San Joaquin Valley
Unified Air Pollution Control District

Guideline for Expedited Application Review (GEAR)
Ethylene Oxide (ETO) Sterilizers and Aerators

Approved By: ____Signed_____ Date:_____8/3/98_____
Seyed Sadredin
Director of Permit Services

Purpose: To outline the procedures for expedited processing of Authority to Construct (ATC) applications for Ethylene Oxide (ETO) Sterilizers and Aerators. These procedures will apply to processing of applications received over the counter or through the mail.

I. Applicability

This guideline applies to processing of applications for Authority to Construct new and modified Ethylene Oxide (ETO) Sterilizers and aerators.

II. Permit Application and Supplementary Forms

The applicant must complete a regular ATC application form.

III. Priority Processing

The applications will be processed on an expedited basis if a complete application, a complete supplemental form, and a $60 filing fee for each permit unit are submitted.

In order to meet the expedited time frame, the engineer assigned for preliminary review will deem the application complete (if appropriate), write the application review, and finalize the project. The application review and final ATC will be submitted to the [lead engineer/supervisor/manager] for review and signature.

Final action on all projects will occur within 14 days after the submittal of the complete application package over the counter. If all necessary items are provided through the mail, the application will be prioritized for issuance within 2 weeks.

The priority processing will be preempted if:

- The application is subject to any public noticing requirements, including school notice per CH&SC 42301.6 (within 1,000 feet of any K-12 school), or
- The application is part of a stationary source project where issuance of the permit will affect the outcome of the stationary source project.
- The public noticing provisions of the Hazardous Material Emissions regulations (AB3205 and AB928) apply.

IV. Application Review

In order to standardize the application reviews for this source category, the application review found in [G:/per/gear/eto_rv.doc] will be used as a base document. The following pages are a hard copy version of this standard review. This hard copy version for the GEAR Policy Manual includes a copy of the standard ATC conditions (Attachment I) and any applicable checklists (Attachment II). These attachments will be referred to, but will not be included in the actual application review done for the pending application. The actual application review will only have a draft ATC attached to it. This will minimize the number of pages for the expedited review.

The use of this standard Application Review will ensure:

A. That the proposed project complies with the Best Available Control Technology (BACT) requirements as specified in the District's current BACT Clearinghouse.

B. That the proposed project will not trigger offset requirements.

C. That the PTO has enforceable daily emission limitations (DELs).

D. That the proposed project complies with all applicable prohibitory rules.

V. Equipment Description

To ensure uniformity, the following standard description will be used in the database:

ETHYLENE OXIDE STERILIZER WITH ACME MODEL ETO-ZAPPER STERILIZER, ACME MODEL PURGE-IT AERATOR, AND ACME DESTRUCT-IT CATALYTIC OXIDIZER.

VI. Health Risk Assessment

Per results of CARB-approved health risk assessment for ETO sterilizers, the following results are the maximum allowable ETO consumption rates which would result in insignificant (or de minimus) level of health risks:

A. Single-story buildings:

Assumptions:
1. Sterilizer complies with ATCM (99% control or better)
2. Residents located within 100 meters
3. Exhaust stack is 7 meters above grade, with a rain cap

Results: Maximum allowable ETO consumption rate is 100 lb/yr.

B. Multi-story buidlings:

Assumptions:
1. Sterilizer complies with ATCM (99% control or better)
2. Residents located within 100 meters
3. Exhaust stack is 11.5 meters above grade, with a rain cap

Results: Maximum allowable ETO consumption rate is 500 lb/yr.

For sources meeting the above criteria, no further health risk assessment is necessary in the application review. However, if the parameters are different than the above, a health risk assessment must be performed by District's Technical Services staff.

VII. Authority to Construct Conditions

To ensure uniformity, a standard set of conditions will be used as a base for all applications (See Attachment I). Additional requirements may be required on a site specific basis due to New Source Review Rule.

VIII. Updates

Each GEAR will be updated as necessary to accommodate any changes in prohibitory rules or changes in the BACT Clearinghouse.

The attached bibliography lists items which are referenced in this GEAR. Changes to the listed items may necessitate revisions to this document. Additionally, alterations to this policy may trigger changes to some of the listed items.

The Permitting Handbook will also be updated whenever this GEAR document is updated.

Each update will be submitted to the BACT coordinator for review and the coordinator will forward the updates for the Director's approval.

ATC APPLICATION REVIEW
ETO sterilizer/aerator unit

Processing Engineer:
Lead Engineer (if applicable):
Date:

Facility Name:
Mailing Address:

Contact Name:
Phone:

Project Number:
Permit Number:

I. PROPOSAL

[Facility Name] is applying for an Authority to Construct (ATC) permit for a ETO sterilizer/aerator unit served by [specify control equipment].

II. APPLICABLE RULES

Rule 2201	New and Modified Stationary Source Review Rule (Amended June 15, 1995)
Rule 4102	Nuisance (Amended December 17, 1992)
Rule 7021	Ethylene Oxide - Sterilizers and Aerators (Amended December 17, 1992)

III. PROJECT LOCATION

This facility is located at [street address or UTM or TSR] in [city name], CA.
This facility is [not] located within 1,000 feet of the outer boundary of any K-12 school.

IV. PROCESS DESCRIPTION

The general purpose of the unit is to sterilize hospital materials that cannot be sterilized by steam without damaging them. The hospital materials to be sterilized are put in the ETO chamber. After application of ethylene oxide by opening the ETO canister valve and sterilizing for a specified period of time, the chamber is then aerated and vented through a control device that removes at least 99% of the ethylene oxide. ETO destroys bacteria, viruses, fungi, and other unwanted organisms on products.

IV. PROCESS DESCRIPTION (continued)

OPERATING SCHEDULE: _ hours/day; _ days/week; _ weeks/year

POUNDS OF ETO/YEAR PER TOTAL STATIONARY SOURCE:

[ ] 25 or less (Exempt from Rule 7021, Section 5.0)
[ ] More than 25, and less than or equal to 600
[ ] More than 600, and less than or equal to 5,000
[ ] More than 5,000
[ ] Aeration ONLY facility

NATURE OF BUSINESS:

[ ] Medical Center/Hospital [ ] Surgical Center [ ] Other

V. EQUIPMENT LISTING

[Include a complete listing of the emission unit(s), control device(s), and any other related equipment]

Description of Sterilizer:
Manufacturer:
Model No.: _____ Serial No.:
Hp Rating: _____ Lbs. of ETO per cycle:
Cycle time: _____

Description of Aerator:
Manufacturer:
Model No.: _____ Serial No.:
Hp Rating: _____ Cycle time:
Air exchanges per hour: _____ ft^3/hr

Description of Control Equipment:
Manufacturer: _____ (if different from above)
Model No.: _____ Serial No. _____

VI. EMISSION CONTROL TECHNOLOGY EVALUATION

This control device will oxidize the ethylene oxide into harmless carbon dioxide and water while releasing not more than 0.1% of the original ETO into the atmosphere.

VI. EMISSION CONTROL TECHNOLOGY EVALUATION (continued)

The oxidation process can be expressed by:

$2C_2H_4O + 5O_2 = 4CO_2 + 4H_2O$ + Heat (exothermic reaction)

Control Efficiency Requirements:

Per Rule 7021, the required minimum Control Efficiency is established by the annual usage of ETO by the facility.

CONTROL CATEGORY	REQUIREMENTS		
Facility-wide Pounds of Ethylene Oxide used per year	Exhaust Streams to be Controlled	Exhaust Streams to be tested	Control Efficiency %
Less than or equal to 25	None	None	None
More than 25 and less than or equal to 600	Sterilizer	Sterilizer	99.0
More than 600 and less than or equal to 5,000	Sterilizer; Aerator; Back-Draft Valve	Sterilizer; Aerator	99.9 95.0
More than 5,000	Sterilizer; Aerator; Sterilizer Door Hood Back-Draft Valve	Sterilizer; Aerator	99.9 99.0
Aeration-only facilities	Aerator	Aerator	95.0

VII. CALCULATIONS

This type of operation will emit ETO.

A. Assumptions:

Maximum stationary source ETO usage is :

[ ] Less than or equal to 600 lbs. ETO/year?
99% total control efficiency of the unit's maximum throughput per year.

[ ] More than 600 lbs ETO/year, but less than or equal to 5,000 lbs. ETO/year?
99.9% control efficiency for the sterilizer part of the unit's maximum throughput per year, PLUS,
95% control efficiency for the aerator part of the unit's maximum throughput per year.

[ ] Greater than 5,000 lbs. ETO/year?
99.9% total control efficiency for the sterilizer part of the unit's maximum throughput per year,
PLUS,
99% control efficiency for the aerator part of the unit's maximum throughput per year.

[ ] Aeration ONLY facility?
95% total control efficiency of the unit's maximum throughput per year

Maximum usage of this unit: _____ lbs/year

B. Emission Calculations:

1. Potential to Emit (PE):

*PE = Uncontrolled ETO Usage (lb/day) * (1-CE) * 365 day/yr*

where:
PE = Potential to Emit, lb/day
CE = Control Efficiency, 99.0%
ETO Usage = XX pound/day per unit

PE = XX lb/day * 0.01
= YY lb VOC/day

Annual PE = XX lb/day * 0.01 * 365 day/yr
= ZZ lb VOC/yr (ZZZ tpy)

VII. CALCULATIONS (continued)

2. BACT:

[**NOTE:** In order for a new ETO sterilizer unit to trigger BACT, it would have to use more than 200 pounds ethylene oxide per day. Since no District facility has used more than this amount, there is no existing BACT determination. In addition, since Rule 7021 requires a minimum of 99% control efficiency, BACT is already satisfied.]

For this new emissions unit, the Increase in Permitted Emissions (IPE) for BACT is equal to the PE calculated above.

3. Increase in Permitted Emissions (IPE):

For a new emissions unit, the IPE = PE.

For a modified emissions unit, assuming there is no increase in control efficiency, the IPE = PE - PEPM

4. New Source Review (NSR) Balance:

Per *Rule 2201* Section 4.2.2.1, offsets shall be required for CO (attainment area), PM_{10}, and SO_x for modified stationary sources if the offset threshold levels are exceeded. Since this project only causes an increase in VOC emissions, the NSR balance for CO, SOx, and PM10 will remain unchanged. Therefore, NSR balance calculations are not required.

5. Stationary Source Potential to Emit (SSPE):

The SSPE for VOCs, calculated according to Section 6.4 of Rule 2201, is equal to the potential to emit for all non-emergency permitted emission units. Because this project only emits VOCs, only the SSPE for VOC will be calculated for the facility.

SSPE		
Permit Number	VOC (lbs/day)	VOC (lbs/yr)
X-XXXX-XX-X	[ ]	[ ]
TOTAL		[ ]
Offset Threshold	---	20,000
Offsets Required?	---	YES/NO

[If the emission unit is exempt from offsets per Rule 2201, Section 4.2.1, justify the exemption and skip the above section.]

VII. CALCULATIONS (continued)

6. Actual Emission Reductions (AER):

[For the projects using these GEARs, typically new emission units are being installed and there would not be any AERs. If the project might generate AERs, document whether information is available to quantify AERs. If data is not available, state that there are no AERs. If data is available, obtain it from the source, but don't actually calculate the AERs in this evaluation (because of the priority timeframe).]

7. Public Notice:

Per Rule 2201 Section 5.1.3.4.2, public notification is required for new and modified sources with increases in permitted emissions (IPE) greater than 100 lb/day of VOC, NOx, or CO in CO non-attainment areas. As shown in the table below, the IPE of the highest emissions unit does not exceed the public notification threshold.

Per R*u*le 2201, Section 5.1.3.4.3 through 5.1.3.4.5, public notification is required for new and modified sources with an increase in permitted emissions for those pollutants reaching the NSR balance notification thresholds, equal to or greater than 140 lb SOx/day or 70 lb PM10/day or 550 lb CO/day in CO attainment areas.

Pollutant	Threshold	Emissions	Public Notice triggered?
NOx	NSR IPE > 100 lb/day	lb/day	
VOC	NSR IPE > 100 lb/day	lb/day	
CO	NSR IPE > 100 lb/day OR NSR IPE and NSR Balance > 550 lb/day	lb/day OR NSR Balance = lb/day	
PM10	NSR IPE and NSR Balance > 70 lb/day	NSR Balance = lb/day	
SOx	NSR IPE and NSR Balance > 140 lb/day	NSR Balance = lb/day	

Based on the above IPE, the requirements relating to Notification and Publication of Preliminary Decisions per Rule 2201, Section 5.1.3.4, are not required.

VII. CALCULATIONS (continued)

8. Daily Emission Limitations (DELs):

The permit will include a condition which limits annual ETO usage and a condition stating the minimum control efficiency of the ETO abator system. These conditions will be considered equivalent to a DEL for this permit unit.

VIII. COMPLIANCE

Rule 2201 New and Modified Stationary Source Review Rule

BACT

BACT is required for a new source or modification if there is an increase in potential to emit (IPE) greater than 2 lb/day for NOx, PM10, VOC or SOx, per Section 4.1.1. For this project, IPE is XX lb VOC/day. Therefore, BACT is not triggered.

Offsets

Section 4.2.3 states that offsets shall be required for increases in VOC emissions if the SSPE exceeds 10 ton-VOC/yr. This facility's SSPE for VOC, as calculated in Section VII of this document, is less than 10 tons/yr. Offsets are not required.

Public Notification

Section 5.1.3.4.1 requires public notification for new major sources and Title I modifications. Section 5.1.3.4.2 requires public notification for projects with an IPE ≥ 100 lb-VOC/day. As shown in Section VII of this document, the IPE for this project does not exceed 100 lb-VOC/day. Public notification is not required.

Daily Emissions Limitation (DEL)

Section 5.1.9.2 requires that the Permit to Operate include enforceable conditions which reflect applicable emission limits. This requirement will be satisfied by including the conditions referred to in Section VII.B.8 of this document on the permit.

VIII. COMPLIANCE (continued)

Rule 4102 Nuisance

Public nuisance conditions are not expected as a result of these operations, provided the equipment is well maintained as required by permit condition.

Because this project results in ETO emissions less than the de minimus levels as specified in District policy GEAR-8, the health risks from ETO emissions are considered insignificant and no further Health Risk Assessment is required.

[or]

Health Risk Assessment (HRA) is required for projects with prioritization scores of one or greater. BACT for toxic emission control (T-BACT) is not required for this project because the HRA (see Attachment XXX) indicates that the risk is below the District acute, chronic, and cancer risk thresholds for triggering T-BACT requirements.

[or]

Health Risk Assessment (HRA) is required for projects with prioritization scores of one or greater. BACT for toxic emission control (T-BACT) is required for this project because the HRA (see Attachment XXX) indicates that the risk is above the District acute, chronic, and cancer risk thresholds for triggering T-BACT requirements. The applicant has proposed T-BACT by using sterilizer with control efficiency meeting the state's Air Toxic Control Measure (17 CCR, section 93108); therefore, compliance with District Risk Management Policy is expected.

Rule 7021 Ethylene Oxide - Sterilizers and Aerators

Use one of the following as applicable:
[Facilities using less than 25 lb ETO per year:]
Section 4.1 of the rule exempts facilities with total ETO usage less than or equal to 25 lb/year from control requirements. ETO usage at this facility is limited to XX lb/year.

[Facilities using more than 25 and less than 600 lb ETO per year:]
The proposed control system for the new sterilizer is expected to achieve 99% control efficiency, which satisfies the requirements of this rule for facilities using more than 25 and less than or equal to 600 pounds of ETO per year. The ETO control system will be source tested to verify compliance with this rule before an operating permit is issued.

[Facilities using more than 600 and less than 5,000 lb ETO per year:]
The proposed control system for the new sterilizer is expected to achieve 99.9% control efficiency, which satisfies the requirements of this rule for facilities using more than 600 and less than or equal to 5,000 lbs per year. The ETO control system will be source tested to verify compliance with this rule before an operating permit is issued.

[Facilities using more than 5,000 lb ETO per year:]
The proposed control system for the new sterilizer is expected to achieve 99.9% control efficiency, which satisfies the requirements of this rule for facilities using more than 5,000 lbs per year. The ETO control system will be source tested to verify compliance with this rule before an operating permit is issued.

Recordkeeping of date and time of each sterilizer operation cycle and all ETO purchases shall be required. In addition, the facility will be required to submit the above information in a written report to the District office by March 1 of the following year. Source testing upon start-up and every year thereafter will also be required.

IX. RECOMMENDATIONS

Compliance with all applicable prohibitory rules and regulations is expected. Issue Authority to Construct subject to the permit conditions on the attached draft Authority to Construct.

X. BILLING INFORMATION

PERMIT NUMBER	FEE SCHEDULE	FEE DESCRIPTION
X-XXXX-XX-X	3020-06-X	*Miscellaneous*

ATTACHMENT I
Authority to Construct
Standard Conditions

The following conditions shall be used for all ETO sterilizers:

1. {118} No air contaminant shall be released into the atmosphere which causes a public nuisance [District Rule 4102]

2. {376} Sterilizer exhaust stream vacuum pump working fluid shall not be discharged to wastewater stream. [District Rule 7020]

3. {377} All the emissions from the sterilizer/aerator shall be vented to the control device. [District Rule 7020]

4. {378} A daily record log shall be maintained with the following: date and time of each sterilizer operation cycle: record of all ethylene oxide purchased. These record shall be retained for 24 months. [District Rule 7020]

5. {379} Permittee shall furnish a written report to the District office by March 1st of the following year with the following: the number of sterilizer cycles; pounds of ethylene oxide purchased, used and returned in the previous year, OR

6. {380} Permittee shall furnish a written report to the District office by march 1st of the following year with the following: total pounds of sterilant gas and total pounds of ethylene oxide purchased, used an returned in the previous calendar year.

7. {381} An initial source test shall be required for the sterilizer and associated emission control device and shall be conducted within 90 days of initial start-up date to establish control efficiency of the control device for the sterilizer.

8. {382} Source testing shall include CARB Method 431 to determine the emissions of ethylene oxide. The contractor performing the source test shall be CARB approved for that method used.

9. {383} Source testing shall be conducted using the methods and procedures approved by the District. The District must be notified 30 days prior to any compliance source test, and a source test plan shall be submitted for approval 15 days prior to testing.

10. {384} Source test reports shall be submitted to the District within 60 days of completion of source testing.

11. {385} Any piping, ducting, fittings, or valves from the sterilizer and aerator to the control device shall be leak free.

[Additional conditions for ETO Sterilizers with ethylene oxide usage of more than 25 pounds and less than or equal to 600 pounds in any one calendar year:]

12. {386} The control efficiency of the ETO Sterilizer shall be at least 99%.

13. {387} Ethylene oxide usage shall not exceed 600 pounds in any one calendar year.

[Additional conditions for ETO Sterilizers with ethylene oxide usage of more than 600 pounds and less than or equal to 5,000 pounds in any one calendar year:]

12 {388} The control efficiency of the ETO Sterilizer shall be at least 99.9%. The control efficiency of the ETO Aerator shall be at least 95%. [District Rule 7021]

13. {389} Ethylene oxide usage shall not exceed 5,000 pounds in any one calendar year.

[Additional conditions for ETO Sterilizers with ethylene oxide usage of more than 5,000 pounds in any one calendar year:]

12. The control efficiency of the ETO Sterilizer shall be at least 99.9%. The control efficiency of the ETO Aerator shall be at least 99%. [District Rule 7021]

[The following general conditions are used for all Aerations Only Facilities:]

1. {118} No air contaminant shall be released into the atmosphere which causes a public nuisance [District Rule 4102]

2. {390} The control efficiency of the ETO aerator shall be at least 95%. [District Rule 7021]

ATTACHMENT II

SAN JOAQUIN VALLEY UNIFIED APCD

PERMIT SERVICES DIVISION

ETO STERILIZER/AERATOR COMPLETENESS CHECK LIST:

	Description
	1. Facility name, mailing address, application signed, contact & contact phone # identified.
	2. Project site address/location
	3. Equipment description of (a) sterilizer; (b) aerator, (c) aeration only facility
	4. Process parameters (operating schedule, cycle time, lbs of ETO/cycle, etc.)
	5. Annual consumption of ETO per Sterilizer and Aerator unit(s)
	6. Daily maximum usage of ETO per Sterilizer and Aerator

BIBLIOGRAPHY

Rules and Regulations		
Rule Number	Title	Last Updated
District Rule 2010	Permits Required	12/17/1992
District Rule 2201	New and Modified Stationary Source Review Rule	6/15/1995
District Rule 4102	Nuisance	12/17/1992
District Rule 7021	Ethylene Oxide - Sterilizers and Aerators	12/17/1992

District Policies		
Policy Number	Title	Last Updated
TOX 1	Risk Management Policy for Permitting New and Modified Sources	6/23/1997
BACT 1	Best Available Control Technology (BACT) Policy	4/18/1995

Electronic Documents		
Document Name	Title	Last Updated
G:/per/gear/eto_rv.doc	Standard Application Review for Ethylene Oxide (ETO) Sterilizers and Aerators	12/1/1997

Reference Materials		
Document Name	Title	Last Updated
17 CCR, Section 93108	Ethylene Oxide Airborne Toxic Control Measure - Sterilizers and Aerator	12/17/1993

Miscellaneous		
Item	Title	Last Updated
General Conditions	General Condition #s 118, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389	12/1/1997
Checklist	Over-the-Counter Processing Checklist	12/1/1997
NSR Calculations	Generic New Source Review Calculations	12/1/1997