



**FLORIDA DEPARTMENT OF
ENVIRONMENTAL PROTECTION**

CENTRAL DISTRICT
3319 MAGUIRE BOULEVARD, SUITE 232
ORLANDO, FLORIDA 32803

RICK SCOTT
GOVERNOR

HERSCHEL T. VINYARD JR.
SECRETARY

Electronically Sent- Received Receipt Requested
michael.mcgrew@covidien.com

Mr. Michael McGrew, Plant Manager
Covidien, LP
2010 International Speedway Boulevard
DeLand, Florida 32724-2010

Re: Project No. 1270094-017-AC
Covidien, LP, DeLand Facility
Major Source Air Construction Permit

Dear Mr. McGrew:

On January 2, 2014, you submitted an application requesting authorization for construction of a new process line to allow for production of medical device needles at the Covidien, LP, DeLand facility. The facility is located in Volusia County at 2010 International Speedway Boulevard, DeLand Florida. Enclosed are the following documents: the Technical Evaluation and Preliminary Determination; the Draft Permit and Appendices; the Written Notice of Intent to Issue Air Permit; and the Public Notice of Intent to Issue Air Permit. The Public Notice of Intent to Issue Air Permit is the actual notice that you must have published in the legal advertisement section of a newspaper of general circulation in the area affected by this project. Please provide proof of publication to the Department at the above address within 7 days of publication.

Please review the draft permit. If you have any comments, recommended changes, or need further information, please contact the project engineer, Stephen Amirault, at (407) 897-2942 or at stephen.amirault@dep.state.fl.us.

Sincerely,

A handwritten signature in cursive script, reading 'F. Thomas Lubozynski'. The signature is written in black ink and is positioned above a horizontal line.

F. Thomas Lubozynski, P.E.
Waste and Air Resource Programs Administrator

Enclosures

1. Written Notice of Intent to Issue Air Permit
2. Public Notice of Intent to Issue Air Permit
3. Draft Permit including Appendices
4. Technical Evaluation and Preliminary Determination

WRITTEN NOTICE OF INTENT TO ISSUE AIR PERMIT

*In the Matter of an
Application for Air Permit by:*

Covidien, LP
2010 International Speedway Boulevard
DeLand, Florida 32724-2010

Project No. 1270094-017-AC
Major Source Air Construction Permit
Volusia County, Florida

Covidien, LP, DeLand Facility
Project: Install new process line

Authorized Representative:
Mr. Michael McGrew, Plant Manager

Facility Location: Covidien, LP operates the existing DeLand Facility, which is located in Volusia County at 2010 International Speedway Boulevard, DeLand, Florida.

Project: The applicant proposes to construct and install a new process line to allow for production of medical device needles. Details of the project are provided in the application and the enclosed Technical Evaluation and Preliminary Determination.

Permitting Authority: Applications for air construction and operation permits are subject to review in accordance with the provisions of Chapter 403, Florida Statutes (F.S.) and Chapters 62-4, 62-210, and 62-212 of the Florida Administrative Code (F.A.C.). The proposed project is not exempt from air permitting requirements and an air permit is required to perform the proposed work. The Permitting Authority responsible for making a permit determination for this project is the Department of Environmental Protection's Waste & Air Resource Programs in the Central District Office. The Permitting Authority's physical address is: 3319 Maguire Blvd., Ste. 232, Orlando, Florida 32803-3767. The Permitting Authority's mailing address is: 3319 Maguire Blvd., Ste. 232, Orlando, Florida 32803-3767. The Permitting Authority's telephone number is 407/897-4100.

Project File: A complete project file is available for public inspection during the normal business hours of 8:00 a.m. to 5:00 p.m., Monday through Friday (except legal holidays), at address indicated above for the Permitting Authority. The complete project file includes the Draft Permit, the Technical Evaluation and Preliminary Determination, the application, and the information submitted by the applicant, exclusive of confidential records under Section 403.111, F.S. Interested persons may contact the Permitting Authority's project review engineer for additional information at the address or phone number listed above. In addition, electronic copies of these documents are available on the following web site:
<http://www.dep.state.fl.us/air/emission/apds/default.asp>.

Notice of Intent to Issue Permit: The Permitting Authority gives notice of its intent to issue an air permit to the applicant for the project described above. The applicant has provided reasonable assurance that operation of the proposed equipment will not adversely impact air quality and that the project will comply with all appropriate provisions of Chapters 62-4, 62-204, 62-210, 62-212, 62-296, and 62-297, F.A.C. The Permitting Authority will issue a Final Permit in accordance with the conditions of the proposed Draft Permit unless a timely petition for an

WRITTEN NOTICE OF INTENT TO ISSUE AIR PERMIT

administrative hearing is filed under Sections 120.569 and 120.57, F.S. or unless public comment received in accordance with this notice results in a different decision or a significant change of terms or conditions.

Public Notice: Pursuant to Section 403.815, F.S. and Rules 62-110.106 and 62-210.350, F.A.C., you (the applicant) are required to publish at your own expense the enclosed Public Notice of Intent to Issue Air Permit (Public Notice). The Public Notice shall be published one time only as soon as possible in the legal advertisement section of a newspaper of general circulation in the area affected by this project. The newspaper used must meet the requirements of Sections 50.011 and 50.031, F.S. in the county where the activity is to take place. If you are uncertain that a newspaper meets these requirements, please contact the Permitting Authority at above address or phone number. Pursuant to Rule 62-110.106(5) and (9), F.A.C., the applicant shall provide proof of publication to the Permitting Authority at the above address within 7 days of publication. Failure to publish the notice and provide proof of publication may result in the denial of the permit pursuant to Rule 62-110.106(11), F.A.C.

Comments: The Permitting Authority will accept written comments concerning the proposed Draft Permit for a period of 14 days from the date of publication of the Public Notice. Written comments must be received by the Permitting Authority by close of business (5:00 p.m.) on or before the end of the 14-day period. If written comments received result in a significant change to the Draft Permit, the Permitting Authority shall revise the Draft Permit and require, if applicable, another Public Notice. All comments filed will be made available for public inspection.

Petitions: A person whose substantial interests are affected by the proposed permitting decision may petition for an administrative hearing in accordance with Sections 120.569 and 120.57, F.S. Petitions filed by any persons other than those entitled to written notice under Section 120.60(3), F.S., must be filed within 14 days of publication of the Public Notice or receipt of a written notice, whichever occurs first. Under Section 120.60(3), F.S., however, any person who asked the Permitting Authority for notice of agency action may file a petition within 14 days of receipt of that notice, regardless of the date of publication. A petitioner shall mail a copy of the petition to the applicant at the address indicated above, at the time of filing. A petition for administrative hearing must contain the information set forth below and must be filed (received) with the Agency Clerk in the Office of General Counsel, 3900 Commonwealth Boulevard, MS 35, Tallahassee, Florida 32399-3000, Agency.Clerk@dep.state.fl.us, before the deadline. The failure of any person to file a petition within the appropriate time period shall constitute a waiver of that person's right to request an administrative determination (hearing) under Sections 120.569 and 120.57, F.S., or to intervene in this proceeding and participate as a party to it. Any subsequent intervention (in a proceeding initiated by another party) will be only at the approval of the presiding officer upon the filing of a motion in compliance with Rule 28-106.205, F.A.C.

A petition that disputes the material facts on which the Permitting Authority's action is based must contain the following information: (a) The name and address of each agency affected and each agency's file or identification number, if known; (b) The name, address, any email address, telephone number and any facsimile number of the petitioner; the name, address, any email address, telephone number, and any facsimile number of the petitioner's representative, if any, which shall be the address for service purposes during the course of the proceeding; and an

WRITTEN NOTICE OF INTENT TO ISSUE AIR PERMIT

explanation of how the petitioner's substantial interests will be affected by the agency determination; (c) A statement of when and how each petitioner received notice of the agency action or proposed decision; (d) A statement of all disputed issues of material fact. If there are none, the petition must so indicate; (e) A concise statement of the ultimate facts alleged, including the specific facts the petitioner contends warrant reversal or modification of the agency's proposed action; (f) A statement of the specific rules or statutes the petitioner contends require reversal or modification of the agency's proposed action including an explanation of how the alleged facts relate to the specific rules or statutes; and, (g) A statement of the relief sought by the petitioner, stating precisely the action the petitioner wishes the agency to take with respect to the agency's proposed action. A petition that does not dispute the material facts upon which the Permitting Authority's action is based shall state that no such facts are in dispute and otherwise shall contain the same information as set forth above, as required by Rule 28-106.301, F.A.C.

Because the administrative hearing process is designed to formulate final agency action, the filing of a petition means that the Permitting Authority's final action may be different from the position taken by it in this written notice of Intent to Issue Air Permit. Persons whose substantial interests will be affected by any such final decision of the Permitting Authority on the application have the right to petition to become a party to the proceeding, in accordance with the requirements set forth above.

Mediation: Mediation is not available in this proceeding.

Executed in Orange County, Florida.



F. Thomas Lubozynski, P.E.
Waste and Air Resource Programs Administrator

WRITTEN NOTICE OF INTENT TO ISSUE AIR PERMIT

CERTIFICATE OF SERVICE

The undersigned duly designated deputy agency clerk hereby certifies that this Written Notice of Intent to Issue Air Permit package (including the Written Notice of Intent to Issue Air Permit, the Public Notice of Intent to Issue Air Permit, the Technical Evaluation and Preliminary Determination and the Draft Permit) was sent by electronic mail (or a link to these documents made available electronically on a publicly accessible server) with received receipt requested before the close of business on January 31, 2014 to the persons listed below.

Matthew McGrew, Plant Manager, Covidien, LP. (**matthew.mcgregw@covidien.com**)
Sue Williams, Covidien, LP (**sue.williams@covidien.com**)
Suzanne Thomas-Cole, P.E., AECOM (**suzanne.t.thomas@aecom.com**)
Ms. Natasha Hazziez, U.S. EPA Region 4: **hazziez.natasha@epa.gov**
Ms. Ana Oquendo, EPA Region 4: **oquendo.ana@epamail.epa.gov**
Ms. Barbara Friday, DEP BAR: **barbara.friday@dep.state.fl.us** (for posting with U.S. EPA, Region 4)

FILED, on this date, pursuant to Section 120.52, Florida Statutes, with the designated Department Clerk, receipt of which is hereby acknowledged.



(Clerk)

January 31, 2014
(Date)

PUBLIC NOTICE OF INTENT TO ISSUE AIR PERMIT

Florida Department of Environmental Protection
Waste & Air Resource Programs, Central District Office
Draft Major Source Air Construction Permit
Project No. 1270094-017-AC
Covidien, LP, DeLand facility
Volusia County, Florida

Applicant: The applicant for this project is Covidien, LP. The applicant's authorized representative and mailing address is:

Mr. Michael McGrew, Plant Manager
Covidien, LP
2010 International Speedway Boulevard
DeLand, Florida 32724-2010

Facility Location: Covidien, LP operates the existing DeLand facility, which is located in Volusia County at 2010 International Speedway Boulevard, DeLand Florida.

Project: The applicant proposes to construct and install a new process line for production of medical device needles.

Permitting Authority: Applications for air construction and operation permits are subject to review in accordance with the provisions of Chapter 403, Florida Statutes (F.S.) and Chapters 62-4, 62-210 and 62-212 of the Florida Administrative Code (F.A.C.). The proposed project is not exempt from air permitting requirements and an air permit is required to perform the proposed work. The Permitting Authority responsible for making a permit determination for this project is the Department of Environmental Protection's Waste & Air Resource Programs in the Central District Office. The Permitting Authority's physical address is: 3319 Maguire Blvd., Ste. 232, Orlando, FL 32803-3767. The Permitting Authority's mailing address is: 3319 Maguire Blvd., Ste. 232, Orlando, FL 32803-3767. The Permitting Authority's telephone number is 407/897-4100.

Project File: A complete project file is available for public inspection during the normal business hours of 8:00 a.m. to 5:00 p.m., Monday through Friday (except legal holidays), at the physical address indicated above for the Permitting Authority. The complete project file includes the Draft Permit, the Technical Evaluation and Preliminary Determination, the application and information submitted by the applicant (exclusive of confidential records under Section 403.111, F.S.). Interested persons may contact the Permitting Authority's project engineer for additional information at the address and phone number listed above. In addition, electronic copies of these documents are available on the following web site: <http://www.dep.state.fl.us/air/emission/apds/default.asp>.

Notice of Intent to Issue Air Permit: The Permitting Authority gives notice of its intent to issue an air construction permit to the applicant for the project described above. The applicant has provided reasonable assurance that operation of proposed equipment will not adversely impact air quality and that the project will comply with all appropriate provisions of Chapters 62-4, 62-204, 62-210, 62-212, 62-296 and 62-297, F.A.C. The Permitting Authority will issue a Final Permit in accordance with the conditions of the proposed Draft Permit unless a timely petition for an administrative hearing is filed under Sections 120.569 and 120.57, F.S. or unless public comment received in accordance with this notice results in a different decision or a significant change of terms or conditions.

Comments: The Permitting Authority will accept written comments concerning the proposed Draft Permit for a period of 14 days from the date of publication of this Public Notice. Written comments must be received by the Permitting Authority by close of business (5:00 p.m.) on or before the end of the 14-day period. If written comments received result in a significant change to the Draft Permit, the Permitting Authority shall revise the Draft Permit and require, if applicable, another Public Notice. All comments filed will be made available for public inspection.

Petitions: A person whose substantial interests are affected by the proposed permitting decision may petition for an administrative hearing in accordance with Sections 120.569 and 120.57, F.S. Petitions filed by any persons other than those entitled to written notice under Section 120.60(3), F.S., must be filed within 14 days of publication of the Public Notice or receipt of a written notice, whichever occurs first. Under Section 120.60(3), F.S., however, any person who asked the Permitting Authority for notice of agency action may file a petition within 14 days of receipt of that notice, regardless of the date of publication. A petitioner shall mail a copy of the petition to the applicant at the address indicated above, at the time of filing. A petition for administrative hearing must contain the information set forth below and must be filed (received) with the Agency Clerk in the Office of General Counsel, 3900 Commonwealth Boulevard, MS 35, Tallahassee, Florida 32399-3000, Agency.Clerk@dep.state.fl.us, before the deadline. The failure of any person to file a petition within the appropriate time period shall constitute a waiver of that person's right to request an administrative determination (hearing) under Sections 120.569 and 120.57, F.S., or to intervene in this proceeding and participate as a party to it. Any subsequent intervention (in a proceeding initiated by another party) will be only at the approval of the presiding officer upon the filing of a motion in compliance with Rule 28-106.205, F.A.C.

A petition that disputes the material facts on which the Permitting Authority's action is based must contain the following information: (a) The name and address of each agency affected and each agency's file or identification number, if known; (b) The name, address, any email address, telephone number and any facsimile number of the petitioner; the name, address, any email address, telephone number, and any facsimile number of the petitioner's representative, if any, which shall be the address for service purposes during the course of the proceeding; and an explanation of how the petitioner's substantial interests will be affected by the agency determination; (c) A statement of when and how each petitioner received notice of the agency action or proposed decision; (d) A statement of all disputed issues of material fact. If there are none, the petition must so indicate; (e) A concise statement of the ultimate facts alleged, including the specific facts the petitioner contends warrant reversal or modification of the agency's proposed action; (f) A statement of the specific rules or statutes the petitioner contends require reversal or modification of the agency's proposed action including an explanation of how the alleged facts relate to the specific rules or statutes; and, (g) A statement of the relief sought by the petitioner, stating precisely the action the petitioner wishes the agency to take with respect to the agency's proposed action. A petition that does not dispute the material facts upon which the Permitting Authority's action is based shall state that no such facts are in dispute and otherwise shall contain the same information as set forth above, as required by Rule 28-106.301, F.A.C.

Because the administrative hearing process is designed to formulate final agency action, the filing of a petition means that the Permitting Authority's final action may be different from the position taken by it in this written notice of Intent to Issue Air Permit. Persons whose substantial interests will be affected by any such final decision of the Permitting Authority on the application have the right to petition to become a party to the proceeding, in accordance with the requirements set forth above.

Mediation: Mediation is not available for this proceeding.



**FLORIDA DEPARTMENT OF
ENVIRONMENTAL PROTECTION**

CENTRAL DISTRICT
3319 MAGUIRE BOULEVARD, SUITE 232
ORLANDO, FLORIDA 32803

RICK SCOTT
GOVERNOR

HERSCHEL T. VINYARD JR.
SECRETARY

Electronically Sent- Received Receipt Requested
michael.mcgregw@covidien.com

DRAFT PERMIT

PERMITTEE

Covidien, LP
2010 International Speedway Boulevard
DeLand, Florida 32724-2010

Authorized Representative:
Mr. Michael McGrew, Plant Manager

Air Permit No. 1270094-017-AC
Permit Effective: 01/30/2014
Permit Expires: 04/30/2015
Site Name: DeLand Facility
Major Source Air Construction Permit
Project Name: Install new process line

This is the draft air construction permit, which authorizes installation of a new process line to allow for production of medical device needles. The proposed work will be conducted at the Covidien, LP. (Standard Industrial Classification No. 3841). The facility is located in Volusia County at 2010 International Speedway Boulevard, DeLand, Florida. The UTM Coordinates are: Zone 17, 474.17 km East and 3214.85 km North.

This final permit is organized by the following sections:

- Section 1. General Information
- Section 2. Administrative Requirements
- Section 3. Facility-wide and Emissions Unit Specific Conditions
- Section 4. Appendices

Because of the technical nature of the project, the permit contains numerous acronyms and abbreviations, which are defined in Appendix A of Section 4 of this permit.

This air pollution permit is issued under the provisions of: Chapter 403 of the Florida Statutes (F.S.) and Chapters 62-4, 62-204, 62-210, 62-212, 62-296 and 62-297 of the Florida Administrative Code (F.A.C.). The permittee is authorized to conduct the proposed work in accordance with the conditions of this permit. This project is subject to the general preconstruction review requirements in Rule 62-212.300, F.A.C., and is not subject to the preconstruction review requirements for major stationary sources in Rule 62-212.400, F.A.C., for the Prevention of Significant Deterioration (PSD) of Air Quality.

Upon issuance of this final permit, any party to this order has the right to seek judicial review of it under Section 120.68 of the Florida Statutes by filing a notice of appeal under Rule 9.110 of the Florida Rules of Appellate Procedure with the clerk of the Department of Environmental Protection in the Office of General Counsel (Mail Station #35, 3900 Commonwealth Boulevard, Tallahassee, Florida, 32399-3000) and by filing a copy of the notice of appeal accompanied by

SECTION 1. GENERAL INFORMATION (FINAL)

FACILITY AND PROJECT DESCRIPTION

Existing Facility

Provide a brief description of the existing facility. The existing facility consists of the following emissions units.

Facility ID No. 1270094	
ID No.	Emission Unit Description
009	Needle Manufacturing
010	Grinding Operations

Project Description and Affected Emission Units

This project will modify the following emissions units.

Facility ID No. 1270102	
ID No.	Emission Unit Description
009	Needle Manufacturing. This project will modify the existing production area with the installation of a new process line in the commerce area of the facility.

***NOTE:** Please reference the Permit No., Facility ID, and Emission Unit ID in all correspondence, test report submittals, applications, etc.*

FACILITY REGULATORY CLASSIFICATION

- The facility is a major source of hazardous air pollutants (HAP).
- The facility has no units subject to the acid rain provisions of the Clean Air Act (CAA).
- The facility is a Title V major source of air pollution for HAPs in accordance with Chapter 213, F.A.C.
- The facility is not a major stationary source in accordance with Rule 62-212.400, Prevention of Significant Deterioration, F.A.C.

PERMIT HISTORY/AFFECTED PERMITS

Facility is currently permitted under Title V permit 1270173-017-AV, issued October 24, 2012.

SECTION 2. ADMINISTRATIVE REQUIREMENTS (FINAL)

1. Permitting Authority: The permitting authority for this project is the Florida Department of Environmental Protection, Central District Waste & Air Resource Programs. The Central District's mailing address and phone number is:

Florida Department of Environmental Protection
Central District Office
3319 Maguire Blvd., Ste. 232
Orlando, FL 32803-3767
Telephone: 407-897-4100

All documents related to applications for permits shall be submitted to the above address or electronically to the following address: **DEP_CD@dep.state.fl.us**. In any electronic submittal clearly identify the Air Permit No. 1270102-013-AC

2. Compliance Authority: The compliance authority for this project is the Florida Department of Environmental Protection, Central District Compliance Assurance Program. All documents related to compliance activities such as reports, tests, and notifications shall be submitted to the Central District Compliance Assurance Program. (Use the above mailing or e-mail address.)
3. Appendices: The following Appendices are attached as part of this permit:
 - a. Appendix A. Citation Formats and Glossary of Common Terms;
 - b. Appendix B. General Conditions; and,
 - c. Appendix C. Common Conditions.
4. Applicable Regulations, Forms, and Application Procedures: Unless otherwise specified in this permit, the construction and operation of the subject emissions units shall be in accordance with the capacities and specifications stated in the application. The facility is subject to all applicable provisions of: Chapter 403, F.S.; and Chapters 62-4, 62-204, 62-210, 62-212, 62-213, 62-296 and 62-297, F.A.C. Issuance of this permit does not relieve the permittee from compliance with any applicable federal, state, or local permitting or regulations.
5. New or Additional Conditions: For good cause shown and after notice and an administrative hearing, if requested, the Department may require the permittee to conform to new or additional conditions. The Department shall allow the permittee a reasonable time to conform to the new or additional conditions, and on application of the permittee, the Department may grant additional time.
[Rule 62-4.080, F.A.C.]
6. Modifications: Unless otherwise exempt by rule, the permittee shall not initiate any construction, reconstruction, or modification at the facility and shall not install/modify any pollution control device at the facility without obtaining prior authorization from the Department. Modification is defined as: Any physical change or changes in the method of operations or addition to a facility that would result in an increase in the actual emissions of any air pollutant subject to air regulations, including any not previously emitted, from any emission unit or facility.
[Rules 62-210.200 - Definition of "Modification" and 62-210.300(1)(a), F.A.C.]
7. Electronic Annual Operating Report and Title V Annual Emissions Fees. The information required by the Annual Operating Report for Air Pollutant Emitting Facility [Including Title V Source Emissions Fee Calculation] (DEP Form No. 62-210.900(5)) shall be submitted by April 1 of each

SECTION 2. ADMINISTRATIVE REQUIREMENTS (FINAL)

year, for the previous calendar year, to the Department of Environmental Protection's Division of Air Resource Management. Each Title V source shall submit the annual operating report using the DEP's Electronic Annual Operating Report (EAOR) software, unless the Title V source claims a technical or financial hardship by submitting DEP Form No. 62-210.900(5) to the DEP Division of Air Resource Management instead of using the reporting software. Emissions shall be computed in accordance with the provisions of subsection 62-210.370(2), F.A.C. Each Title V source must pay between January 15 and April 1 of each year an annual emissions fee in an amount determined as set forth in subsection 62-213.205(1), F.A.C. The annual fee shall only apply to those regulated pollutants, except carbon monoxide and greenhouse gases, for which an allowable numeric emission-limiting standard is specified in the source's most recent construction permit or operation permit. Upon completing the required EAOR entries, the EAOR Title V Fee Invoice can be printed by the source showing which of the reported emissions are subject to the fee and the total Title V Annual Emissions Fee that is due. The submission of the annual Title V emissions fee payment is also due (postmarked) by April 1st of each year. A copy of the system-generated EAOR Title V Annual Emissions Fee Invoice and the indicated total fee shall be submitted to: **Major Air Pollution Source Annual Emissions Fee, P.O. Box 3070, Tallahassee, Florida 32315-3070.** Additional information is available 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>.

[Rules 62-210.370(3), 62-210.900 & 62-213.205, F.A.C.; and, §403.0872(11), F.S. (2013)]

{Permitting Note: Resources to help you complete your AOR are available on the electronic AOR (EAOR) website at: <http://www.dep.state.fl.us/air/emission/eaor>. If you have questions or need assistance after reviewing the information posted on the EAOR website, please contact the Department by phone at (850) 717-9000 or email at eaor@dep.state.fl.us.}

{Permitting Note: The Title V Annual Emissions Fee form (DEP Form No. 62-213.900(1)) has been repealed. A separate Annual Emissions Fee form is no longer required to be submitted by March 1st each year.}

8. Application for a Revised Title V Air Operation Permit: This permit authorizes construction or modification of the permitted emissions unit and initial operation to determine compliance with Department rules. A Title V air operation permit is required for continued operation of the permitted emissions unit. The permittee shall apply for a Revised Title V air operation permit at least 90 days prior to expiration of this permit, but no later than 180 days after commencing operation or commencing operation as modified. Commencing operation means setting into operation of any emissions unit for any purpose. To apply for a Revised Title V air operation permit, the applicant shall submit the following:

- a. the appropriate permit application form (*see current version of Rule 62-210.900, F.A.C. (Forms and Instructions)*), and/or FDEP Division of Air Resource Management website at: <http://www.dep.state.fl.us/air/>;
- b. the appropriate operation permit application fee from Rule 62-4.050(4)(a), F.A.C.;
- c. copies of the most recent two months of records/logs specified in Specific Condition No. **A.4.**

[Rules 62-4.030, 62-4.050, 62-4.070(3), 62-4.090, 62-210.300(2), and 62-210.900, F.A.C.]

SECTION 3. FACILITY-WIDE AND EMISSIONS UNIT SPECIFIC CONDITIONS (FINAL)

A. EU No. 016 Manufacturing Cells

This section of the permit addresses the following emissions unit.

ID No.	Emission Unit Description
016	Needle Manufacturing. This project will modify the existing needle production area of the facility with the installation of a new process line and associated needle and medical device assembly equipment in the commerce area of the facility. The new process line will eventually replace existing needle assembly machines. When that occurs will be determined by production requirements. The new process line will use an ultra-violet (UV) adhesive for device assembly and a laser printer, instead of existing video jet printers, thus eliminating use of inks and cleaners currently used in existing printers. Hexane will continue to be used as a lubricant, but the new line will utilize a cooled dipping process which will reduce the hexane usage and resulting emissions. Since all manufacturing machines will be in use after installation of this new process line, facility-wide emissions will increase to combine existing limits with the projected emissions from this new production line.

PERFORMANCE RESTRICTIONS

- A.1. Restricted Operation: The hours of operation are not limited (8,760 hours per year). [Rules 62-4.070(3) and 62-210. 200(247), “Potential to Emit,” F.A.C.]

EMISSIONS STANDARDS

- A.2. VOC and HAP Emissions Standards – As proposed by the Applicant, the maximum facility total VOC, total HAPs, and individual HAP emissions from this facility shall not exceed the following limits.

Pollutant	Maximum Emissions Rate (Tons Per Any Consecutive 12-month period)
VOC Emissions (including any clean-up solvents)	Less than 82
Total HAP Emissions	Less than 65
Individual HAP Emissions	Less than 65

[Permit Application dated January 2, 2014, Operating Permit 1270094-016-AV dated October 24, 2012, and Rule 62-210.200(247) “Potential to Emit”, F.A.C.]

{Permitting note: These maximum emission rate values are higher than the facility-wide allowable emissions currently authorized in Operating Permit 12700947-016-AV.}

- A.3. Visible Emissions. Visible emissions shall not exceed 20% opacity. [Rule 62-296.320(4)(b)1, F.A.C]

RECORDS AND REPORTS

SECTION 3. FACILITY-WIDE AND EMISSIONS UNIT SPECIFIC CONDITIONS (FINAL)

A. EU No. 016 Manufacturing Cells

- A.4. Monthly Log: In order to demonstrate compliance with Specific Condition **A.2**, the permittee shall maintain a monthly log at the facility for a period of at least five years from the date the data is recorded.

The monthly summary of the log, at a minimum, shall contain the following:

1. Facility Name, Facility ID No. (i.e., Facility Name, Facility # 1270094);
2. Designation of the month and year of operation for which the records are being tabulated;
3. Most recent monthly total of VOC emissions, total HAP emissions, and individual HAP emissions;
4. Consecutive 12-month total of total VOC emissions; total HAP emissions and each individual HAP emissions in tons.

The monthly logs shall be completed no later than the end of the following month.

Note: A consecutive 12-month total is equal to the total for the month in question plus the totals for the eleven months previous to the month in question. A consecutive 12-month total treats each month of the year as the end of a 12-month period. A 12-month total is not a year-to-date total. Facilities that have not been operating for 12 months should retain 12-month totals using whatever number of months of data is available until such a time as a consecutive 12-month total can be maintained each month.

[Rule 62-4.070(3) and Chapter 62-210, F.A.C.]

- A.5. Additional Recordkeeping Requirements: Records specified in Specific Condition No. **A.4**. (previous condition) must document the method, calculations, and formulas used in determining the usage rate and the emission rate. All calculations, including those used to derive emissions, must be clearly documented, and may be presented in the form of a template of sample calculations and available for review on site by the Department.
[Rule 62-4.070(3), F.A.C.]

- A.6. Supporting Documentation: Supporting documentation (chemical usage tracking logs, "As Supplied" sheets, Safety Data Sheets, EPA data sheets, purchase orders, waste shipment/disposal records, etc.) shall be kept for each chemical and associated products. The supporting documentation must include sufficient information to determine usage rates and emissions for a minimum of five (5) years. The documents must be made available to the Department upon request. Documentation of each chemical reclaimed will use a mass balance method to determine usage/emissions (amount used minus amount collected for disposal or recycle). [Rule 62-4.070(3), F.A.C.]

- A.7. Record Retention: The records required in Specific Condition No. **A.4**. shall be recorded in a permanent form suitable for inspection and made available to the Department upon request.

SECTION 3. FACILITY-WIDE AND EMISSIONS UNIT SPECIFIC CONDITIONS (FINAL)

A. EU No. 016 Manufacturing Cells

The records shall be maintained onsite for a minimum of five (5) years.
[Rule 62-4.070(3), F.A.C.]

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SECTION 4. APPENDICES

Contents

- Appendix A. Citation Formats and Glossary of Common Terms
- Appendix B. General Conditions
- Appendix C. Common Conditions

SECTION 4. APPENDIX A

Citation Formats and Glossary of Common Terms

CITATION FORMATS

The following illustrate the formats used in the permit to identify applicable requirements from permits and regulations.

New Permit Numbers

Example: Permit Nos. 0992222-001-AC, 0992222-001-AF, 0992222-001-AO, or 0992222-001-AV

Where: “099” represents the specific county ID number in which the project is located

“2222” represents the specific facility ID number for that county

“001” identifies the specific permit project number

“AC” identifies the permit as an air construction permit

“AF” identifies the permit as a minor source federally enforceable state operation permit

“AO” identifies the permit as a minor source air operation permit

“AV” identifies the permit as a major Title V air operation permit

Florida Administrative Code (F.A.C.)

Example: [Rule 62-213.205, F.A.C.]

Means: Title 62, Chapter 213, Rule 205 of the Florida Administrative Code

Code of Federal Regulations (CFR)

Example: [40 CFR 60.7]

Means: Title 40, Part 60, Section 7

GLOSSARY OF COMMON TERMS

° F: degrees Fahrenheit

AAQS: Ambient Air Quality Standard

acf: actual cubic feet

acfm: actual cubic feet per minute

ARMS: Air Resource Management System (DEP database)

BACT: best available control technology

bhp: brake horsepower

Btu: British thermal units

CAM: compliance assurance monitoring

CEMS: continuous emissions monitoring system

cfm: cubic feet per minute

CFR: Code of Federal Regulations

CAA: Clean Air Act

CMS: continuous monitoring system

CO: carbon monoxide

CO₂: carbon dioxide

COMS: continuous opacity monitoring system

DARM: Division of Air Resource Management

DEP: Department of Environmental Protection

Department: Department of Environmental Protection

dscf: dry standard cubic feet

dscfm: dry standard cubic feet per minute

EPA: Environmental Protection Agency

ESP: electrostatic precipitator (control system for reducing particulate matter)

SECTION 4. APPENDIX A

Citation Formats and Glossary of Common Terms

EU: emissions unit	ppm: parts per million
F.A.C.: Florida Administrative Code	ppmv: parts per million by volume
F.A.W.: Florida Administrative Weekly	ppmvd: parts per million by volume, dry basis
F.D.: forced draft	QA: quality assurance
F.S.: Florida Statutes	QC: quality control
FGD: flue gas desulfurization	PSD: prevention of significant deterioration
FGR: flue gas recirculation	psi: pounds per square inch
Fl: fluoride	PTE: potential to emit
ft²: square feet	RACT: reasonably available control technology
ft³: cubic feet	RATA: relative accuracy test audit
gpm: gallons per minute	RBLC: EPA's RACT/BACT/LAER Clearinghouse
gr: grains	SAM: sulfuric acid mist
HAP: hazardous air pollutant	scf: standard cubic feet
Hg: mercury	scfm: standard cubic feet per minute
I.D.: induced draft	SDS: safety data sheets
ID: identification	SIC: standard industrial classification code
kPa: kilopascals	SIP: State Implementation Plan
lb: pound	SNCR: selective non-catalytic reduction (control system used for reducing emissions of nitrogen oxides)
MACT: maximum achievable technology	SO₂: sulfur dioxide
MMBtu: million British thermal units	TPD: tons/day
MW: megawatt	TPH: tons per hour
NESHAP: National Emissions Standards for Hazardous Air Pollutants	TPY: tons per year
NO_x: nitrogen oxides	TRS: total reduced sulfur
NSPS: New Source Performance Standards	UTM: Universal Transverse Mercator coordinate system
O&M: operation and maintenance	VE: visible emissions
O₂: oxygen	VOC: volatile organic compounds
Pb: lead	
PM: particulate matter	
PM₁₀: particulate matter with a mean aerodynamic diameter of 10 microns or less	

SECTION 4. APPENDIX B

General Conditions

The permittee shall comply with the following general conditions from Rule 62-4.160, F.A.C.

1. The terms, conditions, requirements, limitations and restrictions set forth in this permit, are “permit conditions” and are binding and enforceable pursuant to Sections 403.141, 403.727, or 403.859 through 403.861, F.S. The permittee is placed on notice that the Department will review this permit periodically and may initiate enforcement action for any violation of these conditions.
2. This permit is valid only for the specific processes and operations applied for and indicated in the approved drawings or exhibits. Any unauthorized deviation from the approved drawings, exhibits, specifications, or conditions of this permit may constitute grounds for revocation and enforcement action by the Department.
3. As provided in subsections 403.987(6) and 403.722(5), F.S., the issuance of this permit does not convey any vested rights or any exclusive privileges. Neither does it authorize any injury to public or private property or any invasion of personal rights, nor any infringement of federal, state, or local laws or regulations. This permit is not a waiver of or approval of any other department permit that may be required for other aspects of the total project which are not addressed in this permit.
4. This permit conveys no title to land or water, does not constitute State recognition or acknowledgment of title, and not constitute authority for the use of submerged lands unless herein provided and the necessary title or leasehold interests have been obtained from the State. Only the Trustees of the Internal Improvement Trust Fund may express State opinion as to title.
5. This permit does not relieve the permittee from liability for harm or injury to human health or welfare, animal, or plant life, or property caused by the construction or operation of this permitted source, or from penalties therefore; nor does it allow the permittee to cause pollution in contravention of Florida Statutes and Department rules, unless specifically authorized by an order from the Department.
6. The permittee shall properly operate and maintain the facility and systems of treatment and control (and related appurtenances) that are installed and used by the permittee to achieve compliance with the conditions of this permit, as required by Department rules. This provision includes the operation of backup or auxiliary facilities or similar systems when necessary to achieve compliance with the conditions of the permit and when required by Department rules.
7. The permittee, by accepting this permit, specifically agrees to allow authorized Department personnel, upon presentation of credentials or other documents as may be required by law and at reasonable times, access to the premises where the permitted activity is located or conducted to:
 - a. Have access to and copy any records that must be kept under conditions of the permit;
 - b. Inspect the facility, equipment, practices, or operations regulated or required under this permit; and
 - c. Sample or monitor any substances or parameters at any location reasonably necessary to assure compliance with this permit or Department rules. Reasonable time may depend on the nature of the concern being investigated.
8. If, for any reason, the permittee does not comply with or will be unable to comply with any condition or limitation specified in this permit, the permittee shall immediately provide the Department with the following information:

SECTION 4. APPENDIX B

General Conditions

- a. A description of and cause of noncompliance; and
 - b. The period of noncompliance, including dates and times; or, if not corrected, the anticipated time the noncompliance is expected to continue, and steps being taken to reduce, eliminate, and prevent recurrence of the noncompliance. The permittee shall be responsible for any and all damages which may result and may be subject to enforcement action by the Department for penalties or for revocation of this permit.
9. In accepting this permit, the permittee understands and agrees that all records, notes, monitoring data and other information relating to the construction or operation of this permitted source which are submitted to the Department may be used by the Department as evidence in any enforcement case involving the permitted source arising under the Florida Statutes or Department rules, except where such use is prescribed by Sections 403.111 and 403.73, F.S. Such evidence shall only be used to the extent it is consistent with the Florida Rules of Civil Procedure and appropriate evidentiary rules.
10. The permittee agrees to comply with changes in Department rules and Florida Statutes after a reasonable time for compliance; provided, however, the permittee does not waive any other rights granted by Florida Statutes or Department rules. A reasonable time for compliance with a new or amended surface water quality standard, other than those standards addressed in Rule 62-302.500, F.A.C., shall include a reasonable time to obtain or be denied a mixing zone for the new or amended standard.
11. This permit is transferable only upon Department approval in accordance with Rules 62-4.120 and 62-730.300, F.A.C., as applicable. The permittee shall be liable for any non-compliance of the permitted activity until the transfer is approved by the Department.
12. This permit or a copy thereof shall be kept at the work site of the permitted activity.
13. This permit also constitutes:
- a. Determination of Best Available Control Technology (not applicable);
 - b. Determination of Prevention of Significant Deterioration (not applicable); and
 - c. Compliance with New Source Performance Standards (not applicable).
14. The permittee shall comply with the following:
- a. Upon request, the permittee shall furnish all records and plans required under Department rules. During enforcement actions, the retention period for all records will be extended automatically unless otherwise stipulated by the Department.
 - b. The permittee shall hold at the facility or other location designated by this permit records of all monitoring information (including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation) required by the permit, copies of all reports required by this permit, and records of all data used to complete the application for this permit. These materials shall be retained at least three years from the date of the sample, measurement, report, or application unless otherwise specified by Department rule.
 - c. Records of monitoring information shall include:
 - (a) The date, exact place, and time of sampling or measurements;

SECTION 4. APPENDIX B

General Conditions

- (b) The person responsible for performing the sampling or measurements;
 - (c) The dates analyses were performed;
 - (d) The person responsible for performing the analyses;
 - (e) The analytical techniques or methods used;
 - (f) The results of such analyses.
15. When requested by the Department, the permittee shall within a reasonable time furnish any information required by law which is needed to determine compliance with the permit. If the permittee becomes aware the relevant facts were not submitted or were incorrect in the permit application or in any report to the Department, such facts or information shall be corrected promptly.

SECTION 4. APPENDIX C

Common Conditions

Unless otherwise specified in the permit, the following conditions apply to all emissions units and activities at the facility.

EMISSIONS AND CONTROLS

1. Plant Operation - Problems: If temporarily unable to comply with any of the conditions of the permit due to breakdown of equipment or destruction by fire, wind or other cause, the permittee shall notify each Compliance Authority as soon as possible, but at least within one working day, excluding weekends and holidays. The notification shall include: pertinent information as to the cause of the problem; steps being taken to correct the problem and prevent future recurrence; and, where applicable, the owner's intent toward reconstruction of destroyed facilities. Such notification does not release the permittee from any liability for failure to comply with the conditions of this permit or the regulations. [Rule 62-4.130, F.A.C.]
2. Circumvention: The permittee shall not circumvent the air pollution control equipment or allow the emission of air pollutants without this equipment operating properly. [Rule 62-210.650, F.A.C.]
3. Excess Emissions Allowed: Excess emissions resulting from startup, shutdown or malfunction of any emissions unit shall be permitted providing (1) best operational practices to minimize emissions are adhered to and (2) the duration of excess emissions shall be minimized but in no case exceed 2 hours in any 24-hour period unless specifically authorized by the Department for longer duration. Pursuant to Rule 62-210.700(5), F.A.C., the permit subsection may specify more or less stringent requirements for periods of excess emissions. Rule 62-210-700(Excess Emissions), F.A.C., cannot vary or supersede any federal NSPS or NESHAP provision. [Rule 62-210.700(1), F.A.C.]
4. Excess Emissions Prohibited: Excess emissions caused entirely or in part by poor maintenance, poor operation, or any other equipment or process failure that may reasonably be prevented during startup, shutdown or malfunction shall be prohibited. [Rule 62-210.700(4), F.A.C.]
5. Excess Emissions - Notification: In case of excess emissions resulting from malfunctions, the permittee shall notify the Compliance Authority in accordance with Rule 62-4.130, F.A.C. A full written report on the malfunctions shall be submitted in a quarterly report, if requested by the Department. [Rule 62-210.700(6), F.A.C.]
6. VOC or OS Emissions: No person shall store, pump, handle, process, load, unload or use in any process or installation, volatile organic compounds (VOC) or organic solvents (OS) without applying known and existing vapor emission control devices or systems deemed necessary and ordered by the Department. [Rule 62-296.320(1), F.A.C.]
7. 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. [Rules 62-296.320(2) and 62-210.200(Definitions), F.A.C.]
8. 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%

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opacity. This regulation does not impose a specific testing requirement. [Rule 62-296.320(4)(b)1, F.A.C.]

9. Unconfined Particulate Emissions:

- a. 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.
- b. Any permit issued to a facility with emissions of unconfined particulate matter shall specify the reasonable precautions to be taken by that facility to control the emissions of unconfined particulate matter.
- c. Reasonable precautions include the following:
 - (1) Paving and maintenance of roads, parking areas and yards.
 - (2) Application of water or chemicals to control emissions from such activities as demolition of buildings, grading roads, construction, and land clearing.
 - (3) Application of asphalt, water, oil, chemicals or other dust suppressants to unpaved roads, yards, open stock piles and similar activities.
 - (4) Removal of particulate matter from roads and other paved areas under the control of the owner or operator of the facility to prevent reentrainment, and from buildings or work areas to prevent particulate from becoming airborne.
 - (5) Landscaping or planting of vegetation.
 - (6) Use of hoods, fans, filters, and similar equipment to contain, capture and/or vent particulate matter.
 - (7) Confining abrasive blasting where possible.
 - (8) Enclosure or covering of conveyor systems.

[Rule 62-296.320(4)(c), F.A.C.]

10. Special Compliance Tests. When the Department, after investigation, has good reason (such as complaints, increased visible emissions or questionable maintenance of control equipment) to believe that any applicable emission standard contained in a Department rule or in a permit issued pursuant to those rules is being violated, it shall require the owner or operator of the emissions unit to conduct compliance tests which identify the nature and quantity of pollutant emissions from the emissions unit and to provide a report on the results of said tests to the Department.

[Rule 62-297.310(7), F.A.C.]

RECORDS AND REPORTS

11. Records Retention: All measurements, records, and other data required by this permit shall be documented in a permanent, legible format and retained for at least 3 years following the date on which such measurements, records, or data are recorded, unless otherwise specified by Department rule. Records shall be made available to the Department upon request. [Rule 62-4.160, F.A.C.]

SECTION 4. APPENDIX C

Common Conditions

12. Emissions Computation and Reporting:

- a. *Applicability.* This rule sets forth required methodologies to be used by the owner or operator of a facility for computing actual emissions, baseline actual emissions, and net emissions increase, as defined at Rule 62-210.200, F.A.C., and for computing emissions for purposes of the reporting requirements of subsection 62-210.370(3) and paragraph 62-212.300(1)(e), F.A.C., or of any permit condition that requires emissions be computed in accordance with this rule. This rule is not intended to establish methodologies for determining compliance with the emission limitations of any air permit. [Rule 62-210.370(1), F.A.C.]
- b. *Computation of Emissions.* For any of the purposes set forth in subsection 62-210.370(1), F.A.C., the owner or operator of a facility shall compute emissions in accordance with the requirements set forth in this subsection.
 - (1) **Basic Approach.** The owner or operator shall employ, on a pollutant-specific basis, the most accurate of the approaches set forth below to compute the emissions of a pollutant from an emissions unit; provided, however, that nothing in this rule shall be construed to require installation and operation of any continuous emissions monitoring system (CEMS), continuous parameter monitoring system (CPMS), or predictive emissions monitoring system (PEMS) not otherwise required by rule or permit, nor shall anything in this rule be construed to require performance of any stack testing not otherwise required by rule or permit.
 - (a) If the emissions unit is equipped with a CEMS meeting the requirements of paragraph 62-210.370(2)(b), F.A.C., the owner or operator shall use such CEMS to compute the emissions of the pollutant, unless the owner or operator demonstrates to the department that an alternative approach is more accurate because the CEMS represents still-emerging technology.
 - (b) If a CEMS is not available or does not meet the requirements of paragraph 62-210.370(2)(b), F.A.C., but emissions of the pollutant can be computed pursuant to the mass balance methodology of paragraph 62-210.370(2)(c), F.A.C., the owner or operator shall use such methodology, unless the owner or operator demonstrates to the department that an alternative approach is more accurate.
 - (c) If a CEMS is not available or does not meet the requirements of paragraph 62-210.370(2)(b), F.A.C., and emissions cannot be computed pursuant to the mass balance methodology, the owner or operator shall use an emission factor meeting the requirements of paragraph 62-210.370(2)(d), F.A.C., unless the owner or operator demonstrates to the department that an alternative approach is more accurate.
 - (2) **Continuous Emissions Monitoring System (CEMS).**
 - (a) An owner or operator may use a CEMS to compute emissions of a pollutant for purposes of this rule provided:
 - 1) The CEMS complies with the applicable certification and quality assurance requirements of 40 CFR Part 60, Appendices B and F, or, for an acid rain unit, the certification and quality assurance requirements of 40 CFR Part 75, all adopted by reference at Rule 62-204.800, F.A.C.; or

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- 2) The owner or operator demonstrates that the CEMS otherwise represents the most accurate means of computing emissions for purposes of this rule.
 - (b) Stack gas volumetric flow rates used with the CEMS to compute emissions shall be obtained by the most accurate of the following methods as demonstrated by the owner or operator:
 - 1) A calibrated flow meter that records data on a continuous basis, if available; or
 - 2) The average flow rate of all valid stack tests conducted during a five-year period encompassing the period over which the emissions are being computed, provided all stack tests used shall represent the same operational and physical configuration of the unit.
 - (c) The owner or operator may use CEMS data in combination with an appropriate f-factor, heat input data, and any other necessary parameters to compute emissions if such method is demonstrated by the owner or operator to be more accurate than using a stack gas volumetric flow rate as set forth at subparagraph 62-210.370(2)(b)2., F.A.C., above.
- (3) Mass Balance Calculations.
- (a) An owner or operator may use mass balance calculations to compute emissions of a pollutant for purposes of this rule provided the owner or operator:
 - 1) Demonstrates a means of validating the content of the pollutant that is contained in or created by all materials or fuels used in or at the emissions unit; and
 - 2) Assumes that the emissions unit emits all of the pollutant that is contained in or created by any material or fuel used in or at the emissions unit if it cannot otherwise be accounted for in the process or in the capture and destruction of the pollutant by the unit's air pollution control equipment.
 - (b) Where the vendor of a raw material or fuel which is used in or at the emissions unit publishes a range of pollutant content from such material or fuel, the owner or operator shall use the highest value of the range to compute the emissions, unless the owner or operator demonstrates using site-specific data that another content within the range is more accurate.
 - (c) In the case of an emissions unit using coatings or solvents, the owner or operator shall document, through purchase receipts, records and sales receipts, the beginning and ending VOC inventories, the amount of VOC purchased during the computational period, and the amount of VOC disposed of in the liquid phase during such period.
- (4) Emission Factors.
- a. An owner or operator may use an emission factor to compute emissions of a pollutant for purposes of this rule provided the emission factor is based on site-specific data such as stack test data, where available, unless the owner or operator demonstrates to the department that an alternative emission factor is more accurate. An owner or operator using site-specific data to derive an emission factor, or set of factors, shall meet the following requirements.

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- 1) If stack test data are used, the emission factor shall be based on the average emissions per unit of input, output, or gas volume, whichever is appropriate, of all valid stack tests conducted during at least a five-year period encompassing the period over which the emissions are being computed, provided all stack tests used shall represent the same operational and physical configuration of the unit.
 - 2) Multiple emission factors shall be used as necessary to account for variations in emission rate associated with variations in the emissions unit's operating rate or operating conditions during the period over which emissions are computed.
 - 3) The owner or operator shall compute emissions by multiplying the appropriate emission factor by the appropriate input, output or gas volume value for the period over which the emissions are computed. The owner or operator shall not compute emissions by converting an emission factor to pounds per hour and then multiplying by hours of operation, unless the owner or operator demonstrates that such computation is the most accurate method available.
- b. If site-specific data are not available to derive an emission factor, the owner or operator may use a published emission factor directly applicable to the process for which emissions are computed. If no directly-applicable emission factor is available, the owner or operator may use a factor based on a similar, but different, process.
- (5) Accounting for Emissions During Periods of Missing Data from CEMS, PEMS, or CPMS. In computing the emissions of a pollutant, the owner or operator shall account for the emissions during periods of missing data from CEMS, PEMS, or CPMS using other site-specific data to generate a reasonable estimate of such emissions.
 - (6) Accounting for Emissions During Periods of Startup and Shutdown. In computing the emissions of a pollutant, the owner or operator shall account for the emissions during periods of startup and shutdown of the emissions unit.
 - (7) Fugitive Emissions. In computing the emissions of a pollutant from a facility or emissions unit, the owner or operator shall account for the fugitive emissions of the pollutant, to the extent quantifiable, associated with such facility or emissions unit.
 - (8) Recordkeeping. The owner or operator shall retain a copy of all records used to compute emissions pursuant to this rule for a period of five years from the date on which such emissions information is submitted to the department for any regulatory purpose.

[Rule 62-210.370(2), F.A.C.]

SECTION 4. APPENDIX C

Common Conditions

c. Annual Operating Report for Air Pollutant Emitting Facility

- (1) The Annual Operating Report for Air Pollutant Emitting Facility (DEP Form No. 62-210.900(5)) shall be completed each year for the following facilities:
 - a. All Title V sources.
 - b. All synthetic non-Title V sources.
 - c. All facilities with the potential to emit ten (10) tons per year or more of volatile organic compounds or twenty-five (25) tons per year or more of nitrogen oxides and located in an ozone nonattainment area or ozone air quality maintenance area.
 - d. All facilities for which an annual operating report is required by rule or permit.
- (2) Notwithstanding paragraph 62-210.370(3)(a), F.A.C., no annual operating report shall be required for any facility operating under an air general permit.
- (3) The annual operating report shall be submitted to the appropriate Department of Environmental Protection (DEP) division, district or DEP-approved local air pollution control program office by April 1 of the following year. If the report is submitted using the Department's electronic annual operating report software, there is no requirement to submit a copy to any DEP or local air program office.
- (4) Emissions shall be computed in accordance with the provisions of subsection 62-210.370(2), F.A.C., for purposes of the annual operating report.
- (5) Facility Relocation. Unless otherwise provided by rule or more stringent permit condition, the owner or operator of a relocatable facility must submit a Facility Relocation Notification Form (DEP Form No. 62-210.900(6)) to the Department at least 30 days prior to the relocation. A separate form shall be submitted for each facility in the case of the relocation of multiple facilities which are jointly owned or operated.

[Rule 62-210.370(3), F.A.C.]



**TECHNICAL EVALUATION
&
PRELIMINARY DETERMINATION**

APPLICANT

Covidien, LP
2010 International Speedway Boulevard
DeLand, Florida 32724-2010

Facility ID No. 1270094

PROJECT

Project No. 1270094-017-AC
Application for Major Source Air Construction Permit
Project Name: Install new process line

COUNTY

Volusia County, Florida

PERMITTING AUTHORITY

Florida Department of Environmental Protection
Waste and Air Resource Programs
Central District Office
Orlando, Florida 32803-3767

January 17, 2014

Prepared by Stephen Amirault, Project Engineer

TECHNICAL EVALUATION AND PRELIMINARY DETERMINATION

GENERAL PROJECT INFORMATION

Air Pollution Regulations

Projects at stationary sources with the potential to emit air pollution are subject to the applicable environmental laws specified in Section 403 of the Florida Statutes (F.S.). The statutes authorize the Department of Environmental Protection (Department) to establish regulations regarding air quality as part of the Florida Administrative Code (F.A.C.), which includes the following applicable chapters: 62-4 (Permits); 62-204 (Air Pollution Control – General Provisions); 62-210 (Stationary Sources – General Requirements); 62-212 (Stationary Sources – Preconstruction Review); 62-213 (Operation Permits for Major Sources of Air Pollution); 62-296 (Stationary Sources - Emission Standards); and 62-297 (Stationary Sources – Emissions Monitoring). Specifically, air construction permits are required pursuant to Rules 62-4, 62-210 and 62-212, F.A.C.

In addition, the U. S. Environmental Protection Agency (EPA) establishes air quality regulations in Title 40 of the Code of Federal Regulations (CFR). Part 60 specifies New Source Performance Standards (NSPS) for numerous industrial categories. Part 61 specifies National Emission Standards for Hazardous Air Pollutants (NESHAP) based on specific pollutants. Part 63 specifies NESHAP based on the Maximum Achievable Control Technology (MACT) for numerous industrial categories. The Department adopts these federal regulations on a quarterly basis in Rule 62-204.800, F.A.C.

Glossary of Common Terms

Because of the technical nature of the project, the permit contains numerous acronyms and abbreviations, which are defined in Appendix A of this permit.

I. Project Description:

A. Applicant:

Mr. Michael McGrew, Plant Manager
Covidien, LP
2010 International Speedway Boulevard
DeLand, Florida 32724-2010
michael.mcgregw@covidien.com

B. Application Professional Engineer of Record

Ms. Suzanne Thomas-Cole, P.E.
AECOM
10 Patewood Drive, Building VI, Suite 500
Greenville, SC 29615
suzanne.t.thomas@aecom.com

TECHNICAL EVALUATION AND PRELIMINARY DETERMINATION

B. Project Location:

2010 International Speedway Boulevard
DeLand, Florida 32724-2010

C. Project Summary:

The proposed permit authorizes construction and installation of a new process line to allow for production of medical device needles.

D. Application Information:

Application received on: 1/2/2014
Application Complete Determination: 1/10/2014
Additional information was provided via electronic mail on 1/14/14 and 1/16/14

III. PSD Applicability for Project

As provided in the application, the total project emissions will not exceed the PSD significant emission rates; therefore, the project is not subject to the PSD preconstruction review.

II. Rule Applicability

This project is subject to the preconstruction review requirements of Chapter 403, Florida Statutes, and Chapters 62-204 through 62-297, Florida Administrative Code (F.A.C.), as indicated below.

Subject to:	Y/N	Comments
Rule 62-210.300, F.A.C. – Stationary Source, General Requirements	Y	Not exempt from general permitting requirements
Rule 62-212.400, F.A.C. – Prevention of Significant Deterioration	N	Facility is not a PSD major source
Rule 62-296.320(4), F.A.C. - General Particulate Emission Limiting Standards	Y	Needle assembly operations are a potential source of unconfined particulate matter emissions.
Rules 62-296.320(1) and (2), F.A.C. - General Pollutant Emission Limiting Standards (VOCs and Odor)	Y	Needle assembly operations are a potential source of VOCs and odor.
Rule 62-296.400, F.A.C. - Stationary Source Emission Standards	N	There is no applicable source category.
Rule 62-296.500, F.A.C. - Reasonably Available Control Technology (VOC)	N	Volusia County is an attainment area for ozone.

TECHNICAL EVALUATION AND PRELIMINARY DETERMINATION

Subject to:	Y/N	Comments
Rule 62-296.700, F.A.C. - Reasonably Available Control Technology (PM)	N	There is no applicable source category.
Rule 62-204.800, F.A.C. - Standards of Performance for New Stationary Sources (NSPS)	N	There is no applicable source category.
Rule 62-204.800, F.A.C. National Emission Standard for Hazardous Air Pollutants (NESHAPS – 40 CFR 61)	N	There is no applicable source category.
Rule 62-213, F.A.C. – Operation Permits for Major Source of Air Pollution	Y	Facility is a major source of HAP emissions.

III. Summary of Emissions

As provided by the applicant, emissions from the facility are expected to remain below the following values:

Pollutant	EU No. and brief description	New Process line Potential Emissions tons per year (tpy) ¹	Facility wide allowable Emissions (tpy)
VOC	EU 009 – Needle Manufacturing	7	Less than 82 ²
Total HAP	EU 009 – Needle Manufacturing	5	Less than 65 ²
Individual HAP	EU 009 – Needle Manufacturing	5	Less than 65 tpy ²
VE	EU 009 – Needle Manufacturing		Less than twenty percent (20%) opacity

1. *Based on a maximum annual production of 445.536 million needles, the potential emissions from new process line, as provided in application, will be:*
 - a. *5.023 tons per year of VOC and HAP emissions from needle production operations;*
 - b. *0.204 tons per year of VOC and HAP emissions from adhesive applications; and*
 - c. *1.755 tons per year of VOC emissions from isopropyl alcohol spray.*

Complete calculations are provided in application.

2. *Existing Facility-wide allowable emissions currently included in Title V Operating Permit 12700947-016-AV are: 75 tons per year of VOCs and 60 tons per year of HAPs and 60 tons per year of individual HAPs.*

TECHNICAL EVALUATION AND PRELIMINARY DETERMINATION

IV. Federal NSPS and/or NESHAP Provisions

There are no applicable federal NSPS or NESHAP provisions.

V. Conclusions

The emission limits proposed by the applicant will meet all of the requirements of Chapters 62-204 through 297, F.A.C.

The General and Specific Conditions listed in the proposed permit (attached) will assure compliance with all the applicable requirements of Chapters 62-204 through 297, F.A.C.

VI. Preliminary Determination

The Department makes a preliminary determination that the proposed project will comply with all applicable state and federal air pollution regulations as conditioned by the draft permit. This determination is based on a technical review of the complete application, reasonable assurances provided by the applicant, and the conditions specified in the draft permit. Additional details of this analysis may be obtained by contacting the project engineer, Stephen Amirault, at the Florida Department of Environmental Protection, Waste & Air Resource Programs, Central District Office, 3319 Maguire Blvd., Suite 232, Orlando, Florida 32803-3767, 407/897-4100.