



# South Coast Air Quality Management District

21865 Copley Drive, Diamond Bar, CA 91765-4178  
(909) 396-2000 • [www.aqmd.gov](http://www.aqmd.gov)

June 2, 2010

Mr. Gerardo Rios – via email ([R9AirPermits\\_sc@epa.gov](mailto:R9AirPermits_sc@epa.gov))  
Chief – Permits Office  
U. S. EPA, Region IX  
75 Hawthorne Street, Air 3  
San Francisco, CA 94105

Dear Mr. Rios:

Subject: Loma Linda University Medical Center (ID 800234) – Title V Permit  
Revision

Loma Linda University Medical Center has proposed to revise their Title V permit by replacing an existing ethylene oxide sterilizer and air pollution control device with new ones. The facility (SIC 3840) is located at 10935 Parkland Ave., Loma Linda, CA 92350. This proposed permit revision is considered as a “de minimis significant permit revision” to their Title V permit. Attached for your review are the evaluation and permit for the proposed revision.

If you have any questions or need additional information regarding the proposed permit revision, please call Marcel Saulis at (909) 396-3093.

Very truly yours,

A handwritten signature in black ink that reads "Brian L. Yeh". To the right of the signature, the words "for BRIAN YEH" are written in a similar cursive style.

Brian L. Yeh  
Senior Manager  
General Commercial & Energy Team

BLY:MBS:Cover Letter\_045489

Attachments

<b>SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT</b>  <i>ENGINEERING &amp; COMPLIANCE</i>  <b>APPLICATION PROCESSING AND CALCULATIONS</b>	PAGES 10	PAGE NO. 1
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## ENGINEERING EVALUATION FOR TITLE V DE MINIMIS REVISION

### COMPANY NAME AND ADDRESS

Loma Linda University  
25027 Mound Street  
Loma Linda, CA 92354

CONTACT: Henry Cairus, EH&S, (909) 558-4999

### EQUIPMENT LOCATION

AQMD ID 800234  
11100 Anderson Street  
Loma Linda, CA 92354

### EQUIPMENT DESCRIPTION

A/N 507981

ETHYLENE OXIDE GAS STERILIZER/AERATOR, STERIS MODEL 3017, 1'-8" W. X 2'-8" L. X 1'-8" H. (INTERNAL DIMENSIONS), ELECTRICALLY HEATED CHAMBER, WATER INJECTION SYSTEM AND ELECTRICALLY HEATED VAPORIZER, WITH A 3 HP AIR COMPRESSOR.

A/N 510122

AIR POLLUTION CONTROL SYSTEM CONSISTING OF:

1. ETHYLENE OXIDE ABATEMENT SYSTEM, ADVANCED AIR TECHNOLOGIES, MODEL SAFE CELL II DR-50, 2'-8" D. X 2'-2" H.
2. NON-REGENERATIVE REACTANT MEDIA, 3 CU. FT., 165 LBS.
3. INDUCED DRAFT EXHAUST FAN, 1 H.P., VENTING ONE ETHYLENE OXIDE STERILIZER/AERATOR.

### BACKGROUND/SUMMARY

Loma Linda University Medical Center (LLUMC) submitted applications to install a new ethylene oxide (EtO) sterilizer and an associated air pollution control device. An application was also submitted to amend their Title V operating permit to include the new equipment. Table 1 summarizes the applications that were submitted by LLUMC.

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**Table 1 Application Summary**

A/N	Equipment	Submittal Date	Deemed Complete	BCAT/CCAT	Schedule	Base Filing Fees	XPP Fees	Total Fees
507981	Ethylene Oxide Sterilizer	2/25/10	3/10/10	000288	B	\$2,051.52	\$1,025.76	\$3,077.28
510122	Ethylene Oxide Scrubber	4/21/10	5/25/10	70	B	\$2,051.52	\$1,025.76	\$3,077.28
507987	TV Revision	2/25/10	3/10/10	555012	-	\$843.80	-	\$843.80
							Total	<b>\$6,998.36</b>

LLUMC currently operates two (2) EtO sterilizers both venting to an air pollution control device. The new sterilizer and will replace one of the existing units and the new control device will replace the existing control device. The remaining sterilizer will be kept in operation. Prior to issuance of a Permit to Construct, the project must undergo a 45-day EPA review period.

### COMPLIANCE REVIEW

A review of the compliance database reveals that a Notice of Violation (NOV) P53827 was issued to the facility on 1/30/09 for a violation commencing 5/15/06, for failure to certify CEMS for their cogeneration turbines by 5/14/06. Please refer to project file for a detailed description of the Inspector's report. LLUMC plans to install new CEMS that will comply with District requirements. The facility is currently operating under an order of abatement. NOV P56365 was issued on 8/14/09 for failure to submit required Title V reporting forms as well as exceeding the allowable hours for testing and maintenance for two emergency engines. Enforcement is tracking the compliance status of LLUMC.

### PROCESS DESCRIPTION

EtO is a chemical agent that disrupts the DNA of microorganisms and prevents them from reproducing. It is used to sterilize healthcare products such as: surgical instruments, medical apparatuses and other contaminated hospital supplies. EtO sterilization is used on equipment that cannot withstand the high temperature and moisture levels of steam sterilization. There are three processing phases to EtO sterilization:

- 1) **Pre-conditioning:** Product loads are brought to pre-defined heat and humid conditions to ensure that a repeatable sterilization process is achieved regardless of pre-processing load storage conditions.
- 2) **Sterilization:** Introduction of EtO exposure through process phases designed to assure sterility of the product loads.
- 3) **Aeration:** Used to accelerate the gassing out of exposed product loads and to contain and eliminate residual EtO emissions.

LLUMC is proposing the Steris® Model 3017 100% EtO sterilizer which is a unit that exposes the product load to all three processing phases in one chamber, which allows for minimal EtO release into the atmosphere. LLUMC will run a maximum of 1 cycle per day. The high temperature (130°F) cycle consists of a one hour sterilization period in which the chamber is in a vacuum condition with the sterilizer door locked and inaccessible. The chamber is heated with electric strip heaters attached to the

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chamber sides, wall and door. Optimal humidity is achieved with a humidity system consisting of a distilled water reservoir with a water injection system and electrically heated vaporizer. The load conditioning system heats and humidifies the load according to the parameters selected by the operator. An EtO cartridge (100 grams) is manually installed beforehand and is used for one load per cycle. The control system ensures that the chamber door is locked and the set parameters; vacuum level, temperature, and humidity are all achieved before the cartridge is punctured and the EtO is released through an electrically heated vaporizer. Following the sterilization phase, room air is introduced through a bacteria retentive filter which is then followed by a 12 hour aeration time for the high temperature cycle.

The exhaust gas from the unit will be venting to an air pollution control device. LLUMC is proposing to install a SAFE CELL II – Model DR-50, which is a “dry scrubber”. It will capture the EtO emissions from the sterilizer/aerator through a process known as chemisorption (or chemical adsorption). The EtO gas binds with the media where it undergoes a reaction and cannot escape or be recovered. The unit holds 135lbs of media that is capable of treating up to 45 pounds of EtO, equivalent to 205 cartridges or 205 cycles. Since LLUMC will be operating one cycle per day, the media will have to be changed out after every 205 operating days.

**EMISSION CALCULATIONS**

**Table 1 Data**

Parameter	Value	Unit	Source
Schedule <sup>(a)</sup>	13	hrs/day	Applicant
	5	days/wk	Applicant
	52	wks/yr	Applicant
EtO amount	100	g/cartridge	Applicant
EtO limit	3,000	g/month	Throughput limit
Cartridges per cycle	1	#/cycle	Applicant
Sterilizer Cycles	1	#/day	Applicant
Scrubber Efficiency	98.8	%	Rule 1405

<sup>(a)</sup> LLUMC proposed 5 days/wk and 52 wks/yr of usage; however, to allow the facility flexibility, 7 days/wk and 52 wks/yr will be used.

$$\begin{aligned}
 R1 \text{ (lbs/day)} &= 100 \text{ g/cartridge} \times 1 \text{ cartridge/day} \div 453.6 \text{ g/lb} = 0.22 \text{ lbs/day} \\
 R2 \text{ (lbs/day)} &= 0.22 \text{ lbs/day} \times (1-0.988) = 0.00264 \text{ lbs/day} \\
 \\ 
 R1 \text{ (lbs/hr)} &= 0.22 \text{ lbs/day} \div 13 \text{ hrs/day} = 0.017 \text{ lbs/hr} \\
 R2 \text{ (lbs/hr)} &= 0.00264 \text{ lbs/day} \div 13 \text{ hrs/day} = 0.000203 \text{ lbs/hr} \\
 \\ 
 R1 \text{ (lbs/yr)} &= 3,000 \text{ g/month} \div 453.6 \text{ g/lb} \times 12 \text{ mos/yr} = 79 \text{ lbs/yr} \\
 R2 \text{ (lbs/yr)} &= 79 \text{ lbs/yr} \times (1-0.988) = 0.952 \text{ lbs/yr}
 \end{aligned}$$

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**RULES EVALUATION**

**RULE 212-STANDARDS FOR APPROVING PERMITS AND ISSUING PUBLIC NOTICES**

Rule 212 requires that a person shall not build, erect, install, alter, or replace any equipment, the use of which may cause the issuance of air contaminants or the use of which may eliminate, reduce, or control the issuance of air contaminants without first obtaining written authorization for such construction from the Executive Officer. Rule 212(c) states that a project requires written notification if there is an emission increase for ANY criteria pollutant in excess of the daily maximums specified in Rule 212(g), if the equipment is located within 1,000 feet of the outer boundary of a school, or if the MICR is equal to or greater than one in a million ( $1 \times 10^6$ ) during a lifetime (70 years) for facilities with more than one permitted unit, source under Regulation XX, or equipment under Regulation XXX, unless the applicant demonstrates to the satisfaction of the Executive Officer that the total facility-wide maximum individual cancer risk is below ten in a million ( $10 \times 10^6$ ) using the risk assessment procedures and toxic air contaminants specified under Rule 1402; or, ten in a million ( $10 \times 10^6$ ) during a lifetime (70 years) for facilities with a single permitted unit, source under Regulation XX, or equipment under Regulation XXX.

**FACILITY / EQUIPMENT AND SCHOOL LOCATIONS**

There are no K-12 schools located within 1000 feet of where this EtO sterilizer and dry scrubber will be located; therefore, a public notice is not required for section (c)(1).

**DAILY EMISSIONS**

The daily emissions from this project do not exceed the daily thresholds of Rule 212(g) for ROG; therefore, a public notice is not required for section (c)(2).

**MAXIMUM INDIVIDUAL CANCER RISK (MICR)**

The MICR is less than  $1 \times 10^6$ , as shown in the discussion under the Regulation XIV section; therefore, a public notice is not required for section (c)(3).

**RULE 401 - VISIBLE EMISSIONS**

This rule limits visible emissions to opacity of less than 20 percent (Ringlemann No.1), as published by the United States Bureau of Mines. The equipment at this site is not expected to emit any visible emissions. Therefore, compliance with this rule is expected with the proper operation of the equipment.

**RULE 402 - NUISANCE**

This rule requires that a person not discharge from any source whatsoever such quantities of air contaminants or other material which cause injury, detriment, nuisance, or annoyance to any considerable number of persons or to the public, or which cause, or have a natural tendency to cause injury or damage to business or property.

The odor threshold for EtO varies between 250 and 700 ppm. The National Institute for Occupational Safety and Health (NIOSH) has determined that the Immediately Dangerous to Life or Health (IDLH) level to be 800 ppm. However, the EtO exhaust concentration is expected to be 0.30 ppm as calculated below.

$$\text{Concentration (ppm)} = 10^6 \times 0.00000334 \text{ lbs/min} \times 385.44 \text{ scf/lb-mol} \div (100 \text{ scfm} \times 44.05 \text{ lb/lb-mol}) = 0.30 \text{ ppm}$$

Nuisance issues are not expected from properly operated equipment.

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RULE 1303(a) – BACT

The Executive Officer shall deny the Permit to Construct for any new source which results in an emission increase of any non-attainment air contaminant, any ozone depleting compound, or ammonia unless the applicant can demonstrate that BACT is employed for the new source.

The EtO sterilizer will result in an increase in emissions; however, the increase is less than one pound per day, which does not trigger BACT. LLUMC will be installing a dry scrubber with reactant media capturing the emissions through chemisorption. Therefore, the proposed equipment will be as stringent as the BACT guideline attached in the project file.

RULE 1303(b)(1) – MODELING

Modeling is not required for ROG emissions.

RULE 1303(b)(2) – OFFSETS

The ROG emissions from the new sterilizer are less than 0.5 lbs/day as shown in the calculations section; therefore, the requirements for offsets are not triggered.

RULE 1401 – NEW SOURCE REVIEW OF TOXIC AIR CONTAMINANTS

This rule is applicable to applications deemed complete on or after June 1, 1990 and it imposes specific limits for maximum individual cancer risk (MICR), cancer burden, and non-cancer acute and chronic hazard indices from new permit units, relocations, or modifications to existing permit units which emit toxic air contaminants (TAC) listed in Table I of Rule 1401. The rule establishes allowable risks for permit units requiring new permit pursuant to Rules 201 or 203. The proposed equipment will result in an increase in TAC emissions, thus Rule 1401 applies to this project. The EtO emissions are below tier 1 screening levels. Therefore, this project will comply with the requirements of this rule.

RULE 1405 – CONTROL OF ETHYLENE OXIDE AND CHLOROFLUOROCARBON EMISSIONS FROM STERILIZATION OR FUMIGATION PROCESSES

This rule is applicable to persons that use ethylene oxide for sterilization or fumigation, or aerate products sterilized with ethylene oxide at another facility.

(d)(1)(C) The system proposed by LLUMC has all three processing phases in one chamber. The rule requires that if the sterilizer and aerator vent to the same control equipment, the combined efficiency must be 98.8 percent or more, by weight. The dry scrubber proposed by LLUMC has a removal efficiency of up to 99.9 percent. Source testing will be required to verify the efficiency.

(d)(5) Sterilizers, aerators, control equipment, and emissions collection systems shall be leak free. The maximum sterilant gas mass flow shall be 10 parts per million ethylene oxide for other compositions of sterilant gas, as measured one (1) centimeter away from any portion of a sterilizer, aerator, or control equipment that could have an ethylene oxide leak. LLUMC shall be required to conduct leak tests during conditions of maximum sterilant gas mass flow. Leak tests shall be conducted every six months, as specified in paragraph (f), Test Methods.

(d)(6) LLUMC shall conduct source tests on control equipment within 60 days after the initial operation of the equipment to verify compliance with control efficiency requirements, as specified in paragraph (f), Test Methods. Thereafter, annual source tests shall be conducted.

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(c) LLUMC shall maintain written records for a minimum of two years and shall make them available to the District upon request. Since this is a Title V facility, records shall be required for five years. The records shall include:

- (1) Documentation and results of leak tests; and either
- (2) The number of sterilizer cycles and the pounds of ethylene oxide (measured or calculated) used per cycle for each sterilizer each day; or
- (3) The total pounds of ethylene oxide purchased and used per calendar year, provided that monthly totals are also kept.

(f)(1) Source tests shall be conducted according to ARB Test Method 431 or an acceptable source test method approved by the ARB and the District. In addition, the following requirements shall be met:

- (A) Tests on control equipment shall be run with a typical load in the sterilizer or aerator.
- (B) The inlet and outlet of the control equipment shall be sampled simultaneously during testing to measure the control efficiency.
- (C) The efficiency of control equipment shall be determined under normal operating conditions. To measure the control efficiency on the sterilizer exhaust stream, sampling shall be done during the entire duration of the first sterilizer evacuation and subsequent air washes after ethylene oxide has been introduced. To measure the control efficiency on an aerator exhaust stream with a constant air flow, sampling shall be done during a period of at least 60 minutes, starting 15 minutes after aeration begins. To measure the control efficiency of the control equipment on an aerator exhaust stream with a non-constant air flow, sampling shall be done during the entire duration of the first aerator evacuation after aeration begins.

(f)(2) Leak tests shall be conducted by ARB Test Method 21 using a portable flame ionization detector or a non-dispersive infrared analyzer calibrated with methane, or an acceptable alternative method or analytical instrument approved by the District.

17 CCR §93108 – ETHYLENE OXIDE ATCM FOR STERILIZERS AND AERATORS

The ATCM is divided into two parts; Part I for non-commercial sterilizers and aerators and commercial sterilizers and aerators using less than 2,000 pounds of ethylene oxide per 12 consecutive months and Part II for commercial sterilizers and aerators using 2,000 pounds or more of ethylene oxide per 12 consecutive months. LLUMC will be using no more than 79 pounds per year of ethylene oxide; therefore, it is subject to the requirements of Part I of the ATCM.

(d) A written report must be furnished to the District on an annual basis or a report shall be maintained and made available to the District upon request. The report shall include one of the following:

- (1) the number of sterilizer cycles and the pounds of ethylene oxide used per cycle for each sterilizer during the reporting period, as determined by a method approved by the District; or
- (2) the total pounds of sterilant gas and the total pounds of ethylene oxide purchased, used, and returned in the previous calendar year, as determined by a method approved by the District.

(e)(1) The exhaust systems and EtO supply system including the sterilizer, aerator and control device shall be leak free.

(e)(2) LLUMC will be using no more than 82 pounds of EtO per year; therefore, the sterilizer is subject to a control efficiency of 99 percent. There are no control efficiency requirements for the aerator.

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(g) If a reduction across the control device is demonstrated and the outlet concentration is less than 0.2 ppm, the facility shall be considered to be in compliance with subsection (e)(2).

(h) Source testing shall be conducted in accordance with ARB Method 431.

40 CFR 63 SUBPART O – EMISSION STANDARDS FOR ETHYLENE OXIDE STERILIZATION FACILITIES

§63.360 As previously stated, LLUMC will be using no more than 79 pounds of EtO per year; therefore, it is not subject to this NESHAPS requirement which only applies to facilities using more than one ton of EtO per year.

REGULATION XXX – TITLE V PERMITS

The facility is included in Phase I of the Title V universe. The initial Title V permit, A/N 339979, was issued on 4/12/01.

RULE 3003 – APPLICATIONS

The “de minimis significant permit revision” is expected to comply with all applicable requirements of this rule.

(i)(4) The de minimis significant permit revision will be issued only after the permit revision application has been found to comply with all conditions of this rule.

(j)(1) The permit revision will be forwarded to EPA for a 45 day review period.

RULE 3005 – PERMIT REVISION

(e) The proposed Title V permit revision satisfies all the applicable conditions listed in this rule. The modification constitutes a “de minimis significant permit revision” as defined in Rule 3000(b)(6).

RULE 3006 – PUBLIC PARTICIPATION

(b) The proposed “de minimis significant permit revision” is exempt from public participation.

RECOMMENDATION(S)

Issue a new Section H with the following permit conditions for the units.

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**PERMIT CONDITIONS**

*A/N 507981 – EtO Sterilizer*

1. OPERATION OF THIS EQUIPMENT SHALL BE CONDUCTED IN ACCORDANCE WITH ALL DATA AND SPECIFICATIONS SUBMITTED WITH THE APPLICATION UNDER WHICH THIS PERMIT IS ISSUED UNLESS OTHERWISE NOTED BELOW.  
[RULE 204]
2. THIS EQUIPMENT SHALL BE PROPERLY MAINTAINED AND KEPT IN GOOD OPERATING CONDITION AT ALL TIMES.  
[RULE 204]
3. THIS EQUIPMENT SHALL NOT OPERATE UNLESS IT IS VENTED TO AIR POLLUTION CONTROL EQUIPMENT WHICH IS IN FULL USE AND HAS BEEN ISSUED A PERMIT TO CONSTRUCT BY THE EXECUTIVE OFFICER.  
[RULE 1405, RULE 1401, 17 CCR § 93108]
4. THE ETHYLENE OXIDE USAGE FOR THE STERILIZER SHALL NOT EXCEED 30 CARTRIDGES (EQUIVALENT TO 3,000 GRAMS OF ETHYLENE OXIDE) PER CALENDAR MONTH.  
[RULE 1303(a) – BACT, RULE 1401, RULE 1405, 17 CCR § 93108]
5. THE OWNER OR OPERATOR SHALL MAINTAIN RECORDS FOR THE FOLLOWING:
  - A. DOCUMENTATION AND RESULTS OF THE LEAK TESTS,
  - B. THE NUMBER OF STERILIZER CYCLES AND THE AMOUNT OF ETHYLENE OXIDE USED PER CYCLE FOR THE STERILIZER EACH DAY. THE AMOUNT USED SHALL BE TOTALED FOR EACH MONTH.

RECORDS SHALL BE KEPT FOR A PERIOD OF FIVE YEARS AND SHALL BE MADE AVAILABLE TO DISTRICT PERSONNEL UPON REQUEST.  
[RULE 1405, 17 CCR § 93108]

**Periodic Monitoring:**

6. THE OWNER OR OPERATOR SHALL CONDUCT LEAK TESTS IN ACCORDANCE WITH ARB TEST METHOD 21 USING A PORTABLE FLAME IONIZATION DETECTOR OR A NON-DISPERSIVE INFRARED ANALYZER CALIBRATED WITH METHANE. THE MONITORING EQUIPMENT SHALL BE CALIBRATED IN ACCORDANCE WITH THE MANUFACTURER’S SPECIFICATIONS. THE MAXIMUM STERILANT GAS FLOW SHALL BE 10 PPM AS MEASURED ONE CENTIMETER AWAY FROM ANY PORTION OF THE EXHAUST SYSTEM AND ETHYLENE OXIDE SUPPLY SYSTEM INCLUDING, BUT NOT LIMITED TO, ANY PIPING, DUCTING, FITTINGS, VALVES, OR FLANGES, THROUGH WHICH ETHYLENE OXIDE-CONTAMINATED AIR IS CONVEYED BETWEEN THE STERILIZER, AERATOR AND CONTROL DEVICE. LEAK TESTS SHALL BE CONDUCTED EVERY SIX MONTHS DURING CONDITIONS OF MAXIMUM STERILANT GAS MASS FLOW.  
[RULE 1405, 17 CCR § 93108]

**Emissions And Requirements:**

7. THIS EQUIPMENT IS SUBJECT TO THE APPLICABLE REQUIREMENTS OF THE FOLLOWING RULES AND REGULATIONS:
 

ETHYLENE OXIDE:	RULE 1405, SEE RULE FOR EMISSION LIMIT
ETHYLENE OXIDE:	17 CCR § 93108, SEE RULE FOR EMISSION LIMIT

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*A/N 510122 – Air Pollution Control Device*

1. OPERATION OF THIS EQUIPMENT SHALL BE CONDUCTED IN ACCORDANCE WITH ALL DATA AND SPECIFICATIONS SUBMITTED WITH THE APPLICATION UNDER WHICH THIS PERMIT IS ISSUED UNLESS OTHERWISE NOTED BELOW.  
[RULE 204]
2. THIS EQUIPMENT SHALL BE PROPERLY MAINTAINED AND KEPT IN GOOD OPERATING CONDITION AT ALL TIMES.  
[RULE 204]
3. THE CONTROL SYSTEM SHALL HAVE A MINIMUM CONTROL EFFICIENCY OF 99% FOR ETHYLENE OXIDE DURING THE STERILIZATION PROCESS OR SHALL NOT EXCEED 0.2 PPM-ETHYLENE OXIDE AT THE OUTLET. THE OVERALL MINIMUM CONTROL EFFICIENCY SHALL BE 98.8% FOR BOTH THE STERILIZATION AND THE AERATION PROCESSES.  
[RULE 1405, 17 CCR § 93108]
4. THE OWNER OR OPERATOR SHALL REMOVE AND REPLACE THE SPENT REACTANT MEDIA WITH FRESH REACTANT MEDIA AFTER EVERY 205 STERILIZATION AND AERATION CYCLES (EQUIVALENT TO 20,500 GRAMS OF ETHYLENE OXIDE OR 205 CARTRIDGES).
5. THE OWNER OR OPERATOR SHALL MAINTAIN RECORDS FOR THE FOLLOWING:
  - A. DOCUMENTATION AND RESULTS OF THE LEAK TESTS,
  - B. THE NUMBER OF STERILIZER CYCLES AND THE AMOUNT OF ETHYLENE OXIDE USED PER CYCLE FOR THE STERILIZER EACH DAY. THE AMOUNT USED SHALL BE TOTALED FOR EACH MONTH.
  - C. DOCUMENTATION OF REACTANT MEDIA REPLACEMENT.

RECORDS SHALL BE KEPT FOR A PERIOD OF FIVE YEARS AND SHALL BE MADE AVAILABLE TO DISTRICT PERSONNEL UPON REQUEST.  
[RULE 1405, 17 CCR § 93108]
6. THE OWNER OR OPERATOR OF THIS EQUIPMENT SHALL CONDUCT AN INITIAL SOURCE TEST, AND ANNUALLY THEREAFTER, ON THE CONTROL EQUIPMENT TO DEMONSTRATE COMPLIANCE WITH CONDITION NO. 3, UNDER THE FOLLOWING CONDITIONS:
  - A. A SOURCE TEST PROTOCOL SHALL BE SUBMITTED TO THE DISTRICT ENGINEER IDENTIFIED ON THE PERMIT TO CONSTRUCT NO LATER THAN 30 DAYS BEFORE THE PROPOSED TEST DATE AND SHALL BE APPROVED BY THE DISTRICT BEFORE THE TEST COMMENCES.
  - B. THE SOURCE TEST SHALL DETERMINE CONTROL EFFICIENCY FOR THE STERILIZATION AND AERATION PHASES IN ACCORDANCE WITH ARB TEST METHOD 431. THE TEST SHALL BE RUN UNDER CONDITIONS OF MAXIMUM ETHYLENE OXIDE MASS FLOW TO THE DEVICE, UNDER NORMAL OPERATING CONDITIONS.
  - C. THE INLET AND OUTLET OF THE CONTROL DEVICE SHALL BE SAMPLED SIMULTANEOUSLY.
  - D. TO MEASURE THE CONTROL EFFICIENCY OF THE CONTROL DEVICE ON THE STERILIZER EXHAUST STREAM, SAMPLING SHALL BE DONE DURING THE ENTIRE DURATION OF THE FIRST STERILIZER EVACUATION AFTER ETHYLENE OXIDE HAS BEEN INTRODUCED.
  - E. TO MEASURE THE CONTROL EFFICIENCY OF THE CONTROL DEVICE ON THE AERATOR EXHAUST STREAM, SAMPLING SHALL BE DONE DURING A PERIOD OF AT LEAST 60 MINUTES, STARTING 15 MINUTES AFTER AERATION BEGINS.

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F. THE SOURCE TEST SHALL DETERMINE THE FOLLOWING:

1. THE ETHYLENE CONCENTRATION IN PPMV AND MASS EMISSION RATE IN POUNDS PER HOUR AT THE INLET AND OUTLET OF THE CONTROL DEVICE;
2. FLOW RATES, AND
3. ETHYLENE OXIDE USAGE RATES.

G. A TESTING LABORATORY CERTIFIED BY THE CALIFORNIA AIR RESOURCES BOARD IN THE REQUIRED TEST METHODS FOR CRITERIA POLLUTANT TO BE MEASURED, AND IN COMPLIANCE WITH DISTRICT RULE 304 (NO CONFLICT OF INTEREST) SHALL CONDUCT THE TEST.

7. THE TEST SHALL BE CONDUCTED WITHIN 60 DAYS OF INITIAL OPERATION AND A WRITTEN TEST REPORT SHALL BE SUBMITTED TO THE DISTRICT WITHIN 30 DAYS OF COMPLETION OF THE TEST. TWO COMPLETE COPIES OF SOURCE TEST REPORTS SHALL BE SUBMITTED TO THE DISTRICT (ADDRESSED TO SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT, ATTN: MARCEL SAULIS, PO BOX 4941, DIAMOND BAR, CA 91765-4178,) WITHIN 45 DAYS AFTER THE TEST.
8. THE DISTRICT ENGINEER IDENTIFIED ON THE PERMIT TO CONSTRUCT SHALL BE NOTIFIED OF THE DATE AND TIME OF THE TEST AT LEAST 10 DAYS PRIOR TO THE TEST, OR WITHIN A TIMEFRAME AGREED UPON BY THE DISTRICT ENGINEER.
9. SAMPLING FACILITIES SHALL COMPLY WITH THE DISTRICT GUIDELINES FOR CONSTRUCTION OF SAMPLING AND TESTING FACILITIES, PURSUANT TO RULE 217.

**Periodic Monitoring:**

10. THE OWNER OR OPERATOR SHALL CONDUCT LEAK TESTS IN ACCORDANCE WITH ARB TEST METHOD 21 USING A PORTABLE FLAME IONIZATION DETECTOR OR A NON-DISPERSIVE INFRARED ANALYZER CALIBRATED WITH METHANE. THE MONITORING EQUIPMENT SHALL BE CALIBRATED IN ACCORDANCE WITH THE MANUFACTURER'S SPECIFICATIONS. THE MAXIMUM STERILANT GAS FLOW SHALL BE 10 PPM AS MEASURED ONE CENTIMETER AWAY FROM ANY PORTION OF THE EXHAUST SYSTEM AND ETHYLENE OXIDE SUPPLY SYSTEM INCLUDING, BUT NOT LIMITED TO, ANY PIPING, DUCTING, FITTINGS, VALVES, OR FLANGES, THROUGH WHICH ETHYLENE OXIDE-CONTAMINATED AIR IS CONVEYED BETWEEN THE STERILIZER, AERATOR AND CONTROL DEVICE. LEAK TESTS SHALL BE CONDUCTED EVERY SIX MONTHS DURING CONDITIONS OF MAXIMUM STERILANT GAS MASS FLOW.  
[RULE 1405, 17 CCR § 93108]

**Emissions And Requirements:**

11. THIS EQUIPMENT IS SUBJECT TO THE APPLICABLE REQUIREMENTS OF THE FOLLOWING RULES AND REGULATIONS:

ETHYLENE OXIDE:           RULE 1405, SEE RULE FOR EMISSION LIMIT  
ETHYLENE OXIDE:           17 CCR § 93108, SEE RULE FOR EMISSION LIMIT

## FACILITY PERMIT TO OPERATE LOMA LINDA UNIV

### PERMIT TO CONSTRUCT

A/N 507981

#### Equipment Description:

ETHYLENE OXIDE GAS STERILIZER/AERATOR, STERIS MODEL 3017, 1'-8" W. X 2'-8" L. X 1'-8" H. (INTERNAL DIMENSIONS), ELECTRICALLY HEATED CHAMBER, WATER INJECTION SYSTEM AND ELECTRICALLY HEATED VAPORIZER, WITH A 3 HP AIR COMPRESSOR.

#### Conditions:

1. OPERATION OF THIS EQUIPMENT SHALL BE CONDUCTED IN ACCORDANCE WITH ALL DATA AND SPECIFICATIONS SUBMITTED WITH THE APPLICATION UNDER WHICH THIS PERMIT IS ISSUED UNLESS OTHERWISE NOTED BELOW.  
[RULE 204]
2. THIS EQUIPMENT SHALL BE PROPERLY MAINTAINED AND KEPT IN GOOD OPERATING CONDITION AT ALL TIMES.  
[RULE 204]
3. THIS EQUIPMENT SHALL NOT OPERATE UNLESS IT IS VENTED TO AIR POLLUTION CONTROL EQUIPMENT WHICH IS IN FULL USE AND HAS BEEN ISSUED A PERMIT TO CONSTRUCT BY THE EXECUTIVE OFFICER.  
[RULE 1405, RULE 1401, 17 CCR § 93108]
4. THE ETHYLENE OXIDE USAGE FOR THE STERILIZER SHALL NOT EXCEED 30 CARTRIDGES (EQUIVALENT TO 3,000 GRAMS OF ETHYLENE OXIDE) PER CALENDAR MONTH.  
[RULE 1303(a) – BACT, RULE 1401, RULE 1405, 17 CCR § 93108]
5. THE OWNER OR OPERATOR SHALL MAINTAIN RECORDS FOR THE FOLLOWING:
  - A. DOCUMENTATION AND RESULTS OF THE LEAK TESTS,
  - B. THE NUMBER OF STERILIZER CYCLES AND THE AMOUNT OF ETHYLENE OXIDE USED PER CYCLE FOR THE STERILIZER EACH DAY. THE AMOUNT USED SHALL BE TOTALED FOR EACH MONTH.

RECORDS SHALL BE KEPT FOR A PERIOD OF FIVE YEARS AND SHALL BE MADE AVAILABLE TO DISTRICT PERSONNEL UPON REQUEST.  
[RULE 1405, 17 CCR § 93108]

## FACILITY PERMIT TO OPERATE LOMA LINDA UNIV

### Periodic Monitoring:

6. THE OWNER OR OPERATOR SHALL CONDUCT LEAK TESTS IN ACCORDANCE WITH ARB TEST METHOD 21 USING A PORTABLE FLAME IONIZATION DETECTOR OR A NON-DISPERSIVE INFRARED ANALYZER CALIBRATED WITH METHANE. THE MONITORING EQUIPMENT SHALL BE CALIBRATED IN ACCORDANCE WITH THE MANUFACTURER'S SPECIFICATIONS. THE MAXIMUM STERILANT GAS FLOW SHALL BE 10 PPM AS MEASURED ONE CENTIMETER AWAY FROM ANY PORTION OF THE EXHAUST SYSTEM AND ETHYLENE OXIDE SUPPLY SYSTEM INCLUDING, BUT NOT LIMITED TO, ANY PIPING, DUCTING, FITTINGS, VALVES, OR FLANGES, THROUGH WHICH ETHYLENE OXIDE-CONTAMINATED AIR IS CONVEYED BETWEEN THE STERILIZER, AERATOR AND CONTROL DEVICE. LEAK TESTS SHALL BE CONDUCTED EVERY SIX MONTHS DURING CONDITIONS OF MAXIMUM STERILANT GAS MASS FLOW.  
[RULE 1405, 17 CCR § 93108]

### Emissions And Requirements:

7. THIS EQUIPMENT IS SUBJECT TO THE APPLICABLE REQUIREMENTS OF THE FOLLOWING RULES AND REGULATIONS:  
  
ETHYLENE OXIDE: RULE 1405, SEE RULE FOR EMISSION LIMIT  
ETHYLENE OXIDE: 17 CCR § 93108, SEE RULE FOR EMISSION LIMIT

## FACILITY PERMIT TO OPERATE LOMA LINDA UNIV

### PERMIT TO CONSTRUCT

A/N 510122

#### Equipment Description:

AIR POLLUTION CONTROL SYSTEM CONSISTING OF:

- A. ETHYLENE OXIDE ABATEMENT SYSTEM, ADVANCED AIR TECHNOLOGIES, MODEL SAFE CELL II DR-50, 2'-8" D. X 2'-2" H.
- B. NON-REGENERATIVE REACTANT MEDIA, 3 CU. FT., 165 LBS.
- C. INDUCED DRAFT EXHAUST FAN, 1 H.P., VENTING ONE ETHYLENE OXIDE STERILIZER/AERATOR.

#### Conditions:

1. OPERATION OF THIS EQUIPMENT SHALL BE CONDUCTED IN ACCORDANCE WITH ALL DATA AND SPECIFICATIONS SUBMITTED WITH THE APPLICATION UNDER WHICH THIS PERMIT IS ISSUED UNLESS OTHERWISE NOTED BELOW.  
[RULE 204]
2. THIS EQUIPMENT SHALL BE PROPERLY MAINTAINED AND KEPT IN GOOD OPERATING CONDITION AT ALL TIMES.  
[RULE 204]
3. THE CONTROL SYSTEM SHALL HAVE A MINIMUM CONTROL EFFICIENCY OF 99% FOR ETHYLENE OXIDE DURING THE STERIZATION PROCESS OR SHALL NOT EXCEED 0.2 PPM-ETHYLENE OXIDE AT THE OUTLET. THE OVERALL MINIMUM CONTROL EFFICIENCY SHALL BE 98.8% FOR BOTH THE STERILIZATION AND THE AERATION PROCESSES.  
[RULE 1405, 17 CCR § 93108]
4. THE OWNER OR OPERATOR SHALL REMOVE AND REPLACE THE SPENT REACTANT MEDIA WITH FRESH REACTANT MEDIA AFTER EVERY 205 STERILIZATION AND AERATION CYCLES (EQUIVALENT TO 20,500 GRAMS OF ETHYLENE OXIDE OR 205 CARTRIDGES).
5. THE OWNER OR OPERATOR SHALL MAINTAIN RECORDS FOR THE FOLLOWING:
  - A. DOCUMENTATION AND RESULTS OF THE LEAK TESTS,
  - B. THE NUMBER OF STERILIZER CYCLES AND THE AMOUNT OF ETHYLENE OXIDE USED PER CYCLE FOR THE STERILIZER EACH DAY. THE AMOUNT USED SHALL BE TOTALED FOR EACH MONTH.
  - C. DOCUMENTATION OF REACTANT MEDIA REPLACEMENT.

RECORDS SHALL BE KEPT FOR A PERIOD OF FIVE YEARS AND SHALL BE MADE AVAILABLE TO DISTRICT PERSONNEL UPON REQUEST.

## FACILITY PERMIT TO OPERATE LOMA LINDA UNIV

[RULE 1405, 17 CCR § 93108]

6. THE OWNER OR OPERATOR OF THIS EQUIPMENT SHALL CONDUCT AN INITIAL SOURCE TEST, AND ANNUALLY THEREAFTER, ON THE CONTROL EQUIPMENT TO DEMONSTRATE COMPLIANCE WITH CONDITION NO. 3, UNDER THE FOLLOWING CONDITIONS:
  - A. A SOURCE TEST PROTOCOL SHALL BE SUBMITTED TO THE DISTRICT ENGINEER IDENTIFIED ON THE PERMIT TO CONSTRUCT NO LATER THAN 30 DAYS BEFORE THE PROPOSED TEST DATE AND SHALL BE APPROVED BY THE DISTRICT BEFORE THE TEST COMMENCES.
  - B. THE SOURCE TEST SHALL DETERMINE CONTROL EFFICIENCY FOR THE STERILIZATION AND AERATION PHASES IN ACCORDANCE WITH ARB TEST METHOD 431. THE TEST SHALL BE RUN UNDER CONDITIONS OF MAXIMUM ETHYLENE OXIDE MASS FLOW TO THE DEVICE, UNDER NORMAL OPERATING CONDITIONS.
  - C. THE INLET AND OUTLET OF THE CONTROL DEVICE SHALL BE SAMPLED SIMULTANEOUSLY.
  - D. TO MEASURE THE CONTROL EFFICIENCY OF THE CONTROL DEVICE ON THE STERILIZER EXHAUST STREAM, SAMPLING SHALL BE DONE DURING THE ENTIRE DURATION OF THE FIRST STERILIZER EVACUATION AFTER ETHYLENE OXIDE HAS BEEN INTRODUCED.
  - E. TO MEASURE THE CONTROL EFFICIENCY OF THE CONTROL DEVICE ON THE AERATOR EXHAUST STREAM, SAMPLING SHALL BE DONE DURING A PERIOD OF AT LEAST 60 MINUTES, STARTING 15 MINUTES AFTER AERATION BEGINS.
  - F. THE SOURCE TEST SHALL DETERMINE THE FOLLOWING:
    1. THE ETHYLENE CONCENTRATION IN PPMV AND MASS EMISSION RATE IN POUNDS PER HOUR AT THE INLET AND OUTLET OF THE CONTROL DEVICE;
    2. FLOW RATES, AND
    3. ETHYLENE OXIDE USAGE RATES.
  - G. A TESTING LABORATORY CERTIFIED BY THE CALIFORNIA AIR RESOURCES BOARD IN THE REQUIRED TEST METHODS FOR CRITERIA POLLUTANT TO BE MEASURED, AND IN COMPLIANCE WITH DISTRICT RULE 304 (NO CONFLICT OF INTEREST) SHALL CONDUCT THE TEST.
7. THE TEST SHALL BE CONDUCTED WITHIN 60 DAYS OF INITIAL OPERATION AND A WRITTEN TEST REPORT SHALL BE SUBMITTED TO THE DISTRICT WITHIN 30 DAYS OF COMPLETION OF THE TEST. TWO COMPLETE COPIES OF SOURCE TEST REPORTS SHALL BE SUBMITTED TO THE DISTRICT (ADDRESSED TO SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT, ATTN: MARCEL SAULIS, PO BOX 4941, DIAMOND BAR, CA 91765-4178,) WITHIN 45 DAYS AFTER THE TEST.

## FACILITY PERMIT TO OPERATE LOMA LINDA UNIV

8. THE DISTRICT ENGINEER IDENTIFIED ON THE PERMIT TO CONSTRUCT SHALL BE NOTIFIED OF THE DATE AND TIME OF THE TEST AT LEAST 10 DAYS PRIOR TO THE TEST, OR WITHIN A TIMEFRAME AGREED UPON BY THE DISTRICT ENGINEER.
9. SAMPLING FACILITIES SHALL COMPLY WITH THE DISTRICT GUIDELINES FOR CONSTRUCTION OF SAMPLING AND TESTING FACILITIES, PURSUANT TO RULE 217.

### Periodic Monitoring:

10. THE OWNER OR OPERATOR SHALL CONDUCT LEAK TESTS IN ACCORDANCE WITH ARB TEST METHOD 21 USING A PORTABLE FLAME IONIZATION DETECTOR OR A NON-DISPERSIVE INFRARED ANALYZER CALIBRATED WITH METHANE. THE MONITORING EQUIPMENT SHALL BE CALIBRATED IN ACCORDANCE WITH THE MANUFACTURER'S SPECIFICATIONS. THE MAXIMUM STERILANT GAS FLOW SHALL BE 10 PPM AS MEASURED ONE CENTIMETER AWAY FROM ANY PORTION OF THE EXHAUST SYSTEM AND ETHYLENE OXIDE SUPPLY SYSTEM INCLUDING, BUT NOT LIMITED TO, ANY PIPING, DUCTING, FITTINGS, VALVES, OR FLANGES, THROUGH WHICH ETHYLENE OXIDE-CONTAMINATED AIR IS CONVEYED BETWEEN THE STERILIZER, AERATOR AND CONTROL DEVICE. LEAK TESTS SHALL BE CONDUCTED EVERY SIX MONTHS DURING CONDITIONS OF MAXIMUM STERILANT GAS MASS FLOW.  
[RULE 1405, 17 CCR § 93108]

### Emissions And Requirements:

11. THIS EQUIPMENT IS SUBJECT TO THE APPLICABLE REQUIREMENTS OF THE FOLLOWING RULES AND REGULATIONS:  
  
ETHYLENE OXIDE: RULE 1405, SEE RULE FOR EMISSION LIMIT  
ETHYLENE OXIDE: 17 CCR § 93108, SEE RULE FOR EMISSION LIMIT

## FACILITY PERMIT TO OPERATE LOMA LINDA UNIV

### PERMIT TO CONSTRUCT

A/N 510122

#### Equipment Description:

AIR POLLUTION CONTROL SYSTEM CONSISTING OF:

- A. ETHYLENE OXIDE ABATEMENT SYSTEM, ADVANCED AIR TECHNOLOGIES, MODEL SAFE CELL II DR-50, 2'-8" D. X 2'-2" H.
- B. NON-REGENERATIVE REACTANT MEDIA, 3 CU. FT., 165 LBS.
- C. INDUCED DRAFT EXHAUST FAN, 1 H.P., VENTING ONE ETHYLENE OXIDE STERILIZER/AERATOR.

#### Conditions:

1. OPERATION OF THIS EQUIPMENT SHALL BE CONDUCTED IN ACCORDANCE WITH ALL DATA AND SPECIFICATIONS SUBMITTED WITH THE APPLICATION UNDER WHICH THIS PERMIT IS ISSUED UNLESS OTHERWISE NOTED BELOW.  
[RULE 204]
2. THIS EQUIPMENT SHALL BE PROPERLY MAINTAINED AND KEPT IN GOOD OPERATING CONDITION AT ALL TIMES.  
[RULE 204]
3. THE CONTROL SYSTEM SHALL HAVE A MINIMUM CONTROL EFFICIENCY OF 99% FOR ETHYLENE OXIDE DURING THE STERIZATION PROCESS OR SHALL NOT EXCEED 0.2 PPM-ETHYLENE OXIDE AT THE OUTLET. THE OVERALL MINIMUM CONTROL EFFICIENCY SHALL BE 98.8% FOR BOTH THE STERILIZATION AND THE AERATION PROCESSES.  
[RULE 1405, 17 CCR § 93108]
4. THE OWNER OR OPERATOR SHALL REMOVE AND REPLACE THE SPENT REACTANT MEDIA WITH FRESH REACTANT MEDIA AFTER EVERY 205 STERILIZATION AND AERATION CYCLES (EQUIVALENT TO 20,500 GRAMS OF ETHYLENE OXIDE OR 205 CARTRIDGES).
5. THE OWNER OR OPERATOR SHALL MAINTAIN RECORDS FOR THE FOLLOWING:
  - A. DOCUMENTATION AND RESULTS OF THE LEAK TESTS,
  - B. THE NUMBER OF STERILIZER CYCLES AND THE AMOUNT OF ETHYLENE OXIDE USED PER CYCLE FOR THE STERILIZER EACH DAY. THE AMOUNT USED SHALL BE TOTALED FOR EACH MONTH.
  - C. DOCUMENTATION OF REACTANT MEDIA REPLACEMENT.

RECORDS SHALL BE KEPT FOR A PERIOD OF FIVE YEARS AND SHALL BE MADE AVAILABLE TO DISTRICT PERSONNEL UPON REQUEST.

## FACILITY PERMIT TO OPERATE LOMA LINDA UNIV

[RULE 1405, 17 CCR § 93108]

6. THE OWNER OR OPERATOR OF THIS EQUIPMENT SHALL CONDUCT AN INITIAL SOURCE TEST, AND ANNUALLY THEREAFTER, ON THE CONTROL EQUIPMENT TO DEMONSTRATE COMPLIANCE WITH CONDITION NO. 3, UNDER THE FOLLOWING CONDITIONS:
  - A. A SOURCE TEST PROTOCOL SHALL BE SUBMITTED TO THE DISTRICT ENGINEER IDENTIFIED ON THE PERMIT TO CONSTRUCT NO LATER THAN 30 DAYS BEFORE THE PROPOSED TEST DATE AND SHALL BE APPROVED BY THE DISTRICT BEFORE THE TEST COMMENCES.
  - B. THE SOURCE TEST SHALL DETERMINE CONTROL EFFICIENCY FOR THE STERILIZATION AND AERATION PHASES IN ACCORDANCE WITH ARB TEST METHOD 431. THE TEST SHALL BE RUN UNDER CONDITIONS OF MAXIMUM ETHYLENE OXIDE MASS FLOW TO THE DEVICE, UNDER NORMAL OPERATING CONDITIONS.
  - C. THE INLET AND OUTLET OF THE CONTROL DEVICE SHALL BE SAMPLED SIMULTANEOUSLY.
  - D. TO MEASURE THE CONTROL EFFICIENCY OF THE CONTROL DEVICE ON THE STERILIZER EXHAUST STREAM, SAMPLING SHALL BE DONE DURING THE ENTIRE DURATION OF THE FIRST STERILIZER EVACUATION AFTER ETHYLENE OXIDE HAS BEEN INTRODUCED.
  - E. TO MEASURE THE CONTROL EFFICIENCY OF THE CONTROL DEVICE ON THE AERATOR EXHAUST STREAM, SAMPLING SHALL BE DONE DURING A PERIOD OF AT LEAST 60 MINUTES, STARTING 15 MINUTES AFTER AERATION BEGINS.
  - F. THE SOURCE TEST SHALL DETERMINE THE FOLLOWING:
    1. THE ETHYLENE CONCENTRATION IN PPMV AND MASS EMISSION RATE IN POUNDS PER HOUR AT THE INLET AND OUTLET OF THE CONTROL DEVICE;
    2. FLOW RATES, AND
    3. ETHYLENE OXIDE USAGE RATES.
  - G. A TESTING LABORATORY CERTIFIED BY THE CALIFORNIA AIR RESOURCES BOARD IN THE REQUIRED TEST METHODS FOR CRITERIA POLLUTANT TO BE MEASURED, AND IN COMPLIANCE WITH DISTRICT RULE 304 (NO CONFLICT OF INTEREST) SHALL CONDUCT THE TEST.
7. THE TEST SHALL BE CONDUCTED WITHIN 60 DAYS OF INITIAL OPERATION AND A WRITTEN TEST REPORT SHALL BE SUBMITTED TO THE DISTRICT WITHIN 30 DAYS OF COMPLETION OF THE TEST. TWO COMPLETE COPIES OF SOURCE TEST REPORTS SHALL BE SUBMITTED TO THE DISTRICT (ADDRESSED TO SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT, ATTN: MARCEL SAULIS, PO BOX 4941, DIAMOND BAR, CA 91765-4178,) WITHIN 45 DAYS AFTER THE TEST.

## FACILITY PERMIT TO OPERATE LOMA LINDA UNIV

8. THE DISTRICT ENGINEER IDENTIFIED ON THE PERMIT TO CONSTRUCT SHALL BE NOTIFIED OF THE DATE AND TIME OF THE TEST AT LEAST 10 DAYS PRIOR TO THE TEST, OR WITHIN A TIMEFRAME AGREED UPON BY THE DISTRICT ENGINEER.
9. SAMPLING FACILITIES SHALL COMPLY WITH THE DISTRICT GUIDELINES FOR CONSTRUCTION OF SAMPLING AND TESTING FACILITIES, PURSUANT TO RULE 217.

### Periodic Monitoring:

10. THE OWNER OR OPERATOR SHALL CONDUCT LEAK TESTS IN ACCORDANCE WITH ARB TEST METHOD 21 USING A PORTABLE FLAME IONIZATION DETECTOR OR A NON-DISPERSIVE INFRARED ANALYZER CALIBRATED WITH METHANE. THE MONITORING EQUIPMENT SHALL BE CALIBRATED IN ACCORDANCE WITH THE MANUFACTURER'S SPECIFICATIONS. THE MAXIMUM STERILANT GAS FLOW SHALL BE 10 PPM AS MEASURED ONE CENTIMETER AWAY FROM ANY PORTION OF THE EXHAUST SYSTEM AND ETHYLENE OXIDE SUPPLY SYSTEM INCLUDING, BUT NOT LIMITED TO, ANY PIPING, DUCTING, FITTINGS, VALVES, OR FLANGES, THROUGH WHICH ETHYLENE OXIDE-CONTAMINATED AIR IS CONVEYED BETWEEN THE STERILIZER, AERATOR AND CONTROL DEVICE. LEAK TESTS SHALL BE CONDUCTED EVERY SIX MONTHS DURING CONDITIONS OF MAXIMUM STERILANT GAS MASS FLOW.  
[RULE 1405, 17 CCR § 93108]

### Emissions And Requirements:

11. THIS EQUIPMENT IS SUBJECT TO THE APPLICABLE REQUIREMENTS OF THE FOLLOWING RULES AND REGULATIONS:

ETHYLENE OXIDE: RULE 1405, SEE RULE FOR EMISSION LIMIT  
ETHYLENE OXIDE: 17 CCR § 93108, SEE RULE FOR EMISSION LIMIT