

ADEQ OPERATING AIR PERMIT

Pursuant to the Regulations of the Arkansas Operating Air Permit Program, Regulation 26:

Permit No. : 544-AOP-R5

Renewal #1

IS ISSUED TO:

Baxter Healthcare Corporation

1900 N. Hwy. 201

Mountain Home, AR 72653

Baxter County

AFIN: 03-00002

THIS PERMIT AUTHORIZES THE ABOVE REFERENCED PERMITTEE TO INSTALL, OPERATE, AND MAINTAIN THE EQUIPMENT AND EMISSION UNITS DESCRIBED IN THE PERMIT APPLICATION AND ON THE FOLLOWING PAGES. THIS PERMIT IS VALID BETWEEN:

January 4, 2005

AND

January 3, 2010

THE PERMITTEE IS SUBJECT TO ALL LIMITS AND CONDITIONS CONTAINED HEREIN.

Signed:

Mike Bates
Chief, Air Division

Date Modified

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List of Acronyms and Abbreviations

A.C.A.	Arkansas Code Annotated
AFIN	ADEQ Facility Identification Number
CFR	Code of Federal Regulations
CO	Carbon Monoxide
HAP	Hazardous Air Pollutant
lb/hr	Pound Per Hour
MVAC	Motor Vehicle Air Conditioner
No.	Number
NO _x	Nitrogen Oxide
PM	Particulate Matter
PM10	Particulate Matter Smaller Than Ten Microns
SNAP	Significant New Alternatives Program (SNAP)
SO ₂	Sulfur Dioxide
SSM	Startup, Shutdown, and Malfunction Plan
Tpy	Tons Per Year
UTM	Universal Transverse Mercator
VOC	Volatile Organic Compound

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SECTION I: FACILITY INFORMATION

PERMITTEE: Baxter Healthcare Corporation

AFIN: 03-00002

PERMIT NUMBER: 544-AOP-R5

FACILITY ADDRESS: 1900 N. Hwy. 201
Mountain Home, AR 72653

MAILING ADDRESS 1900 N. Hwy. 201
Mountain Home, AR 72653

COUNTY: Baxter

CONTACT POSITION: Carolyn Walker

TELEPHONE NUMBER: 870-424-5336

REVIEWING ENGINEER: Amanda Leamons

UTM North South (Y): Zone 15: 4023.75

UTM East West (X): Zone 15: 555.0

SECTION II: INTRODUCTION

Summary of Permit Activity

Baxter Healthcare Corporation (Baxter), previously known as Travenol Laboratories, Inc., operates a facility in Mountain Home, AR, which manufactures items used in the healthcare field. With this significant modification, Baxter requested the following changes:

- Annual and short-term plant-wide VOC and HAP emissions caps. The caps will replace source-specific VOC and HAP emission rate requirements and related production and throughput limits. The requested VOC annual cap is 95 tons per year (tpy), the HAP cap is 23.75 tpy (aggregated HAPs) and 9.5 tpy (individual HAPs), calculated monthly as a 12-month rolling total. The requested short-term HAP emission limit (the hourly maximum usage rate) shall be demonstrated by keeping mass balances or approved throughput records on a monthly basis of all HAP containing materials that qualify under the HAP screening matrix and HAP emission limits.
- The ability to move existing equipment to different locations within the facility, modify existing equipment, add new equipment, or change raw materials (including solvents) provided that these changes are made in compliance with the HAP screening matrix limits, plant-wide HAP and VOC limits, and other applicable requirements addressed in the permit.
- The ability to install, move, and modify other equipment or processes not listed in Appendix A of the permit, provided that the installation, move, or modification does not trigger any new applicable federal or state regulatory requirements that are not already addressed in the permit and provided that the installation, move, or modification passes the HAP screening matrix review and that the plant is able to maintain emissions below the plant-wide VOC and HAP limits.
- Approval for the replacement of one of the existing boilers with a new boiler having a maximum design heat input capacity of 42 MMBtu/hour. Or as an alternative keep the existing boilers and install an additional boiler with the maximum design heat input capacity of 42 MMBtu/hour. The replacement boiler or additional new boiler will not exceed the emission limits contained in this permit for SN-18. The “commencement of construction window” will be extended to allow installation of a new boiler at any time during the full permit term (5 years), consistent with rule language [19(410)(b)].
- Approval for the installation of two new [1330 ft³ (200 lb)] ethylene oxide sterilization chambers. Alternative Scenario #1 includes installation of one additional vessel (vessel #7). Alternative Scenario #2 includes installation of one more additional vessel (vessel #8). The “commencement of construction window” will be extended to allow installation of a new ethylene oxide sterilization chambers at any time during the full permit term (5 years), consistent with rule language [19(410)(b)].
- Approval for the installation of one plastics grinder and associated baghouse filter with efficiency rate of 99%. The commencement of construction window will be 5 years.
- Needle grinding operation (SN-45) has been changed to an insignificant activity (Group A.13) because the PM captured with a fabric filter is located within the warehouse; therefore, no emissions are directly discharged to the atmosphere.

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- Approval for installation of an additional needles grinder (Grinder #2). The PM captured will be captured with a fabric filter located within the warehouse, no emissions are directly discharged to the atmosphere. Therefore, Needles Grinder #2 is considered an insignificant activity (Group A.13).
- Removal of sources from the permit which are no longer in service at the facility. The removed sources are SN-03 (Vacuum Dryers), SN-04 (Orbital Centrifuge), SN-05 (Orbital Centrifuge), and SN-06 (Drum Cutter).

Overall annual permitted emissions decreased 12.7 tons of VOC and increased 2.6 tons of PM, 15.2 tons SO₂, 3 tons of CO, 11 tons of NO_x, and 15.7 tons total combined HAPs.

Process Description

Baxter Healthcare Corporation (Baxter) operates a facility in Mountain Home, AR, that manufactures items used in the healthcare field (SIC 3081, 3089, and 3841).

Baxter manufactures peritoneal dialysis disposables, blood cell separation disposables, patient connectors, donor needles (SN-45) and produces plastics for the disposables manufacturing. Most of the manufactured products are sterilized at the facility using ethylene oxide (EtO) (SN-11 through SN-15, SN-57, SN-74 through SN-83, SN-94, and SN-101).

Ethylene Oxide Sterilization

The ethylene sterilization process involves the placement of manufactured, packaged health care items in a chamber. A partial vacuum is pulled on the chamber by using a steam jet injector (SN-11 through SN-15, and SN-57). When the evacuation process is completed, the chamber is filled with ethylene oxide. After a pre-determined time, a maximum of 95% of the ethylene oxide is pulled from the chamber by the vacuum pump and routed to the scrubber. The ethylene oxide is converted to ethylene glycol and stored in an 8,000 gallon storage tank (SN-88).

Manual and Automated Assembly

In manual and automated assembly (SN-97), plastic parts are assembled to one another to produce sets, cassettes and many other products. Plastic parts that are assembled to produce medical devices include tubing, valves, housings, roller clamps, slide clamps, membranes, luer connectors, luer locks, spikes, needle adapters, filters, couplers, Y-connectors and others. Assembly for non-medical device products may involve a wide variety of plastic parts. Plastic parts are affixed or bonded to another using one of several techniques, including solvent bonding, ultrasonic bonding, ultraviolet (UV) energy, radio frequency (RF) energy, thermal energy, friction or others. In the case of solvent bonding, a variety of solvents can be used including both HAPs and non-HAPs.

Needles

The Needles process is used to produce and assemble needles for various blood collection products. The stainless steel cannula is taped and the tip is ground. Water used to cool the grinding wheel captures the majority of PM generated. A hood over the grinding process captures some PM that is emitted through the fabric filter (SN-45) located within the warehouse; therefore, no emissions are directly discharged to the atmosphere.

Compounding/Pelletizing and Film/Tubing Extrusion

At SN-95 raw materials are received in bulk and packaged for manufacturing of plastic film and tubing. The first step is blending. After blending, the blend is then sent to the film extrusion area, tubing extrusion area, pelletizing area, or exported to other locations for processing. Small amounts of miscellaneous fugitive VOCs may result from the above described operations. The pollutant of concern is bis(2-ethylhexyl)phtalate (DEHP), a listed HAP. Fugitive DEHP emissions are captured with ventilation equipment from pelletizing, tubing extrusion, and film extrusion processes and routed to filters. Filters used in the plastics manufacturing are either roof mounted or located within the building. In either case, effluent from the filters is routed back into the warehouse. As such, no emissions are directly discharged to the atmosphere, but rather are all fugitive. Also included in SN-95 are emissions from inside DEHP storage tanks. Also included: Jet Cleaner (SN-72) consists of a closed insulated chamber with internal heaters, into which parts are placed for cleaning. The Jet Cleaner cleans PVC and other residue polymers off of steel plates used in extrusion of plastic tubing/film. It cleans using a pyrolysis cleaning cycle at full vacuum followed by an oxidation cycle at reduced vacuum. All heat is provided by electric heating elements. A primary trap beneath the chamber collects the polymer that drains from the parts. A secondary trap, fitted with water spray nozzles, condenses and collects vapors before they can enter the vacuum pump. There are two Jet Cleaners in the room. After the steel plates are removed from the cleaner, they are cooled and blasted using a totally enclosed glass-bead blaster. The unit vents inside the room. There are two hoods located over each Jet Cleaner. Both hoods vent to the atmosphere through the same roof vent (SN-72). SN-89, SN-90 DEHP Storage Tanks are located outside in the plastics tank farm.

Regulations

The following table contains the regulations applicable to this permit.

Regulations
Arkansas Air Pollution Control Code, Regulation 18, effective February 15, 1999
Regulations of the Arkansas Plan of Implementation for Air Pollution Control, Regulation 19, effective December 19, 2005
Regulations of the Arkansas Operating Air Permit Program, Regulation 26, effective September 26, 2002
40 CFR Part 63 National Emission Standard for Hazardous Air Pollutants (NESHAP), Subpart O - <i>Ethylene Oxide Emission Standards for Sterilization Facilities (Appendix A)</i>

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The following table is a summary of emissions from the facility. This table, in itself, is not an enforceable condition of the permit.

Emission Summary

EMISSION SUMMARY				
Source Number	Description	Pollutant	Emission Rates	
			lb/hr	tpy
Total Allowable Emissions		PM	3.2	7.5
		PM ₁₀	3.2	7.5
		SO ₂	60.3	43.2
		VOC	108.8	97.6
		CO	4.4	9.5
		NO _x	17.5	35.0
		Methylene Chloride (MeCl)	5.0	5.0
		Cumene*	8.35	0.50
		Ethylene Oxide (EtO)*	0.87	0.71
		Bis(2-ethylhexyl)phthalate (DEHP)*	0.37	2.0
		Ethylene Glycol*	1.00	0.05
		Xylene*	16.69	0.50
		Individual HAP	-	9.5
		Total Combined HAPs	-	23.75
09	Filter Integrity Test Station Exhaust	Included in SN-97		
11-15	Sterilization Chamber Air Evacuation Exhaust	Ethylene Oxide ¹	0.0	0.0

EMISSION SUMMARY				
Source Number	Description	Pollutant	Emission Rates	
			lb/hr	tpy
16	35 MMBTU/HR Lasker Boiler	PM	0.5	1.1
		PM ₁₀	0.5	1.1
		SO ₂	18.0	12.7
		VOC	0.2	0.5
		CO	1.3	3.0
		NO _x	5.0	11.0
17	42 MMBTU/HR Babcock & Wilcox Boiler	PM	0.6	1.1
		PM ₁₀	0.6	1.1
		SO ₂	21.1	15.2
		VOC	0.3	0.5
		CO	1.5	3.0
		NO _x	6.0	11.0
18	42 MMBTU/HR Boiler #3	PM	0.6	1.1
		PM ₁₀	0.6	1.1
		SO ₂	21.1	15.2
		VOC	0.1	0.5
		CO	1.5	3.0
		NO _x	6.0	11.0
21-27	Ovens for Needles Covers	Included in SN-109, Plant-wide HAP cap.		
28	Oven for Needles Assemblies	Included in SN-109, Plant-wide HAP cap.		
41	Plastics Grinding Process	PM	1.0	2.3
		PM ₁₀	1.0	2.3
45	Needles Grinder #1	Insignificant Activity		
57	Sterilization Chamber Air Evacuation Exhaust	Ethylene Oxide ¹	0.0	0.0
59-66	Resin Storage Silos	Insignificant Activity		
67-69	Water Chillers	Insignificant Activity		
72	Jet Cleaner	Included in SN-109		
73	Plastics Grinder #2	PM	0.4	1.7
		PM ₁₀	0.4	1.7
76, 77	Aeration Rooms 3 & 4	Routed to SN-94 ²		
78-81	(4) 150 lb Sterilization Chamber Rear Exhaust	Routed to SN-101 ²		

EMISSION SUMMARY				
Source Number	Description	Pollutant	Emission Rates	
			lb/hr	tpy
82, 83	(2) 200 lb Sterilization Chamber Rear Exhaust	Routed to SN-101 ²		
85	Print Shop	Included in SN-109		
87	Isolex 300 Sets	Insignificant Activity		
88	Ethylene Glycol Tanks	VOC Ethylene Glycol*	1.0 1.0	0.1 0.05
89	DEHP Storage Tank	Included in SN-109		
90	DEHP Storage Tank	Included in SN-109		
94	Sterilization Catalytic Oxidizer	PM PM ₁₀ SO ₂ VOC CO NO _x Ethylene Oxide*	0.1 0.1 0.1 0.2 0.1 0.5 0.8	0.2 0.2 0.1 0.5 0.5 2 0.33
95	Plastics Manufacturing	Included in SN-109		
96	Molding Process	Insignificant Activity		
97	Plantwide VOC Emission Cap	VOC	100.0	95.0
98	Needles Blasting	Insignificant Activity		
100	Fuel #2 Storage Tank	VOC	6.0	0.1
101	Ethylene Oxide Absorber Tower	VOC Ethylene Oxide*	0.7 0.7	0.3 0.3
102	Methylene Chloride Etching	Included in SN-109		
103	E-Beam Ionizing Radiation	Insignificant Activity		
107	Coextured Non-PVC Plastics	Insignificant Activity		
108	Pump Housing and Sets Assembly	Included in SN-109		
109	Plantwide HAP Emissions	MeCl Cumene Bis(2-ethylhexyl)phthalate (DEHP)	5.0 8.35 0.47	5.00 0.50 2.00

EMISSION SUMMARY				
Source Number	Description	Pollutant	Emission Rates	
			lb/hr	tpy
		Xylene	16.69	0.50
110	200 lb Sterilization Chamber Air Evacuation Exhaust/Rear Exhaust	Routed to SN-101		
111	200 lb Sterilization Chamber Air Evacuation Exhaust/Rear Exhaust	Routed to SN-101		

*HAPs included in the VOC totals. Other HAPs are not included in any other totals unless specifically stated.

**Air Contaminants such as ammonia, acetone, and certain halogenated solvents are not VOCs or HAPs.

¹ Ethylene Oxide shall be emitted only as a result of emergency or upset conditions.

² Ethylene Oxide shall be emitted only as a result of emergency or upset conditions (Specific Conditions 25 and 43). Aeration rooms 3 & 4 controlled by catalytic oxidizer, effective December 6, 1999.

Sources Removed from Service, Rescinded, or Never Installed		
Source Number	Description	Action
01	Bundle Centrifuge & Drum Cutter	Removed from Service
02	Capco Assembly Area	Removed from Service (April 2002)
03	Vacuum Dryers	Removed from Service
04	Orbital Centrifuge	Removed from Service
05	Orbital Centrifuge	Removed from Service
06	Drum Cutter	Removed from Service
07	Carbon Absorber C-1	Removed from Service
08	Pellet Cooler Discharge	Removed From Service
10	Alcohol Storage Tanks	Removed From Service
19	Degreasing Unit	Removed From Service

Sources Removed from Service, Rescinded, or Never Installed		
Source Number	Description	Action
20	Ultrasonic Degreaser Unit Freon TF	Removed From Service
29-40	Extruders	Removed From Service
42	Pelletizer	Removed From Service
43	Procedyne Cleaner	Removed From Service
44	Paint Booth	Removed from Service (May 2004)
46, 84	Marathon Filter Vapor Recovery System	Removed From Service
47	Bundle Centrifuge	Removed From Service
48	Capco Assembly Area	Removed From Service
49	Vacuum Dryer	Removed From Service
50	Urethane Dispenser	Removed From Service
51	Orbital Centrifuge	Removed From Service
52	Drum Cutter	Removed From Service
53	Phase V Freon System	Removed From Service
54	Pre-Heat Tunnel	Removed From Service
55	Alcohol Wash Centrifuge	Removed From Service
56	Dry Heat Oven	Removed From Service
58	Ethylene Oxide Absorber Tower	Removed From Service
70, 71	N/A	Rescinded
74, 75	Aeration Rooms 1 & 2	Removed from service
86	Chlorine Shed	Removed from Service (May 2000)
91	Pallet Treatment Kiln Chamber	Never Installed
92	Diapez Dialyzer Hot Wire Cutting	Never Installed
93, 99	Pallet Treatment Oven	Removed From Service
104	Syntra + Dialyzer	Removed from Service (May 2004)

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Sources Removed from Service, Rescinded, or Never Installed		
Source Number	Description	Action
105	Vacuum Dryers Oil Mist Stack	Never Installed
106	Laser Sealing of Syntra Dialyzer	Removed from Service

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SECTION III: PERMIT HISTORY

Travenol Laboratories, Inc. was issued its first air permit, Permit **#530-A**, in 1978. Travenol was permitted to install two grinders (SN-41) and three boilers (SN-16, SN-17, and SN-18). The boilers were permitted to use fuel oil #2 as a secondary fuel. Natural gas was used as a primary fuel.

In 1978, Travenol Laboratories was permitted to construct three sterilization chambers (Permit **#544-A**). Ethylene oxide was permitted to be used as a sterilization agent (SN-11, SN-12, and SN-13).

In 1979, the permit **#544-A** was modified. A degreasing unit (SN-19) was permitted to be installed.

In 1980, Permit **#530-A** was modified. Fuel oil #5 was permitted to be burned in the boilers as a backup fuel.

In 1982, Permit **#544-A** was modified again. Travenol Laboratories had proposed to begin manufacturing the CF Dialyzers (SN-07).

In 1986, first consolidated Permit **#544-AR-3** was issued for the facility. All previous permits were voided. Many existing sources previously not permitted were included in the permit. A total of 45 sources were included in the consolidated permit. The second function of the permit was to allow Travenol Laboratories, Inc. to install and operate a ten-place ethylene oxide (EtO) sterilizer. By that time, four chambers were operated at the facility and one more chamber was permitted (SN-11 through SN-15).

In 1988, the facility's name was changed to Baxter Healthcare Corporation (Baxter). Permit **#544-AR-4** allowed the facility to install equipment to manufacture Marathon Filters (SN-46). The facility was required to test Freon 113 emissions from SN-46 and install, calibrate, and maintain a device to continuously monitor the hydrocarbons emissions from SN-46.

In 1988 (Permit **#544-AR-5**), Baxter was permitted to install a second Capillary Flow (CF) Dialyzer manufacturing line (SN-47 through SN-56). The permittee was required to measure the Freon TF emissions from the phase V Freon system (SN-53).

In 1990 (Permit **#544-AR-6**), Baxter was allowed to construct a scrubber (SN-58) as a part of the ethylene oxide sterilization system. The facility was required to route ethylene oxide from sterilization chambers to the scrubber. The following sources had been removed from service: Boiler #3 (SN-18), Degreasing unit (SN-19), Ultrasonic Degreaser (SN-20), and Incinerator (SN-28). Some other minor changes were included in the permit.

In 1994 (Permit **#544-AR-7**), Baxter was allowed to install a high intensity plastics blend system (SN-59 through SN-66). The following sources had been removed from service: SN-08, SN-10, SN-29, SN-42, SN-43, SN-45, SN-47, SN-48, SN-52, SN-53, SN-55, SN-56. The permit also

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included some other minor changes. All processes at the facility were permitted to be operated 24 hours per day, 7 days per week, and 52 weeks per year (8760 hours per year) unless otherwise specified.

In 1995, Baxter was issued a minor permit modification (Permit #**544-AR-8**). The facility was allowed to upgrade the pressure relief protection of the chillers in the boiler room complex to comply with ASHRAE Standard 15 (SN-67, SN-68, and SN-69). Other changes in the minor permit modification included the removal from service SN-49, SN-50, SN-51, and SN-54. The facility was identified as subject to requirements of Ethylene Oxide Emissions Standards for Sterilization Facilities (40 CFR Part 63, Subpart O). The facility was also identified as subject to requirements of the Title V air permitting (40 CFR Part 70).

In 1996, Baxter was issued a minor permit modification (Permit #**544-AR-9**) to add Pallet Treatment Process (SN-91).

In 1999, Permit # **544-AOP-R0** was the first Title V permit for the facility. The following changes, new sources and sources previously not permitted were included in that permit:

- SN-01 was removed from service;
- A new boiler, SN-18, was installed;
- The Needles Process (SN-45) that was not previously permitted;
- SN-73, a second needles grinder;
- Aeration rooms (SN-74 through SN-77) that were not previously permitted;
- Sterilization chamber rear exhausts (SN-78 through SN-83) that were not previously permitted;
- Marathon Filters (SN-46 and SN-84) were removed from service as of July, 1997;
- Two Bis(2-ethylhexyl)phthalate (DEHP) storage tanks (SN-89, SN-90) that were not previously permitted;
- The DiaPES Dialyzer to be manufactured at the facility (SN-92);
- A pallet treatment oven (kiln) (SN-92);
- The pallet treatment ovens (SN-93 and SN-99) that were not previously permitted;
- The catalytic oxidizer (SN-94) constructed in order to comply with 40 CFR Part 63, Subpart O;
- The fugitive emissions (SN-95 through SN-97);
- Fuel oil tank (SN-100) that was not previously permitted; and
- The addition of an acid-water scrubber (SN-101).

In 2002, Permit # **544-AOP-R1** was issued. This permit was a minor modification that included the following changes:

- Production rate of dialyzers increased to a maximum of 5.5 MM units per year;
- The throughput of Dynasolve CU-6 increased to 2000 lb/yr;
- Specific Condition #126 was changed to require monthly preventive maintenance of SN-45;
- All references to SN-86, chloride shed, were removed;
- Specific Condition #163 was changed to increase the throughput of Methyl Ethyl Ketone (MEK);
- Emissions of MEK were increased to 2.5 tons per year for SN-97;

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Added SN-102, Methylene chloride etching;
New source, SN-104, for the production of Syntra dialyzers was added;
SN-18, SN-73, SN-91, and SN-92 were removed from the permit;
SN-103, E-Beam Ionizing Radiation was added as an insignificant activity; and
All conditions and emissions rates that were superseded by MACT Subpart O on December 6, 1999 were removed.

Permit # **544-AOP-R2** was a modification issued on November 26, 2002. The modification encompassed the following changes:

Addition of an oil mist separator to SN-03, Vacuum Dryers, in order to minimize the oil mist emitted from the vacuum dryers;
Installation of SN-105, Vacuum Dryers Oil Mist Stack, in order to operate the oil mist separator at its optimum level;
SN-04, Orbital Centrifuge, production rate of dialyzers increased from 5.5 MM units per year to a maximum of 6.0 MM units per year;
The facility discontinued use of methylene chloride to clean parts (Alternative Scenario #1) as of January 1999; therefore, conditions and emission rates associated with Alternative Scenario #1 (use of methylene chloride) were removed from the permit;
SN-04, Alternate Scenario #3 included in the permit to allow the facility to use Dynasolve 180 (VOC emission);
The VOC emissions from SN-04 increased to 1.0 lb/hr and 0.8 tpy;
SN-106, Laser Sealing of Syntra Dialyzer, added to the list of Insignificant Activities under Group A.13;
SN-58, Ethylene Oxide Absorber Tower, removed from service December 1999; therefore, related emissions were removed from the permit; and
The section of the permit containing sources related to the sterilization process (11-15, 57, 76-83, 88, 94, 101) was updated to match the current operations at the facility, thus removing Alternative Operating Scenario #1 and related conditions.

Permit # **544-AOP-R3** was a minor modification issued on November 12, 2003 to allow Baxter an alternative evacuation process for the EtO Sterilization Chambers. This alternative evacuation method allowed Baxter the option of using vacuum pumps or steam ejectors to evacuate the chambers during the initial evacuation and the after gassing portion of the EtO Sterilization cycle. This modification did not change any permitted emission limits.

Permit # **544-AOP-R4** was the first Title V Renewal issued on January 5, 2005. With this renewal the Syntra plus Dialyzer sources (SN-104 and related insignificant activities), the CF repair station (SN-07), the Paint Booth (SN-44), and the pallet treatment process (SN-93 and SN-99) were removed from the permit because the facility has removed these sources from service. In addition several emission limits and conditions were updated based on current emission factors, equipment capacity limitations, historical usage records, and to fit the Department's currently accepted permitting format. Overall annual permitted emissions increased 0.46 tons methylene chloride and less than 0.01 tons for each of the following hazardous air pollutants: cumene, dibutyl phthalate, chromium compounds, nickel compounds and xylene. All other permitted annual emissions decreased with this renewal.

SECTION IV: SPECIFIC CONDITIONS

SN-11 thru 15 and 57: Sterilization Chamber Air Evacuation Vent
SN- 76 and 77: Aeration Rooms #3 and #4
SN-78 thru 83: Sterilization Chamber Rear Exhaust Vents
SN-88: Ethylene Glycol Tanks
SN-94: EtO Catalytic Oxidizer
SN-101: EtO Sterilization Scrubber
SN-110 and SN-111: EtO Sterilization Units

Source Description

The currently used equipment was installed in 1990-1996. The aeration rooms #1, #2, and #3 have been used since 1985, 1987, and 1993, respectively. Effective December 6, 1999, aeration rooms #1 and #2 were combined and re-designated as aeration room #4.

There are six (6) ethylene oxide (EtO) gas sterilization chambers at the facility; there are two 1330 ft³ (200 lb) and four 667 ft³ (150 lb) chambers. After chambers are loaded with packaged items, the air from the chambers is pulled out by the vacuum pumps (SN-101) or the steam jet ejectors (SN-11 through SN-15, and SN-57). Then, the chambers are filled with ethylene oxide. Negative gauge pressure is kept within the chambers during sterilization process. At the end of sterilization cycle, ethylene oxide is pulled out by vacuum pumps and routed to the scrubber. In the scrubber, >99% of EtO is absorbed from the exhaust gas by water. The sterilization chambers vent as SN-101.

After ethylene oxide is evacuated from the chamber, the chamber's front door is opened to remove sterilized product. Simultaneously, the rear chamber exhaust vent starts pulling air and remaining ethylene oxide from the chamber. Sterilization chamber rear exhaust vents (SN-78 through SN-83) and vacuum pumps are controlled by a scrubber (SN-101). The absorbed EtO is converted to ethylene glycol by acid-catalyzed reaction with water in the plug flow reactor. In order to keep from exceeding the maximum glycol concentration or level in the scrubber, small amounts of liquor are discharged periodically from the system into an 8,000 gallon holding tank (SN-88). Water is automatically replaced as required. Acid is automatically or manually replaced as well. Ethylene glycol production is limited by the throughput of ethylene oxide. Maximum of 340 lb/hr of ethylene oxide is evacuated to the scrubber based on history of cycle times and process flow.

In case of scrubber malfunction, rear chamber exhausts vents (SN-78 through SN-83) could be exhausted to the atmosphere. Emissions from the rear chamber exhaust vents (SN-78 through SN-83) are controlled through SN-101.

Product sterilized in any of the six sterilizers is moved to an aeration room to facilitate off gassing of the EtO. There are two (2) aeration rooms designated as aeration rooms #3 and #4 at the facility, currently controlled by the catalytic oxidizer (SN-94). Product can be moved to any

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of the two aeration rooms, and may be moved from one aeration room to another. Therefore, EtO emissions from the two aeration rooms are bubbled as though they were a single source.

Aeration rooms 3 and 4 vents (SN-76 and SN-77) are controlled by the catalytic oxidizer and vent as SN-94. During the period of shutdown or malfunction of the catalytic oxidizer, the emissions of ethylene oxide from the aeration room vents (SN-76 and SN-77) may be routed directly to the atmosphere or the exhaust fans to the aeration rooms are shut off and the vents are closed to prevent venting to the atmosphere.

It is anticipated that in case of vacuum pump(s) failure to draw ethylene oxide from sterilization chambers to the absorber tower, the EtO from the chambers will be vented to the atmosphere through steam ejectors SN-11 through SN-15, SN-57. This situation would be considered to be an upset condition. The modeling of short time period (1 hour) gas discharge from equipment opening (PUFF) for 200 lb sterilization chamber has shown that ethylene oxide concentration in the air outside the facility boundary at the ground level may exceed OSHA¹ 15 minute excursion limit. If the sterilizer vacuum pumps fail or malfunction, the vessels can only be evacuated manually. If the manual key switch is activated, the switch will enable the steam ejectors to pull gas from the chamber. This is not normal and would only be done in the case of an emergency, due to unsafe conditions (ex: LEL). The decision to manually evacuate the chambers is made by management only and would be documented on the sterilization record and reported in accordance with General Provision 8 of this permit.

The ethylene oxide is received in sealed drums. The handling of EtO drums is specified by Baxter's Document #14-03-05-002. According to the document, all the pipes must be filled with nitrogen prior to connection/disconnection operations (Section 4.4.A. of the Document). As a result, there are no ETO emissions to the atmosphere associated with drum handling. The handling of ETO drums according to alternative procedure (Section 4.4.B.) is considered an upset condition by the Department and should be reported in accordance with General Provision 8 (Section VIII of the permit).

The facility is subject to the EtO NESHAP, 40 CFR Part 63, Subpart O. The facility uses more than 10 tons of EtO in sterilization.

The NESHAP General Provisions, 40 CFR §63.6(e)(3), requires sources to prepare a startup, shutdown, and malfunction plan (the Plan). The purpose of the Plan is to reduce the reporting burden associated with periods of startup, shutdown, and malfunctions. However, the Subpart O does not contain any operation and maintenance plan requirements. The facility voluntarily has proposed to include the Plan in the permit to reduce the reporting burden associated with periods of startup, shutdown, and malfunction. In particular, the facility experiences power blinks, sometime as often as monthly. A power blink would trigger the catalytic oxidizer safety systems and shut the unit down. The startup cycle can take up to one (1) hour.

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This permit also allows two alternate scenarios, which involve the installation of two EtO sterilization chambers.

Alternative Scenario #1

Installation of an ethylene oxide (EtO) gas sterilization chamber (SN-110) at the facility: 1330 ft³ (200 lb) chamber.

Alternative Scenario #2

Installation of an additional ethylene oxide (EtO) gas sterilization chamber (SN-111) at the facility: 1330 ft³ (200 lb) chamber.

Specific Conditions

- The permittee shall not exceed the emission rates set forth in the following table. The permittee shall demonstrate compliance with this condition by Specific Condition 3. [Regulation 19, §19.501 et seq. and 40 CFR Part 52, Subpart E]

Source No.	Pollutant	Emission Rate (lb/hr)	Emission Rate (tpy)
11-15, 57*	Emergency Evacuation Only		
76-77*	Emissions routed to SN-94		
78-83	Emissions routed to SN-101		
88	VOC	1.0	0.1
94	PM ₁₀	0.1	0.2
	SO ₂	0.1	0.1
	VOC	0.2	0.5
	CO	0.1	0.5
	NO _x	0.5	2
101	VOC	0.7	0.3

* VOC (Ethylene Oxide) may be emitted only as a result of emergency or upset conditions.

- The permittee shall not exceed the emission rates set forth in the following table. The permittee shall demonstrate compliance with this condition by Specific Condition 3. [Regulation 18, §18.801, and A.C.A. §8-4-203 as referenced by §8-4-304 and §8-4-311]

Source No.	Pollutant	Emission Rate (lb/hr)	Emission Rate (tpy)
11-15, 57*	Emergency Evacuation Only		
76-77*	Emissions routed to SN-94		
78-83	Emissions routed to SN-101		

Source No.	Pollutant	Emission Rate (lb/hr)	Emission Rate (tpy)
88	Ethylene Glycol	1.0	0.05
94	PM	0.1	0.2
	Ethylene Oxide	0.05	0.23
101	Ethylene Oxide	0.7	0.30

* Ethylene oxide may be emitted only as a result of emergency or upset conditions.

3. The permittee shall not exceed a usage of 300,000 pounds of ethylene oxide at the sterilization chambers for any consecutive twelve (12) month period. [§19.705, 40 CFR 70.6, and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
4. The permittee shall maintain records that demonstrate compliance with the limit set in Specific Condition 3 and may be used by the Department for enforcement purposes. The records shall be updated on a monthly basis, shall be kept on site, and shall be provided to the Department personnel upon request. An annual total and each individual month's data shall be submitted in accordance with General Provision 7. [§19.705 and 40 CFR, Part 52, Subpart E]
5. The facility is subject to the provisions of 40 CFR, Part 63, Subpart O, Ethylene Oxide Emissions Standards for Sterilization Facilities as a source using more than 10 tons of ethylene oxide (EtO) during any consecutive 12-month period. A copy of Subpart O is provided in Appendix B. Applicable provisions of Subpart O are included, but are not limited to, in specific conditions listed below. [40 CFR 63.360(a) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
6. The permittee shall comply with the requirements of 40 CFR 63, Subpart A, General Provisions according to the applicability of general provisions to the facility in Table 1 (Appendix C). [40 CFR 63.360(a) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
7. The permittee shall comply with the provisions of Subpart O according to the applicability of the emissions standards to the facility in Table 2 (Appendix D). [40 CFR 63.1(c) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
8. The permittee shall operate a catalytic oxidizer to reduce emissions to the atmosphere from each aeration room vent (SN-76 and SN-77) to a maximum concentration of 1 ppmv (Scenario #1). [40 CFR 63.362(a), 40 CFR 63.362(d) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
9. Within 180 days after December 6, 1999, the permittee shall conduct an initial performance test (IPT) of the catalytic oxidizer (SN-94) using the procedures listed in §63.7 of Subpart A of 40 CFR 63 according to the applicability in Table 1 (Appendix C).

This test was conducted on May 22-23, 2000. [40 CFR 63.363(a) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]

10. During the performance test required in Specific Condition 9, the permittee shall determine the concentration of ethylene oxide emitted from the aeration room into the atmosphere after the catalytic oxidizer (SN-94) using the methods in §63.365(c)(1) of 40 CFR 63, Subpart O. [40 CFR 63.363(c)(1)(i) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
11. During the performance test required in Specific Condition 9, the permittee shall also establish as a site-specific operating parameter the baseline temperature using the procedures described in §63.365(f)(2) of 40 CFR 63, Subpart O. [40 CFR 63.363(c)(2) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
12. The permittee shall install, calibrate, operate, and maintain a temperature monitor accurate to within ± 5.6 °C (± 10 °F) to measure the oxidation temperature. [40 CFR 63.364(c)(4) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
13. The permittee shall not operate the facility with the oxidation temperature, averaged over three hours, more than 5.6 °C (10 °F) below the baseline oxidation temperature (effective May 24, 2000). [40 CFR 63.363(c)(3)(ii) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
14. The permittee shall continuously monitor and record the oxidation temperature at the outlet to the catalyst bed or at the exhaust point from the thermal combustion chamber using the temperature monitor described in 40 CFR 63.364(c)(4). A data acquisition system for the temperature monitor shall compute and record an average oxidation temperature each hour and a 3-hour block average every third hour. [40 CFR §63.364(c)(2), 40 CFR §63.364(f) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
15. The facility shall establish the baseline temperature for the aeration room vent as the temperature for the catalytic oxidation unit or the oxidation temperature at the exhaust point from the thermal oxidation unit averaged over three test runs using the procedures in 40 CFR 63.365(d)(1). The permittee determined the baseline temperature to be 325°F. [40 CFR 63.365(f)(2) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
16. An owner or operator seeking to demonstrate compliance with the standards found at §63.362 (d) or (e) with a monitoring device or procedure other than a gas chromatograph shall provide to the Department information describing the operation of the monitoring device or procedure and the parameters that would indicate proper operation and maintenance of the device or procedure. The Department may request further information and will specify appropriate test methods and procedures. [40 CFR 63.365(h) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]

17. The permittee shall operate an acid-water scrubber (SN-101) to reduce emissions to the atmosphere from the vacuum pumps and the sterilization chamber rear exhaust vents (SN-78 through SN-83). [40 CFR 63.362(a), 40 CFR 63.362(c), 40 CFR 63.362(e)(1), and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
18. The permittee shall conduct a performance test of the acid-water scrubber (SN-101) using the procedures listed in §63.7 of Subpart A of 40 CFR 63 according to the applicability in Table 1 (Appendix B), the procedures listed in §63.363(b), and the test methods listed in §63.365(b)(1) of Subpart O. The facility shall also establish the maximum scrubber tank level as an operating parameter using the procedures described in 63.365(e). (performance test conducted May 22-23, 2000) [40 CFR 63.363(a), (b) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
19. Operation of the facility with the liquor tank level in excess of the maximum liquor tank level, 18ft, shall constitute a violation of the sterilization chamber vent standard. [40 CFR 63.363(b)(2)(i) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
20. The permittee shall measure and record once per week the level of the scrubber liquor in the recirculation tank using the test methods and procedures in §63.365(e). The owner or operator shall install, maintain, and use a liquor level indicator to measure the scrubber liquor tank level. [40 CFR 63.364(b) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
21. The permittee shall monitor the control device to which emissions from the rear chamber exhaust are manifolded using requirements in §63.364(b). [40 CFR 63.364(f) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
22. The permittee shall comply with the recordkeeping requirements in §63.10(b) and (c) of Subpart A, according to the applicability in Table 1 (Appendix B). [40 CFR 63.367(a) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
23. The permittee shall develop and implement a written startup, shutdown, and malfunction plan (the Plan) that describes, in detail, procedures for operating and maintaining the catalytic oxidizer (SN-94) and sources controlled by the oxidizer during periods of startup, shutdown, and malfunction and a program of corrective action. [40 CFR 63.6(e)(3)(i) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
24. The written Plan shall be kept at the facility for the life of SN-94 and shall be made available for inspection by Department personnel upon request. If the Plan is revised, the permittee shall keep all previous versions for 5 years after each revision and make them available for inspection. [40 CFR 63.6(e)(3)(v) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]

25. During periods of startup, shutdown, and malfunction, the permittee shall operate the catalytic oxidizer (SN-94) in accordance with the procedures specified in the Plan developed under Specific Condition 23. [40 CFR 63.6(e)(3)(ii) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
26. The permittee shall keep records for all actions taken during a startup, shutdown, or malfunction (including actions taken to correct a malfunction). The permittee shall keep records of these events as specified in 40 CFR 63.10(b). If period of shutdown did not exceed one (1) hour venting directly to the atmosphere, the permittee does not have to report to the Department. [40 CFR 63.6(e)(3)(iii) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
27. If an action taken by the permittee during a startup, shutdown, and malfunction (including an action taken to correct malfunction) is not consistent with the procedures specified in the Plan (Appendix E), particularly, if the aeration room is vented directly to the atmosphere for a period exceeding one (1) hour, the permittee shall report such actions to the Department in accordance with General Provision 8 (Section VII of the permit). [40 CFR 63.6(e)(3)(iv) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
28. The permittee shall submit semiannually startup, shutdown, and malfunction reports to the Department. The report shall be due within 30 days of the end of the reporting period. The report shall consist of a letter, containing the name, title, and signature of the responsible official as defined in §26.2 of Regulation 26 and shall state all actions taken during a startup, shutdown, and malfunction of SN-94 (including actions taken to correct a malfunction). [40 CFR 63.10(b)(5)(i) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]

Approved Changes
Alternative Scenario #1

Upon installation of SN-110: Specific Conditions 29 through 32 will supercede Specific Conditions 1 through 4.

29. The permittee shall not exceed the emission rates set forth in the following table. The permittee shall demonstrate compliance with this condition by Specific Condition 31. [Regulation 19, §19.501 et seq. and 40 CFR Part 52, Subpart E]

Source No.	Pollutant	Emission Rate (lb/hr)	Emission Rate (tpy)
11-15, 57*	Emergency Evacuation Only		
76-77*	Emissions routed to SN-94		
78-83, 110	Emissions routed to SN-101		

Source No.	Pollutant	Emission Rate (lb/hr)	Emission Rate (tpy)
88	VOC	1.0	0.1
94	PM ₁₀	0.1	0.2
	SO ₂	0.1	0.1
	VOC	0.2	0.5
	CO	0.1	0.5
	NO _x	0.5	2
101	VOC	0.8	0.4

* VOC (Ethylene Oxide) may be emitted only as a result of emergency or upset conditions.

30. The permittee shall not exceed the emission rates set forth in the following table. The permittee shall demonstrate compliance with this condition by Specific Condition 31. [Regulation 18, §18.801, and A.C.A. §8-4-203 as referenced by §8-4-304 and §8-4-311]

Source No.	Pollutant	Emission Rate (lb/hr)	Emission Rate (tpy)
11-15, 57*	Emergency Evacuation Only		
76-77*	Emissions routed to SN-94		
78-83, 110	Emissions routed to SN-101		
88	Ethylene Glycol	1.0	0.05
94	PM	0.1	0.2
	Ethylene Oxide	0.06	0.27
101	Ethylene Oxide	0.80	0.34

* Ethylene oxide may be emitted only as a result of emergency or upset conditions.

31. The permittee shall not exceed a usage of 355,000 pounds of ethylene oxide at the sterilization chambers for any consecutive twelve (12) month period. [§19.705, 40 CFR 70.6, and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
32. The permittee shall maintain records that demonstrate compliance with the limit set in Specific Condition 31 and may be used by the Department for enforcement purposes. The records shall be updated on a monthly basis, shall be kept on site, and shall be provided to the Department personnel upon request. An annual total and each individual month's data shall be submitted in accordance with General Provision 7. [§19.705 and 40 CFR, Part 52, Subpart E]

Alternative Scenario #2

Upon installation of SN-111: Specific Conditions 33 through 36 will supercede Specific Conditions 29 through 32 (which previously superceded Specific Conditions 1 through 4).

33. The permittee shall not exceed the emission rates set forth in the following table. The permittee shall demonstrate compliance with this condition by Specific Condition 35. [Regulation 19, §19.501 et seq. and 40 CFR Part 52, Subpart E]

Source No.	Pollutant	Emission Rate (lb/hr)	Emission Rate (tpy)
11-15, 57*	Emergency Evacuation Only		
76-77*	Emissions routed to SN-94		
78-83, 110, 111	Emissions routed to SN-101		
88	VOC	1.0	0.1
94	PM ₁₀	0.1	0.2
	SO ₂	0.1	0.1
	VOC	0.2	0.5
	CO	0.1	0.5
	NO _x	0.5	2
101	VOC	0.8	0.4

* VOC (Ethylene Oxide) may be emitted only as a result of emergency or upset conditions.

34. The permittee shall not exceed the emission rates set forth in the following table. The permittee shall demonstrate compliance with this condition by Specific Condition 35. [Regulation 18, §18.801, and A.C.A. §8-4-203 as referenced by §8-4-304 and §8-4-311]

Source No.	Pollutant	Emission Rate (lb/hr)	Emission Rate (tpy)
11-15, 57*	Emergency Evacuation Only		
76-77*	Emissions routed to SN-94		
78-83, 110, 111	Emissions routed to SN-101		
88	Ethylene Glycol	1.0	0.05
94	PM	0.1	0.2
	Ethylene Oxide	0.07	0.31
101	Ethylene Oxide	0.8	0.4

* Ethylene oxide may be emitted only as a result of emergency or upset conditions.

35. The permittee shall not exceed a usage of 410,000 pounds of ethylene oxide at the sterilization chambers for any consecutive twelve (12) month period. [§19.705, 40 CFR 70.6, and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
36. The permittee shall maintain records that demonstrate compliance with the limit set in Specific Condition 35 and may be used by the Department for enforcement purposes. The records shall be updated on a monthly basis, shall be kept on site, and shall be provided to the Department personnel upon request. An annual total and each individual month's data shall be submitted in accordance with General Provision 7. [§19.705 and 40 CFR, Part 52, Subpart E]

Alternate Scenarios #1 and #2

The following conditions apply after the installation of SN-110 and SN-111.

37. Within 180 days after installation of sterilization chamber SN-110 (Approved Change, Alternative Scenario #1) and after installation of sterilization chamber SN-111 (Approved Change, Alternative Scenario #2), the permittee shall conduct a performance test of the acid-water scrubber (SN-101) using the procedures listed in §63.7 of Subpart A of 40 CFR 63 according to the applicability in Table 1 (Appendix B), the procedures listed in §63.363(b), and the test methods listed in §63.365(b)(1) of Subpart O. The facility shall also establish the maximum scrubber tank level as an operating parameter using the procedures described in 63.365(e). [40 CFR 63.363(a), (b) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
38. Operation of the facility with the liquor tank level in excess of the maximum liquor tank level, shall constitute a violation of the sterilization chamber vent standard. [40 CFR 63.363(b)(2)(i) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
39. The permittee shall measure and record once per week the level of the scrubber liquor in the recirculation tank using the test methods and procedures in §63.365(e). The owner or operator shall install, maintain, and use a liquor level indicator to measure the scrubber liquor tank level. [40 CFR 63.364(b) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
40. The permittee shall monitor the control device to which emissions from the rear chamber exhaust are manifolded using requirements in §63.364(b). [40 CFR 63.364(f) and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]

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SN-16: Lasker Boiler
SN-17: Babcock & Wilcox Boiler
SN-100: Fuel #2 Storage Tank
SN-18: Future Boiler #3

Source Description

Currently, there are two boilers at the facility: Lasker boiler (SN-16) and Babcock & Wilcox boiler (SN-17). The Lasker boiler with the maximum design heat input capacity of 35 million (MM) Btu per hour (Btu/hr) (SN-16) was installed in 1964. The Babcock & Wilcox boiler with the maximum design heat input capacity of 42.8 MM Btu/hr (SN-17) was installed in 1975.

No. 2 fuel oil is used as a back up fuel and is stored in three (3) 15,000 gallon storage tanks (SN-100). The fuel oil throughput at the storage tanks is limited by the limit of the fuel usage in the boilers. Two tanks were installed in 1964 and one tank was installed in 1975. The storage tanks are not subject to the provisions of 40 CFR, Part 60, Subpart K because each individual tank's capacity is less than 40,000 gallons.

This permit also allows two alternate scenarios, which involve the replacement of a boiler and/or the addition of a new boiler with the maximum heat input capacity of 42 MM Btu/hr.

Approved Changes

Alternative Scenario #1

Replace one of the existing boilers (SN-16 or SN-17) with a new boiler with a maximum heat input capacity of 42 MM Btu/hr. The new boiler will be SN-17a.

Alternative Scenario #2

Add one additional boiler (SN-18) with a maximum heat input capacity of 42 MM Btu/hr.

Specific Conditions

41. The permittee shall not exceed the emission rates set forth in the following table. The permittee shall demonstrate compliance with this condition by Specific Conditions 43, 45, and 47. [Regulation 19, §19.501 et seq. and 40 CFR Part 52, Subpart E]

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Source No.	Pollutant	Emission Rate (lb/hr)	Emission Rate (tpy)
16	Natural Gas Combustion		
	PM ₁₀	0.5	1.1
	SO ₂	0.1	0.1
	VOC	0.2	0.5
	CO	1.3	3.0
	NO _x	5.0	11.0
	Fuel #2 Combustion		
	PM ₁₀	0.5	0.4
	SO ₂	18.0	12.7
	VOC	0.1	0.1
	CO	1.3	1.0
	NO _x	5.0	3.6
Total Emission			
PM ₁₀	0.5	1.1	
SO ₂	18.0	12.7	
VOC	0.2	0.5	
CO	1.3	3.0	
NO _x	5.0	11.0	
17 or 17a	Natural Gas Combustion		
	PM ₁₀	0.6	1.1
	SO ₂	0.1	0.1
	VOC	0.3	0.5
	CO	1.5	3.0
	NO _x	6.0	11.0
	Fuel #2 Combustion		
	PM ₁₀	0.6	0.5
	SO ₂	21.1	15.2
	VOC	0.1	0.1
	CO	1.5	1.1
	NO _x	6.0	4.3
Total Emission			
PM ₁₀	0.6	1.1	
SO ₂	21.1	15.2	
VOC	0.3	0.5	
CO	1.5	3.0	
NO _x	6.0	11.0	

Source No.	Pollutant	Emission Rate (lb/hr)	Emission Rate (tpy)
18	Natural Gas Combustion		
	PM ₁₀	0.6	1.1
	SO ₂	0.1	0.1
	VOC	0.3	0.5
	CO	1.5	3.0
	NO _x	6.0	11.0
	Fuel #2 Combustion		
	PM ₁₀	0.6	0.5
	SO ₂	21.1	15.2
	VOC	0.1	0.1
	CO	1.5	1.1
	NO _x	6.0	4.3
	Total Emission		
	PM ₁₀	0.6	1.1
SO ₂	21.1	15.2	
VOC	0.3	0.5	
CO	1.5	3.0	
NO _x	6.0	11.0	
100	VOC	6.0	0.1

42. The permittee shall not exceed the emission rates set forth in the following table. The permittee shall demonstrate compliance with this condition by Specific Conditions 43, 45, and 47. [Regulation 18, §18.801, and A.C.A. §8-4-203 as referenced by §8-4-304 and §8-4-311]

Source No.	Pollutant	Emission Rate (lb/hr)	Emission Rate (tpy)
16	Natural Gas Combustion		
	PM	0.5	1.1
	Fuel #2 Combustion		
	PM	0.5	0.4
	Total Emission		
	PM	0.5	1.1
17 or 17a	Natural Gas Combustion		
	PM	0.6	1.1
	Fuel #2 Combustion		
	PM	0.6	0.5
	Total Emission		
PM	0.6	1.1	

Source No.	Pollutant	Emission Rate (lb/hr)	Emission Rate (tpy)
18	Natural Gas Combustion		
	PM	0.6	1.1
	Fuel #2 Combustion		
	PM	0.6	0.5
	Total Emission		
	PM	0.6	1.6

43. The permittee shall use only No.2 fuel oil that contains 0.5% or less sulfur by weight as a back-up fuel in the boilers (SN-16 and SN-17). [§19.705, 40 CFR 70.6, and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
44. The permittee shall maintain certifications from the fuel supplier that demonstrate compliance with the limits set in Specific Condition 43 and may be used by the Department for enforcement purposes. Fuel supplier certification for No.2 oil fuel shall include the name of the oil supplier and a statement from the oil supplier that the oil complies with the specifications under the definition of distillate oil in §60.41c of 40 CFR 60. The certifications shall be kept on site, and shall be provided to Department personnel upon request. [§19.705 and 40 CFR Part 52, Subpart E]
45. The permittee shall not exceed a natural gas usage throughput of 300,000,000 cubic feet for the two boilers, SN-16 and SN-17, for any consecutive twelve (12) month period. [§19.705, 40 CFR 70.6, and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
46. The permittee shall not exceed a natural gas usage throughput of 450,000,000 cubic feet for any consecutive twelve (12) month period once installation of SN-18 is complete (Alternative Scenario #2). [§19.705, 40 CFR 70.6, and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
47. The permittee shall not exceed a No.2 fuel oil throughput of 1,211,000 gallons for any consecutive twelve (12) month period. [§19.705, 40 CFR 70.6, and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
48. The permittee shall maintain records that demonstrate compliance with the limits set in Specific Conditions 45 and 47. The records may be used by the Department for enforcement purposes. The records shall be updated on a monthly basis, shall be kept on site, and shall be provided to Department personnel upon request. An annual total and each individual month's data shall be submitted in accordance with General Provision 7. [§19.705 and 40 CFR Part 52, Subpart E]
49. The permittee shall not exceed 5% opacity from SN-16 and SN-17 while burning natural gas as measured by EPA Reference Method 9. Compliance shall be demonstrated by

only burning natural gas. [Regulation 18, §18.501 and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]

50. The permittee shall not exceed 20% opacity from SN-16 and SN-17 while burning No.2 fuel oil. Compliance with this Specific Condition shall be demonstrated through compliance with Specific Condition 51. [Regulation 18, §18.501 and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
51. In the event the permittee burns fuel oil for three (3) hours or more in any consecutive 24 hour period or a total of 14 hours² or more in any consecutive 12 month period in SN-16 or SN-17, the permittee shall conduct an EPA Reference Method 9, 6-minute opacity reading from each boiler while burning No. 2 fuel oil. Should the burning of fuel oil continue for seven (7) or more consecutive days, the permittee shall conduct a 6-minute opacity reading from each boiler again on the seventh day and every seven (7) days thereafter as long as fuel oil is being burned. [Regulation 19, §19.703, 40 CFR Part 52, Subpart E, and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
52. The permittee shall maintain records of the type of fuel burned in the boilers and opacity readings or observations (if required) that demonstrate compliance with the limits set in Specific Conditions 49 through 51. These records may be used by the Department for enforcement purposes. The records shall be updated on a weekly basis, shall be kept on site, and shall be provided to Department personnel upon request. An annual total and each individual month's data shall be submitted in accordance with General Provision 7. [Regulation 19, §19.705 and 40 CFR Part 52, Subpart E]
53. The permittee shall perform stack testing of SN-16 and SN-17 for carbon monoxide (CO) and nitrogen oxides (NO_x) emissions while burning No. 2 fuel oil. Testing shall be performed no later than sixty (60) days after the permittee burns 121,100 gallons (10 percent of the permitted annual throughput) or more of No. 2 fuel oil for any consecutive 12 month period. Testing shall be performed in accordance with Plantwide Condition 5 and EPA Reference Methods 10 and 7E, respectively, as found in 40 CFR, Part 60, Appendix A. [Regulation 19, §19.702 and 40 CFR Part 52, Subpart E]

² Burning fuel oil in all boilers for 14 hours represents less than one (1) percent of the total annual permitted fuel oil consumption.

SN-41: Plastics Grinding Operations
 SN-73: Plastics Grinder #2

Source Description

The waste plastic from the facility is ground into granular material suitable for recycling. Waste plastic is fed to a mechanical grinder. It is assumed that 98% of the plastic fed to the grinder is routed directly to silos. The remaining 2% is captured as particulate matter and routed through a cyclone to a baghouse (SN-41). The plastic captured by the cyclone is fed to the silos. The silos are controlled by the same baghouse. The equipment was installed in 1978. SN-41 was permitted for the first time in 1986 in permit No. 544-AR-3.

Specific Conditions

54. The permittee shall not exceed the emission rates set forth in the following table. The permittee shall demonstrate compliance with this condition by Specific Condition 60. [Regulation 19, §19.501 et seq. and 40 CFR Part 52, Subpart E]

Source No.	Pollutant	Emission Rate (lb/hr)	Emission Rate (tpy)
41	PM ₁₀	1.0	2.3
73	PM ₁₀	0.4	1.7

55. The permittee shall not exceed the emission rates set forth in the following table. The permittee shall demonstrate compliance with this condition by Specific Condition 60. [Regulation 18, §18.801, and A.C.A. §8-4-203 as referenced by §8-4-304 and §8-4-311]

Source No.	Pollutant	Emission Rate (lb/hr)	Emission Rate (tpy)
41	PM	1.0	2.3
73	PM	0.4	1.7

56. The permittee shall perform initial stack testing of SN-41 for PM emissions. Testing shall be performed in accordance with Plantwide Conditions 4 & 5 and EPA Reference Methods 1 through 5 as found in 40 CFR, Part 60, Appendix A. Testing was performed on December 8-9, 1999. [Regulation 19, §19.705 and 40 CFR, Part 52, Subpart E]
57. The permittee shall not exceed 5% opacity from SN-41 as measured by EPA Reference Method 9. Compliance with this Specific Condition shall be demonstrated through compliance with Specific Condition 58. [Regulation 18, §18.501 and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]

58. The permittee shall conduct preventive maintenance of the baghouse (SN-41) every 3 months. The preventive maintenance shall include the following: check filter bank for loose filter clamps; check filters for holes; check shaker system and linkage. Filters shall be changed as needed when indicative of preventive maintenance. [Regulation 18, §18.1003 and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
59. The permittee shall maintain records that demonstrate compliance with Specific Condition 58 and may be used by the Department for enforcement purposes. The records shall be updated every three months, shall be kept on site, and shall be provided to Department personnel upon request. [Regulation 18, §18.1004 and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
60. The permittee shall not grind more than 8,000 tons of waste plastic for any consecutive twelve month period. [Regulation 19, §19.705, 40 CFR 70.6, and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
61. The permittee shall not grind more than 16,000 tons of waste plastic for any consecutive twelve month period commencing upon installation of SN-73. [Regulation 19, §19.705, 40 CFR 70.6, and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
62. The permittee shall maintain records that demonstrate compliance with Specific Condition 60 and may be used by the Department for enforcement purposes. The records shall be updated on a monthly basis, shall be kept on site, and shall be provided to Department personnel upon request. An annual total and each individual month's data shall be submitted in accordance with General Provision 7. [Regulation 19, §19.705 and 40 CFR Part 52, Subpart E]

SN-97: Plantwide VOC Emissions Cap
(formerly permitted separately as SNs-09, 85, and 95)

Source Description

Manual and Automated Assembly - In manual and automated assembly, plastic parts are assembled to one another to produce sets, cassettes and many other products. Plastic parts that are assembled to produce medical devices include tubing, valves, housings, roller clamps, slide clamps, membranes, luer connectors, luer locks, spikes, needle adapters, filters, couplers, Y-connectors and others. Assembly for non-medical device products may involve a wide variety of plastic parts. Plastic parts are affixed or bonded to another using one of several techniques, including solvent bonding, ultrasonic bonding, ultraviolet (UV) energy, radio frequency (RF) energy, thermal energy, friction or others. In the case of solvent bonding, a variety of solvents can be used including both HAPs and non-HAPs.

Compounding/Pelletizing and Film/Tubing Extrusion – Raw materials are received in bulk and packaged for manufacturing of plastic film and tubing. The first step is blending. After blending, the blend is sent to the film extrusion area, tubing extrusion area, palletizing area, or exported to other locations for processing. VOCs are generated from miscellaneous cleaning and lubricate for cutting process.

Filter Integrity Test Station Exhaust

Filters are filled with or submerged into 60% or 100% isopropyl alcohol (IPA). After the alcohol is drained off, air is introduced to the filter to determine the bubble point. The filters are then dried by continuous air flow until all IPA is dispersed. The used IPA is collected and recycled. The testing is conducted several times per year, as necessary.

Miscellaneous Cleaning – VOCs are generated from miscellaneous cleaning using isopropyl alcohol and water through the facility.

Print Shop

The print shop prints miscellaneous forms and labels. The soybean based ink is used for printing. There is no VOC emitted from the ink. Varn is the chemical used as a cleaning agent for equipment and associated parts. Solex 121 is used as a cleaning agent for equipment and associated parts containing: 3% xylene and 1% cumene. The print shop also makes lead slugs for stamps and labels.

The facility estimates maximum consumption of VOCs is 190,000 pounds per year (excluding EtO and DEHP, which are HAPs and tracked separately).

Specific Conditions

63. The permittee shall not exceed the emission rates set forth in the following table. The permittee shall demonstrate compliance with this condition by Specific Condition 64. [Regulation 19, §19.501 and 40 CFR Part 52, Subpart E]

Source No.	Pollutant	Emission Rate (lb/hr)	Emission Rate (tpy)
97	VOC	100	95.0

64. The permittee shall maintain records of VOC emissions that demonstrate compliance with the limits set in Specific Condition 63 and may be used by the Department for enforcement purposes. The emissions shall be calculated according to the following formula: [Regulation 19, §19.705 and 40 CFR 70.6]

$$\text{VOC emissions} = \text{VOC usage} - \text{VOC waste collected}$$

The records shall be updated on a monthly basis, shall be kept on site, and shall be provided to Department personnel upon request. An annual total and each individual month's data shall be submitted in accordance with General Provision 7.

65. The permittee shall maintain material safety data sheets (MSDS) of all volatile organic compounds (VOC) used at the facility. The records shall be kept on site and shall be provided to Department personnel upon request. [Regulation 18, §18.1004 and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
66. The permittee is authorized to add new equipment, modify existing and new equipment, move existing and new equipment to different locations within the facility, and change raw materials (including solvents) without further approval provided the following conditions are met [A.C.A. §8-4-203 as referenced by §8-4-304 and §8-4-311]:
- a. Equipment must be within the categories listed in Appendix A or, for equipment not listed in Appendix A, the installation and use of such equipment must not change the fundamental nature of the business. This condition does not authorize the addition of new boilers, ethylene oxide sterilization chambers, or plastics grinders which are addressed elsewhere.
 - b. Total facility-wide VOC and HAP emissions from existing, new, and modified equipment must continue to comply with the Plant-wide VOC Caps in Specific 63 and Specific Condition 64.
 - c. Total facility-wide emissions of any HAP from existing, new and modified equipment must continue to comply with the Facility-wide HAPs limits in Specific Condition 69.
 - d. The addition, modification, or relocation of equipment shall not cause any new requirement, not already included in this permit, to become applicable to any emission unit at the facility.
 - e. The addition, modification, or relocation of equipment shall not impact the ability to demonstrate compliance with the Plant-wide VOC and HAP Caps and Facility-wide HAP limits using a mass balance approach. Mass balance calculations shall

be adjusted to reflect all new raw materials and changes to raw materials associated with any existing, new, modified, or relocated equipment.

67. The permittee shall maintain on-site records of all changes made pursuant to Specific Condition 66, including but not limited to, the date on which construction and/or modification of any equipment began, the date that operation of any new and/or modified equipment began and the date that any new raw materials were introduced or change in raw materials was made. The permittee shall include a source description for any new or modified source, the updated location of the source (including an updated plot plan), and the type of emissions resulting from the new/modified source. The permittee shall maintain on-site records of equipment removed from installation and the date on which it was removed. The on-site records shall be available for review by the permitting authority at any time. [Regulation No. 19 §19.705 and 40 CFR Part 52, Subpart E]
68. The permittee shall notify the permitting authority of all changes made pursuant to Specific Condition 66 through the semi-annual reports submitted in accordance with General Provision 7. [Regulation No. 19 §19.705 and 40 CFR Part 52, Subpart E]

SN-109: Plantwide HAP Emissions

Source Description

Manual and Automated Assembly - In manual and automated assembly, plastic parts are assembled to one another to produce sets, cassettes and many other products. Plastic parts that are assembled to produce medical devices include tubing, valves, housings, roller clamps, slide clamps, membranes, luer connectors, luer locks, spikes, needle adapters, filters, couplers, Y-connectors and others. Assembly for non-medical device products may involve a wide variety of plastic parts. Plastic parts are affixed or bonded to another using one of several techniques, including solvent bonding, ultrasonic bonding, ultraviolet (UV) energy, radio frequency (RF) energy, thermal energy, friction or others. In the case of solvent bonding, a variety of solvents can be used including both HAPs and non-HAPs.

Compounding/Pelletizing and Film/Tubing Extrusion (SN-95) - Raw materials are received in both bulk and packaged for manufacturing of plastic film and tubing. The first step is blending. After blending, the blend is then sent to the film extrusion area, tubing extrusion area, pelletizing area, or exported to other locations for processing. Small amounts of miscellaneous fugitive VOCs may result from the above described operations. The pollutant of concern is bis(2-ethylhexyl)phthalate (DEHP), a listed HAP. Fugitive DEHP emissions are captured with ventilation equipment from pelletizing, tubing extrusion, and film extrusion processes and routed to filters. Filters used in the plastics manufacturing are either roof mounted or located within the building. In either case, effluent from the filters is routed back into the warehouse. As such, no emissions are directly discharged to the atmosphere, but rather are all fugitive. Also included in SN-95 are emissions from inside DEHP storage tanks.

Jet Cleaner (SN-72) consists of a closed insulated chamber with internal heaters, into which parts are placed for cleaning. The Jet Cleaner cleans PVC and other residue polymers off of steel plates used in extrusion of plastic tubing/film. It cleans using a pyrolysis cleaning cycle at full vacuum followed by an oxidation cycle at reduced vacuum. All heat is provided by electric heating elements. A primary trap beneath the chamber collects the polymer that drains from the parts. A secondary trap, fitted with water spray nozzles, condenses and collects vapors before they can enter the vacuum pump. There are two Jet Cleaners in the room. After the steel plates are removed from the cleaner, they are cooled and blasted using a totally enclosed glass-bead blaster. The unit vents inside the room. There are two hoods located over each Jet Cleaner. Both hoods vent to the atmosphere through the same roof vent (SN-72). SN-89, SN-90 DEHP Storage Tanks are located outside in the plastics tank farm.

Injection/Blow Molding - Process by which plastic formulations are heated and mechanically processed. It is then injected into a mold and held under pressure until the part has solidified.

Ovens for Needle Covers (SN-21 through SN-28) - PVC needle covers are sent to electric ovens for curing. The needle covers are heated in the ovens for about 45 minutes at 250°F. The following hazardous air pollutant (HAP) is emitted during the process: bis(2-ethylhexyl)phthalate (DEHP). There are nine (9) ovens. All ovens exhaust to the atmosphere

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through one stack (SN-21). Ovens, SN-21 through SN-27 were installed in 1986 and permitted in Air Permit #544-AR-3. SN-28 is a proposed oven that will be installed after issuance of Air Permit #544-AOP-R5.

Print Shop (SN-85) - The print shop prints miscellaneous forms and labels. The soybean based ink is used for printing. There is no VOC emitted from the ink. Solex 121 is used as a cleaning agent for equipment and associated parts containing: 3% xylene and 1% cumene. The print shop also makes lead slugs for stamps and labels.

Specific Conditions

69. The permittee shall not exceed the emission rates set forth in the following table. The permittee shall demonstrate compliance with this condition by Specific Condition 70. [Regulation 18, §18.801, and A.C.A. §8-4-203 as referenced by §8-4-304 and §8-4-311]

Pollutant	lb/hr	tpy
Individual HAP	*	9.5
Total Combined HAPs	*	23.75

* The hourly emissions must comply with Specific Condition 71.

70. The permittee shall maintain records that demonstrate compliance with the limits set in Specific Condition 69 and may be used by the Department for enforcement purposes. The records shall be updated on a monthly basis, kept on site, and shall be provided to Department personnel upon request. An annual total and each individual month's data shall be submitted in accordance with General Provision 7. [Regulation No. 18 §18.1004 and A.C.A. §8-4-203 as referenced by §8-4-304 and §8-4-311]
71. The permittee may substitute or introduce new HAP containing materials to the facility provided that the materials are compliant with the facility-wide HAP content limits set forth in the following table and the annual HAP emissions do not exceed 23.75 tpy for combined HAPs and 9.5 tpy for an individual HAP. [Regulation No. 18 §18.801 and A.C.A. §8-4-203 as referenced by §8-4-304 and §8-4-311]:

Table 3: Facility-wide Hazardous Air Pollution Limits		
Minimum TLV (mg/m³)	PAIL** (µg/m³)	Maximum Rate (lb/hr)
0.1	1	0.02
0.5	5	0.08
1	10	0.17
10	100	1.67
20	200	3.34
30	300	5.01
40	400	6.68
50	500	8.35
75	750	12.52
100	1000	16.69
150	1500	25.04
200	2000	33.39
250	2500	41.74
300	3000	50.08
350	3500	58.43
400	4000	66.78
450	4500	75.13
500	5000	83.47

* Some HAPs with low TLVs such as EtO and HMDI are not covered under the limits of this table. Those HAPs are covered by other specific conditions.

** PAIL is equal to 1/100th of the TLV.

72. The permittee shall maintain records that demonstrate compliance with the limits set in Specific Condition 71 [i.e., the HAP matrix], and that may be used by the Department for enforcement purposes. Compliance shall be determined by inspecting the ACGIH Threshold Limit Values (TLVs) as listed on current MSDS, or in the most recently published ACGIH handbook of TLVs and Biological Exposure Indices (BEIs) and properly noting on the monthly HAP records whether the material in question is compliant with the table contained in Specific Condition 71. The hourly maximum usage rate shall be demonstrated by keeping mass balances on record on a monthly basis of all HAP containing materials in use that qualify under Specific Condition 71. All records shall be maintained on site and shall be provided to the Department upon request.

In the case where keeping a new mass balance is not feasible or relevant, the permittee shall propose a recordkeeping scheme to the Department for review and approval in writing from the Department. The permittee shall secure the approval for the new recordkeeping scheme prior to utilizing the proposed scheme. [§18.1004 and A.C.A. §8-4-203 as referenced by §8-4-304 and §8-4-311]

73. The permittee is authorized to add new equipment, modify existing and new equipment, move existing and new equipment to different locations within the facility, and change raw materials (including solvents) without further approval provided the following conditions are met [A.C.A. §8-4-203 as referenced by §8-4-304 and §8-4-311]:
- a. Equipment must be within the categories listed in Appendix A or, for equipment not listed in Appendix A, the installation and use of such equipment must not change the fundamental nature of the business. This condition does not authorize the addition of new boilers, ethylene oxide sterilization chambers, or plastics grinders which are addressed elsewhere.
 - b. Total facility-wide VOC and HAP emissions from existing, new, and modified equipment must continue to comply with the Plant-wide VOC Caps in Specific Condition 63 and Specific Condition 69.
 - c. Total facility-wide emissions of any HAP from existing, new and modified equipment must continue to comply with the Facility-wide HAP limits in Specific Condition 69.
 - d. The addition, modification, or relocation of equipment shall not cause any new requirement, not already included in this permit, to become applicable to any emission unit at the facility.
 - e. The addition, modification, or relocation of equipment shall not impact the ability to demonstrate compliance with the Plant-wide VOC and HAP Caps and Facility-wide HAP limits using a mass balance approach. Mass balance calculations shall be adjusted to reflect all new raw materials and changes to raw materials associated with any existing, new, modified, or relocated equipment.
74. The permittee shall maintain on-site records of all changes made pursuant to Specific Condition 73, including but not limited to, the date on which construction and/or modification of any equipment began, the date that operation of any new and/or modified equipment began and the date that any new raw materials were introduced or change in raw materials was made. The permittee shall include a source description for any new or modified source, the updated location of the source (including an updated plot plan), and the type of emissions resulting from the new/modified source. The permittee shall maintain on-site records of equipment removed from installation and the date on which it was removed. The on-site records shall be available for review by the permitting authority at any time. [Regulation No. 18 §18.1004 and A.C.A. §8-4-203 as referenced by §8-4-304 and §8-4-311]
75. The permittee shall notify the permitting authority of all changes made pursuant to Specific Condition 73 through the semi-annual reports submitted in accordance with General Provision 7. [Regulation No. 18 §18.1004 and A.C.A. §8-4-203 as referenced by §8-4-304 and §8-4-311]

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SECTION V: COMPLIANCE PLAN AND SCHEDULE

Baxter Healthcare Corporation will continue to operate in compliance with those identified regulatory provisions. The facility will examine and analyze future regulations that may apply and determine their applicability with any necessary action taken on a timely basis.

SECTION VI: PLANTWIDE CONDITIONS

1. The permittee shall notify the Director in writing within thirty (30) days after commencing construction, completing construction, first placing the equipment and/or facility in operation, and reaching the equipment and/or facility target production rate. [Regulation 19, §19.704, 40 CFR Part 52, Subpart E, and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
2. If the permittee fails to start construction within eighteen months or suspends construction for eighteen months or more, the Director may cancel all or part of this permit. [Regulation 19, §19.410(B) and 40 CFR Part 52, Subpart E]
3. The permittee must test any equipment scheduled for testing, unless stated in the Specific Conditions of this permit or by any federally regulated requirements, within the following time frames: (1) new equipment or newly modified equipment within sixty (60) days of achieving the maximum production rate, but no later than 180 days after initial start up of the permitted source or (2) operating equipment according to the time frames set forth by the Department or within 180 days of permit issuance if no date is specified. The permittee must notify the Department of the scheduled date of compliance testing at least fifteen (15) days in advance of such test. The permittee shall submit the compliance test results to the Department within thirty (30) days after completing the testing. [Regulation 19, §19.702 and/or Regulation 18 §18.1002 and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
4. The permittee must provide: [Regulation 19, §19.702 and/or Regulation 18, §18.1002 and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
 - a. Sampling ports adequate for applicable test methods;
 - b. Safe sampling platforms;
 - c. Safe access to sampling platforms; and
 - d. Utilities for sampling and testing equipment.
5. Unless otherwise approved by the Department, all air contaminant emissions sampling shall be performed with the equipment being tested operating at least at 90% of its permitted capacity. Emissions results shall be extrapolated to correlate with 100% of permitted capacity to determine compliance. Failure to test at the permitted capacity shall limit the facility to 10 percent above the tested capacity. [Regulation 19, §19.702(D)]
6. The permittee must operate the equipment, control apparatus and emission monitoring equipment within the design limitations. The permittee shall maintain the equipment in good condition at all times. [Regulation 19, §19.303 and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
7. This permit subsumes and incorporates all previously issued air permits for this facility. [Regulation 26 and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]

8. The permittee must prepare and implement a Startup, Shutdown, and Malfunction Plan (SSM) for SN-94. If the Department requests a review of the SSM, the permittee will make the SSM available for review. The permittee must keep a copy of the SSM at the source's location and retain all previous versions of the SSM plan for five years. [Regulation 19, §19.304 and 40 CFR 63.6(e)(3)]

Title VI Provisions

9. The permittee must comply with the standards for labeling of products using ozone-depleting substances. [40 CFR Part 82, Subpart E]
 - a. All containers containing a class I or class II substance stored or transported, all products containing a class I substance, and all products directly manufactured with a class I substance must bear the required warning statement if it is being introduced to interstate commerce pursuant to §82.106.
 - b. The placement of the required warning statement must comply with the requirements pursuant to §82.108.
 - c. The form of the label bearing the required warning must comply with the requirements pursuant to §82.110.
 - d. No person may modify, remove, or interfere with the required warning statement except as described in §82.112.
10. The permittee must comply with the standards for recycling and emissions reduction, except as provided for MVACs in Subpart B. [40 CFR Part 82, Subpart F]
 - a. Persons opening appliances for maintenance, service, repair, or disposal must comply with the required practices pursuant to §82.156.
 - b. Equipment used during the maintenance, service, repair, or disposal of appliances must comply with the standards for recycling and recovery equipment pursuant to §82.158.
 - c. Persons performing maintenance, service repair, or disposal of appliances must be certified by an approved technician certification program pursuant to §82.161.
 - d. Persons disposing of small appliances, MVACs, and MVAC like appliances must comply with record keeping requirements pursuant to §82.166. ("MVAC like appliance" as defined at §82.152)
 - e. Persons owning commercial or industrial process refrigeration equipment must comply with leak repair requirements pursuant to §82.156.
 - f. Owners/operators of appliances normally containing 50 or more pounds of refrigerant must keep records of refrigerant purchased and added to such appliances pursuant to §82.166.
11. If the permittee manufactures, transforms, destroys, imports, or exports a class I or class II substance, the permittee is subject to all requirements as specified in 40 CFR Part 82, Subpart A, Production and Consumption Controls.

12. If the permittee performs a service on motor (fleet) vehicles when this service involves ozone depleting substance refrigerant (or regulated substitute substance) in the motor vehicle air conditioner (MVAC), the permittee is subject to all the applicable requirements as specified in 40 CFR part 82, Subpart B, Servicing of Motor Vehicle Air Conditioners.

The term “motor vehicle” as used in Subpart B does not include a vehicle in which final assembly of the vehicle has not been completed. The term “MVAC” as used in Subpart B does not include the air tight sealed refrigeration system used as refrigerated cargo, or the system used on passenger buses using HCFC 22 refrigerant.

13. The permittee can switch from any ozone depleting substance to any alternative listed in the Significant New Alternatives Program (SNAP) promulgated pursuant to 40 CFR Part 82, Subpart G.

Permit Shield:

14. Compliance with the conditions of this permit shall be deemed compliance with all applicable requirements, as of the date of permit issuance, included in and specifically identified in item A of this condition:
- a. The following have been specifically identified as applicable requirements based upon information submitted by the permittee in an application dated June 25, 1996.

Source	Regulation	Description
Facility	Arkansas Regulation 19	Compilation of Regulations of the Arkansas State Implementation Plan for Air Pollution Control
Facility	Arkansas Regulation 26	Regulations of the Arkansas Operating Air Permit Program
SN-101	40 CFR, Part 63, Subpart A	National Emission Standards for Hazardous Air Pollutants for Source Categories. General Provisions.
SN-101	40 CFR, Part 63, Subpart O	Ethylene Oxide Emissions Standards for Sterilization Facilities
SN-74 through SN-83	40 CFR, Part 63, Subpart A	National Emission Standards for Hazardous Air Pollutants for Source Categories. General Provisions.
SN-74 thru SN-83	40 CFR, Part 63, Subpart O	Ethylene Oxide Emissions Standards for Sterilization Facilities
SN-94	40 CFR, Part 63, Subpart A	National Emission Standards for Hazardous Air Pollutants for Source Categories. General Provisions.
SN-94	40 CFR, Part 63, Subpart O	Ethylene Oxide Emissions Standards for Sterilization Facilities

- b. The following requirements have been specifically identified as not applicable, based upon information submitted by the permittee in an application dated June 25, 1996.

Source	Regulation	Description	Basis for Determination
SN-16, SN-17	40 CFR, Part 60, Subpart Dc	Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units	Boilers were constructed in 1964 and 1975 respectfully.
SN-89 and SN-90	40 CFR, Part 60, Subpart K	Standards of Performance for Storage Vessels for Petroleum Liquids for which Construction, Reconstruction, or Modification Commenced after June 1, 1973, and Prior to May 19, 1978.	Both tanks were constructed in 1971.
SN-100	40 CFR, Part 60, Subpart K	Standards of Performance for Storage Vessels for Petroleum Liquids for which Construction, Reconstruction, or Modification Commenced after June 1, 1973, and Prior to May 19, 1978.	The storage tank's capacity is less than 40,000 gal.

- c. Nothing shall alter or affect the following:
 - i. Provisions of Section 303 of the Clean Air Act;
 - ii. The liability of an owner or operator for any violation of applicable requirements prior to or at the time of permit issuance;
 - iii. The applicable requirements of the acid rain program, consistent with section 408(a) of the Clean Air Act; or
 - iv. The ability of the EPA to obtain information under Section 114 of the Clean Air Act.

SECTION VII: INSIGNIFICANT ACTIVITIES

The following sources are insignificant activities. Any activity that has a state or federal applicable requirement shall be considered a significant activity even if this activity meets the criteria of §304 of Regulation 26 or listed in the table below. Insignificant activity determinations rely upon the information submitted by the permittee in an application dated June 25, 1996, May 15, 2001, and December 17, 2003.

Description	Category
Chillers #1-3 (former SN-67)	Group A. 1
Chiller #5 (former SN-68)	Group A. 1
Chiller #4 (former SN-69)	Group A. 1
570 gal Diesel Fuel Tank	Group A. 3
300 gal Diesel Fuel Tank	Group A. 3
Nitric Acid Tanks	Group A. 3
Citric Acid Tank	Group A. 3
Sodium Hydroxide Tanks	Group A. 3
500 and 300 gal Propane Tanks	Group A. 3
Maintenance Passivation Tank	Group A. 3
Needles Passivation Tank	Group A. 3
Salt Brine Tank	Group A. 3
Distilled Water Tank	Group A. 3
De-aeration Tank	Group A.3
R O Water Tank	Group A. 3
Isolex 300 Process	Group A. 3
Linseed Oil, Epoxidized (LOE) Storage Tank	Group A. 4
Linseed Oil, Epoxidized (LOE) Storage Tank	Group A. 4
Linseed Oil, Epoxidized (LOE) Storage Tank	Group A. 4
Linseed Oil, Epoxidized (LOE) Storage Tank	Group A. 4
Epoxol Storage Tank	Group A. 4
Epoxol Storage Tank	Group A. 4
Epoxol Storage Tank	Group A. 4
Vikoflex Storage Tank	Group A. 4
Vikoflex Storage Tank	Group A. 4
Citroflex Storage Tank	Group A. 4
Citroflex Storage Tank	Group A. 4
Vikoflex Storage Tank	Group A. 4

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Description	Category
Vikoflex Storage Tank	Group A. 4
Laboratories	Group A. 5
30,000 gal Emergency Fuel Oil #2 Storage Tank (empty under normal conditions)	Group A. 12
Resin Storage Silo 3A (former SN-59)	Group A. 13
Resin Storage Silo 4A (former SN-60)	Group A. 13
Resin Storage Silo 4B (former SN-61)	Group A. 13
Resin Storage Silo 5 (former SN-62)	Group A. 13
Resin Storage Silo 3B (former SN-63)	Group A. 13
Resin Storage Silo 3C (former SN-64)	Group A. 13
Resin Storage Silo (former SN-65)	Group A. 13
Resin Storage Silo (former SN-66)	Group A. 13
Needles Silicone	Group A. 13
Needles Cleaning/Electropolishing	Group A. 13
E-beam Ionizing Radiation	Group A. 13
Vacuum Pumps – Plastics	Group A. 13
Dust Collector (PE172) Home Choice	Group A. 13
Molding Process (SN-96)	Group A. 13
Needles Blasting	Group A. 13
E-Beam Ionizing Radiation (SN-103)	Group A. 13
Coextruded Non-PVC Plastics (SN-107)	Group A. 13
Particulate Matter (PM) Removal Vacuum Systems	Group A. 13
Needles Grinder #1 (SN-45)	Group A. 13
Needles Grinder #2	Group A. 13
Grounds Maintenance	Group B. 13
Air Compressors – Air Cooled	Group B. 14
Building Maintenance & Equipment (includes containment/floor covering)	Group B.14
Misc. maintenance, upkeep painting activity	Group B. 14, 15
Compressed Air Receiving Tank	Group B. 21
Hot Air Vents	Group B. 36

SECTION VIII: GENERAL PROVISIONS

1. Any terms or conditions included in this permit which specify and reference Arkansas Pollution Control & Ecology Commission Regulation 18 or the Arkansas Water and Air Pollution Control Act (A.C.A. §8-4-101 et seq.) as the sole origin of and authority for the terms or conditions are not required under the Clean Air Act or any of its applicable requirements, and are not federally enforceable under the Clean Air Act. Arkansas Pollution Control & Ecology Commission Regulation 18 was adopted pursuant to the Arkansas Water and Air Pollution Control Act (A.C.A. §8-4-101 et seq.). Any terms or conditions included in this permit which specify and reference Arkansas Pollution Control & Ecology Commission Regulation 18 or the Arkansas Water and Air Pollution Control Act (A.C.A. §8-4-101 et seq.) as the origin of and authority for the terms or conditions are enforceable under this Arkansas statute. [40 CFR 70.6(b)(2)]
2. This permit shall be valid for a period of five (5) years beginning on the date this permit becomes effective and ending five (5) years later. [40 CFR 70.6(a)(2) and §26.701(B) of the Regulations of the Arkansas Operating Air Permit Program (Regulation 26), effective August 10, 2000]
3. The permittee must submit a complete application for permit renewal at least six (6) months before permit expiration. Permit expiration terminates the permittee's right to operate unless the permittee submitted a complete renewal application at least six (6) months before permit expiration. If the permittee submits a complete application, the existing permit will remain in effect until the Department takes final action on the renewal application. The Department will not necessarily notify the permittee when the permit renewal application is due. [Regulation 26, §26.406]
4. Where an applicable requirement of the Clean Air Act, as amended, 42 U.S.C. 7401, et seq. (Act) is more stringent than an applicable requirement of regulations promulgated under Title IV of the Act, the permit incorporates both provisions into the permit, and the Director or the Administrator can enforce both provisions. [40 CFR 70.6(a)(1)(ii) and Regulation 26, §26.701(A)(2)]
5. The permittee must maintain the following records of monitoring information as required by this permit. [40 CFR 70.6(a)(3)(ii)(A) and Regulation 26, §26.701(C)(2)]
 - a. The date, place as defined in this permit, and time of sampling or measurements;
 - b. The date(s) analyses performed;
 - c. The company or entity performing the analyses;
 - d. The analytical techniques or methods used;
 - e. The results of such analyses; and
 - f. The operating conditions existing at the time of sampling or measurement.
6. The permittee must retain the records of all required monitoring data and support information for at least five (5) years from the date of the monitoring sample, measurement, report, or application. Support information includes all calibration and

maintenance records and all original strip chart recordings for continuous monitoring instrumentation, and copies of all reports required by this permit. [40 CFR 70.6(a)(3)(ii)(B) and Regulation 26, §26.701(C)(2)(b)]

7. The permittee must submit reports of all required monitoring every six (6) months. If permit establishes no other reporting period, the reporting period shall end on the last day of the anniversary month of the initial Title V permit. The report is due within thirty (30) days of the end of the reporting period. Although the reports are due every six months, each report shall contain a full year of data. The report must clearly identify all instances of deviations from permit requirements. A responsible official as defined in Regulation No. 26, §26.2 must certify all required reports. The permittee will send the reports to the address below: [40 C.F.R. 70.6(a)(3)(iii)(A) and Regulation 26, §26.701(C)(3)(a)]

Arkansas Department of Environmental Quality
Air Division
ATTN: Compliance Inspector Supervisor
Post Office Box 8913
Little Rock, AR 72219

8. The permittee shall report to the Department all deviations from permit requirements, including those attributable to upset conditions as defined in the permit.
 - a. For all upset conditions (as defined in Regulation 19, § 19.601), the permittee will make an initial report to the Department by the next business day after the discovery of the occurrence. The initial report may be made by telephone and shall include:
 - i. The facility name and location
 - ii. The process unit or emission source deviating from the permit limit,
 - iii. The permit limit, including the identification of pollutants, from which deviation occurs,
 - iv. The date and time the deviation started,
 - v. The duration of the deviation,
 - vi. The average emissions during the deviation,
 - vii. The probable cause of such deviations,
 - viii. Any corrective actions or preventive measures taken or being taken to prevent such deviations in the future, and
 - ix. The name of the person submitting the report.

The permittee shall make a full report in writing to the Department within five (5) business days of discovery of the occurrence. The report must include, in addition to the information required by the initial report, a schedule of actions taken or planned to eliminate future occurrences and/or to minimize the amount the permit's limits were exceeded and to reduce the length of time the limits were exceeded. The permittee may submit a full report in writing (by facsimile, overnight courier, or other

means) by the next business day after discovery of the occurrence, and the report will serve as both the initial report and full report.

- b. For all deviations, the permittee shall report such events in semi-annual reporting and annual certifications required in this permit. This includes all upset conditions reported in 8a above. The semi-annual report must include all the information as required by the initial and full reports required in 8a.

[Regulation 19, §19.601 and §19.602, Regulation 26, §26.701(C)(3)(b), and 40 CFR 70.6(a)(3)(iii)(B)]

9. If any provision of the permit or the application thereof to any person or circumstance is held invalid, such invalidity will not affect other provisions or applications hereof which can be given effect without the invalid provision or application, and to this end, provisions of this Regulation are declared to be separable and severable. [40 CFR 70.6(a)(5), Regulation 26, §26.701(E), and A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]
10. The permittee must comply with all conditions of this Part 70 permit. Any permit noncompliance with applicable requirements as defined in Regulation 26 constitutes a violation of the Clean Air Act, as amended, 42 U.S.C. §7401, et seq. and is grounds for enforcement action; for permit termination, revocation and reissuance, for permit modification; or for denial of a permit renewal application. [40 CFR 70.6(a)(6)(i) and Regulation 26, §26.701(F)(1)]
11. It shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity to maintain compliance with the conditions of this permit. [40 CFR 70.6(a)(6)(ii) and Regulation 26, §26.701(F)(2)]
12. The Department may modify, revoke, reopen and reissue the permit or terminate the permit for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, termination, or of a notification of planned changes or anticipated noncompliance does not stay any permit condition. [40 CFR 70.6(a)(6)(iii) and Regulation 26, §26.701(F)(3)]
13. This permit does not convey any property rights of any sort, or any exclusive privilege. [40 CFR 70.6(a)(6)(iv) and Regulation 26, §26.701(F)(4)]
14. The permittee must furnish to the Director, within the time specified by the Director, any information that the Director may request in writing to determine whether cause exists for modifying, revoking and reissuing, or terminating the permit or to determine compliance with the permit. Upon request, the permittee must also furnish to the Director copies of records required by the permit. For information the permittee claims confidentiality, the Department may require the permittee to furnish such records directly to the Director

- along with a claim of confidentiality. [40 CFR 70.6(a)(6)(v) and Regulation 26, §26.701(F)(5)]
15. The permittee must pay all permit fees in accordance with the procedures established in Regulation 9. [40 CFR 70.6(a)(7) and Regulation 26, §26.701(G)]
 16. No permit revision shall be required, under any approved economic incentives, marketable permits, emissions trading and other similar programs or processes for changes provided for elsewhere in this permit. [40 CFR 70.6(a)(8) and Regulation 26, §26.701(H)]
 17. If the permit allows different operating scenarios, the permittee shall, contemporaneously with making a change from one operating scenario to another, record in a log at the permitted facility a record of the operational scenario. [40 CFR 70.6(a)(9)(i) and Regulation 26, §26.701(I)(1)]
 18. The Administrator and citizens may enforce under the Act all terms and conditions in this permit, including any provisions designed to limit a source's potential to emit, unless the Department specifically designates terms and conditions of the permit as being federally unenforceable under the Act or under any of its applicable requirements. [40 CFR 70.6(b) and Regulation 26, §26.702(A) and (B)]
 19. Any document (including reports) required by this permit must contain a certification by a responsible official as defined in Regulation 26, §26.2. [40 CFR 70.6(c)(1) and Regulation 26, §26.703(A)]
 20. The permittee must allow an authorized representative of the Department, upon presentation of credentials, to perform the following: [40 CFR 70.6(c)(2) and Regulation 26, §26.703(B)]
 - a. Enter upon the permittee's premises where the permitted source is located or emissions related activity is conducted, or where records must be kept under the conditions of this permit;
 - b. Have access to and copy, at reasonable times, any records required under the conditions of this permit;
 - c. Inspect at reasonable times any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under this permit; and
 - d. As authorized by the Act, sample or monitor at reasonable times substances or parameters for assuring compliance with this permit or applicable requirements.
 21. The permittee shall submit a compliance certification with the terms and conditions contained in the permit, including emission limitations, standards, or work practices. The permittee must submit the compliance certification annually within 30 days following the last day of the anniversary month of the initial Title V permit. The permittee must also submit the compliance certification to the Administrator as well as to the Department.

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All compliance certifications required by this permit must include the following: [40 CFR 70.6(c)(5) and Regulation 26, §26.703(E)(3)]

- a. The identification of each term or condition of the permit that is the basis of the certification;
 - b. The compliance status;
 - c. Whether compliance was continuous or intermittent;
 - d. The method(s) used for determining the compliance status of the source, currently and over the reporting period established by the monitoring requirements of this permit;
 - e. and Such other facts as the Department may require elsewhere in this permit or by §114(a)(3) and §504(b) of the Act.
22. Nothing in this permit will alter or affect the following: [Regulation 26, §26.704(C)] The provisions of Section 303 of the Act (emergency orders), including the authority of the Administrator under that section; the liability of the permittee for any violation of applicable requirements prior to or at the time of permit issuance; the applicable requirements of the acid rain program, consistent with §408(a) of the Act or, the ability of EPA to obtain information from a source pursuant to §114 of the Act.
23. This permit authorizes only those pollutant emitting activities addressed in this permit. [A.C.A. §8-4-203 as referenced by A.C.A. §8-4-304 and §8-4-311]

APPENDIX A

Approved Additional Equipment and Equipment Descriptions

Baxter may move existing equipment to different locations within the facility, modify existing equipment, add new equipment, or change raw materials (including solvents) provided that these changes are made in compliance with the HAP screening matrix limits, plant-wide HAP and VOC limits, and other applicable requirements addressed in the permit.

Baxter has approval for the following specific types of changes:

Permit Approval to	Equipment Categories – see below for details	
Move: move any of the listed equipment/ operations that were in existence at the facility as of the date of permit issuance, or modify equipment/operations that were installed subsequent to permit issuance	(a)	Manual and Automated Assembly
	(b)	Compounding/Pelletizing and Film/Tubing Extrusion
	(c)	Injection/Blow Molding
	(d)	E-Beam
Modify: modify any of the listed equipment/ operations that were in existence at the facility as of the date of permit issuance, or modify equipment/operations that were installed subsequent to permit issuance	(e)	Filter Integrity Test
	(f)	Vacuum Dryers
	(g)	Fuel #2 Storage Tanks
	(h)	Ovens for Needle Covers
	(i)	Jet Cleaner
Install: install or construct any one or more of the listed equipment and/or operations	(j)	Print Shop
	(k)	Plastics Manufacturing
	(l)	DEHP Storage Tanks
Change Materials: change raw materials	(l)	DEHP Storage Tanks
	(m)	Methylene Chloride Etching

Baxter may also install, move, and modify other equipment or processes not listed in the table above, provided that the installation, move, or modification does not trigger any new applicable federal or state regulatory requirement that are not already addressed in the permit and provided that the installation, move, or modification passes the HAP screening matrix review and that the plant is able to maintain emissions below the plant-wide VOC and HAP limits.

Equipment Descriptions

(a) Manual and Automated Assembly - In manual and automated assembly, plastic parts are assembled to one another to produce sets, cassettes and many other products. Plastic parts that are assembled to produce medical devices include tubing, valves, housings, roller clamps, slide clamps, membranes, luer connectors, luer locks, spikes, needle adapters, filters, couplers, Y-connectors and others. Assembly for non-medical device products may involve a wide variety of plastic parts. Plastic parts are affixed or bonded to another using one of several techniques, including solvent bonding, ultrasonic bonding, ultraviolet (UV) energy, radio frequency (RF) energy, thermal energy, friction or others. In the case of solvent bonding, a variety of solvents can be used including both HAPs and non-HAPs.

(b) Compounding/Pelletizing and Film/Tubing Extrusion (SN-95)- Raw materials are received in both bulk and packaged for manufacturing of plastic film and tubing. The first step is blending. After blending, the blend is then sent to the film extrusion area, tubing extrusion area,

pelletizing area, or exported to other locations for processing. Small amounts of miscellaneous fugitive VOCs may result from the above described operations. The pollutant of concern is bis(2-ethylhexyl)phthalate (DEHP), a listed HAP. Fugitive DEHP emissions are captured with ventilation equipment from pelletizing, tubing extrusion, and film extrusion processes and routed to filters. Filters used in the plastics manufacturing are either roof mounted or located within the building. In either case, effluent from the filters is routed back into the warehouse. As such, no emissions are directly discharged to the atmosphere, but rather are all fugitive. Also included in SN-95 are emissions from inside DEHP storage tanks and the Jet Cleaner (SN-72).

(c) Injection/Blow Molding - Process by which plastic formulations are heated and mechanically processed. It is then injected into a mold and held under pressure until the part has solidified.

(d) E-Beam - Radiation is generated by electron beam acceleration to sterilize medical devices. During the radiation process ozone is emitted.

(e) Filter Integrity Test (SN-09) - Filters are filled with or submerged into 60% or 100% isopropyl alcohol (IPA). After the alcohol is drained off, air is introduced to the filter to determine the bubble point. The filters are then dried by continuous air flow until all IPA is dispersed. The used IPA is collected and recycled. The testing is conducted several times per year, as necessary. For cleaning the parts are placed in a container and submerged into 99% isopropyl alcohol (IPA). Then they are removed and dried. The used alcohol is collected and recycled. Isopropyl alcohol is received and collected in sealed containers. VOC emissions are vented to the atmosphere through normal powered room exhaust.

(g) Fuel #2 Storage Tanks - The fuel oil #2 used as a back up fuel is stored in three (3) 15,000 gallon and one (1) 30,000 gallon storage tanks (SN-100). The fuel oil throughput at the storage tanks is limited by the limit of the fuel usage in the boilers. Two tanks were installed in 1964 and one tank was installed in 1975. The storage tanks are not subject to the provisions of 40 CFR, Part 60, Subpart K because each individual tank's capacity is less than 40,000 gallons.

(h) Ovens for Needle Covers - PVC needle covers are sent to electric ovens for curing. The needle covers are heated in the ovens for about 45 minutes at 250°F. The following HAP is emitted during the process: bis(2-ethylhexyl)phthalate (DEHP). There are eight (8) ovens. All ovens exhaust to the atmosphere through one stack (SN-21). The ovens were installed in 1986 and permitted as SN-21 through SN-27 in Permit #544-AR-3.

(i) Jet Cleaner (SN-72) which consists of a closed insulated chamber with internal heaters, into which parts are placed for cleaning. The Jet Cleaner cleans PVC and other residue polymers off of steel plates used in extrusion of plastic tubing/film. It cleans using a pyrolysis cleaning cycle at full vacuum followed by an oxidation cycle at reduced vacuum. All heat is provided by electric heating elements. A primary trap beneath the chamber collects the polymer that drains from the parts. A secondary trap, fitted with water spray nozzles, condenses and collects vapors before they can enter the vacuum pump. There are two Jet Cleaners in the room. After the steel plates are removed from the cleaner, they are cooled and blasted using a totally enclosed glass-

bead blaster. The unit vents inside the room. There are two hoods located over each Jet Cleaner. Both hoods vent to the atmosphere through the same roof vent (SN-72).

(j) Print Shop- The print shop prints miscellaneous forms and labels. The soybean based ink is used for printing. There is no VOC emitted from the ink. A plate cleaner is used as a cleaning agent for equipment and associated parts containing: 3% xylene and 1% cumene. The print shop also makes lead slugs for stamps and labels.

(l) DEHP Storage Tanks (SN-89, SN-90) – Store DEHP and are located outside in the plastics tank farm.

(k) Methylene Chloride Etching – The process of overmolding molds a plastic component over another plastic component to create a functional portion of the end product. During the overmolding, an elastomer end is molded onto each end of an extruded tube. To insure adequate adhesion of the over molded part, the tubes must be treated with methylene chloride prior to the overmolding process. The use of MeCl etches the surface and imparts a porous finish onto the tubing surface. The MeCl also makes the surface soft and tacky. The surface layer of the tubing is melted after the application of the solvent and resolidifies after the solvent flashes off.

APPENDIX B
40 CFR Part 63, Subpart O

APPENDIX C

Table 1. 40 CFR Part 63, Subpart A

TABLE 1. 40 CFR Part 63, Subpart A: Applicability to Baxter Healthcare Corporation

Reference	Applicability	Comment
63.1(a)(1)	Yes	Additional terms defined in § 63.361; when overlap between subparts A and O occurs, subpart O takes precedence.
63.1(a)(2)	Yes	
63.1(a)(3)	Yes	
63.1(a)(4)	Yes	Subpart O clarifies the applicability of each paragraph in subpart A to sources subject to subpart O
63.1(a)(5)	No	Reserved
63.1(a)(6)	Yes	
63.1(a)(7)	Yes	
63.1(a)(8)	Yes	
63.1(a)(9)	No	Reserved
63.1(a)(10)	Yes	
63.1(a)(11)	Yes	§ 63.366(a) of subpart O also allows report submissions via fax and on electronic media.
63.1(a)(12)-(14)	Yes	
63.1(b)(1)-(2)	Yes	
63.1(b)(3)	No	<i>§ 63.367 clarifies the applicability of recordkeeping requirements for sources that determine they are not subject to the emissions standards.</i>
63.1(c)(1)	Yes	Subpart O clarifies the applicability of each paragraph in subpart A to sources subject to subpart O in this table.
63.1(c)(2)	Yes	Subpart O also specifies which sources are required to obtain a Title V permit in § 63.360.
63.1(c)(3)	No	Reserved
63.1(c)(4)	Yes	
63.1(c)(5)	No	§ 63.360 specifies applicability.
63.1(d)	No	Reserved
63.1(e)	Yes	
63.2	Yes	Additional terms defined in § 63.361; when overlap between subparts A and O occurs, subpart O takes precedence.
63.3	Yes	Other units used in subpart O are defined in the text of subpart O.
63.4(a)(1)-(3)	Yes	
63.4(a)(4)	No	Reserved
63.4(a)(5)	Yes	
63.4(b)	Yes	
63.4(c)	Yes	
63.5(a)	No	<i>§ 63.366(b)(1) contains applicability requirements for constructed or reconstructed sources.</i>
63.5(b)(1)	Yes	
63.5(b)(2)	No	Reserved
63.5(b)(3)	No	<i>See § 63.366(b)(2)</i>
63.5(b)(4)	Yes	
63.5(b)(5)	Yes	
63.5(b)(6)	Yes	
63.5(c)	No	Reserved
63.5(d)(1)-(2)	No	<i>See § 63.366(b)(3).</i>
63.5(d)(3)-(4)	Yes	
63.5(e)	Yes	

Reference	Applicability	Comment
63.5(f)(1) and (2)	No	<i>See § 63.366(b)(4).</i>
63.6(a)(1)	Yes	
63.6(a)(2)	No	<i>§ 63.360 specifies applicability.</i>
63.6(b) and (c)	No	<i>§ 63.360(g) specifies compliance dates for sources.</i>
63.6(d)	No	Reserved
63.6(e)	No	Subpart O does not contain any operation and maintenance plan requirements.
63.6(f)(1)	No	<i>§ 63.362(b) specifies when the standards apply.</i>
63.6(f)(2)(i)	Yes	
63.6(f)(2)(ii)	No	<i>§ 63.363 specifies parameters for determining compliance.</i>
63.6(f)(2)(iii)-(iv)	Yes	
63.6(f)(2)(v)	No	
63.6(f)(3)	Yes	
63.6(g)	Yes	
63.6(h)	No	Subpart O does not contain any opacity or visible emission standards.
63.6(i)(1)-(14)	Yes	
63.6(i)(15)	No	Reserved
63.6(i)(16)	Yes	
63.6(j)	Yes	
63.7(a)(1)	Yes	
63.7(a)(2)	No	<i>§ 63.365(a)(2) specifies performance test dates.</i>
63.7(a)(3)	Yes	
63.7(b)	Yes	
63.7(c)	Yes	
63.7(d)	Yes	
63.7(e)	Yes	<i>§ 63.365 also contains test methods specific to sources subject to the emissions standards.</i>
63.7(f)	Yes	
63.7(g)(1)	Yes	
63.7(g)(2)	No	Reserved
63.7(g)(3)	Yes	
63.7(h)	Yes	
63.8(a)(1)	Yes	
63.8(a)(2)	Yes	
63.8(a)(3)	No	Reserved
63.8(a)(4)	Yes	
63.8(b)(1)	Yes	
63.8(b)(2)	Yes	
63.8(b)(3)	No	
63.8(c)(1)(i) and (ii)	No	A startup, shutdown, and malfunction plan is not required for these standards.
63.8(c)(1)(iii)	Yes	
63.8(c)(2)-(3)	Yes	
63.8(c)(4)-(5)	No	<i>Frequency of monitoring measurements is provided in § 63.364; opacity monitors are not required for these standards.</i>
63.8(c)(6)	No	<i>Performance specifications for gas chromatographs and temperature monitors are contained in § 63.365.</i>
63.8(c)(7)(i)(A)-(B)	No	<i>Performance specifications for gas chromatographs and temperature monitors are contained in § 63.365.</i>

Reference	Applicability	Comment
63.8(c)(7)(i)(C)	No	Opacity monitors are not required for these standards.
63.8(c)(7)(ii)	No	<i>Performance specifications for gas chromatographs and temperature monitors are contained in § 63.365.</i>
63.8(c)(8)	No	
63.8(d)	Yes	
63.8(e)(1)	Yes	
63.8(e)(2)	Yes	
63.8(e)(3)	Yes	
63.8(e)(4)	Yes	
63.8(e)(5)(i)	Yes	
63.8(e)(5)(ii)	No	Opacity monitors are not required for these standards.
63.8(f)(1)-(5)	Yes	
63.8(f)(6)	No	
63.8(g)(1)	Yes	
63.8(g)(2)	No	
63.8(g)(3)-(5)	Yes	
63.9(a)	Yes	
63.9(b)(1)(i)	Yes	
63.9(b)(1)(ii)-(iii)	No	<i>§ 63.366(c)(1)(i) contains language for sources that increase usage such that the source becomes subject to the emissions standards.</i>
63.9(b)(2)-(3)	Yes	<i>§ 63.366(c)(3) contains additional information to be included in the initial report for existing and new sources.</i>
63.9(b)(4)-(5)	No	<i>§ 63.366(c)(1)(ii) and (iii) contains requirements for new or reconstructed sources subject to the emissions standards.</i>
63.9(c)	Yes	
63.9(d)	No	
63.9(e)	Yes	
63.9(f)	No	Opacity monitors are not required for these standards.
63.9(g)(1)	Yes	
63.9(g)(2)-(3)	No	Opacity monitors and relative accuracy testing are not required for these standards.
63.9(h)(1)-(3)	Yes	
63.9(h)(4)	No	Reserved
63.9(h)(5)	No	<i>§ 63.366(c)(2) instructs sources to submit actual data.</i>
63.9(h)(6)	Yes	
63.9(i)	Yes	
63.9(j)	Yes	
63.10(a)	Yes	
63.10(b)(1)	Yes	
63.10(b)(2)(i)	No	Not applicable due to batch nature of the industry.
63.10(b)(2)(ii)	Yes	
63.10(b)(2)(iii)	No	
63.10(b)(2)(iv)-(v)	No	A startup, shutdown, and malfunction plan is not required for these standards.
63.10(b)(2)(vi)-(xiv)	Yes	
63.10(b)(2)(xiii)	No	
63.10(b)(2)(xiv)	Yes	
63.10(b)(3)	No	<i>§ 63.367(b) and (c) contains applicability determination requirements.</i>
63.10(c)(1)	Yes	

Reference	Applicability	Comment
63.10(c)(2)-(4)	No	Reserved
63.10(c)(5)	Yes	
63.10(c)(6)	No	
63.10(c)(7)	No	Not applicable due to batch nature of the industry.
63.10(c)(8)	Yes	
63.10(c)(9)	No	Reserved
63.10(c)(10)-(13)	Yes	
63.10(c)(14)	Yes	
63.10(c)(15)	No	A startup, shutdown, and malfunction plan is not required for these standards.
63.10(d)(1)	Yes	
63.10(d)(2)	Yes	
63.10(d)(3)	No	Subpart O does not contain opacity or visible emissions standards.
63.10(d)(4)	Yes	
63.10(d)(5)	No	A startup, shutdown, and malfunction plan is not required for these standards.
63.10(e)(1)	Yes	
63.10(e)(2)(i)	Yes	
63.10(e)(2)(ii)	No	Opacity monitors are not required for these standards.
63.10(e)(3)(i)-(iv)	Yes	
63.10(e)(3)(v)	No	<i>§ 63.366(a)(3) specifies contents and submittal dates for excess emissions and monitoring system performance reports.</i>
63.10(e)(3)(vi)-(viii)	Yes	
63.10(e)(4)	No	Opacity monitors are not required for these standards.
63.10(f)	Yes	
63.11	Yes	
63.12-63.15	Yes	

APPENDIX D

Table 2. 40 CFR Part 63, Subpart O

Table 2. 40 CFR Part 63, Subpart O: Applicability to Baxter Healthcare Corporation.

Reference	Applicability	Comment
§ 63.360(a)	Yes	
§ 63.360(b)-(e)	No	
§ 63.360(f)	Yes	
§ 63.360(g)(1)	Yes	
§ 63.360(g)(2)-(3)	No	
§ 63.361	Yes	When overlap between subparts A and O occurs, subpart O takes precedence.
§ 63.362(a)-(d)	Yes	
§ 63.362(e)(1)	Yes	
§ 63.362(e)(2)	No	
§ 63.363(a)(1)-(2)	Yes	
§ 63.363(b)(1)(i)	Yes	The facility is going to continue to use the acid-water scrubber to control emissions from sterilization chamber vents.
§ 63.363(b)(1)(ii)	No	
§ 63.363(b)(2)(i)	Yes	The facility is going to continue to use the acid-water scrubber to control emissions from sterilization chamber vents.
§ 63.363(b)(2)(ii)	No	
§ 63.363(c)(1)-(2)	Yes	
§ 63.363(c)(3)(i)	No	
§ 63.363(c)(3)(ii)	Yes	
§ 63.363(d)(1)	Yes	
§ 63.363(d)(2)	No	
§ 63.363(e)-(f)	No	
§ 63.364(a)(1)-(2)	Yes	
§ 63.364(b)(1)	No	
§ 63.364(b)(2)	Yes	The facility is going to continue to use the acid-water scrubber to control emissions from sterilization chamber vents.
§ 63.364(c)(1)	No	
§ 63.364(c)(2),(4)	Yes	
§ 63.364(c)(3)	No	
§ 63.364(d)	No	
§ 63.364(e)	No	
§ 63.364 (f)	Yes	
§ 63.365(a)-(c)	Yes	
§ 63.365 (d)(1)	Yes	
§ 63.365(d)(2)	No	
§ 63.365(e)(1)	No	
§ 63.365(e)(2)	Yes	The facility is going to continue to use the acid-water scrubber to control emissions from sterilization chamber vents.
§ 63.365(f)(1)	No	
§ 63.365(f)(2)	Yes	
§ 63.365(f)(3)	No	
§ 63.365(g)	No	

Reference	Applicability	Comment
§ 63.365(h)	No	
§ 63.366(a)-(c)	Yes	
§ 63.367(a)	Yes	
§ 63.367(b)-(c)	No	

APPENDIX E
40 CFR Part 60, Subpart Dc

