Department of Environmental Protection

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

Jeb Bush
Governor

Colleen M. Castille
Secretary

ELECTRONIC MAIL
wmathis@isl-fl.com

Wes Mathis, Plant Manager
International Sterilization Laboratory
217 Sampey Road
Groveland, FL 34736

Re: Title V Air Operation Permit
PROPOSED Permit No.: 0694823-006-AV
(Revision of Permit No.: 0694823-004-AV)
Sterilization Facility

Dear Mr. Mathis:

One copy of the PROPOSED PERMIT DETERMINATION for the PROPOSED Title V Air Operation Permit for the Sterilization Facility located at 217 Sampey Road, Groveland, Lake County, Florida is enclosed. This letter is only a courtesy to inform you that the DRAFT permit has become a PROPOSED permit.

An electronic version of this determination has been posted on the Division of Air Resources Management's world wide web site for the United States Environmental Protection Agency (USEPA) Region 4 office's review. The web site address is:

http://www.dep.state.fl.us/air/eproducts/ards/default.asp

Pursuant to Section 403.0872(6), Florida Statutes, if no objection to the PROPOSED permit is made by the USEPA within 45 days, the PROPOSED permit will become a FINAL permit no later than 55 days after the date on which the PROPOSED permit was mailed (posted) to USEPA. If USEPA has an objection to the PROPOSED permit, the FINAL permit will not be issued until the permitting authority receives written notice that the objection is resolved or withdrawn.

If you have any questions, please contact Alan Zahm, P.E., at 407/894-7555.

Sincerely,

L.T. Kozlov, P.E.
Program Administrator
Air Resources Management

Date 9-12-06

LTK/jt
Enclosures

cc: Robert A. Baker, P.E. **(baker@atlantic.net)**
Caroline Shine, FDEP
Barbara Friday, BAR **[Barbara.Friday@dep.state.fl.us]** (for posting with Region 4, U.S. EPA)

PROPOSED PERMIT DETERMINATION

PROPOSED Permit No.: 0694823-006-AV

I. Public Notice.

An "INTENT TO ISSUE A TITLE V AIR OPERATION PERMIT REVISION" to International Sterilization Laboratory, located at 217 Sampey Road, Groveland, Lake County, Florida was clerked on August 2, 2006. The "PUBLIC NOTICE OF INTENT TO ISSUE A TITLE V AIR OPERATION PERMIT REVISION" was published in **The South Lake Press** newspaper on August 11, 2006. The DRAFT Title V Air Operation Permit was available for public inspection at the permitting authority's office in Orlando. Proof of publication of the "PUBLIC NOTICE OF INTENT TO ISSUE A TITLE V AIR OPERATION PERMIT REVISION" was received on August 21, 2006.

II. Public Comment(s).

No comments were received during the 30 (thirty) day public comment period. Since no comments were received, the DRAFT Permit becomes the PROPOSED Permit.

III. Conclusion.

Since there were no comments received during the Public Notice period, no changes were made to the DRAFT Permit and the permitting authority hereby issues the PROPOSED Permit.

International Sterilization Laboratory
Sterilization Facility
Facility ID No.: 0694823
Lake County

Title V Air Operation Permit

PROPOSED Permit No.: 0694823-006-AV
Revision of 0694823-004-AV

Permitting Authority:
Florida Department of Environmental Protection
3319 Maguire Boulevard, Suite 232
Orlando, Florida 32803
Telephone: 407/893-3334
Fax: 407/897-5963

PROPOSED Title V Air Operation Permit No.: 0694823-006-AV

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Department of Environmental Protection

Jeb Bush
Governor

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

Colleen M. Castille
Secretary

Permittee:

International Sterilization Laboratory
217 Sampey Road
Groveland, FL 34736
Attention: Wes Mathis,
Plant Manager

PROPOSED Permit No.: 0694823-006-AV
Facility ID No.: 0694823
SIC Nos.: 38
Project: Title V Air Operation Permit
(Revision of 0694823-004-AV)

This permit is for the operation of the International Sterilization Laboratory, Sterilization Facility. This facility is located at 217 Sampey Road, Groveland, Lake County; UTM Coordinates: Zone 17, 417.97 km East and 3159.55 km North; Latitude: 28° 37' 19" North and Longitude: 81° 50' 37" West.

Statement of Basis: This 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, and 62-213. The above named permittee is hereby authorized to perform the work or operate the facility shown on the application and approved drawing(s), plans, and other documents, attached hereto or on file with the permitting authority, in accordance with the terms and conditions of this permit.

Referenced attachments made a part of this permit:
Appendix I-1, LIST of INSIGNIFICANT EMISSION UNITS and/or ACTIVITIES
Appendix TV-6, TITLE V CONDITIONS
Appendix O, NESHAP Subpart O (includes NESHAP Subpart A, General Provisions)

Effective Date:	**to be determined**
Renewal Application Due Date:	**December 30, 2010**
Expiration Date:	**June 30, 2011**

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL PROTECTION

L.T. Kozlov, P.E.
Program Administrator
Air Resources Management

LTK/jt

SPECIFIC CONDITIONS

Section I. Facility Information.

Subsection A. Facility Description.

This facility is a Sterilization Facility that includes five sterilization chambers and four aeration rooms. The five sterilizers are equipped with an acid scrubber that reduces ethylene oxide emissions by 99%. The four aeration rooms are also equipped with an acid scrubber with a packed tower that reduces ethylene oxide emissions by 99%. Alternately, the four aeration rooms may be equipped with a continuous emission monitor to ensure ethylene oxide emissions do not exceed 1 ppm.

Also included in this permit are miscellaneous insignificant emission units and/or activities

Based upon the Title V permit application received December 12, 2005 and Title V permit revision application received April 20, 2006, this facility is not a major source of hazardous air pollutants (HAPs).

Subsection B. Summary of Emissions Unit ID No(s). and Brief Description(s).

E.U. ID No./Brief Description

001 Five Sterilization Chambers and Four Aeration Rooms

Please reference the Permit No., Facility ID No., and appropriate Emissions Unit(s) ID No(s). on all correspondence, test report submittals, applications, etc.

Subsection C. Relevant Documents.

The documents listed below are not a part of this permit, however, are specifically related to this permitting action.

These documents are provided to the permittee for information purposes only:
Appendix A-1, Abbreviations, Acronyms, Citations, and Identification Numbers
Appendix H-1, Permit History/ID Number Changes

These documents are on file with permitting authority:
Combined Air Construction and Title V Permit Application received December 12, 2005.
Combined Air Construction and Title V Permit Revision Application received April 20, 2006.

SPECIFIC CONDITIONS

Section II. Facility-wide Conditions.

The following conditions apply facility-wide:

1. APPENDIX TV-6, TITLE V CONDITIONS is a part of this permit.

2. General Pollutant Emission Limiting Standards. Objectionable Odor Prohibited. The permittee shall not cause, suffer, allow, or permit the discharge of air pollutants which cause or contribute to an objectionable odor.
[Rule 62-296.320(2), F.A.C.]

3. General Particulate Emission Limiting Standards. General Visible Emissions Standard. Except for emissions units that are subject to a particulate matter or opacity limit set forth or established by rule and reflected by conditions in this permit, no person shall cause, let, permit, suffer or allow to be discharged into the atmosphere the emissions of air pollutants from any activity, the density of which is equal to or greater than that designated as Number 1 on the Ringelmann Chart (20 percent opacity). EPA Method 9 is the method of compliance pursuant to Rule 62-297, F.A.C.
[Rule 62-296.320(4)(b)1., F.A.C.]

4. Prevention of Accidental Releases (Section 112(r) of CAA).

a) The permittee shall submit its Risk Management Plan (RMP) to the Chemical Emergency Preparedness and Prevention Office (CEPPO) RMP Reporting Center when, and if, such requirement becomes applicable. Any Risk Management Plans, original submittals, revisions or updates to submittals, should be sent to:

RMP Reporting Center
Post Office Box 1515
Lanham-Seabrook, MD 20703-1515
Telephone: 301/429-5018

b) The permittee shall 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]

5. Insignificant Emissions Units and/or Activities. Appendix I-1, List of Insignificant Emissions Units and/or Activities, is a part of this permit.
[Rules 62-213.440(1), 62-213.430(6), and 62-4.040(1)(b), F.A.C.]

6. General Pollutant Emission Limiting Standards. 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 (VOC) or organic solvents (OS) without applying known and existing vapor emission control devices or systems deemed necessary and ordered by the Department.

SPECIFIC CONDITIONS

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,
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)(a), F.A.C.]

7. Emissions of Unconfined Particulate Matter. Reasonable precautions to prevent emissions of unconfined particulate matter at this facility include:

a) Maintenance of paved areas as needed;
b) Regular mowing of grass and care of vegetation;
c) Limited access to plant property by unnecessary vehicles.

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

8. When appropriate, any recordings, monitoring, or reporting requirements that are time-specific shall be in accordance with the effective date of the permit, which defines day one.
[Rule 62-213.440, F.A.C.]

9. Annual Statement of Compliance. The annual statement of compliance pursuant to Rule 62-213.440(3)(a)2., F.A.C., shall be submitted to the air compliance section of this office and EPA within 60 (sixty) days after the end of the calendar year using DEP Form No. 62-213.900(7), F.A.C.
[Rules 62-213.440(3) and 62-213.900, F.A.C.]
{Permitting note: This condition implements the requirements of Rules 62-213.440(3)(a)2. &3., F.A.C. (see Condition 51 of APPENDIX TV-6, TITLE V CONDITIONS)}

10. The permittee shall submit all compliance related notifications and reports required of this permit to the following office:

Florida Department of Environmental Protection
3319 Maguire Blvd., Suite 232
Orlando, Florida 32803
Telephone: 407/893-3334; Fax: 407/897-5963

11. Any reports, data, notifications, certifications, and requests required to be sent to the United States Environmental Protection Agency, Region 4, should be sent to:

United States Environmental Protection Agency
Region 4
Air, Pesticides & Toxic Management Division
Air and EPCRA Enforcement Branch
Air Enforcement Section
61 Forsyth Street
Atlanta, Georgia 30303-8960
Telephone: 404/562-9155; Fax: 404/562-9163

SPECIFIC CONDITIONS

12. Certification by Responsible Official (RO). In addition to the professional engineering certification required for applications by Rule 62-4.050(3), F.A.C., any application form, report, compliance statement, compliance plan and compliance schedule submitted pursuant to Chapter 62-213, F.A.C., shall contain a certification signed by a responsible official that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete. Any responsible official who fails to submit any required information or who has submitted incorrect information shall, upon becoming aware of such failure or incorrect submittal, promptly submit such supplementary information or correct information.
[Rule 62.213.420(4), F.A.C.]

13. Annual Operating Report. A DEP Form No. 62-210.900(5), "Annual Operating Report for Air Pollutant Emitting Facility", including the Emissions Report, shall be completed for each calendar year, **on or before March 1** of the following year and submitted to the air compliance section of this office.
[Rule 62-210.370(3), F.A.C.]

SPECIFIC CONDITIONS

Section III. Emissions Unit(s) and Conditions.

Subsection A. This section addresses the following emissions unit(s).

E.U. ID No./ Brief Description

001 Five Sterilization Chambers and Four Aeration Rooms

The following conditions apply to the emissions unit(s) listed above:

Essential Potential to Emit (PTE) Parameters

A1. Capacity. The maximum facility-wide ethylene oxide usage rate is 60 tons per consecutive twelve month period.
[Rule 62-210.200, (PTE), F.A.C., construction permit 0694823-005-AC, and Title V application received 4/20/06]

A2. Hours of Operation. Continuous operation is allowed.
[Rule 62-210.200, (PTE), F.A.C., construction permit 0694823-005-AC, and Title V application received 4/20/06]

A3. No person shall circumvent any pollution control device or allow the emissions of air pollutants without the applicable air pollution control device operating properly.
[Rule 62-210.200, (PTE), F.A.C. and Rule 62-210.650, F.A.C.]

Emission Limitations and Standards

A4. The maximum facility wide combined volatile organic compound (VOC) emission rate is limited to less than 25.0 tons per twelve consecutive months, combined HAP emissions are limited to less than 25.0 tons per consecutive twelve months, and any individual HAP emission is limited to less than 10.0 tons per consecutive twelve months, updated monthly, as requested by the applicant.
[Rule 62-210.200, (PTE), F.A.C., construction permit 0694823-005-AC, and Title V application received 4/20/06]

A5. Pursuant to 40CFR63.362(c), each owner or operator of a sterilization source using 1 ton shall reduce ethylene oxide emissions to the atmosphere by at least 99 percent from each sterilization chamber vent. Pursuant to 40CFR63.362(d), each owner or operator of a sterilization source using 10 tons shall reduce ethylene oxide emissions to the atmosphere from each aeration room vent to a maximum concentration of 1 ppmv or at least 99 percent whichever is least stringent, from each aeration room vent.
[Rule 62-210.200, (PTE), F.A.C., construction permit 0694823-005-AC, and Title V application received 4/20/06]

SPECIFIC CONDITIONS

Recordkeeping and Reporting Requirements

A6. In order to demonstrate compliance with specific conditions number **A1.** and **A4.,** 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 log, at a minimum, shall contain the following:

Monthly
a) month
b) Consecutive 12 month total of:
- facility-wide ethylene oxide usage rate
- facility-wide VOC, combined HAPs and single HAP emission rates

[Rules 62-4.070(3) and 62-213.440(1)(b)2., F.A.C.]

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 are available until such a time as a consecutive 12 month total can be maintained each month.

NESHAP Conditions

A7. The sterilization chambers and aeration rooms are subject to 40 CFR Part 63, Subpart O, Ethylene Oxide Emissions Standards for Sterilization Facilities and 40 CFR Part 63, Subpart A, General Provisions.
[Rule 62-204.800(11)(b)9., F.A.C.; 40 CFR Part 63, Subpart A; and Title V permit 0694823-006-AV, Appendix O]

Appendix A-1, Abbreviations, Acronyms, Citations, and Identification Numbers

Abbreviations and Acronyms:

°F:	Degrees Fahrenheit
BACT:	Best Available Control Technology
CFR:	Code of Federal Regulations
DEP:	State of Florida, Department of Environmental Protection
DARM:	Division of Air Resource Management
EPA:	United States Environmental Protection Agency
F.A.C.:	Florida Administrative Code
F.S.:	Florida Statute
ISO:	International Standards Organization
LAT:	Latitude
LONG:	Longitude
MMBtu:	million British thermal units
MW:	Megawatt
ORIS:	Office of Regulatory Information Systems
SOA:	Specific Operating Agreement
UTM:	Universal Transverse Mercator

Citations:

The following examples illustrate the methods used in this permit to abbreviate and cite the references of rules, regulations, guidance memorandums, permit numbers, and ID numbers.

Code of Federal Regulations:

Example: **[40 CFR 60.334]**

Where:	40	reference to	Title 40
	CFR	reference to	Code of Federal Regulations
	60	reference to	Part 60
	60.334	reference to	Regulation 60.334

Florida Administrative Code (F.A.C.) Rules:

Example: **[Rule 62-213, F.A.C.]**

Where:	62	reference to	Title 62
	62-213	reference to	Chapter 62-213
	62-213.205	reference to	Rule 62-213.205, F.A.C.

ISO: International Standards Organization refers to those conditions at 288 degrees K, 60 percent relative humidity, and 101.3 kilopascals pressure.

Identification Numbers:

Facility Identification (ID) Number:

Example: Facility ID No.: 1050221

Where:

105 = 3-digit number code identifying the facility is located in Polk County
0221 = 4-digit number assigned by state database.

Permit Numbers:

Example: 1050221-002-AV, or
1050221-001-AC

Where:

AC = Air Construction Permit
AV = Air Operation Permit (Title V Source)
105 = 3-digit number code identifying the facility is located in Polk County
0221 = 4-digit number assigned by permit tracking database
001 or 002 = 3-digit sequential project number assigned by permit tracking database

Example: PSD-FL-185
PA95-01
AC53-208321

Where:

PSD = Prevention of Significant Deterioration Permit
PA = Power Plant Siting Act Permit
AC = old Air Construction Permit numbering

Appendix H-1, Permit History/ID Number Changes

International Sterilization Laboratory
Sterilization Facility

PROPOSED Permit No.: 0694823-006-AV
Facility ID No.: 0694823

Permit History (for tracking purposes):

E.U. ID No.	Description	Permit No.	Issue Date	Expiration Date
001	Sterilization Facility	0694823-006-AV	August 2, 2006, draft	
001	Sterilization Facility	0694823-005-AC	August 2, 2006	July 30, 2007
001	Sterilization Facility	0694823-004-AV	September 11, 2006	September 11, 2011
001	Sterilization Facility	0694823-003-AC	December 8 ,2005	March 28, 2011
001	Sterilization Facility	0694823-002-AG	August 2, 2002	September 11, 2006
001	Sterilization Facility	0694823-001-AG	November 10,1997	October 2, 2002

Appendix I-1, List of Insignificant Emissions Units and/or Activities.

International Sterilization Laboratory
Sterilization Facility

PROPOSED Title V Permit No. 0694823-006-AV
Facility ID No.: 0694823

The facilities, emissions units, or pollutant-emitting activities listed in Rule 62-210.300(3)(a), F.A.C., Categorical Exemptions, are exempt from the permitting requirements of Chapters 62-210 and 62-4, F.A.C.; provided, however, that exempt emissions units shall be subject to any applicable emission limiting standards and the emissions from exempt emissions units or activities shall be considered in determining the potential emissions of the facility containing such emissions units. Emissions units and pollutant-emitting activities exempt from permitting under Rule 62-210.300(3)(a), F.A.C., shall not be exempt from the permitting requirements of Chapter 62-213, F.A.C., if they are contained within a Title V source; however, such emissions units and activities shall be considered insignificant for Title V purposes provided they also meet the criteria of Rule 62-213.430(6)(b), F.A.C. No emissions unit shall be entitled to an exemption from permitting under Rule 62.210.300(3)(a), F.A.C., if its emissions, in combination with the emissions of other units and activities at the facility, would cause the facility to emit or have the potential to emit any pollutant in such amount as to make the facility a Title V source.

The below listed emissions units and/or activities are considered insignificant pursuant to Rule 62-213.430(6), F.A.C.

Brief Description of Emissions Units and/or Activities

1. Liquid Nitrogen Tank
2. Neutralization Tank for Liquid Scrubber
3. 3.0 MMBTU/hr natural gas fired Boiler (Hurtz)
4. 2.0 MMBTU/hr natural gas fired Boiler (Kewanee)

APPENDIX TV-6, TITLE V CONDITIONS (version dated 06/23/06)

[Note: This attachment includes "canned conditions" developed from the "Title V Core List."]

{Permitting note: APPENDIX TV-6, TITLE V CONDITIONS, is distributed to the permittee only. Other persons requesting copies of these conditions shall be provided one copy when requested or otherwise appropriate.}

Chapter 62-4, F.A.C.

1. **Not federally enforceable.** General Prohibition. Any stationary installation which will reasonably be expected to be a source of pollution shall not be operated, maintained, constructed, expanded, or modified without the appropriate and valid permits issued by the Department, unless the source is exempted by Department rule. The Department may issue a permit only after it receives reasonable assurance that the installation will not cause pollution in violation of any of the provisions of Chapter 403, F.S., or the rules promulgated thereunder. A permitted installation may only be operated, maintained, constructed, expanded or modified in a manner that is consistent with the terms of the permit.
[Rule 62-4.030, Florida Administrative Code (F.A.C.); and, Section 403.087, Florida Statute (F.S.)]

2. **Not federally enforceable.** Procedures to Obtain Permits and Other Authorizations; Applications.
(1) Any person desiring to obtain a permit from the Department shall apply on forms prescribed by the Department and shall submit such additional information as the Department by law may require.
(2) All applications and supporting documents shall be filed in quadruplicate with the Department.
(3) To ensure protection of public health, safety, and welfare, any construction, modification, or operation of an installation which may be a source of pollution, shall be in accordance with sound professional engineering practices pursuant to Chapter 471, F.S. All applications for a Department permit shall be certified by a professional engineer registered in the State of Florida except, when the application is for renewal of an air pollution operation permit at a non-Title V source as defined in Rule 62-210.200, F.A.C., or where professional engineering is not required by Chapter 471, F.S. Where required by Chapter 471 or 492, F.S., applicable portions of permit applications and supporting documents which are submitted to the Department for public record shall be signed and sealed by the professional(s) who prepared or approved them.
(4) Processing fees for air construction permits shall be in accordance with Rule 62-4.050(4), F.A.C.
(5)(a) To be considered by the Department, each application must be accompanied by the proper processing fee. The fee shall be paid by check, payable to the Department of Environmental Protection. The fee is non-refundable except as provided in Section 120.60, F.S., and in this section.
(b) When an application is received without the required fee, the Department shall acknowledge receipt of the application and shall immediately notify the applicant by certified mail that the required fee was not received and advise the applicant of the correct fee. The Department shall take no further action until the correct fee is received. If a fee was received by the Department which is less than the amount required, the Department shall return the fee along with the written notification.
(c) Upon receipt of the proper application fee, the permit processing time requirements of Sections 120.60(2) and 403.0876, F.S., shall begin.
(d) If the applicant does not submit the required fee within ten days of receipt of written notification, the Department shall either return the unprocessed application or arrange with the applicant for the pick up of the application.
(e) If an applicant submits an application fee in excess of the required fee, the permit processing time requirements of Sections 120.60(2) and 403.0876, F.S., shall begin upon receipt, and the Department shall refund to the applicant the amount received in excess of the required fee.
(6) Any substantial modification to a complete application shall require an additional processing fee determined pursuant to the schedule set forth in Rule 62-4.050, F.A.C., and shall restart the time requirements of Sections 120.60 and 403.0876, F.S. For purposes of this subsection, the term "substantial modification" shall mean a modification which is reasonably expected to lead to substantially different environmental impacts which require a detailed review.
(7) Modifications to existing permits proposed by the permittee which require substantial changes in the existing permit or require substantial evaluation by the Department of potential impacts of the proposed modifications shall require the same fee as a new application for the same time duration except for modification under Chapter 62-45, F.A.C.
[Rule 62-4.050, F.A.C.]

APPENDIX O

[Last Updated 3/9/06]

Subpart O--Ethylene Oxide Emissions Standards for Sterilization Facilities (07/29/98)

Sec.
63.360 Applicability.
63.361 Definitions.
63.362 Standards.
63.363 Compliance and performance testing.
63.364 Monitoring requirements.
63.365 Test methods and procedures.
63.366 Reporting requirements.
63.367 Recordkeeping requirements.
§ 63.368 Implementation and enforcement.

Appendix A to Subpart O- General Provisions

§ 63.360 Applicability.

(a) All sterilization sources using 1 ton (see definition) in sterilization or fumigation operations are subject to the emissions standards in §63.362, except as specified in paragraphs (b) through (e) of this section. Owners or operators of sources using 1 ton (see definition) subject to the provisions of this subpart must comply with the requirements of subpart A, of this part according to the applicability of subpart A of this part to such sources in Appendix A of this section.

(b) Sterilization sources using less than 1 ton (see definition) are not subject to the emissions standards in §63.362. The recordkeeping requirements of §63.367(c) apply.

(c) This subpart does not apply to beehive fumigators.

(d) This subpart does not apply to research or laboratory facilities as defined in section 112(c)(7) of title III of the Clean Air Act Amendment of 1990.

(e) This subpart does not apply to ethylene oxide sterilization operations at stationary sources such as hospitals, doctors offices, clinics, or other facilities whose primary purpose is to provide medical services to humans or animals.

(f) If you are an owner or operator of an area source subject to this subpart, you are exempt from the obligation to obtain a permit under 40 CFR part 70 or 71, provided you are not required to obtain a permit under 40 CFR 70.3(a) or 71.3(a) for a reason other than your status as an area source under this subpart. Notwithstanding the previous sentence, you must continue to comply with the provisions of this subpart applicable to area sources.

(g) The owner or operator shall comply with the provisions of this subpart as follows:

STATEMENT OF BASIS

International Sterilization Laboratory
Sterilization Facility
Facility ID No.: 0694823
Lake County

PROPOSED Title V Air Operation Permit No.: 0694823-006-AV

This Title V air operation permit revision is issued under the provisions of Chapter 403, Florida Statutes (F.S.), and Florida Administrative Code (F.A.C.) Chapters 62-4, 62-210, and 62-213. The above named permittee is hereby authorized to perform the work or operate the facility shown on the application and approved drawing(s), plans, and other documents, attached hereto or on file with the permitting authority, in accordance with the terms and conditions of this permit.

At the existing Sterilization Facility the permittee may operate an additional Sterilization Chamber (5 total) and an additional Aeration Room (4 total). The five sterilization chambers are equipped with an acid scrubber designed to reduce ethylene oxide emissions by 99%. The four aeration rooms are equipped with an acid scrubber with a packed tower designed to reduce ethylene oxide emission by 99%. Alternately, the four aeration rooms may be equipped with a continuous emission monitor to ensure ethylene oxide emissions do not exceed 1 ppm.

The permit will also allow an increase in VOC emissions from 4.0 tons/year to less than 25.0 tons/year, any single HAP emission from 4.0 tons/year to less than 10.0 tons/year, and combined HAP emissions from 4.0 tons/year to less than 25.0 tons/year. The facility is subject to 40CFR63, Subpart O and will comply with the subpart and maintain records to show compliance.

Based on the initial Title V permit application received December 12, 2005 and the Title V permit revision application received April 20, 2006, this facility is a minor source of hazardous air pollutants (HAPs). Also included in this permit are miscellaneous insignificant emission units and/or activities.