

## Air Permit Review

**Region:** Raleigh Regional Office  
**County:** Wake  
**NC Facility ID:** 9200349  
**Inspector's Name:** Brian Bland  
**Date of Last Inspection:** 09/25/2009  
**Compliance Code:** 3 / Compliance - inspection

**Permit Issue Date:**

<b>Facility Data</b>			<b>Permit Applicability (this application only)</b>
<b>Applicant (Facility's Name):</b> Mallinckrodt Inc  <b>Facility Address:</b> Mallinckrodt Inc 8801 Capital Boulevard Raleigh, NC 27616  <b>SIC:</b> 2833 / Medicinals And Botanicals <b>NAICS:</b> 325411 / Medicinal and Botanical Manufacturing  <b>Facility Classification: Before:</b> Synthetic Minor <b>After:</b> Synthetic Minor <b>Fee Classification: Before:</b> Synthetic Minor <b>After:</b> Synthetic Minor			<b>SIP:</b> 2D .0515, 2D. 0516, 2D. 0521, 2D. 0958 <b>NSPS:</b> 60-Dc, VV, NNN <b>NESHAP:</b> 63-EEE <b>PSD:</b> N/A <b>PSD Avoidance:</b> Yes <b>NC Toxics:</b> Yes <b>112(r):</b> Yes <b>Other:</b> Odors (2D .1806)
<b>Contact Data</b>			<b>Application Data</b>
<b>Facility Contact</b>	<b>Authorized Contact</b>	<b>Technical Contact</b>	<b>Application Number:</b> 9200349.08C <b>Date Received:</b> 10/15/2008 <b>Application Type:</b> Modification <b>Application Schedule:</b> TV-1st Time <b>Existing Permit Data</b> <b>Existing Permit Number:</b> 01479R44 <b>Existing Permit Issue Date:</b> 04/30/2009 <b>Existing Permit Expiration Date:</b> 12/31/2011
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<b>Review Engineer:</b> Fern Paterson, P.E.  <b>Review Engineer's Signature:</b> _____ <b>Date:</b> _____		<b>Comments / Recommendations:</b> Issue 01479T45 <b>Permit Issue Date:</b> _____ <b>Permit Expiration Date:</b> _____	

### I. General Facility Description

The Mallinckrodt Inc. facility located in Raleigh, Wake County, North Carolina, includes a Pharmaceutical Plant and an Imaging Plant. The Pharmaceutical plant manufactures para-aminophenol (PAP) in a continuous chemical process and acetyl-para-aminophenol (APAP) in a batch chemical process. The plant also includes four boilers, including two boilers that burn RCRA-regulated waste, a wastewater pre-treatment plant, and various other ancillary operations that are a potential source of air emissions.

The Imaging Plant produces a full line of imaging agents and delivery systems, radiopharmaceuticals, and urology imaging systems for the diagnosis and treatment of disease. The Imaging Plant includes three small boilers, one generator, and two laboratory hoods that are a potential source of pollution. The manufacturing processes at the Imaging Plant are not air emission sources.

The facility falls under the Standard Industrial Classification (SIC) codes of 2833 for medicinal and botanical manufacturing, 2834 for pharmaceuticals preparation, 2873 for nitrogenous fertilizer manufacturing, 2869 for industrial organic chemical manufacturing, and 2865 for cyclic crudes and intermediates manufacturing.

Mallinckrodt has calculated its facility-wide potential to emit, as summarized in the following table:

<b>Pollutants</b>	<b>Potential to Emit (tpy)</b>
PM (PM/PM-10/PM-2.5)	21.9
SO <sub>2</sub>	261*
NO <sub>x</sub>	185*
CO	78
VOC	47
Individual HAP (Nitrobenzene)	9.5
Total HAP	17.2

*\* The facility is choosing to accept 100 tpy limits for both SO<sub>2</sub> and NO<sub>x</sub> to maintain minor source status under the PSD program pursuant to 15A NCAC 2D .0530.*

## **II. Purpose of the Application – Title V Applicability**

This facility is currently operating under Synthetic Minor Air Quality Permit No. 01479R44, issued on April 30, 2009. Mallinckrodt Inc. elected to limit potential NO<sub>x</sub> and SO<sub>2</sub> emissions to 100 tpy to avoid Title V applicability, and has the potential to emit below Title V major source thresholds for all other pollutants, including HAP.

However, two boilers at the facility (**ID Nos. BH-1 and BH-2**) are permitted to burn aniline still bottoms, which is a RCRA-regulated hazardous waste. The boilers are thereby subject to the area source standards of the Hazardous Waste Combustor (HWC) MACT provided in 15A NCAC 2D .1111 and 40 CFR 63, Subpart EEE. Pursuant to 40 CFR 60.1200(a)(2), “Both area sources and major sources, not previously subject to title V, are immediately subject to the requirement to apply for and obtain a title V permit . . .” Because the MACT standard specifically requires that area sources affected by the HWC MACT obtain a Title V permit pursuant to 40 CFR 60.1200(a)(2), this facility is required to obtain and operate in accordance with a Title V air quality permit according to the procedures in 15A NCAC 2Q .0500.

Mallinckrodt will continue to comply with the NO<sub>x</sub> and SO<sub>2</sub> emissions limitations in order to maintain existing minor source status under the PSD and non-attainment NSR requirements provided in 15A NCAC 2D .0530 and 2D .0531 respectively.

## **III. Statement of Compliance**

The last full inspection of this facility was completed on September 25, 2009 by Mr. Brian Bland of the Raleigh Regional Office (RRO). At this time, Mallinckrodt Inc. appeared to be operating in compliance with applicable requirements. Further, a compliance record review of the past five years did not reveal any Notices of Violation issued to the facility by the NC DAQ.

## **IV. Regulatory Review**

### **A. Process Equipment**

1. 15A NCAC 2D .0524 – 40 CFR 60, Subpart VV, NSPS for Equipment Leaks of VOC from SOCMIFacilities – This regulation is applicable to equipment leaks, and provides inspection and performance standards for various types of potential sources of fugitive VOC emissions. According to the forms provided in the Title V application, this facility has the following types of affected equipment:

#### **PAP Process**

Valves in heavy liquid service – 892

Pumps in heavy liquid service – 18

Connectors (flanges) – 2,454

Agitators – 26

**APAP Process (Associated with the Acetic Acid Evaporator)**

Valves in light liquid service – 348

Pumps in light liquid service – 22

Connectors (flanges) in light liquid service – 821

All affected light liquid service equipment is in acetic acid service. According to a letter submitted from Mr. Kevin Scott, P.E. (Arcadis) to Mr. Charles McEachern (NC DAQ) on behalf of Mallinckrodt, the maximum vapor concentration of acetic acid in air at P = 1 atm and T = 20 degrees C) is approximately 2,000 ppmv. The leak threshold for affected valves and pumps pursuant to 40 CFR 60, Subpart VV is 10,000 ppmv. Using the Ideal Gas Law, ambient temperatures surrounding the affected process lines would have to reach 107 degrees Fahrenheit before reaching the 10,000 ppmv leak threshold.

In accordance with 40 CFR 60.13(i), NC DAQ (Administrator) approved an alternative monitoring procedure for these affected light liquid service, removing the requirement to conduct Method 21 instrument monitoring at the source. NC DAQ believes the use of Method 21 instrument monitoring at the source is ineffective as acetic acid is unlikely to ever reach a concentration 10,000 ppmv around a leaking fugitive source at the conditions at this facility.

As an alternative monitoring procedure, NC DAQ has approved a weekly visual inspection of affected light liquid pumps without any supplemental, monthly instrument monitoring requirements. For affected light liquid valves, NC DAQ has also approved the replacement of the monthly Method 21 inspection requirements with a monthly visual inspection.

The facility does not have any affected compressors, pressure relief devices, sampling connection systems, open-ended valves or lines, or closed-vent systems and control devices. Mallinckrodt did not indicate that it has elected to comply with either the “Allowable Percentage of Valves Leaking” or other alternative standards for valves.

2. 15A NCAC 2D .0524 – 40 CFR 60, Subpart NNN, NSPS for VOC Emissions from SOCOMI Distillation Operations – This regulation is applicable to distillation operations that are part of a process unit that produces any of the chemicals listed in 40 CFR 60.667 as a product, co-product, by-product, or intermediate. The acetic acid evaporator (**ID No. APAP-1**) is an affected source in the APAP process.

All Subpart NNN-regulated distillation units in the PAP production operations are located in Building 201 as part **ID No. PAP-22**. The location of these units in Building 201 has been consistently noted in our semi-annual reports submitted to the NCDAQ Raleigh Regional Office. Also, note that these units fall under the partial exemption in 40 CFR 60.660(c)(4) due to their high TRE values (TRE Index Value >> 8 without the use of controls).

Although emissions from the affected sources at Mallinckrodt are controlled by the use of packed bed scrubbers (absorbers), the use of the scrubbers is not required to maintain a TRE index value of greater than 8.0. Pursuant to 40 CFR 60.660(c)(4), each affected facility that has a total resource effectiveness (TRE) index value greater than 8.0 is exempt from all provisions of the subpart except for 40 CFR 60.662, 40 CFR 60.664 (d), (e), and (f); and 40 CFR 60.665 (h) and (l). The facility is demonstrating compliance with 40 CFR 60.662 by maintaining a TRE index value greater than 1.0 for each of the affected sources (**ID Nos. PAP-22 and APAP-1**) without use of VOC emission control devices

While the existing synthetic minor permit (No. 01479R37) indicates that Subpart NNN applies to ID No. PAP-23, there are no continuous distillation units in this process area, and it is unaffected by this subpart.

**B. Drying, Sizing, Packaging, and Housekeeping Equipment**

1. 15A NCAC 2D .0515: PARTICULATES FROM MISCELLANEOUS INDUSTRIAL PROCESSES – This regulation limits allowable particulate matter emissions from any stack, vent, or outlet of any industrial process for which no other emissions control standards apply based on the process weight rate.

Each of the potential sources of particulate matter listed in this section are controlled by fabric filters. In addition, each source has a maximum product throughput of less than 30 tons per hour.

For process weights less than or equal to 60,000 pounds per hour (30 tons per hour), allowable PM emissions are limited as follows:

$$E = 4.10 * P^{(0.67)}$$

where: E = allowable PM emission rate in pounds per hour, and  
P = process weight in tons per hour

No monitoring, recordkeeping, or reporting is required to demonstrate compliance with this particulate matter standard for pneumatic conveyor systems (**ID Nos. APAP-8, APAP-17, APAP-18, and APAP-21**) or APAP sources equipped with broken bag detectors (**ID Nos. APAP-2, APAP-3, APAP-10, APAP-11, and APAP-12**).

To assure compliance with the remaining PAP sources, the permit requires the Permittee to perform inspections and maintenance as recommended by the manufacturer. In addition to the manufacturer's inspection and maintenance recommendations, or if there is no manufacturer's inspection and maintenance recommendations, as a minimum, the Permittee will be required to conduct a monthly visual inspection of the system ductwork and material collection unit for leaks and an annual (for each 12 month period following the initial inspection) internal inspection of the bagfilters' and dust collection system's structural integrity.

2. 15A NCAC 2D .0521: CONTROL OF VISIBLE EMISSIONS – This regulation limits allowable visible emissions from any industrial process where a visible emission can reasonably be expected to occur to no more than 20 percent opacity when averaged over a 6-minute period, except that 6-minute periods averaging more than 87 percent opacity may occur not more than once in any hour not more than four times in any 24-hour period. Each of the potential sources of particulate matter is a potential source of visible emissions. Each such source listed in this section is controlled by a fabric filter.

No monitoring, recordkeeping, or reporting will be required to demonstrate compliance with the pneumatic systems (**ID Nos. APAP-8, APAP-17, APAP-18, and APAP-21**), which are used to transport valuable product, or the APAP sources (**ID Nos. APAP-2, APAP-3, APAP-10, APAP-11, and APAP-12**), which are equipped with bag leak detectors.

*Monitoring.* To demonstrate compliance with this standard for the PAP sources, the permit will require monthly visible emissions observations of each affected exhaust point, to check for visible emissions above "normal". The Permittee shall be required to establish what constitutes "normal" emissions within 30 days of permit issuance.

### C. Miscellaneous Storage, Loading, and Unloading Operations

These sources are only affected by facility-wide requirements, including VOC work practice standards and TAP limitations. See Section F of this review for information of facility-wide applicable standards.

### D. Combustion Sources

1. 15A NCAC 2D .0503 – Particulates from Fuel Burning Indirect Heat Exchangers – This regulation limits particulate matter (PM) emissions from the firing of fuel in indirect heat exchangers (in lb/mmBtu) based on the facility-wide heat input in accordance with the following equation:

$$E = 1.090(Q)^{-0.2594}$$

Where: E = Allowable emission limit for PM (in lb/mmBtu); and  
Q = Maximum heat input in mmBtu/hr

The PM limits in the existing synthetic minor permit were carried over to the proposed Title V permit. Using AP-42 emission factors, PM emissions from the worst-case fuel (No. 2 fuel oil) are estimated to be less than 0.03 lb/mmBtu, as follows:

$$\frac{\left( 2 \frac{\text{lbPM}_{\text{filterable}}}{1,000 \text{ gal}} + 1.3 \frac{\text{lbPM}_{\text{condensable}}}{1,000 \text{ gal}} \right)}{140 \frac{\text{mmBtu}}{1,000 \text{ gal}}} = 0.023 \frac{\text{lbPM}_{\text{total}}}{\text{mmBtu}}$$

Because worst-case PM emission rates are estimated to be less than the allowable PM emission rates, no monitoring, recordkeeping, or reporting shall be required to demonstrate compliance with this limitation.

2. 15A NCAC 2D .0516– Sulfur Dioxide Emissions From Combustion Sources – This regulation limits sulfur dioxide (SO<sub>2</sub>) emissions to no greater than 2.3 lb/mmBtu of heat input for combustion sources. The boilers are affected by this rule.

The worst-case fuel, No. 2 fuel oil, has a sulfur content far below 2.1 percent by weight. As shown in the following calculations based on AP-42 emission factors, combustion of No. 2 fuel oil with a sulfur content of less than 2.1 percent by weight results in sulfur dioxide emissions less than the allowable limit:

*No. 2 Fuel Oil:*

$$142(2.1) \text{ lb SO}_2/1,000 \text{ gal} / 140 \text{ mmBtu}/1,000 \text{ gal} = 2.1 \text{ lb SO}_2/\text{mmBtu}$$

Because worst-case SO<sub>2</sub> emission rates are estimated to be less than the allowable SO<sub>2</sub> emission rates, no monitoring, recordkeeping, or reporting shall be required to demonstrate compliance with this limitation.

3. 15A NCAC 2D .0521 – Control of Visible Emissions – VE standards provided in this regulation are applicable to potential VE emissions from any stack, vent, or outlet that is not affected by another standard. The boilers are affected by this rule, which limits visible emissions to no more than 20 percent opacity when averaged over a 6-minute period, except that 6-minute periods averaging more than 87 percent opacity may occur not more than once in any hour not more than four times in any 24-hour period.

No monitoring, recordkeeping, or reporting is required to demonstrate compliance with this standard while firing natural gas, No. 2 fuel oil, or K-083 liquid waste.

4. 15A NCAC 2D .0524 – 40 CFR 60, Subpart Dc, NSPS for Small Industrial-Commercial-Institutional Steam Generating Units – This regulation is applicable to boilers that commenced construction, reconstruction, or modification after June 9, 1989 AND that have a maximum heat input capacity equal to or greater than 10 million Btu per hour and less than or equal to 100 million Btu per hour (i.e., 10 mmBtu/hr  $\leq$  Q  $\leq$  100 mmBtu/hr). Only one boiler at this facility (**ID No. BH-5**)

*NSPS-affected boilers are subject to the following standards and requirements, in addition to the SIP requirements described above:*

- Sulfur Dioxide. The maximum sulfur content of any fuel oil received and fired in the Subpart Dc-affected boiler shall not exceed 0.5 percent by weight. To demonstrate compliance with this standard, the Permittee is required to retain copies of each fuel supplier certification, including the sulfur content of the oil (in percent by weight). The Permittee is also required to submit a semiannual report summarizing the monitoring activities (January 30<sup>th</sup> and July 30<sup>th</sup>).
- Visible Emissions. For any Subpart Dc-affected boiler with a maximum heat input capacity of greater than or equal to 30 mmBtu/hr, visible emissions 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. To demonstrate compliance with this standard, the Permittee is required to conduct a

Method 9 test (6-minute average of 24 observations) to determine the opacity of stack emissions within 60 days of installing any temporary, back-up boiler subject to the opacity limitation.

The Permittee is also required to keep a monthly record of the quantity of each fuel fired in the back-up boilers pursuant to 40 CFR 60.48c(g)(2), as follows:

*“As an alternative to meeting the requirements of paragraph (g)(1) of this section, the owner or operator of an affected facility that combusts only natural gas, wood, fuels using fuel certification in §60.48c(f) to demonstrate compliance with the SO<sub>2</sub> standard, fuels not subject to an emissions standard (excluding opacity), or a mixture of these fuels may elect to record and maintain records of the amount of each fuel combusted during each calendar month.”*

In addition, pursuant to 40 CFR 60.7(a)(3) the Permittee is required to submit a written notification of the actual date of initial startup of any NSPS-affected temporary boilers (**ID Nos. ES01-Temp and ES02-Temp**) within 15 days of such date. This notification shall be submitted to the NC DAQ Regional Supervisor.

5. 15A NCAC 2D .1111 – 40 CFR 63, Subpart EEE – MACT for HAZARDOUS WASTE COMBUSTORS

- a. The Permittee shall comply with all applicable provisions, including the notification, testing, recordkeeping, and monitoring requirements contained in Environmental Management Commission Standard 15A NCAC 2D .1111, “Maximum Achievable Control Technology” (MACT), as promulgated in 40 CFR 63, Subpart GGGGG, “National Emission Standards for Hazardous Air Pollutants: Site Remediation”, including Subpart A, “General Provisions”, for the affected sources.

This MACT has both area and major source standards for sources that burn hazardous waste, as defined in 40 CFR 261.3. Mallinckrodt is an area source of hazardous air pollutants (HAP), with the potential to emit less than 10 tpy of all individual HAPs and less than 25 tpy of all HAPs combined. Mallinckrodt has two boilers (**ID Nos. BH-1 and BH-2**) that burn a liquid aniline waste product (K-083) that meets the definition of a hazardous waste.

The heat content of the aniline waste is greater than 10,000 Btu/lb. Mallinckrodt uses a statistical methodology, as described in the feedstream analysis plan (FAP) to determine the heat content of the waste stream. The K-083 aniline tar is generated on-site from a production process that does not vary appreciably, and the heat content is relatively consistent. The historical variability of the heat content of the tar based on 129 analyses is a minimum of 12,000 Btu/lb and a maximum of 16,000 Btu/lb with an average value of approximately 14,000 Btu/lb (standard deviation = 762 Btu/lb). NC DAQ is not requiring a batch-by-batch analysis of the heat content of each individual batch.

The boilers will be controlled by a cloud chamber system (CCS), which is a patented process designed and constructed by Tri-Mer Corporation. The CCS includes the following:

- A quench system that cools the combustion gases to avoid damaging plastic components in the control device.
- A preconditioning chamber in which the quenched combustion gas stream will flow countercurrent to the downflow of water. The purpose of the preconditioning chamber is to further reduce the combust gas temperature, remove the majority of entrained coarse particulate matter, begin removing acid gases (including HCl and SO<sub>2</sub>), and “grow” the size of the ultra fine particulates.
- Two Cloud Generation Vessels oriented in series. Each vessel injects scrubber water to control acid gases and creates an electrostatic field to control particulate emissions. The chambers work by charging the water droplets in the electrostatic field. The droplets entrain both neutral and charged particulate and are then collected by gravity at the bottom of the cloud chamber. Unlike an electrostatic precipitator (ESP), there is little to no particle charging in the chamber, reducing the detrimental corona discharging effects. The cloud chamber operates with a very consistent charging voltage as opposed to the cyclical charging voltage of a typical ESP.
- A chevron-type mist eliminator.

- An induced draft fan.
- A stack (approximate 50 ft. height).

All liquid purge streams from the CCS will be routed to a blowdown tank, through a solids recovery filters, and on to the City of Raleigh publicly-owned treatment works (POTW). Scrubbed air is emitted after passing through a mist eliminator.

These boilers are affected by the standards for existing liquid fuel burners that burn hazardous waste, as provided in 40 CFR 63.1217(a), as follows:

- **Dioxins/Furans (D/F)** – Sources with wet control systems, such as the cloud chamber system, are not given a numerical D/F standard, but instead are required to demonstrate compliance with either the carbon monoxide (CO) or total hydrocarbon (THC) standard. Mallinckrodt has chosen to demonstrate compliance with the CO standard, as discussed below.
- **Mercury (Hg)** –  $4.2 \times 10^{-5}$  lbs/MMBtu on an annual averaging period
- **Cadmium & Lead, Combined** –  $8.2 \times 10^{-5}$  lbs/MMBtu on an annual averaging period\*
- **Chromium** –  $1.3 \times 10^{-4}$  lbs/MMBtu\*
- **CO or THC** – Affected sources can choose to comply with either a CO or THC standard. Mallinckrodt has chosen to comply with the CO standard of 100 ppmdv (7% oxygen) on a one hour basis, as measured by a CEMS.
  - Facilities choosing this option are also required to test the THC emission rate during DRE test runs to show that it is less than 10 ppmdv (7% oxygen), reported as propane, and on a hourly, rolling basis. Compliance with the THC limit is demonstrated by the highest hourly rolling average emission rate achieved during the DRE test runs, as provided in 40 CFR 60.1206(b)(6)(i). Mallinckrodt satisfied this THC testing requirement in its initial DRE testing conducted in September 2004. No further THC testing is required, unless additional DRE testing is required. The 2004 testing showed that, in six runs, the average THC emission rate did not exceed 2 ppmdv.
- **Hydrogen Chloride and Chloride** –  $5.1 \times 10^{-2}$  lbs/MMBtu\*
- **Particulate Matter** – 80 mg/dscm, corrected to 7% oxygen\*

\* These standards apply to Mallinckrodt, an area source of HAP, pursuant to 40 CFR 63.1217(f).

These boilers are also affected by the standard for existing liquid fuel burners that burn hazardous waste, as provided in 40 CFR 63.1217(c)(1), as follows:

- **Destruction Removal Efficiency (DRE)** – At least 99.99% by weight for each principle organic hazardous constituent (POHC) in the waste material.
  - The Permittee demonstrated compliance with this standard during a September 2004 performance test. No further compliance demonstration is required, provided the Permittee does not modify the design or operation of the sources in a manner that could affect the ability to achieve the standard, as provided in 40 CFR 63.1206(b)(7)(i).

## E. Generators

1. 15A NCAC 2D .0516– Sulfur Dioxide Emissions From Combustion Sources – This regulation limits sulfur dioxide (SO<sub>2</sub>) emissions to no greater than 2.3 lb/mmBtu of heat input for combustion sources. The boilers are affected by this rule.

The worst-case fuel, No. 2 fuel oil, has a sulfur content far below 2.1 percent by weight. Because worst-case SO<sub>2</sub> emission rates are estimated to be less than the allowable SO<sub>2</sub> emission rates, no monitoring, recordkeeping, or reporting shall be required to demonstrate compliance with this limitation.

2. 15A NCAC 2D .0521 – Control of Visible Emissions – VE standards provided in this regulation are applicable to potential VE emissions from any stack, vent, or outlet that is not affected by another standard. The boilers are affected by this rule, which limits visible emissions to no more than 20 percent opacity

when averaged over a 6-minute period, except that 6-minute periods averaging more than 87 percent opacity may occur not more than once in any hour not more than four times in any 24-hour period.

No monitoring, recordkeeping, or reporting is required to demonstrate compliance with this standard while firing natural gas or No. 2 fuel oil.

3. 15A NCAC 2D .1111 – 40 CFR 63, Subpart ZZZZ – MACT for STATIONARY RECIPROCATING INTERNAL COMBUSTION ENGINES – This MACT has both area and major source standards for stationary reciprocating internal combustion engines (RICE), including emergency generators. The emergency generators at this facility, which was constructed prior to June 12, 2006, are classified as existing sources. Pursuant to 40 CFR 63.6590(b)(3), existing emergency stationary RICE do not have any applicable requirements under the rule. No initial notification for is necessary for these source.

**F. Facility-Wide Applicable Limits**

1. 15A NCAC 2Q .0317: AVOIDANCE CONDITIONS for 15A NCAC 2D .0530: PREVENTION OF SIGNIFICANT DETERIORATION

Mallinckrodt is located in Wake County, which is currently designated as attainment or unclassified for all PSD regulated pollutants. The facility is a chemical processing plant, which is one of the 28 listed source categories with major source thresholds of 100 tpy. Mallinckrodt has the potential to emit greater than 100 tpy of both nitrogen oxides (NOx) and sulfur dioxide (SO<sub>2</sub>). However, it is requesting a facility-wide 100 tpy emissions limitation for both pollutants to maintain minor source status.

In the existing synthetic minor permit, there are two existing PSD avoidance conditions limiting facility-wide SO<sub>2</sub> emissions to less than 100 tpy and NOx emissions to less than 101.73 tpy. These limits are replaced by the limits in the proposed permit.

The combustion sources, including the Pharmaceutical and Medical Imaging Plant boilers and generators and the wastewater plant generator, are the only source of NOx and SO<sub>2</sub> emissions at the facility. The permit requires monthly emissions calculations from the combustion sources, and specifies higher heating values and emission factors that should be used to demonstrate compliance with the two emissions limitations.

All emissions factors are based on USEPA AP-42 emission factors except for aniline tar and landfill gas factors and NOx emissions factors for Boiler Nos. BH-1, BH-2, BH-3, BH-5 (fuel oil only).

2. 15A NCAC 2D .1100: CONTROL OF TOXIC AIR POLLUTANTS (State-Enforceable Only)  
The facility has existing TAP emissions limitations based on previously submitted compliance demonstrations consistent with the requirements in 15A NCAC 2D .1100. The limits in this proposed Title V permit are consistent with the limits in the existing permit. Mallinckrodt submitted its most recent TAP compliance demonstration for aniline, benzene, chlorine, chromium 5, and hydrogen chloride with the modification to add CCS system and revise the emission factors for landfill gas (Permit No. 01479R43). The modeling was approved in a memo from Tom Anderson (NC DAQ – AQAB) dated February 7, 2008. All toxics were below their respective AALs.

3. 15A NCAC 2Q .1100: TOXIC AIR POLLUTANT EMISSION RATES REQUIRING A PERMIT (State-Enforceable Only)

The facility has the potential to emit various TAP emissions, but is currently emitting the pollutants at below *de minimus* thresholds, as listed in the following table:

Pollutant	Carcinogens (lb/yr)	Chronic Toxicants (lb/day)	Acute Systemic Toxicants (lb/hr)	Acute Irritants (lb/hr)
Benzo(a)pyrene (Component of 83329/POMTV & 56553/7PAH) (50-32-8)	2.2			

Pollutant	Carcinogens (lb/yr)	Chronic Toxicants (lb/day)	Acute Systemic Toxicants (lb/hr)	Acute Irritants (lb/hr)
Cadmium Metal (elemental unreacted, Component of CDC) (7440-43-9)	0.37			
Carbon disulfide (75-15-0)		3.9		
Formaldehyde (50-00-0)				0.04
Manganese & compounds (MNC)		0.63		
Mercury, vapor (Component of HGC) (7439-97-6)		0.013		
Methylene chloride (75-09-2)	1,600		0.39	
Nickel metal (Component of 373024/NIC) (7440-02-0)		0.13		
Polychlorinated biphenyls (PCB) (1336-36-3)	5.6			
Toluene (108-88-3)		98		14.4

The Permittee shall not exceed the *de minimus* emission rates listed above without first obtained a modification to its air quality permit in accordance with the procedures in 15A NCAC 2D .1100.

4. 15A NCAC 2D .0958: WORK PRACTICES FOR SOURCES OF VOLATILE ORGANIC COMPOUNDS – This regulation specifies work practices (e.g., material storage, handling, and cleaning procedures) and associated recordkeeping/monitoring requirements to reduce VOC emissions for all sources that use VOCs as solvents, carriers, material processing media, or industrial chemical reactants, or in similar uses that mix, blend, or manufacture VOCs, or emit VOCs as a product of chemical reactions, and whose emissions of VOC are greater than 15 pounds per day.
5. 15A NCAC 2D .1806: CONTROL AND PROHIBITION OF ODOROUS EMISSIONS (State-Enforceable Only) – This standard forbids the Permittee from operating the manufacturing operations without implementing management practices or installing and operating odor control equipment sufficient to prevent odorous emissions from the facility from causing or contributing to objectionable odors beyond the facility's boundary.

**G. Non-Applicable Regulations**

1. 15A NCAC 2D .1111: Maximum Available Control Technology (MACT) – 40 CFR 63, Subparts F, G, and H (The “HON”)  
This facility is a minor source of hazardous air pollutants (HAP), with the potential to emit less than 10 tpy of all individual HAPs and less than 25 tpy of all HAPs combined. The HON requirements in 40 CFR 63, Subpart F, G, and H would affect the PAP and APAP processes if the facility became a major source of HAP. The facility is subject to the area source standards in the Hazardous Waste Combustor MACT pursuant to 40 CFR 63, Subpart EEE.
2. 15A NCAC 2D .1111: Maximum Available Control Technology (MACT) – 40 CFR 63, Subpart VVVVVV (Chemical Manufacturing Area Sources)  
This facility is a minor source of hazardous air pollutants (HAP), with the potential to emit less than 10 tpy of all individual HAPs and less than 25 tpy of all HAPs combined. On October 29, 2009, U.S. EPA promulgated 40 CFR 63, Subpart VVVVVV, an area source MACT for chemical manufacturing areas. The facility is not subject to this MACT because it does not use as a feedstock, generate as a byproduct, or produce as a product any of the HAP listed in Table 1 of the standard, as follows:

- 1,3-butadiene
- 1,3-dichloropropene
- Acetaldehyde
- Chloroform
- Ethylene dichloride
- Hexachlorobenzene
- Methylene chloride
- Quinoline
- Arsenic compounds
- Cadmium compounds
- Chromium compounds
- Lead compounds
- Manganese compounds
- Nickel compounds
- Hydrazine

3. 15A NCAC 2D .0948: VOC from Transfer Operations

This standard requires submerged loading for any loading operation that loads more than 20,000 gallons per day of VOCs with a vapor pressure of 1.5 pounds per square inch or greater under actual conditions. This standard does not apply to the acetic acid loading operation (**ID No. APAP-7**) because acetic acid has a vapor pressure of 0.167 psi at 60 degree F. It does not apply to the aniline loading operations (**ID Nos. PAP-25T & PAP-25R**) because aniline has a vapor pressure of 0.006 psi at 60 degrees F.

**V. Other Regulatory Considerations**

- No application fee is required for this application.
- The Reduction and Recycling Form was received on October 14, 2008.
- A Professional Engineers Seal is not required for this application.
- A zoning consistency determination is not required for this application.
- Public notice and U.S. EPA review is required for this initial Title V air quality permit.

**VI. Draft Permit Review Summary**

Mr. Brian Bland of the Raleigh Regional Office (RRO) was provided a draft permit and permit review document for review on November 3, 2009.

Mr. Tim Roberts of Mallinckrodt Inc. and Mr. Kevin Scott of Arcadis were provided a draft permit and permit review document for review on November 3, 2009.

Ms. Katy Forney and Ms. Gracy DeNois (U.S. EPA, Region IV) were provided a draft permit for review on **<ENTER DATE/SUMMARY>**

**VII. Recommendations**

This permit modification application for the Mallinckrodt Inc. facility, located in Raleigh, Wake County, North Carolina, has been reviewed by NC DAQ to determine compliance with all procedures and requirements. NC DAQ has determined that this facility appears to be complying or will achieve compliance as specified in the permit with all applicable requirements.

**Issue Permit No. 01479T45**