

Regulation 1138

Emission Standards for Hazardous Air Pollutants for Source Categories

Section 9.0

Hospital Ethylene Oxide Sterilizers

December 3, 2008

Public Hearing



**DNREC
Air Quality Management Section**

**A New Breed of
Federal Air Toxics
Regulations**

112(k) of the CAA

Reducing Potential Adverse Health Impacts from Small Facilities

- Under Section 112(k) of the CAA, Congress mandated EPA to reduce cancer attributed to small area sources by at least 75%
- Congress required EPA to
 - Identify 30+ HAPs that present the greatest threat to public health
 - Identify source categories that emit 90% of these 30+ HAPs
 - Issue regulations to achieve the 75% reduction in cancer

Reducing Potential Adverse Health Impacts from Small Facilities

- **Ethylene oxide** is one of 33 identified
- **Hospital ethylene oxide sterilizers (ETO sterilizer)** is one of the 70 source categories identified
- Federal **ETO sterilizer** rule (40 CFR Part 63 Subpart WWWW) was finalized in December 2007

ETO

Its Public Health Concerns

Public Health Concerns

Potential health impacts from exposure to **ETO** based on EPA's Integrated Risk Information System (IRIS) database

- Cause problems in the proper function of the brain and nervous system
- Irritates the eyes, skin, and mucous membranes
- Classed as a probable human carcinogen
- Increased incidences of
 - Leukemia
 - Pancreatic cancer
 - Stomach cancer
 - Hodgkin's disease

Federal & DNREC

Regulatory Requirements for Hospital Ethylene Oxide Sterilizers

Federal Adoption of the Area Source Standard

40 CFR Part 63 Subpart WWWW

Proposed Rule 71 FR 64907, November 6, 2006

Final Rule 72 FR 73611, December 28, 2007

This Federal rule served as the starting point
in the development of Section 9 of Regulation 1138

DNREC's Proposed Section 9

- Proposed Section 9 of Regulation 1138 appeared in the November 1, 2008 Delaware Register of Regulations
- DNREC proposed rule is more stringent than federal
 - Provides additional best management practices
 - Requires development and implementation of a Startup, Shutdown & Malfunction Plan
 - For ETO Sterilizers equipped with pollution control devices
 - Establishes emission limitations
 - Requires additional compliance requirements, i.e. monitoring, recordkeeping & reporting

DNREC's Proposed Section 9 - Corrections

- Recommending corrections to the proposed Section 9 of Regulation 1138 to . . .
 - Correct errors
 - Improve clarity of the requirements
 - To avoid reopening the regulation when EPA mailing addresses change

DNREC's Proposed Section 9 - Corrections

- Correcting Errata - Example

9.6.1 . . . shall demonstrate ongoing compliance with the requirements of ~~[9.4.1]~~ [9.4.1.1] of this regulation by . . .

DNREC's Proposed Section 9 - Corrections

- Clarify Applicable Requirements - Example

9.7.1 ~~[For affected sources electing to comply with]~~
[The owner or operator of an affected source
subject to] 9.4.1.1 of this regulation [shall comply
with 9.7.1.1 through 9.7.1.3 of this regulation].

9.7.2 ~~[For affected sources electing to comply with]~~
[The owner or operator of an affected source
subject to] 9.4.1.2 of this regulation [shall comply
with 9.7.2.1 and 9.7.2.2 of this regulation].

DNREC's Proposed Section 9 - Corrections

- Avoid Reopening for Stale EPA Addresses - Example

~~9.7.4 The owner or operator shall send this notification via either of the following:~~

~~9.7.4.1 Electronic mail to CCG-ONG@EPA.GOV~~

~~9.7.4.2 U.S. EPA, Sector Policies and Programs
Coatings and Chemicals Group (E143-01)
Attn: Hospital Sterilizers Project Leader
Research Triangle Park, NC 27711]~~

Air Quality developed a compliance assistance tool to provide appropriate EPA addressing for notification, thus eliminating the need to reopen regulation

**Regulatory Requirements
For Public Noticing and
Participation Met**

Public Noticings during Development of Section 9

- Email communications with Interested Parties during development of draft and proposed language
- Public hearing notices in
 - The Delaware State News and Sunday News Journal
 - Mailing to people on the Public Hearing Notice List
 - Delaware Register of Regulations
 - State Calendar of Public Meetings
 - Publication in Air & Waste NEWS (e-news update)
 - DNREC NEWS press release
 - AQM's Section 9 regulatory web page

Other information

- Listing of known affected sources at the time of the public hearing
 - St Francis Hospital (Wilmington)
 - Christiana Hospital (Newark)
- The Department conducted a determination and found that Delaware's 2 affected sources do not qualify for additional consideration for less stringent requirements under the Regulatory Flexibility Act

OTHER PUBLIC HEARING HANDOUTS

In addition to the power point presentation, the Public Hearing Handouts included the following, which are available on the Hospital Ethylene Oxide Sterilizer regulatory website:

- List of the Departmental Exhibits entered into the hearing record
- EPA's Health Effects Fact Sheet for ethylene oxide
- Revised proposed regulation

<http://www.awm.delaware.gov/Info/Regs/Pages/ETOSterilizer.aspx>