Tyco Healthcare Kendall (dba Covidien)
DeLand Manufacturing Facility
Facility ID No. 1270094
Volusia County

Title V Air Operation Permit Revision

Permit No. 1270094-016-AV
(Revision to Title V Air Operation Permit No. 1270094-013-AV)

Permitting Authority:

State of Florida
Department of Environmental Protection
Air Resource Management, Central District

3319 Maguire Boulevard, Suite 232
Orlando, Florida 32803-3767

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Department of Environmental Protection
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DRAFT/PROPOSED PERMIT

PERMITTEE:
Tyco Healthcare Kendall (dba Covidien)
2010 East International Speedway Blvd.
DeLand, Florida 32724

Permit No. 1270094-016-AV
DeLand Manufacturing Facility
Facility ID No. 1270094
Title V Air Operation Permit Revision

The purpose of this permit is to revise the Title V air operation permit for the above referenced facility. The existing DeLand Manufacturing Facility is located in Volusia County at 2010 East International Speedway Boulevard, DeLand, Florida. UTM Coordinates are: Zone 17, 474.17 East and 3214.85 North. Latitude is: 29˚03'42.25" North; and, Longitude is: 81˚15'55.31" West.

The Title V air operation permit is issued under the provisions of Chapter 403, Florida Statutes (F.S.), and Florida Administrative Code (F.A.C.) Chapters 62-4, 62-210, 62-213. The above named permittee is hereby authorized to operate the facility in accordance with the terms and conditions of this permit.

Effective Date: TBD
Renewal Application Due Date: TBD
Expiration Date: TBD

(Draft/Proposed)

_____

Caroline D. Shine
Air Program Administrator

CDS/jr/ngm

Subsection A. Facility Description.

The facility consists of needle manufacturing operations that contain the following processes: needle lube mixing, grinding, needle assembly, sterilization, packaging, prototypical equipment testing, and medivative machine operations. The medivative machine produces adult and pediatric needle cartridges for a hand held administration system. The grinding area has a cyclone, wet scrubber, and Trimmer wet scrubber.

Subsection B. Summary of Emissions Units.

EU No.	Brief Description
Regulated Emissions Units	
009	Needle Manufacturing including Medivative Machine
010	Grinding Operations

Subsection C. Applicable Regulations.

Based on the Title V air operation permit revision application received June 20, 2012, this facility **is a major** source of hazardous air pollutants (HAP).

A summary of applicable regulations is shown in the following table.

Regulation	EU No(s).
State Rule Citations: 62-210.300, F.A.C. 62-296.320, F.A.C. 62-213, F.A.C.	-All

The following conditions apply facility-wide to all emission units and activities:

FW1. Appendices. The permittee shall comply with all documents identified in Section IV, Appendices, listed in the Table of Contents. Each document is an enforceable part of this permit unless otherwise indicated. [Rule 62-213.440, F.A.C.]

Emissions and Controls

FW2. Not federally Enforceable. Objectionable Odor Prohibited. No person shall cause, suffer, allow or permit the discharge of air pollutants, which cause or contribute to an objectionable odor. An "objectionable odor" means any odor present in the outdoor atmosphere which by itself or in combination with other odors, is or may be harmful or injurious to human health or welfare, which unreasonably interferes with the comfortable use and enjoyment of life or property, or which creates a nuisance. [Rule 62-296.320(2) and 62-210.200(Definitions), F.A.C.]

FW3. General Volatile Organic Compounds (VOC) Emissions or Organic Solvents (OS) Emissions. The permittee shall allow no person to store, pump, handle, process, load, unload or use in any process or installation, volatile organic compounds or organic solvents without applying known and existing vapor emission control devices or systems deemed–necessary and ordered by the Department. To comply, procedures to minimize pollutant emissions shall include the following:

a. tightly cover or close all VOC containers when they are not in use,
b. tightly cover, where possible, all open troughs, basins, baths, tanks, etc. when they are not in use,
c. maintain all piping, valves, fittings, etc. in good operating condition,
d. prevent excessive air turbulence across exposed VOC's, and
e. immediately confine and clean up VOC spills and make sure certain wastes are placed in closed containers for reuse, recycling or proper disposal.

[Rule 62-296.320(1), F.A.C.]

FW4. General Visible Emissions. No person shall cause, let, permit, suffer or allow to be discharged into the atmosphere the emissions of air pollutants from any activity equal to or greater than 20% opacity. EPA Method 9 is the method of compliance pursuant to Chapter 62-297, F.A.C. This regulation does not impose a specific testing requirement. [Rule 62-296.320(4)(b)1, F.A.C.]

FW5. Unconfined Particulate Matter. No person shall cause, let, permit, suffer or allow the emissions of unconfined particulate matter from any activity, including vehicular movement; transportation of materials; construction; alteration; demolition or wrecking; or industrially related activities such as loading, unloading, storing or handling; without taking reasonable precautions to prevent such emissions. [Rule 62-296.320(4)(c), F.A.C.]

Annual Reports and Fees

See Appendix RR, Facility-wide Reporting Requirements for additional details.

FW6. Annual Operating Report. The permittee shall submit an annual report that summarizes the actual operating rates and emissions from this facility. Annual operating reports shall be submitted to the Compliance Authority by April 1st of each year. [Rule 62-210.370(3), F.A.C.]

FW7. Annual Emissions Fee Form and Fee. The annual Title V emissions fees are due (postmarked) by March 1st of each year. The completed form and calculated fee shall be submitted to: Major Air Pollution Source Annual Emissions Fee, P.O. Box 3070, Tallahassee, Florida 32315-3070. The forms are available for download by accessing the Title V Annual Emissions Fee On-line

Information Center at the following Internet web site: http://www.dep.state.fl.us/air/emission/tvfee.htm. [Rule 62-213.205, F.A.C.]

FW8. Annual Statement of Compliance. The permittee shall submit an annual statement of compliance to the compliance authority at the address shown on the cover of this permit within 60 days after the end of each calendar year during which the Title V permit was effective. [Rules 62-213.440(3)(a)2. & 3. and (3)(b), F.A.C.]

FW9. Prevention of Accidental Releases (Section 112(r) of CAA). If and when the facility becomes subject to 112(r), the permittee shall:

a. Submit its Risk Management Plan (RMP) to the Chemical Emergency Preparedness and Prevention Office (CEPPO) RMP Reporting Center. Any Risk Management Plans, original submittals, revisions or updates to submittals, should be sent to: RMP Reporting Center, Post Office Box 10162, Fairfax, VA 22038, Telephone: (703) 227-7650.

b. Submit to the permitting authority Title V certification forms or a compliance schedule in accordance with Rule 62-213.440(2), F.A.C.

[40 CFR 68]

The specific conditions in this section apply to the following emissions units:

EU No.	Brief Description
-009	The Needle Manufacturing including Medivative Machine consists of needle lube mixing, needle assembly, sterilization, packaging, prototypical equipment testing, and medivative machine operations. The process uses a Loctite adhesive along with a hexane lubricant during manufacturing. The specific processes contained within the Medivative Machine include: – Plasma Treater/Cannula – Deionizer/Adhesive Introduction – UV Cure (Med-UV01 Exhaust System) – Lube Injection (NL03 Exhaust System) – Occlusion Test Two of the processes, UV Cure and Lube Injection, exhaust to the atmosphere. The UV Cure exhausts through the Med-UV01 Exhaust System and the Lube Injection exhausts through the NL03 Exhaust System. The plasma treater is an Enercon machine that does not release any pollutants.
-010	The Grinding Area includes wet blast, grit blast, and electrolytic grinding operations.

Essential Potential to Emit (PTE) Parameters

A.1. Hours of Operation. These emissions units may operate continuously (8,760 hours/year). [Rule 62-210.200(PTE), F.A.C., Permit No. 1270094-014-AC]

Emission Limitations and Standards

A.2. Visible Emissions. Visible emissions are limited to less than 20 percent opacity. [Rule 62-296.320(4)(b)1., F.A.C.]

A.3. Emission Limitations. The total **facility-wide** VOC and HAP emission operation limits are as follows:

Pollutant	Emission Limits (tons/any consecutive 12 month period)
Total Volatile Organic Compounds (VOCs)	75.0
Total Hazardous Air Pollutants (HAPs)	less than 60.0
Individual Hazardous Air Pollutants (HAPs)	less than 60.0

[Permit Application dated 06/20/2012; Rules 62-210.200(PTE) and 62-210.300(2)(a)1, F.A.C.]

Recordkeeping and Reporting Requirements

A.4. Monthly Recordkeeping Requirements. In order to demonstrate compliance with Specific Condition No. **A.3.,** the permittee shall maintain monthly records to support the VOC/HAP usage and emissions. At a minimum, the logs shall contain the following:

a. Monthly Records

1) Date (Month and Year);
2) The usage of all lubricants, solvents, and adhesives containing VOCs and HAPs
3) The total VOC content and total HAP content of each lubricant and adhesive;
4) The total of VOC/HAP emissions for each month; and
5) The cumulative 12-month running total of VOC/HAP emissions to ensure the annual VOC/HAP emission limits are not exceeded.

Supporting documentation may consist of "As Supplied" sheets, MSDS sheets, EPA data sheets, purchase orders, waste shipment/disposal records, etc. that includes information to determine VOC and HAP emissions.

All records shall include the Facility Name, Facility ID No. (1270094), Emission Unit ID No., and the Date. **Monthly records shall be completed by the end of the following month.** [Rule 62-4.070(3), F.A.C.]

A.5. Other Reporting Requirements. See Appendix RR, Facility-Wide Reporting Requirements, for additional reporting requirements.

SECTION IV. APPENDICES.

The Following Appendices Are Enforceable Parts of This Permit:

Appendix A, Glossary.
Appendix I, List of Insignificant Emissions Units and/or Activities.
Appendix RR, Facility-wide Reporting Requirements.
Appendix TV, Title V General Conditions.