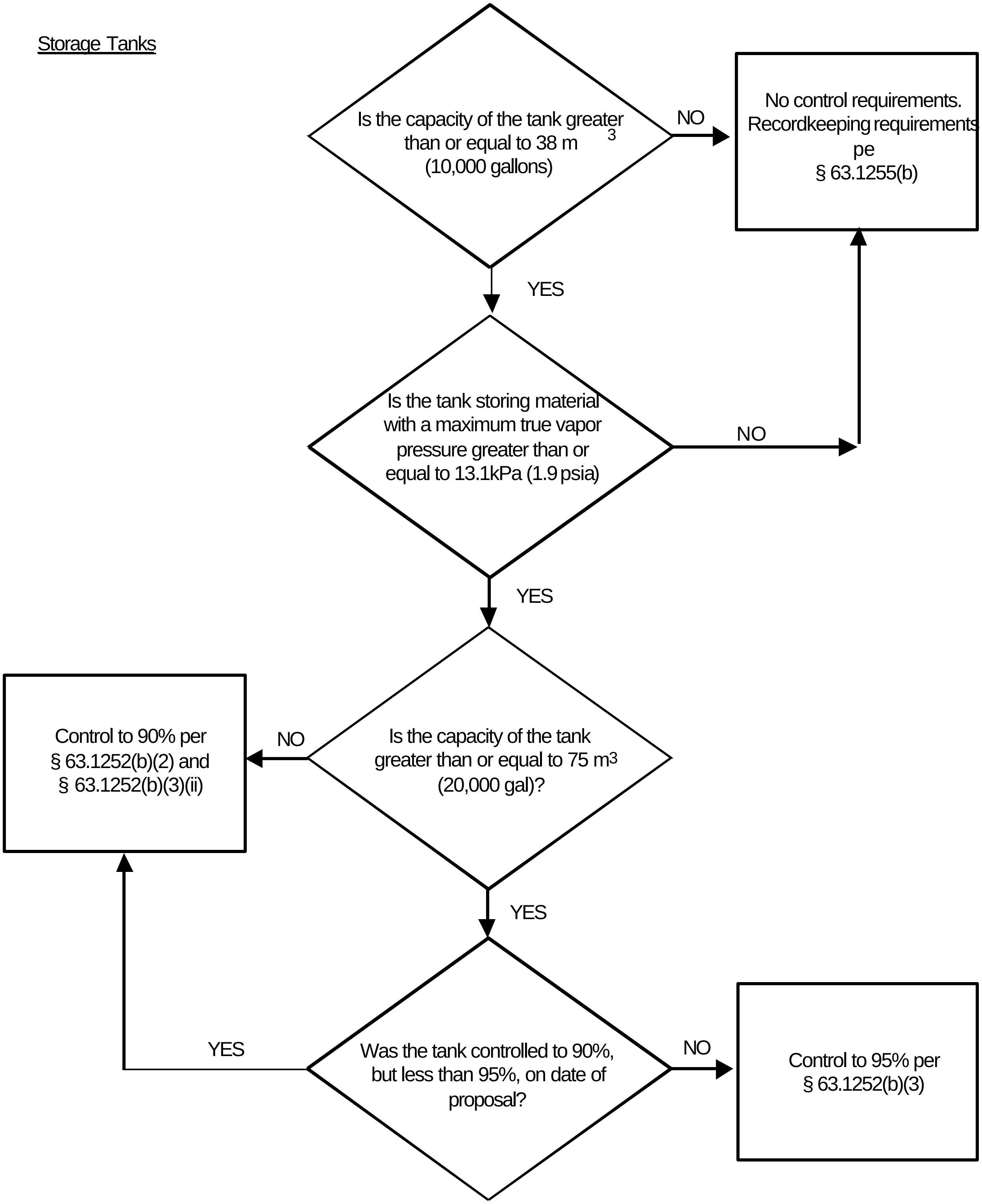

Figure 8-2. Storage tank standards.

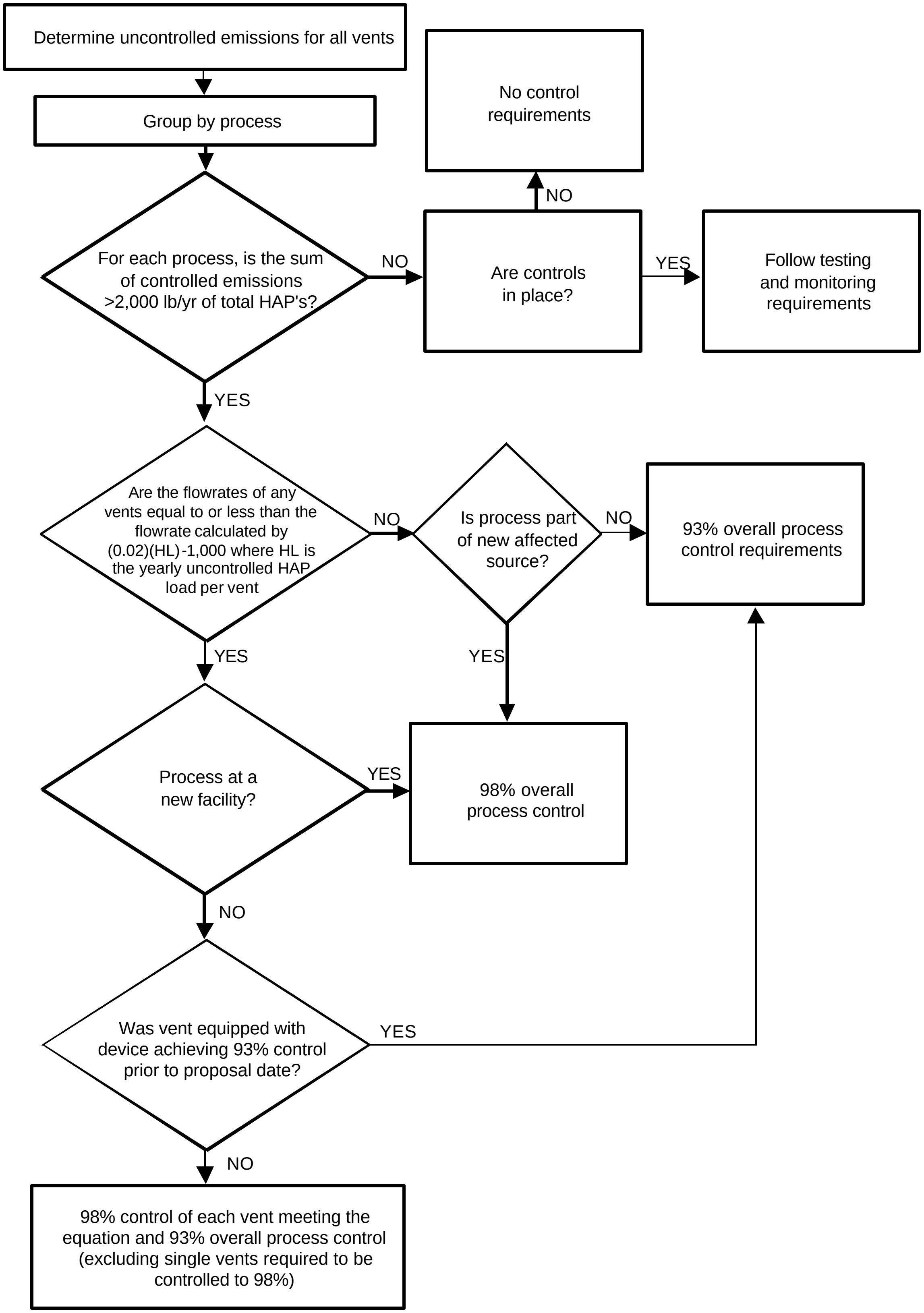

Figure 8-3. Process vent standards.

Wastewater

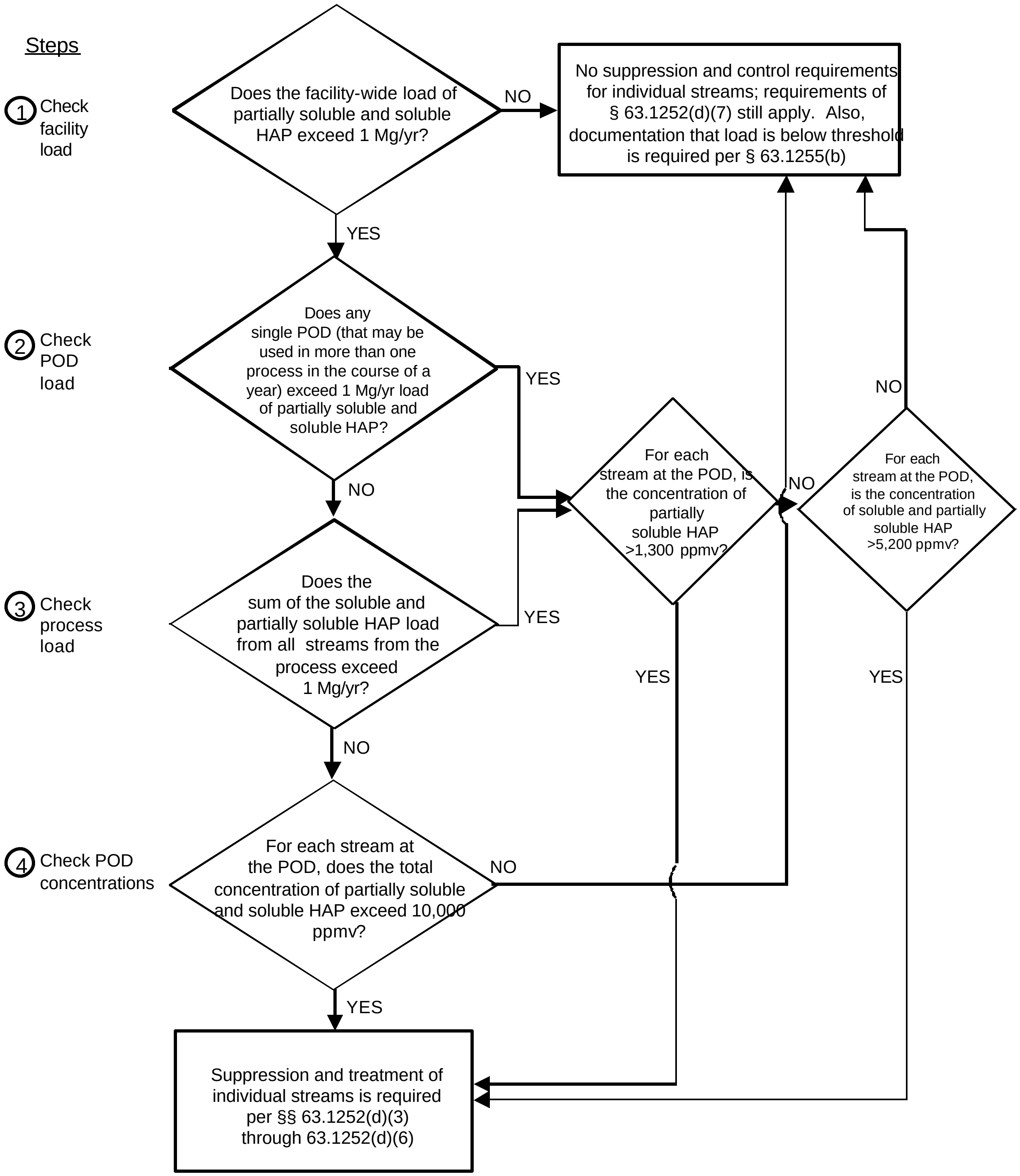

Figure 8-4. Wastewater standards.

same vapor pressure cutoff are required to be controlled to 95 percent. One of the following control systems be applied to meet these requirements: (1) an internal floating roof with proper seals and fittings, (2) an external floating roof with proper seals and fittings; (3) an external floating roof converted to an internal floating roof with proper seals and fittings; or (4) a closed vent system with the appropriate 90 or 95 percent efficient control device.

For wastewater system components at new and existing affected sources, any wastewater stream whose characteristics at the point of determination (POD) include: (1) partially soluble HAP compound concentration of 1,300 ppmw or greater and 1 Mg/yr HAP load from the process or single POD, or (2) any stream having a combined total HAP concentration of 5,200 ppmw or greater and a total yearly HAP load of 1 Mg from the process or single POD, or (3) any stream having a total HAP concentration of 10,000 ppmw located at a facility having greater than 1 Mg/yr from the sum of all processes and POD's are required to be collected without significant potential for volatilization and treated in one of the following manners: (1) using a design biotreatment system for soluble HAP's, (2) using a technology that achieves 99 percent removal by weight of partially soluble compounds, and 90 percent by weight of soluble compounds, and (3) using a technology that achieves 95 percent by weight removal of total organic HAP. Additionally, for new sources with a soluble HAP compound concentration of 110,000 ppmw or greater and 1 Mg/yr HAP load from the process or single POD a technology that achieves 99 percent removal by weight of soluble compounds must be used.

New and existing affected sources would also be required to implement an leak detection and repair (LDAR) program that is slightly modified from the program specified in the Negotiated Regulation for Equipment Leaks (40 CFR 63, subpart H). The LDAR program specified under subpart H requires specific equipment modifications and work practices that reduce emissions from equipment leaks. Modifications to this program that have been made include the lessening of the monitoring frequency for pumps from monthly to quarterly monitoring, and the elimination of phases I and II of the LDAR strategy and the requirement that facilities begin at phase III.

8.1.3.2 Alternative P2 Standard. Owners and operators of existing affected sources may also comply with one of two pollution prevention (P2) alternatives that can be implemented in lieu of the requirements described above. The P2 options were developed to provide a way for proactive facilities to demonstrate compliance with the MACT standard by demonstrating that they have effected reductions in overall waste from their processes. In the P2 options, which are applicable to existing affected sources, owners and operators can satisfy the MACT requirements for all planks associated with each process by demonstrating that the production-indexed consumption of HAP's has decreased from a baseline set during the first year of operation of the process or the year 1987. The production-indexed consumption factor is expressed as kg HAP consumed/kg product produced. The numerator in the kg/kg factor is the total consumption of material, which describes all the different areas where material can be consumed, either through losses to the environment, consumption in the process as a reactant, or otherwise destroyed.

In general, rationale for the P2 standard is that a reduction in consumption of HAP material can be associated with a reduction in losses to air, water, or solid waste. The first P2 option requires that a 75 percent reduction in the production-indexed consumption factor be achieved from the 1987 baseline year. The second P2 option requires that the production-indexed consumption factor be reduced by at least 50 percent, and that actual mass reductions equivalent to 25 percent of the kg/kg value be achieved using add-on controls. A total reduction of 75 percent will be required under both P2 options. The basis of the 75 percent is the reduction from uncontrolled emissions achieved by the standard for all four planks.

8.2 RATIONALE FOR THE SELECTION OF THE PROPOSED STANDARDS FOR EXISTING SOURCES

The approach for determining the MACT floor and developing regulatory alternatives is discussed in Chapter 6.0. The chapter also discusses the results of the MACT floor analysis and identifies the regulatory alternatives considered.

8.2.1 Process Vents

The Administrator selected Regulatory Alternative No. 1 over the MACT floor regulatory option because the incremental cost effectiveness of $1,000/Mg was judged to be acceptable in moving from the floor to a more stringent alternative. Additionally, Regulatory Alternative No. 1 is more cost effective than the floor. Technical reasons for going beyond the MACT floor for large emission sources that are currently controlled to less than 93 percent (sources meeting the equation criteria) also exist. Because there are situations in this industry where very large emission streams can dominate overall emissions from processes and facilities, the control levels associated with these streams should be considered separately from the controls allocated to the remaining sources within the processes. Without separate consideration of these sources, it is likely that the control of only these sources would satisfy overall process control requirements of 93 percent, even though the sizes of these emission streams alone would warrant the installation of control systems.

The decision to not require 98 percent control of emission sources meeting the equation criteria that are already controlled to the level of the MACT floor (93 percent) is based on the rationale that the incremental 5 percent control achieved in stepping up control from 93 percent to 98 percent may be difficult for many facilities to achieve without great expense. Because 98 percent control efficiency in many cases cannot be achieved by retrofitting or modifying existing control systems, there is a possibility that owners and operators that have made a good faith effort to control their emission sources to high levels (93 percent) would be required to scrap existing controls and install completely new control systems.

8.2.2 Storage Tanks

The Administrator chose Regulatory Alternative No. 1 over the MACT floor regulatory alternative for the following reason: floating roof technology has been demonstrated to achieve 95 percent control and is considerably less expensive than other technologies, even technologies that achieve control levels of less than 95 percent; therefore, it is the preferred method of control for tanks with capacities of greater than 75 m^3 (20,000 gallons). Regulatory Alternative No. 1 takes advantage of this fact for tanks that can be equipped with floating roof technology and merely requires the level of control that has been demonstrated to be cost effective and technically feasible to achieve.

In evaluating the floor and regulatory alternative for storage tanks, the Administrator also decided that storage tanks meeting the applicability requirements of Regulatory Alternative No. 1 that are currently equipped with control devices achieving 90 percent should not be required to step controls up to 95 percent, because the incremental reductions achieved in moving above the floor from 90 percent to 95 percent are not cost effective.

8.2.3 Wastewater

The MACT floor option was the only option identified for wastewater. The Administrator chose not to develop other regulatory options beyond the floor because the MACT floor option represents a limit of reasonable cost effectiveness. The criteria for application of collection and treatment controls are based on a site-specific maximum cost effectiveness of $3,500/Mg.

8.2.4 Equipment Leaks

The LDAR program proposed in this regulation was judged to be technically and economically feasible to implement for this industry.

8.3 SELECTION OF BASIS AND LEVEL OF PROPOSED STANDARDS FOR NEW SOURCES

For new sources, the MACT floor shall be no less stringent than the level of control achieved by the best performing similar source. The regulatory alternatives chosen represent a high level of control for two of the four planks and the limit of technical feasibility for this diverse source category. Therefore, no additional regulatory requirements have been developed for new sources for storage tanks or equipment leaks. The new source standard for process vents from processes emitting over 400 lb/yr, on an uncontrolled basis, was established at 98 percent, based on the level of control exhibited by a number of representative processes in the MACT floor facilities. For wastewater, only soluble compounds have a requirement for new sources that differs from existing sources. These compounds must be reduced by 99 percent if the concentration is above 110,000 ppmw. This requirement is based on the best performing similar source found in the industry that operates a RCRA incinerator to control wastewater.

8.4 SELECTION OF THE FORMAT OF THE PROPOSED STANDARDS

Of the formats considered (mass emission limits, percent concentration, percent reduction, equipment standards, work practice standards), the percent reduction format was chosen for the process vent, wastewater, and storage tank planks because it allows owners and operators the most flexibility possible in achieving the level of control required. For such diverse sources as batch process vents, the percent reduction format, in conjunction with strict definitions for the interpretation of the uncontrolled baseline, allows for a consistent implementation of requirements across the many types of process vent emission sources in the industry. Because the majority of process vents result from batch processing, characteristics of flow and concentration vary with time; therefore, a concentration-based standard is not feasible. Also, mass emission limits, which tend to encourage facilities to reduce emissions through process changes, work practice changes, and other methods to avoid costly add-on controls, cannot be universally applied to all process vents because of the diversity in emission stream characteristics. The proposed LDAR program is a combination of an equipment standard/work practice format. Under section 112 of the Act, national emission standards must, whenever possible, take the format of a numerical emission standard. Typically, an emission standard is written in terms of an allowable emission rate, performance level, or allowable concentration. These types of standards require the direct measurement of emissions to determine compliance. For some emission points, emission standards cannot be prescribed because it is not feasible to measure emissions. Section 112(h)(2) recognizes this situation by defining two conditions under which it is not feasible to establish an emission standard. These conditions are: (1) if the pollutants cannot be emitted through a conveyance designed and constructed to emit or capture the pollutant; or (2) if the application of measurement methodology is not practicable due to technological and economic limitations. If an emission standard cannot be established, EPA may instead establish a design, equipment, work practice, or operational standard or combination thereof.

The first condition is analogous to the situation involving wastewater conveyance and collection systems for which a means of demonstrating compliance with overall percent reduction is to demonstrate that the system is completely closed to the atmosphere.

For equipment leak emission points, such as pumps and valves, EPA has previously determined that it is not feasible to prescribe or enforce emission standards. Except for those items of equipment for which standards can be set at a specific concentration, the only method of measuring emissions is total enclosure of individual items of equipment, collection of emissions for a specified time period, and measurement of the emissions. This procedure, known as bagging, is a time-consuming and prohibitively expensive technique considering the great number of individual items of equipment in a typical process unit. Moreover, this procedure would not be useful for routine monitoring and identification of leaking equipment for repair. Therefore the LDAR work practice standard was chosen for the equipment leaks emission point.

The P2 alternative standard is in the format of a process specific production-indexed material consumption limit. This unique format allows for tracking of material consumption, while considering fluctuations in production rates. A very important facet of this format is that demonstration of compliance is achieved through periodic tracking of production and consumption.

8.5 SELECTION OF COMPLIANCE AND PERFORMANCE TESTING PROVISIONS AND MONITORING REQUIREMENTS

The proposed regulation contains compliance provisions that will require owners or operators to conduct an initial performance test on control devices that handle greater than 10 tons/yr of HAP to demonstrate compliance with the proposed standards. For devices controlling streams totaling less than 10 tons/yr, design evaluations or emission estimation methodologies can be used to calculate reduction efficiencies and make compliance demonstrations. As a means of demonstrating compliance with the standards following the initial performance test or other initial compliance demonstration, the owner or operator must also establish source-specific parameters based on the characteristics of the emission stream, process, or type of control device used. The Administrator determined that these provisions were necessary to meet the monitoring requirements of the General Provisions (40 CFR 63, subpart A).

8.5.1 Testing and Monitoring

Compliance is comprised of initial performance testing or compliance determination and continuous compliance verification, or monitoring. The proposed requirements for initial compliance testing and any periodic or continuous measurement to verify ongoing compliance are based on the emission stream characteristics that would be encountered either at the inlet and outlet of the control device and at the point of release to the atmosphere for uncontrolled emission streams. Figure 8-5

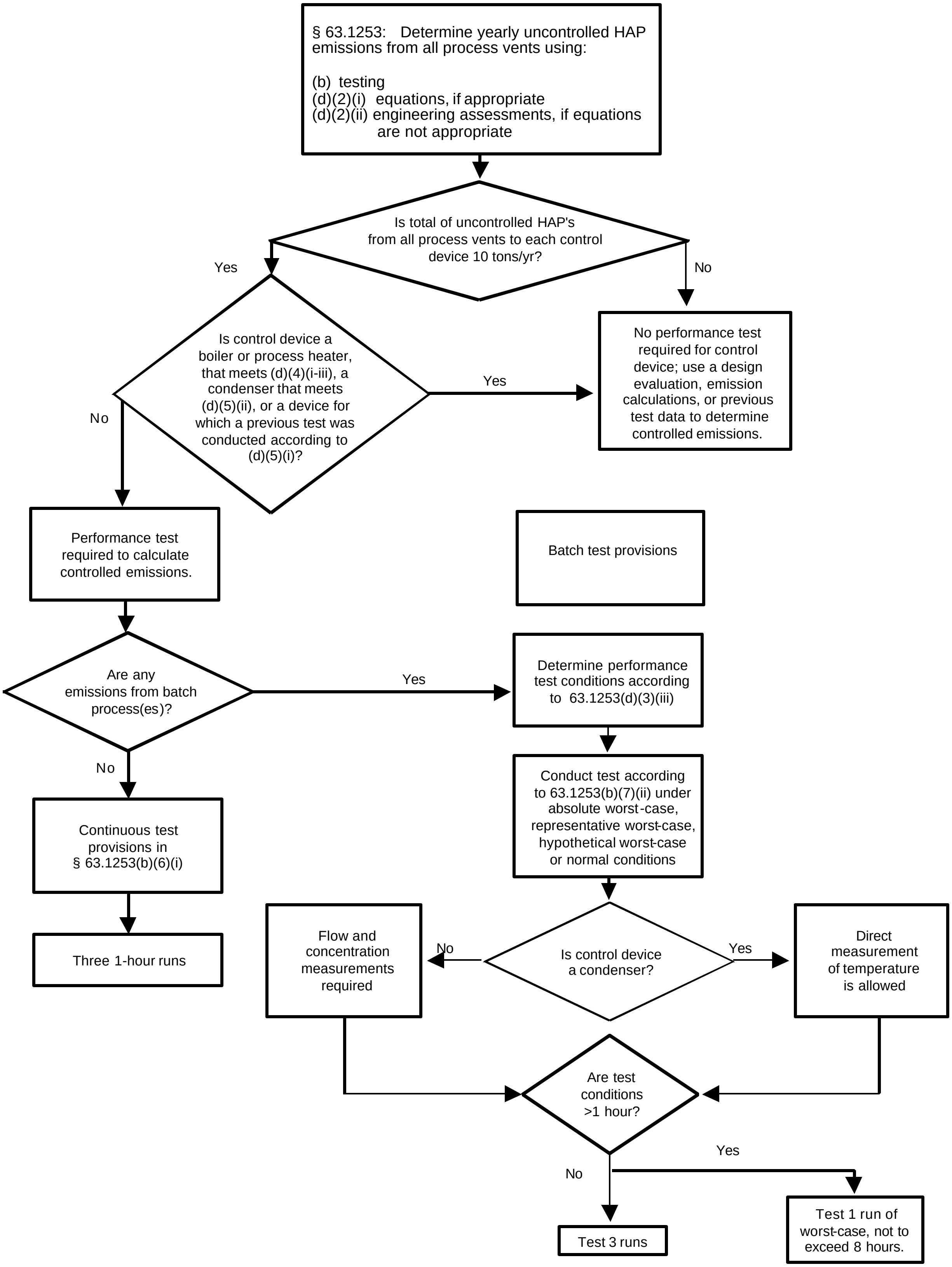

Figure 8-5. Initial compliance determination—process vents.

presents a logic diagram for the demonstration of initial compliance. From the figure, an initial performance test is required only if the total of uncontrolled HAP's routed to a control device is greater than 10 tons/yr. For condensers handling uncontrolled emissions in excess of 10 tons/yr, no performance test is required, provided the condenser is equipped with a temperature sensor and recorder. If the device is a boiler or process heater meeting certain criteria, or if a previous test was conducted at conditions that meet test criteria, the results of the previous performance test can be used to calculate controlled emissions. From the figure, uncontrolled and controlled emissions are the only parameters needed to demonstrate compliance with the percent reduction requirement (i.e., 93 percent control).

The demonstration that emission points within various plants meet emission limits (i.e., 2,000 lb/process for process vents) is based on the calculation or measurement of controlled emissions.

For batch performance testing, owners and operators have the option of testing during worst case conditions in addition to normal conditions. Worst-case conditions are defined in three ways: absolute worst-case, hypothetical worst-case, and representative worst-case. Absolute worst-case conditions have been defined as the period of time in which the pollutant stream entering the device will contain any of the following: (1) at least 50 percent of the total HAP load from the combination of processes that could concurrently be emitted to the device, not to exceed 8 hours, (2) the highest hourly HAP mass loading rate from the combination of episodes that can concurrently be emitted to the device, or (3) the highest hourly heat load from the combination of episodes that can concurrently be emitted to the device if the device being tested is a condenser. An option to simulate such conditions is also available in the rule, if the owner or operator cannot predictably product worst case conditions; this option is referred to as hypothetical worst-case.

The intent of testing under worst case conditions is to document the control efficiency of the device under its most challenging conditions and thereby establish a lower limit of the expected efficiency of the device for the purposes of documenting initial and continuous compliance with the standard. Presumably, the device should function as well or better under conditions that are not as challenging. Owners or operators have the option to test all control devices under absolute or hypothetical test conditions. Additionally, for incinerators, owners and operators may conduct performance testing under representative worst-case conditions provided that they operate the incinerator within design constraints. Representative worst-case conditions must include the highest HAP mass loading rate, in lb/hr, from a single process, or well as any other emission events that are emitting to the control device during the test.

Testing under normal conditions is also allowed for all control devices, provided that the conditions under which testing is conducted are never exceeded during operation of the device.

8.5.2 Selection of Test Methods and Criteria for Performance Testing

An important characteristic to consider when evaluating measurement methods are whether the streams are from continuous sources or whether they are from batch sources. Streams that are from continuous sources would have minimal variation in characteristics; the test measurement method therefore can be intermittent in nature. For example, flowrate and concentration can be sampled on an intermittent basis to obtain an average emission value that presumably will not vary significantly. Batch emission streams, however, are expected to have wide variation in flowrate, composition, and conditions throughout the course of a batch (i.e., with time).

Often, proportional sampling of flowrate and composition over the course of a batch to arrive at a total emission number over the entire batch is necessary. Alternatively, simultaneous measurement of flowrate and composition must be made to arrive at an instantaneous emission rate. Because these methods are difficult, an initial compliance demonstration requiring testing is required only for control devices that handle HAP emissions of greater than 10 tons per year. Rationale for this criterion is based on the application of the major source cutoffs. Specifically for this NESHAP, equations are provided in the regulation to determine HAP emissions from various pharmaceutical production process vents.

A second important characteristic of the emission stream to consider during selection of a test method is the composition. If organic material other than HAP are contained in the stream, it may be necessary to speciate the stream or at least identify the HAP constituents in the stream. This identification limits how continuously the stream can be sampled. The most common technology that will be used in identification is gas chromatography, specified in EPA Reference Method 18 of 40 CFR part 60, appendix A. Gas chromatography, coupled with the quantification of material typically done with a flame-ionization device (FID), EPA Reference Method 25A, can be done at sub-minute intervals, but not continuously. However, if identification of organic species is not necessary, an FID alone can be used. This technology will provide a continuous reading of organic concentration.

8.5.3 Consideration of Control Devices in Monitoring and Performance Test Requirements

The devices used to abate HAP emissions will affect the outlet stream composition and conditions and therefore affect the degree of confidence of the initial and continuous compliance methods. Devices that are commonly used in the pharmaceutical manufacturing industry to control process vents and storage tank emissions are condensers, gas absorbers (water scrubbers), carbon adsorbers, and incinerators. These devices differ from one another in the type of streams that they control and the outlet conditions of the streams and should be considered in establishing monitoring requirements. A discussion of specific control devices and consideration for establishing monitoring parameters and performance test requirements is presented below.

8.5.3.1 Condensers. In the case of condensers, which are usually applied to saturated emission streams and by design yield saturated streams, it can be assumed that the components will be present at levels corresponding to their saturated values (equilibrium) at the outlet conditions. This measure provides a worst-case estimate of emissions. Therefore, the direct measurement of concentration often may be foregone in lieu of the measurement of stream temperature and flow rate and subsequent calculation to yield mass emissions. For batch reactors in this industry, this is the required measurement to determine HAP concentration.

8.5.3.2 Gas Absorbers. Gas absorbers (water scrubbers), however, differ in that there is no parameter that can be measured and used to establish a limit of HAP concentration. Often, the streams routed to scrubbers are more dilute, and the control device functions in not only changing the conditions of the gas temperature like a condenser would do, but in employing concentration gradients to remove materials from gas streams. In order to predict the performance of a gas absorber, information must be known about the appropriate mass transfer coefficients for the specific system. Most often, the mass transfer coefficients are experimentally derived for specific applications and are usually functions of the mass velocities and contacting path variables. While it is possible to calculate the scrubber outlet compositions without mass transfer information by assuming that the amount of material transferred to the liquid is limited by the equilibrium-defined composition, this information is not indicative of the physical scrubber because it does not provide for the evaluation of the contacting path. Therefore, a direct measurement of composition is required during the initial performance test.

Evaluation of continuous compliance need not be done by continuous direct measurement of HAP concentration from the scrubber effluent, however. Another parameter, the liquid to gas molar ratio through the scrubber, can be monitored on a continuous basis to ensure required removal. The L/G ratio, which often reduces to the measurement of L, the liquid molar flow rate, because G, the gas molar flow rate is often constant, can be measured during the initial performance test to evaluate the sensitivity of the ratio with removal efficiency. Thereafter, the L/G ratio can be used to verify removal on a continuous basis by comparison to the limits established during the initial compliance test.

8.5.3.3 Carbon Adsorbers. Streams controlled by carbon adsorption will usually be dilute, compared to those controlled by condensers and scrubbers. No surrogate parameters have been identified as measures of HAP concentration or removal efficiencies. Therefore, a direct measurement of uncontrolled and controlled emissions (i.e., concentration and flowrate) will be required during the initial performance test as well as in continuous compliance monitoring.

8.5.3.4 Incinerators. Incinerators are sometimes used in this industry to control emission streams that have been manifolded together from one or more processes. As such, they often contain mixtures of HAP's and other organics. An initial performance test of incinerator efficiency involving the direct measurement of stream composition is required. The continuous monitoring of incinerator operating parameter such as combustion temperature is required for continuous compliance demonstrations.

8.5.3.5 Wastewater. The proposed testing and monitoring requirements for wastewater are based on the requirements in the HON. Further, the treatment systems and control devices likely to be used in complying with the proposed requirements were already considered as part of the HON. As a result, EPA has determined that there is no need to change performance testing provisions or the parameters selected for monitoring. Performance testing provisions are specified in 40 CFR 63.145, and monitoring requirements are specified in 40 CFR 63.143. Rationale for the selected provisions was presented in detail in the proposal and promulgation preambles to the HON, and in the preamble for the proposed amendments to the final rule. The discussion below summarizes the rationale for the selected provisions.

Initial performance tests for control of wastewater streams are not required by the proposed rule for nonbiological or closed biological treatment processes. For these treatment processes, facilities have the choice of using either performance tests or design evaluations (i.e., engineering calculations) to demonstrate the compliance of these units with the standards. Engineering calculations, supported by the appropriate documentation, were allowed to provide a less costly alternative to that of testing.

The proposed rule requires performance tests for open biological treatment processes because volatilization is an important issue for these treatment processes. To demonstrate compliance, the owner or operator must determine the mass of compounds that is removed by biodegradation rather than volatilization. However, the proposed rule exempts a facility from the performance test requirement if the open biological treatment system meets the definition of an enhanced biological treatment system and it receives streams that contain only soluble HAP and less than 50 ppmv partially soluble HAP. In an enhanced biological treatment system, the soluble HAP compounds are more readily biodegraded than the other HAP compounds, with minimal volatilization. Therefore, the EPA believes that the proposed exemption provides additional flexibility without sacrificing emissions reductions.

If the design steam stripper option is selected to comply with the control requirements, neither a design evaluation nor a performance test is required. Installation of the specified equipment, along with monitoring to show attainment of the specified operating parameter levels, demonstrates compliance with the equipment design and operation provisions.

The proposed wastewater provisions include requirements for periodic monitoring and inspections to ensure proper operation and maintenance of the control system and continued compliance. Waste management units are required to be visually inspected semiannually for improper work practices and control equipment failures that potentially may be a source of emissions. For biological treatment processes, the proposed rule requires the owner or operator to submit a request for approval from the permitting authority to monitor appropriate parameters. For steam strippers, the proposed rule requires continuous monitoring of the steam flow rate, the wastewater feed mass flow rate, and the wastewater feed temperature. Continuous monitoring is necessary to ensure proper operation of the stripper, thereby maximizing emission reductions. The proposed rule also includes monitoring requirements for control devices used with vapor collection or closed vent systems. The monitoring equipment, parameters, and frequency of monitoring for each control device are given in the proposed rule. The parameters were selected because they are good indicators of control device performance, and instruments are available at a reasonable cost to monitor these parameters.

8.5.3.6 Storage Tanks. Storage tank emissions vary greatly over time, which prohibits testing over reasonable periods of time. Therefore, no initial compliance test is proposed for this emission point, unless emissions are manifolded with process vents, in which case the compliance tests specified for process vents apply. For any tank that is not controlled with a floating roof, the proposed rule requires an owner or operator to prepare a design evaluation. The design evaluation consists of documentation showing the control device achieves the required control efficiency when the tank is filled at the expected maximum rate. The needed documentation includes a description of the gas stream entering the control device, and the design and operating parameters for the control device. Because storage tank emissions are not dependent on parameters that can be controlled, no continuous monitoring requirements are proposed for this emission point, except that facilities that control storage tank emissions must certify that such control devices are in proper working order.

8.5.3.7 Equipment Leaks. Like wastewater emissions, equipment leak emissions occur in open areas and in most cases cannot feasibly be captured. Therefore, no performance test is required for the equipment leaks source. Instead, facilities must demonstrate that they have an LDAR program in place that meets the proposed requirements. No monitoring requirements other than those contained in the LDAR requirement are proposed for equipment leaks, as the proposed standard for equipment leaks is a work practice/equipment standard.

8.5.4 Averaging Times

8.5.4.1 Initial Compliance. For continuous processes, a 1-hour averaging time is specified for process vent compliance tests; the emission rate would be the average of the results of three 1-hour tests. For batch process vents, the uncontrolled and controlled emission rates used to determine compliance would be the average of three tests taken over three runs or one test taken over a longer period of time. Averaging times for wastewater treatment system control efficiency determinations should be taken over three 1-hour runs, as specified in 40 CFR 63.145(c).

8.5.4.2 Monitoring. Figure 8-6 presents a logic diagram for monitoring requirements. For control devices handling over 0.91 Mg/yr (1 ton/yr) of HAP emissions, monitoring systems measuring either emissions or an operating parameter shall complete a minimum of one measurement cycle (sampling, analyzing, and data recording) for each successive 15-minute period during which time the device is operating in reducing emissions.

Owners and operators complying with the standard may be determined to be out of compliance with the standard if, for any 24-hour period, the average operating parameter value exceeds or is less than the value established during the initial compliance demonstration, as applicable.

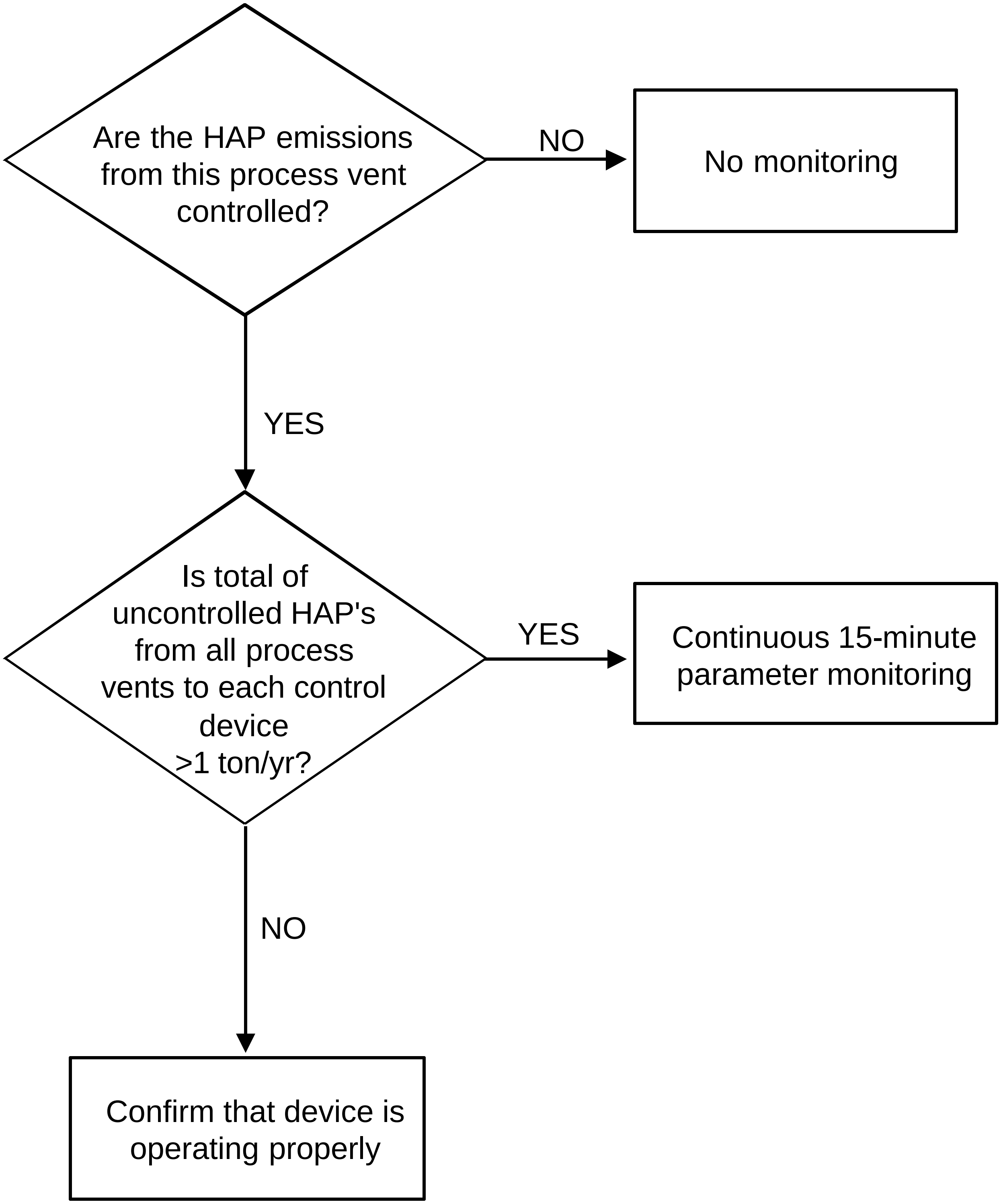

Figure 8-6. Monitoring provisions—process vents.

For devices handling emissions of less than 1 ton per year, only a periodic verification that the device is operating properly is required. This verification is a site-specific determination which requires approval from the Administrator.

8.6 SELECTION OF REPORTING AND RECORDKEEPING REQUIREMENTS

The owner or operator of any pharmaceutical manufacturing facility subject to these standards would be required to fulfill reporting requirements outlined in the General Provisions 40 CFR part 63 and in the rule.

8.7 OPERATING PERMIT PROGRAM

Under Title V of the CAA, all HAP-emitting facilities will be required to obtain an operating permit. Often, emission limits, monitoring, and reporting and recordkeeping requirements are scattered among numerous provisions of State implementation plans (SIP's) or Federal regulations. As discussed in the proposed rule for the operating permit program published on May 10, 1991 (58 FR 21712), this new permit program would include in a single document all of the requirements that pertain to a single source. Once a State's permit program has been approved, each facility containing that source within that State must apply for and obtain an operating permit. If the State wherein the source is located does not have an approved permitting program, the owner or operator of a source must submit the application under the proposed General Provisions of 40 CFR part 63.