NORTH CAROLINA DIVISION OF AIR QUALITY

Application Review

Issue Date:

Region: Asheville Regional Office
County: McDowell
NC Facility ID: 5600164
Inspector's Name: Patrick Ballard
Date of Last Inspection: 10/01/2020
Compliance Code: 3 / Compliance - inspection

Facility Data

Applicant (Facility's Name): Baxter Healthcare Corporation

Facility Address:
Baxter Healthcare Corporation
65 Pitts Station Road
Marion, NC 28752

SIC: 4961 / Steam Supply
NAICS: 22133 / Steam and Air-Conditioning Supply

Facility Classification: Before: Title V **After:** Title V
Fee Classification: Before: Title V **After:** Title V

Permit Applicability (this application only)

SIP: 02D .0503, .0504, .0516, .0521, .0524, .0614, .1100, .1111; 02Q .0317
NSPS:
NESHAP:
PSD:
PSD Avoidance: 02D .0317
NC Toxics: 02Q .0711
112(r): Yes
Other:

Contact Data

Facility Contact	Authorized Contact	Technical Contact
Corey Carpentier Sr. Environmental Engineer (828) 756-6636 65 Pitts Station Road Marion, NC 28752 corey_carpentier@baxter.com	Tim Marini Site Director (828) 756-6850 65 Pitts Station Road Marion, NC 28752 timothy_marini@baxter.com	Corey Carpentier Sr. Environmental Engineer (828) 756-6636 65 Pitts Station Road Marion, NC 28752 corey_carpentier@baxter.com

Application Data

Application Number: 5600164.22A
Date Received: 01/28/2022
Application Type: Renewal
Application Schedule: TV-Renewal

Existing Permit Data
Existing Permit Number: 05600/T21
Existing Permit Issue Date: 11/29/2017
Existing Permit Expiration Date: 10/31/2022

Total Actual emissions in TONS/YEAR:

CY	SO2	NOX	VOC	CO	PM10	Total HAP	Largest HAP
2020	12.66	133.43	115.15	208.80	59.20	12.98	4.90 [Hydrogen chloride (hydrochlori]
2019	12.53	131.80	119.05	206.32	58.60	12.67	4.59 [Hydrogen chloride (hydrochlori]
2018	11.73	124.22	114.64	193.59	54.88	11.89	4.34 [Hydrogen chloride (hydrochlori]
2017	11.98	125.01	111.02	194.86	52.02	12.47	4.37 [Hydrogen chloride (hydrochlori]
2016	11.78	124.22	100.19	194.04	55.10	12.20	4.56 [Hydrogen chloride (hydrochlori]

Review Engineer: Eric L. Crump, P.E.

Review Engineer's Signature: **Date:**

Comments / Recommendations:
Issue 05600/T22
Permit Issue Date:
Permit Expiration Date:

1. Purpose of Application

Baxter Healthcare Corporation (hereinafter referred to as Baxter) is a pharmaceutical and medicine manufacturing facility located in Marion, McDowell County, North Carolina. The facility currently operates under Title V Permit No. 05600T21 with an expiration date of October 31, 2022. Baxter has applied for renewal of their Title V air quality permit. The renewal application was received on January 28, 2022, or at least six months prior to the expiration date as required by General Condition 3.K of the current permit. Therefore, the existing permit shall not expire until the renewal permit has been issued or denied. All terms and conditions of the existing permit shall remain in effect until the renewal permit has been issued or denied.

Through permit application No. 5600164.22A, Baxter has not indicated any sources to be added to, removed from, or modified within the existing permit. Baxter has requested the addition of a 75 horsepower (hp) diesel emergency pump as an off permit change.

2. Facility Description

Baxter manufactures sterile intravenous (IV) solutions for use in the medical industry. The facility stamps bags from polyvinyl chloride (PVC) sheets, labels the bags for content, extrudes the fill tube (from PVC), extrudes a high density polyethylene (HDPE) overwrap, and fills the bags with several different types of IV solutions (salt/sugar/medication/water). Steam for the facility is produced primarily by a wood-fired boiler. In addition to wood, the boiler is permitted to fire used oil generated on site. The Baxter facility operates 24 hours a day, seven days a week, and employs approximately 2200 people.

3. Application Chronology

November 29, 2017	Division of Air Quality (DAQ) issues Permit No. 05600T21 to Baxter as a Title V renewal.
January 28, 2022	DAQ sends letter to Baxter acknowledging receipt of air permit renewal application No. 5600164.22A on January 28, 2022.
May 20, 2022	DAQ sends draft permit to Stationary Source Compliance Branch (SSCB) for review and comment.
May 27, 2022	DAQ receives comments on draft permit from SSCB.
July 28, 2022	Draft permit and review sent for DAQ supervisory review.
August 23, 2022	DAQ supervisor provides comments on draft permit and review
November 18, 2022	DAQ sends draft permit to Baxter and Asheville Regional Office (ARO) for review and comment.
December 8, 2022	DAQ receives comments on draft permit from Baxter.
December 12, 2022	DAQ receives comments on draft permit from ARO.
xxx	Permit renewal notice published, 30-day public notice and comment period begins, and 45-day EPA comment period begins.

xxx 30-day public notice and comment period ends.

xxx 45-day EPA comment period ends.

4. Changes to Permit and Title V Equipment Editor (TVEE) Discussion

The following table summarizes changes made to Baxter permit No. 05600T21 as a result of this permit renewal:

Page No.	Section	Description of Changes
Cover and throughout	---	• Updated all dates and permit revision numbers • Changed all citations of 15A NCAC 2D to 15A NCAC 02D • Changed all citations of 15A NCAC 2Q to 15A NCAC 02Q
Insignificant Activities List	Attachment	List moved to Section 3 of the permit
	Table of Contents	• Changed Section 3 to "Insignificant Activities per 15A NCAC 02Q .0503(8)" • Added new Section 4, "General Permit Conditions"
	List of Acronyms	Relocated here (formerly the last page of permit)
4	1	• Changed "hp" to "horsepower" • Changed "Area Source MACT" in Emission Source ID No. column to "GACT" • Changed "MACT ZZZZ" in Emission Source ID No. column to "GACT ZZZZ"
5	2.1 A 2.1 A.1.c	Updated limits/standards table to current format Clarified testing deadlines for boiler ID No. WBES-1
6	2.1 A.1.h	Added referral to monitoring and recordkeeping activities given in Sections 2.1 A.1.d through f
7	2.1 A.3.e 2.1 A.4	Added referral to monitoring and recordkeeping activities given in Sections 2.1 A.3.c and d Updated section to reflect the most current stipulations for 15A NCAC 02D .0614, Compliance Assurance Monitoring
9	2.1 A.5 2.1 A.5.d	Updated section to reflect the most current stipulations for 15A NCAC 02D .1111, 40 CFR Part 63 Subpart JJJJJJ (note: several paragraphs have been renumbered) Added date initial tune-up requirement was met.
11	2.1 B	Updated limits/standards table to current format
12	2.1 B.4	Replaced 15A NCAC 02D .0524 (40 CFR Part 60 Subpart Dc) stipulation with 15A NCAC 02Q .0317, Avoidance Conditions for NSPS
13	2.1 B.6	Replaced 15A NCAC 02D .1111 (40 CFR Part 63 Subpart JJJJJJ) stipulation with 15A NCAC 02Q .0317, Avoidance Conditions for MACT

Page No.	Section	Description of Changes
14	2.1 C 2.1 C.3	Removed "Beginning May 3, 2014" heading from hazardous air pollutants limits/standards summary in table Updated section to reflect the most current stipulations for 15A NCAC 02D .1111, 40 CFR Part 63 Subpart ZZZZ (note: several paragraphs have been renumbered)
20	2.1 D.4	Updated section to reflect the most current stipulations for 15A NCAC 02D .0524, 40 CFR Part 60 Subpart Dc (note: several paragraphs were renumbered, and testing requirements are revised throughout)
22	2.1 D.5	Updated section to reflect the most current stipulations for 15A NCAC 02D .1111, 40 CFR Part 63 GACT JJJJJJ (simplified since boilers have oxygen trim and will only burn low sulfur fuel)
25	2.1 E.3	Updated section to reflect the most current stipulations for 15A NCAC 02D .1111, 40 CFR Part 60 Subpart IIII (note: several paragraphs have been renumbered)
28	2.1 E.4	Changed "these sources" to "this engine (ID No. EP-13)"
29	2.2 A	Updated limits/standards table to current format
30	2.2 A.1.f 2.2 A.3	Added reference to Sections 2.2 A.1.c through e Updated section to reflect the most current stipulations for 15A NCAC 02Q .0317, Avoidance Conditions for MACT
32	2.3 B	Deleted permit shield for 15A NCAC 02D .1111, since it is superfluous to the avoidance condition for MACT
33	3	• Moved General Conditions to new Section 4 • Moved insignificant activities list to this section • Added 75 horsepower diesel-fired emergency pump (ID No. I-EP14) to the insignificant activities list • Removed nine laser engravers (ID No. I-Laser Engravers) from the insignificant activities list
34-42	4	Updated General Conditions to Version 6.0 dated January 7, 2022

The following revisions were made to the TVEE as a result of this renewal:

Source ID No.	Previous Description	Revised Description
I-EP10, I-EP11	One 250 hp diesel-fired emergency fire pump engine	One 250 horsepower diesel-fired emergency fire pump engine
I-EP12	One 75 hp (50kW electrical) diesel-fired emergency lighting engine	One 75 horsepower (50 killowatt electrical) diesel-fired emergency lighting engine
EP-1 through EP-7	Seven diesel fuel-fired peak shaver generators (2,598 hp each)	Seven diesel fuel-fired peak shaver generators (2,598 horsepower each)
EP-13	Diesel fuel-fired emergency generator (2,220 hp)	Diesel fuel-fired emergency generator (2,220 horsepower)

The following addition was made to the TVEE: ID No. I-EP14, One 75 horsepower diesel-fired emergency pump engine.

The following deletion was made to the TVEE: ID No. I-Laser Engravers, Nine laser engravers installed one each on Keifel production lines (Baxter informed DAQ of this deletion in their comments on the draft permit).

5. Description of Changes and Estimated Emissions

In an October 22, 2022 letter, Baxter submitted an off permit change notification under the General Conditions of their air permit for the installation of a new 75 hp diesel-fired emergency pump (Ameri Sykes Pumps model GP200). The new pump will serve as a backup to tow existing pumps that serve as a wastewater sump in case of a loss of electricity. Baxter submitted an estimate of potential emissions from the new pump, using NC DAQ's emission estimation spreadsheet for small gasoline and diesel engines (Revision S, 6/22/2015). While this new pump would be subject to 40 CFR 63 Subpart ZZZZ, the engine meets the requirements for classification as an insignificant activity under 15A NCAC 02Q .0503(8) because its emissions would not violate any applicable emissions standard, its potential uncontrolled criteria pollutant emissions are no more than five tons per year and its potential uncontrolled HAP emissions are below 1000 pounds per year. For this reason, no conditions are included in the permit for this new pump, which will be assigned Source ID No. I-EP14. This new source is not subject to any permit conditions.

It should be noted that classifying an emission source or activity as insignificant does not mean it is exempt from any applicable requirement, or that Baxter is exempted from demonstrating compliance with any applicable requirement. Baxter is required to have documentation— including calculations, if necessary—available at the facility at all times that demonstrates that an emission source or activity is insignificant.

6. Regulatory Review

Baxter is subject to the following state regulations, in addition to the requirements in the General Conditions:

15A NCAC 02D .0402, Sulfur Oxides. This rule establishes the following ambient air standards for any emission source that emits sulfur oxides (SO_X):

SO_X Emission Limit		**Form of Standard**
Micrograms per cubic meter ($\mu g/m^3$)	**Parts per million (ppm)**	
80	0.03	annual arithmetic mean
365	0.14	maximum 24-hour concentration not to be exceeded more than once per year
1300	0.5	maximum three-hour concentration not to be exceeded more than once per year

As discussed in a prior permit review (J. Kelvington, October 28, 2011, Air Permit No. 05600T12), sulfur dioxide (SO_2) emissions from these boilers are limited to **1.6 pounds per million Btu (lb/MMBtu) of heat input**. This limit is lower than the 2.3 lb/MMBtu of heat input limit in 15A NCAC 02D .0516 and was intended to prevent a violation of the SO_2 ambient standard (see November 10, 1993, AQ16[1]). The SO_2 limit appears to date back to the 1980s. The appendix to 02D

[1] AQ16 is an inspection report.

.0516 (Appendix 6-7)[2] references a public hearing on June 25, 1986 (Travenol Laboratories[3], Air Permit No. 1915R6) and states that "in no case shall sulfur dioxide emissions from the fuel burning equipment exceed 1.6 pounds per million Btu input." While this limit was established for several fuel-oil fired boilers that no longer exist at the Baxter facility, the limit applies to all fossil fuel-fired sources onsite: temporary boiler **(ID No. B-Temp-1)**, the peak shaver generators **(ID Nos. EP-1 through EP-7)**, the natural gas/No. 2 fuel oil-fired boilers **(ID Nos. B-10 and B-11)**, and the 2220 hp diesel-fired emergency generator **(ID No. EP-13).**

Because natural gas and No.2 fuel oil are both low-sulfur fuels, emissions from these sources are not expected to exceed the emissions limit. No monitoring, recordkeeping, or reporting is required for sulfur dioxide emissions from the firing of No. 2 fuel oil in this source.

15A NCAC 02D .0503, Particulates from Fuel Burning Indirect Heat Exchangers. This rule applies to particulate matter (PM) emissions from the combustion of fuel in indirect heat exchangers, such as boilers, that are discharged from any stack or chimney into the atmosphere. The regulation provides the following equation for determining the allowable emissions limit as a function of maximum heat input:

$$E = 1.090 \times Q^{-0.2594}$$

Where:

E = allowable emissions limit for PM in pounds per million Btu (lb/MMBtu); and

Q = maximum heat input in million Btu per hour (MMBtu/hr). The maximum heat input is the total heat content of all fuels and is the sum of maximum heat input of all fuel burning indirect heat exchangers at a plant site which are in operation, under construction, or permitted when determining the allowable emission limit for each fuel burning indirect heat exchanger.

The following boilers at the Baxter facility are subject to this rule and the following limits established using the above equation:

Source ID No.	Description	Maximum heat input (MMBtu/hr)	Allowable Emissions Limit (lb/MMBtu)
B-Temp-1	No. 2 fuel oil-fired temporary boiler	≤ 79	0.27
B-10	natural gas/No. 2 fuel oil-fired boiler	60.52	0.27
B-11	natural gas/No. 2 fuel oil-fired boiler	60.52	0.27

Monitoring, recordkeeping, reporting is not required for PM emissions from the firing of natural gas or No. 2 fuel oil in these sources, as both of these fuels. tend to burn relatively cleanly. Continued compliance is expected.

15A NCAC 02D .0504, Particulates from Wood Burning Indirect Heat Exchangers. This regulation applies to fuel burning equipment that burns 100 percent wood (with no other fuels in combination)

[2] Appendix to the North Carolina Air Quality Rules (Revised May 1, 2007)
[3] Travenol Laboratories was the owner of this facility prior to Baxter Healthcare Corporation.

for the primary purpose of producing heat or power by indirect heat transfer. PM emissions from wood combustion shall not exceed the allowable limits in the following table:

Maximum Heat Input (MMBtu/hr)	Allowable Emission Limit (lb/MMBtu)
≤ 10	0.70
100	0.41
1,000	0.25
≥ 10,000	0.15

If the heat input falls between any two consecutive heat inputs listed in the above table, the allowable PM emission limit shall be calculated using the following equation:

$$E = 1.1698 \times Q^{-.2230}$$

Where:

E = allowable emissions limit for PM in pounds per million Btu (lb/MMBtu); and
Q = maximum heat input in million Btu per hour (MMBtu/hr).

The water tube design wood-fired boiler with an overfire air system **(ID No. WBES-1)** has a maximum heat input capacity of 162.9 MMBtu/hr. Using the above equation, PM emissions from this boiler shall not exceed 0.38 lb/MMBtu heat input. Baxter is required to demonstrate compliance with this limit by conducting stack testing every five years. If test results show the emission rate exceeds 80 percent of the allowable limit, then testing shall be done annually. Once annual testing is triggered, when two consecutive tests indicate PM emissions below 80 percent of the allowable limit, the testing frequency will revert back to five years.

The wood-fired boiler is controlled by a multicyclone **(ID No. MCCD-2)** followed by a venturi scrubber **(ID No. WSCD-2)**. Baxter is required to inspect and maintain these control devices as recommended by the manufacturer. At a minimum, this must include:

- monthly external visual inspection of the ductwork and material collection unit for leaks,
- annual internal inspection of the multicycle's structural integrity,
- annual inspection of the scrubber spray nozzle and internal components
- annual inspection, cleaning, and calibration of all instrumentation

A pressure drop indicator on the scrubber is required, and the pressure drop must be maintained at or above at least 2.0 inches of water.

The description of the boiler in Section 1 of the permit indicates that used oil generated on site may also be burned in this boiler. The amount of used oil used to fire this boiler is relatively small compared to the amount of wood burned, and is expected to contribute very little to overall PM emissions. Required PM stack testing was last conducted on January 25, 2018, and it demonstrated compliance with the allowable emission limit. Continued compliance is expected.

15A NCAC 02D .0516, Sulfur Dioxide Emissions from Combustion Sources. Under this regulation, emissions of sulfur dioxide (SO_2) from any source of combustion discharged from any vent, stack, or chimney shall not exceed 2.3 lb/MMBtu of heat input. The wood-fired boiler **(ID No. WBES-1)** is subject to this regulation. No monitoring, recordkeeping, or reporting is required for SO_2emissions

from the combustion of wood or a combination of wood and used oil in this boiler, due to the low levels of sulfur present in these fuels. Continued compliance is expected.

15A NCAC 02D .0521, Control of Visible Emissions. The following sources at the Baxter facility are subject to this regulation:

- Wood-fired boiler **(ID No. WBES-1)**
- Seven No. 2 fuel oil-fired peak shaver generators **(ID Nos. EP-1 through EP-7)**
- Two natural gas/No. 2 fuel oil-fired boilers **(ID Nos. B-10 and B-11)**
- 2220 horsepower diesel-fired emergency generator **(ID No. EP-13)**

Because these sources were manufactured after July 1, 1971, this regulation limits them to 20 percent opacity averaged over a six-minute period. The six-minute averaging periods may exceed 20 percent not more than once in any hour, and not more than four times in any 24-hour period. In no event shall the six-minute average exceed 87 percent opacity.

For the wood-fired boiler **(ID No. WBES-1)**, daily observations of the emission points to identify any visible emissions above normal are required (three days of missed observations per semiannual period are allowed). If visible emissions from this boiler are observed to be above normal, Baxter must either take appropriate action to correct the above-normal emissions within the monitoring period and record the action taken as provided in the recordkeeping requirements below, or demonstrate compliance with the visibility limit in accordance with 15A NCAC 02D .2610 (Method 9).

For the peak shaver generators, the gas/No.2 fuel oil-fired boilers, and the diesel-fired emergency generator, the potential for violating visible emission limits is limited because they are fired with cleaner fuels. Therefore, monitoring, recordkeeping, and reporting is not required for visible emissions from these sources. Continued compliance is expected.

15A NCAC 02D .0524, New Source Performance Standards. See Section 8 of this review.

15A NCAC 02D .0614: Compliance Assurance Monitoring. See Section 11 of this review.

15A NCAC 02D .1100, Control of Toxic Air Pollutants. See Section 12 of this review.

15A NCAC 02D .1111, Maximum Achievable Control Technology. See Section 7 of this review.

15A NCAC 02Q .0711, Emission Rates Requiring a Permit. See Section 12 of this review.

15A NCAC 02Q .0317, Avoidance Conditions. Under this regulation, the owner or operator of a facility may ask DAQ to place terms and conditions in that facility's permit to avoid the applicability of certain regulatory requirements. DAQ may require monitoring, recordkeeping, and reporting as needed to provide assurance that the avoidance conditions are being met. The Baxter permit includes avoidance conditions for the following regulations:

- 15A NCAC 02D .0530, Prevention of Significant Deterioration – see Section 9 of this review.
- 15A NCAC 02D .1111, Maximum Achievable Control Technology – see Section 7 of this review.

The permit has been updated to reflect the most current stipulations for all applicable regulations.

7. National Emission Standards for Hazardous Air Pollutants (NESHAPS): Maximum and/or Generally Achievable Control Technology (MACT/GACT)

The Baxter facility is subject to the NESHAPs listed below.

40 CFR 63, Subpart ZZZZ—National Emissions Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines.
The 2220 hp diesel-fired emergency generator **(ID No. EP-13)** is subject to 40 CFR 63 Subpart ZZZZ. As stated in 40 CFR 63.6590(c)(1), EP-13 fulfills the requirements of Subpart ZZZZ by meeting the requirements of the Stationary Compression Ignition Internal Combustion Engine NSPS—40 CFR Part 60 Subpart IIII. No further requirements apply for these engines under 40 CFR 63 Subpart ZZZZ and Subpart A.

The seven No. 2 fuel oil-fired peak shaver generators **(ID Nos. EP-1 through EP-7)** are considered existing stationary reciprocating internal combustion engines (RICE) located at an area source of HAP emissions. They are subject to the following requirements under Subpart ZZZZ:

- Submittal of various notifications for performance testing, quality assurance program, performance evaluation of continuous parameter monitoring systems (CPMS), alternative monitoring methods, and initial notifications.
- Operation and maintenance of the generators, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. [40 CFR 63.6605(b)]
- Fire diesel fuel meeting the requirements of 40 CFR 63.6604(a) and 80.510(b)—a maximum sulfur content of 15 ppm; and a minimum cetane index of 40 or a maximum aromatic content of 35 volume percent.
- using an oxidation catalyst, limit the concentration of CO in the stationary RICE exhaust to 23 ppmvd at 15 percent O_2; or reduce CO emissions by 70 percent or more. [40 CFR 63.6603(a), Table 2d, Table 2b]
- Except during periods of start-up, maintain the catalyst so that the pressure drop across the catalyst does not change by more than 2 inches of water from the pressure drop across the catalyst that was measured during the most recent performance test. [40 CFR 63.6603(a), Table 2b]
- During periods of startup of the engine, minimize the engine's time spent at idle and minimize the engine's startup time at startup to a period needed for appropriate and safe loading of the engine, not to exceed 30 minutes, after which time the non-startup emission limitations apply. [40 CFR 63.6625(h), Table 2d]
- If the engines are not equipped with a closed crankcase ventilation system, install either of the following: (a) a closed crankcase ventilation system that prevents crankcase emissions from being emitted to the atmosphere, or (b) an open crankcase filtration emission control system that reduces emissions from the crankcase by filtering the exhaust stream to remove oil mist, particulates and metals. Baxter must follow the manufacturer's specified maintenance requirements for operating and maintaining the open or closed crankcase ventilation systems and replacing the crankcase filters, or can request the Administrator to approve different maintenance requirements that are as protective as manufacturer requirements. [40 CFR 63.6625(g)]
- Conduct performance tests in accordance with Tables 4 and 5 of Subpart ZZZZ.
- Install, operate, and maintain CPMS to monitor the catalyst inlet temperature for each catalyst and reduce the temperature data to 4-hour rolling averages. [40 CFR 63 Subpart ZZZZ Table 5, 63.6625(b), 63.6640(a), Table 6]
- Keep records of the monitoring data, required notifications, and reports, and submit semiannual summary reports of monitoring and recordkeeping activities to NC DEQ.

This permit renewal does not affect this status. Continued compliance is expected.

40 CFR 63, Subpart JJJJJJ, National Emission Standards for Hazardous Air Pollutants for Area Sources: Industrial, Commercial, and Institutional Boilers. The four boilers at the Baxter facility are subject to this area source GACT standard. The requirements for each boiler are summarized below.

*Wood-fired boiler **(ID No. WBES-1)***: Baxter is required to:

- Operate and maintain the wood-fired boiler, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. [40 CFR 63.11205(a)]
- Conduct biennial tune-ups [40 CFR 63.11196(a), 63.11210(c), 63.11201(b), Table 2, and 63.11223(a), (b)]
- Conduct a one-time energy assessment performed by a qualified energy assessor (Baxter accomplished this on February 4, 2014. [40 CFR 63.11201(b), Table 2]
- Maintain required records (copies of each notification and report required, documentation of tune-ups, malfunctions, and corrective actions, etc. [40 CFR 63.11225(c), 63.11223(b)(6)]

*Temporary boiler **(ID No. B-Temp-1)***: Baxter does not anticipate this boiler will be onsite for more than 12 consecutive months; as such it is unlikely to trigger the applicability of GACT Subpart JJJJJJ. For this reason, only a general paragraph describing its subjectivity to the rule had been included in the permit. Upon review, it has been decided that this general paragraph should be replaced in this permit renewal with an avoidance condition for GACT Subpart JJJJJJ under 15A NCAC 02Q .0317. As long as boiler B-Temp-1 As long as Baxter maintains records that demonstrate this boiler is meeting the definition of a temporary boiler as defined in 40 CFR 63.11237, no additional requirements apply. Continued compliance is expected.

*Natural gas/No. 2 fuel oil-fired boilers **(ID Nos. B-10 and B-11)***: Except during periods of startup and shutdown, neither of these two boilers shall emit PM emissions at a rate greater than 3.0E-02 lb per MMBtu of heat input. 40 CFR 63.11201, Table 1 to Subpart JJJJJJ]. However, boilers that combust only ultra-low-sulfur liquid fuel as defined in §63.11237 (i.e., distillate oil with less than or equal to 15 parts per million (ppm) sulfur), are not subject to this PM emission limit. All fuel oil burned at Baxter is ultra-low sulfur fuel, per inspection reports, so Baxter does not need to demonstrate compliance with this limit. They must keep records of monthly fuel use by each boiler, including the types of fuel, amounts used, and the sulfur content of each fuel burned.

As noted in an earlier application review for the Baxter facility[4], potential uncontrolled facility-wide HAP emissions would exceed 10 tons per year of HCl (individual HAP) and 25 tons per year of total HAPs. To avoid classification as a major source for MACT applicability (in particular, the boiler MACT requirements in 40 CFR 63, Subpart DDDDD), Baxter accepted avoidance conditions under 15A NCAC 02Q .0317, limiting facility-wide hazardous air pollutant (HAP) emissions to less than 10 tons of any single HAP per consecutive 12-month period, and less than 25 tons of any combination of HAPs per consecutive 12-month period. As noted earlier, natural gas/No. 2 fuel oil-fired boilers **(ID Nos.B-10 and B-11)** are subject to the HAP emission requirements of Subpart JJJJJJ, an Area Source GACT regulation; so to ensure Baxter meets this avoidance condition, HAP emissions from the wood-fired boiler **(ID No. WBES-1)** shall be controlled by a multicyclone **(ID No. MCCD-2)** followed by a venturi scrubber **(ID No. WSCD-2).**

This permit renewal does not affect this status. Continued compliance is expected.

[4] J. Kelvington, Application Review for Air Permit No. 5600T12, October 28, 2011.

8. New Source Performance Standards (NSPS)

Baxter is subject to two NSPS standards as discussed below.

40 CFR 60, Subpart Dc, Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units. – Temporary boiler (**ID No. B-Temp-1),** natural gas/No. 2 fuel oil-fired boilers **(ID Nos. B-10 and B-11)**

*For the temporary boiler **(ID No. B-Temp-1)***: Until now, this boiler had been subject to the following permit requirements:

- The maximum sulfur content of any fuel oil burned shall not exceed 0.5 percent by weight—even during periods of startup, shutdown, and malfunction. [40 CFR 60.42c(d), 40 CFR 60.42c(i)];
- Visible emissions when burning No. 2 fuel oil shall not be more than 20 percent opacity when averaged over a six-minute period, except for one six-minute period per hour of not more than 27 percent opacity. This opacity standard applies at all times except during periods of startup, shutdown, or malfunction. [40 CFR 60.43c(c), 40 CFR 60.43(d)];
- Baxter must retain a copy of the fuel supplier certification for any oil fired in the boiler with the name of the supplier, the sulfur content, and a statement of compliance from the supplier that the oil complies with the specifications under the definition of distillate oil in 40 CFR 60.41c.; and
- Baxter must conduct Method 9 performance tests under the schedule specified in the permit to verify compliance with the visible emissions standard.

Upon review, it has been decided that because this boiler meets the definition of a temporary boiler in 40 CFR 63.11237, it is more appropriate to replace these conditions in this permit renewal with an avoidance condition for Subpart Dc. As long as Baxter maintains records to demonstrate that B-Temp-1 is meeting the requirements for a temporary boiler, no additional requirements apply. Continued compliance is expected.

*For the two natural gas/No. 2 fuel oil-fired boilers **(ID Nos. B-10 and B-11)***

- No oil shall be burned in the boilers that contains greater than 0.5 weight percent sulfur. [40 CFR 60.42c(d), (i)]
- Visible emissions when firing No. 2 fuel oil shall not be more than 20 percent opacity when averaged over a six-minute period, except for one six-minute period per hour of not more than 27 percent opacity. [40 CFR 60.43c(c)]
- The opacity standard applies at all times when firing No. 2 fuel oil, except during periods of startup, shutdown, or malfunction. [40 CFR 60.43c(d)]
- No fuel sulfur limits or opacity limits apply under 15A NCAC 02D .0524 when firing natural gas.
- Baxter must conduct a performance test using Method 9 (Appendix A-4 of 40 CFR Subpart 60 and in accordance with Permit General Condition JJ) to demonstrate compliance with the opacity limit within 45 days of switching fuel firing from natural gas to No. 2 fuel oil, or within 180 days after initial startup of the boiler when firing No. 2 fuel oil, whichever is later.

*For all three boilers **(ID Nos. B-Temp-1, B-10, and B-11)**, Baxter must do the following:*

- Conduct Method 9 performance tests using the applicable schedule specified in the permit for each boiler to verify compliance with the visible emissions standard.
- Record and maintain records of the amounts of each type of fuel fired each month, along with opacity monitoring records for each performance test
- Record and maintain records of any occurrence and duration of any startup, shutdown, or malfunction in the operation of the affected boiler.

- Submit semiannual summary reports of monitoring and recordkeeping activities to NC DEQ.

This permit renewal does not affect this status. Continued compliance is expected.

40 CFR Part 60 Subpart IIII, Standards of Performance for Stationary Compression Ignition Internal Combustion Engines. Under this NSPS, the 2220 hp diesel-fired emergency generator **(ID No. EP-13)** is required to meet the following requirements:

- Comply with the emission standards 40 CFR 60.4202 for all pollutants, for the same model year and maximum engine power for this engine. The engine shall be installed and configured according to the manufacturer's emission-related specifications. [40 CFR 60.4205(b), 60.4211(c)]
- Fire diesel fuel meeting the requirements of 40 CFR 80.510(b)—a maximum sulfur content of 15 ppm; and a minimum cetane index of 40 or a maximum aromatic content of 35 volume percent.
- Equip the engine with a non-resettable hour meter. [40 CFR 60.4209(a)]
- If the engine has a diesel particulate filter, it must be installed with a backpressure monitor that notifies the owner or operator when the high backpressure limit of the engine is approached. [40 CFR 60.4209(b)]
- Operate and maintain the engine and its control devices according to the manufacturer's emission related-written instructions over the entire life of the engine; change only those emission-related settings that are permitted by the manufacturer; and meet the requirements of 40 CFR 89, 94 and/or 1068 as applicable. [40 CFR 60.4206 and 60.4211(a)]
- To be considered an emergency stationary internal combustion engine under this rule, any operation other than emergency operation, maintenance and testing, and operation in non-emergency situations for 50 hours per year, as described in 40 CFR 60.4211(f), is prohibited.
- To ensure compliance, Baxter shall perform inspections and maintenance on the engine as recommended by the manufacturer per 40 CFR 60.4206 and 40 CFR 60.4211(a). The results of inspection and maintenance shall be maintained in a logbook (written or electronic format) on site and made available to an authorized representative upon request.
- Submit semiannual summary reports of monitoring and recordkeeping activities to NC DEQ.

This permit renewal does not affect this status. Continued compliance is expected.

9. New Source Review (NSR)/Prevention of Significant Deterioration (PSD)

To avoid applicability of 15A NCAC 02D .0530(g), Prevention of Significant Deterioration for major sources, Baxter has accepted permit conditions under 15A NCAC 02Q .0317 that limit the discharge from all facility wide emission sources combined into the atmosphere less than 250 tons each of PM, SO_2, nitrogen oxide (NO_X), and carbon monoxide (CO) per consecutive 12-month period. 40 CFR Part 51.166(b)(1)(iii) states that unless a stationary source is one of the 28 categories listed, its fugitive emissions shall not be included in determining whether it is a major stationary source. Therefore, fugitive emissions should not be included in the 250 ton limit for Baxter.

To determine compliance, the permit requires Baxter to calculate and record the amounts of PM, SO_2, NO_X, and CO emissions from the wood-fired boiler **(ID No. WBES-1)** each month, using the following equations:

PM (tons/month), $E_{PM10} = (Q_w)(0.13 \text{ lb } PM_{10}/ \text{ MMBtu}^5) / 2000$

[5] Emission factor is based on 5/22/07 stack test.

SO_2 (tons/month), $E_{SO2} = (Q_w)$ (0.0025 lb SO_2/MMBtu[6]) / 2000
NO_X (tons/month), $E_{NOx} = (Q_w)$(0.263 lb NO/MMBtu[7]) / 2000
CO (tons/month), $E_{CO} = (Q_w)$(0.408 lb CO/MMBtu[8]) / 2000

Where Q_W = quantity of wood combusted in million Btu per month

In addition, each calendar month Baxter is required to calculate and record the total amounts of PM, SO_2, NO_X, and CO emitted from the fossil fuel-fired boilers, engines, and generators **(ID Nos. B-10, B-11, B-Temp-1, EP-1 through EP-7, and I-EP10 through I-EP12)** using emission factors based on U.S. EPA AP-42 emission factors, NC DAQ emission spreadsheets, or NC DAQ approved stack testing. The permit also requires the submittal of semiannual reports which must contain

- The monthly quantity of wood combusted for the previous 17 months;
- Facility-wide totals of actual PM, SO_2, NO_X, and CO emissions for each month during the previous 17 months; and
- Facility-wide rolling totals of actual PM, SO_2, NO_X, and CO emissions for each of the 12-month periods over the previous 17 months.

Baxter appears to be in compliance with these requirements. Continued compliance is expected.

10. Risk Management Plan (RMP) Requirements

40 CFR Part 68 requires stationary sources storing more than threshold quantities of regulated substances to develop a RMP in accordance with Section 112(r) of the Clean Air Act. The RMP lists the potential effects of a chemical accident at the facility, steps the facility is taking to prevent an accident, and emergency response procedures to be followed if an accident should occur.

To avoid the applicability of 40 CFR Part 68, Baxter has accepted permit conditions stating they will not use, store, or handle, within any process, more than:

- 20,000 pounds of aqueous ammonia at concentrations greater than 20%; and,
- 2,500 pounds (193 gallons) of chlorine.

From all indications, Baxter has been in compliance with these conditions. Continued compliance is expected.

11. Compliance Assurance Monitoring (CAM)

The CAM rule (40 CFR 64) applies to each pollutant specific emissions unit located at a major source that is required to obtain a Title V, Part 70 or 71 permit if it meets all of the following criteria:

- It is subject to an emission limitation or standard, and
- It uses a control device to achieve compliance, and
- It has potential pre-control emissions that equal or exceed the major source threshold (i.e., either 100 tons per year (tpy) for criteria pollutants, 10 tpy of any individual HAP, or 25 tpy of any combination of HAP).

[6] Emission factor is based on 4/12/01 stack test.
[7] Emission factor is based on 7/26/02 stack test.
[8] Emission factor is based on 7/26/02 stack test.

The following emission limitations or standards are exempted from the CAM rule:

- NSPS or NESHAP standards proposed after November 15, 1990;
- Stratospheric ozone protection requirements under Title VI of the Clean Air Act
- Acid rain program requirements;
- Emission limitations or standards or other requirements that apply solely under an approved emissions trading program;
- An emissions cap that meets requirements of 40 CFR 70.4(b)(12) or 71.6(a)(13);
- Emission limitations or standards for which a Part 70 or 71 permit specifies a continuous compliance determination method, as defined in 40 CFR 64.1, unless the applicable compliance method includes an assumed control device emission reduction factor that could be affected by the actual operation and maintenance of the control device (e.g., a surface coating line controlled by an incinerator for which continuous compliance is determined by calculating emissions on the basis of coating records and an assumed control device efficiency factor based on an initial performance test; in this example, this part would apply to the control device and capture system, but not to the remaining elements of the coating line, such as raw material usage).
- Certain municipally-owned utility units, as defined in 40 CFR 72.2.

Please note that the emission unit is not exempted from the CAM rule if nonexempt emission limitations or standards (e.g. a state rule or an older NSPS emission limits) apply to the emissions unit.

The following table summarizes the application of the criteria listed above to the emission sources to determine which sources at the Baxter facility are subject to the CAM rule.

Source ID No.	Description	Subject to non-exempt emission standard?	Add-on control device required to meet that standard?	Pre-control PTE ≥ major source level?	Subject to CAM?
WBES-1	Wood-fired boiler	15A NCAC 02D .0504	Multicyclone (MCCD-2) in series w/ wet scrubber (WSCD-2)	Yes	**Yes**
B-10	Natural gas/No. 2 fuel oil-fired boiler	Yes	No	NA	No
B-11	Natural gas/No. 2 fuel oil-fired boiler	Yes	No	NA	No
B-Temp-1	No. 2 fuel oil-fired temporary boiler	No	No	NA	No
EP-1 through EP-7	Seven diesel fuel-fired peak shaver generators	Yes	No	No	No

Source ID No.	Description	Subject to non-exempt emission standard?	Add-on control device required to meet that standard?	Pre-control PTE ≥ major source level?	Subject to CAM?
EP-13	Diesel fuel-fired emergency generator	Yes	No	No	No
ES-6	Cyclohexanone and cumene bonding process	No	NA	NA	No
ES-7	Isopropyl alcohol facility cleanup operations	No	NA	NA	No

The wood-fired boiler **(ID No. WBES-1)** is the only source at the Baxter facility subject to CAM requirements, because it requires a multicyclone in series with a venturi scrubber to meet the requirements of 15A NCAC 02D .0504, Particulates from Wood Burning Indirect Heat Exchangers. The key elements of the monitoring approach for particulate matter, including parameters to be monitored, parameter range and performance criteria are presented in the following table.

Element	Description
I. Indicator Measurement Approach	Scrubber water flow rate Water flow entering the scrubber will be monitored with a flow meter.
II. Indicator Range Quality Improvement Plan (QIP) Threshold	An excursion is defined as an hourly average flow less than 250 gallons per minute (gpm). A QIP will be required if the total duration of excursions is greater than 5% of the total boiler operating time during the reporting period (excluding start-ups and shut-downs)

Element	Description
III. Performance Criteria	
A. Data Representativeness	The flow meter can be installed on the water line as flow will be consistent throughout this line. The gauge has an accuracy of ± 5%.
B. Verification of Operational Status	A water flow meter will be installed with a transmitter that feeds to a data logger installed in the control room. The new meter will be installed and calibrated according to manufacturer's recommendations. The data logging program will be audited upon installation to verify that averages are being computed correctly.
C. QA/QC Practices	The flow meter will be calibrated annually based on manufacturer's instructions.
D. Monitoring Frequency	Measured at 15-minute intervals (maximum).
E. Data Collection Procedures	A data logging system will collect the individual readings and reduce them to a 1-hour average. Any 1-hour average below the specified indicator range will be flagged and reported as an excursion.
F. Averaging Periods	1 hour

Baxter is required to submit a summary report of the monitoring activities described above semiannually. This permit renewal does not affect this status. Continued compliance is expected.

12. Facility-wide Air Toxics Review

To avoid having to perform an air toxics compliance demonstration and establish permit limits under 15A NCAC 02D .1100, "Control of Toxic Air Pollutants," Baxter requested in Application No. 5600164.13B that DAQ limit the use of temporary boiler **(ID No. B-Temp-1)** to times when either of the other two boilers **(ID Nos. B4 or B5)** on site was not in operation. This condition was included in Air Permit No. 05600T14 (December 18, 2013), with a requirement that Baxter maintain records demonstrating that either boiler B4 or B5 was shut down when B-Temp-1 was operating.

In a subsequent permit modification (Application No. 5600164.17B, received on May 24, 2017), Baxter requested the removal of two boilers (**ID Nos. B-8 and B-9)**, along with the replacement of boilers B4 and B5 with two boilers **(ID Nos. B-10 and B-11)**. This would necessitate an update of the aforementioned permit condition to continue to avoid an air toxics compliance demonstration or air toxic limits in the permit.

To allow the Baxter facility greater operational flexibility, this permit condition was amended to allow all three boilers **(ID Nos. B-Temp-1, B-10, and B-11)** to operate simultaneously under the following conditions:

- The Permittee may operate the boilers (**ID Nos. B-10, B-11, and B-Temp-1)** simultaneously, while firing No. 2 fuel oil in all three boilers, at a total heat input rate not to exceed 163.12 MMBtu/hr.
- The Permittee may operate the boilers (**ID Nos. B-10, B-11, and B-Temp-1)** simultaneously while firing natural gas in at least one boiler when the wood-fired boiler **(ID No. WBES-1)** is not operating.

The amended permit conditions were crafted so that there would be no increase in toxic air pollutants (TAP) based on the following:

When firing No.2 Fuel Oil

- The two boilers being removed from the permit **(ID Nos. B-8 and B-9)** were each No. 2 fuel oil-fired boilers with a 11.8 MMBtu/hr maximum heat input rate.
- Prior to removal of the two boilers, Baxter's air permit allowed a total of 163.12 MMBtu/hr heat input from burning No. 2 fuel oil in their four boilers **(ID Nos. B-8, B-9, B-Temp-1, and either B-10 or B-11)**.
- The total heat input of 163.12 MMBtu/hr from fuel oil would be maintained as a result of this permit modification. The only change would be that this heat input would now be allocated among the three remaining boilers permitted to burn No. 2 fuel oil (**ID Nos. B-10, B-11, and B-Temp-1)**.

When Firing Natural Gas:

- Comparatively, TAP emissions from firing wood (in pounds per MMBtu – see table below) are higher than those from firing natural gas, with the exception of ammonia and n-hexane.
- The current permit at the time allowed Baxter to fire a total of 121.06 million Btu/hr of natural gas from the two new boilers (**ID Nos. B-10 and B-11)**
- The modified permit does not change the total heat input of natural gas that can be fired; therefore, operating boilers **ID Nos. B-10, B-11, and B-Temp-1** simultaneously while firing natural gas in at least one of the boilers while not firing the wood-fired boiler **(ID No. WBES-1)** would not result in an increase of ammonia or n-hexane emissions.

TAP Emitted from Both Natural Gas and Wood Combustion		
TAP	**Natural gas**	**Wood**
	Emissions in lb/MMBtu	
Acetaldehyde	1.49×10^{-8}	8.3×10^{-4}
Acrolein	1.76×10^{-8}	4.0×10^{-4}
Ammonia	3.14×10^{-3}	N/A
Formaldehyde	7.35×10^{-5}	4.4×10^{-3}
Hexane, n-	1.76×10^{-3}	N/A
Toluene	3.33×10^{-6}	9.2×10^{-4}
Benzene	2.06×10^{-6}	4.2×10^{-3}
Benzo(a)pyrene	1.18×10^{-9}	2.6×10^{-6}

Emission factors are as shown on NCDAQ Emissions Inventories spreadsheets
[http://deq.nc.gov/about/divisions/air-quality/air-quality-data/emission-inventories]

The permit lists the following TAP and its respective toxic permit emission rate (TPER) as established in 15A NCAC 02Q .0711, "Emission Rates Requiring a Permit".

Pollutant	**Carcinogens (lb/yr)**	**Chronic Toxicants (lb/day)**	**Acute Systemic Toxicants (lb/hr)**	**Acute Irritants (lb/hr)**
Hydrogen chloride (hydrochloric acid) (7647-01-0)				0.18

Baxter has made a demonstration that its facility-wide actual emissions do not exceed the TPERs. The permit requires Baxter to operate and maintain the facility so that emissions of any listed TAPs from the facility, including fugitive emissions, will not exceed the TPERs; and to maintain records that demonstrate compliance with this TPER. Based on the most recent inspection, Baxter has been complying with this regulation. Continued compliance is expected and will be determined during subsequent inspections.

12. Facility Emissions Review

The table in the header page of this review summarizes emissions Baxter has reported in the emissions inventories for the years 2016 through 2020 after application of required emission controls. The inventories indicate a slight increase in most criteria pollutants during that time period (with VOC emissions increasing by 14.9%; the other criteria pollutants increasing by 7.4 to 7.6%). Total HAP emissions increased by 6.4% over that time period, the largest individual HAP being hydrogen chloride (increasing by 7.4%). The increases are likely due to changes in throughput or production at the facility.

No changes made to the permit as a result of this renewal should cause any changes in the facility's potential to emit.

13. Compliance History and Status

The following chronology dates from when the Baxter permit was last renewed on November 29, 2017.

August 20, 2018	DAQ issues Notice of Deficiency (NOD) to Baxter for failure to submit a semiannual compliance summary report by the required date.
January 22, 2019	Patrick Ballard, Asheville Regional Office (ARO) conducts facility compliance inspection. Facility appeared to be operating in compliance with all permit requirements.
June 24, 2019	Patrick Ballard, ARO investigates complaint about black smoke from the boiler at the Baxter facility, and dust from the wood stock piles and trailer parking lot. While white smoke and some dust were present, no opacity violations were observed during this site visit, and no fugitive dust was observed traveling offsite.
July 16, 2019	Patrick Ballard, ARO, conducts follow-up to the initial complaint investigation visit on June 24, 2019. No opacity violations were observed during this site visit. Continued surveillance from DAQ personnel when they are in the area is recommended.
October 1, 2020	Patrick Ballard, ARO conducts facility compliance inspection. Facility appeared to be operating in compliance with all permit requirements.
February 10, 2021	Memorandum from Brent Hall, Stationary Source Compliance Branch to Brendan Davey, ARO Supervisor on carbon monoxide emissions testing of Generators EP-1 through EP-7 conducted from September 29 through October 2, 2020 by Grace Consulting, Inc. The emissions test results demonstrated compliance with the applicable regulations.

April 19, 2022 Patrick Ballard, ARO conducts facility compliance inspection. Facility appeared to be operating in compliance with all permit requirements.

In summary, other than a single instance of a required report submitted late, Baxter facility appears to be in compliance with the requirements of its air permit. Continued compliance is expected.

14. Public Notice/EPA and Affected State(s) Review

A notice of the DRAFT Title V Permit shall be made pursuant to 15A NCAC 02Q .0521. The notice will provide for a 30-day comment period, with an opportunity for a public hearing. Consistent with 15A NCAC 02Q .0525, the EPA will have a concurrent 45-day review period. Copies of the public notice shall be sent to persons on the Title V mailing list and EPA. Pursuant to 15A NCAC 02Q .0522, a copy of each permit application, each proposed permit and each final permit shall be provided to EPA. Also, pursuant to 02Q .0522, a notice of the DRAFT Title V Permit shall be provided to each affected State at or before the time notice is provided to the public under 02Q .0521 above.

South Carolina and Tennessee are affected states within 50 miles of the facility, and the Asheville-Buncombe Air Quality Agency is an affected local program within 50 miles of the facility.

Notice of the DRAFT Title V Permit to Affected States ran from XXXX XX, 202X, to XXXX XX, 202X. ***Discuss here any comments received from Affected States or Local Programs.***

Public Notice of the DRAFT Title V Permit ran from XXXX XX, 202X, to XXXX XX, 202X. ***Discuss here any public comments received.***

EPA's 45-day review period ran concurrent with the 30-day Public Notice, from XXXX XX, 202X, to XXXX XX, 202X. ***Discuss here any comments received from the U.S. EPA and EPA Region 4.***

15. Other Regulatory Considerations

The following items were not required in Permit Application No. 5600164.22A:

- Professional Engineer's seal
- Zoning consistency determination
- Permit fee.

16. Recommendations

DAQ has reviewed the permit application for Baxter Healthcare Corporation located in Marion, McDowell County to determine compliance with all procedures and requirements. DAQ has determined that this facility is complying or will achieve compliance, as specified in the permit, with all requirements that are applicable to the affected sources. DAQ recommends the issuance of Air Permit No. 05600T22.