

DETERMINATION OF CYCLE TIMES FOR ETHYLENE OXIDE PROCESSES



TECHNICAL TIP #18

Background

Price setting for gamma sterilization is, in most cases, straightforward and simple. The amount of radiation dose requested by the Customer and the product density are used in a simple formula to calculate cycle time. Cycle time is defined as the time that each carrier dwells in each position within an irradiator and is directly proportional to cost per carrier or cost per cubic foot of product processed.

Since all irradiators have multiple dwell positions, cycle time determines the amount of time the product remains in the irradiator, which determines the amount of radiation energy delivered to the Customer's product. This holds true for both a batch type irradiator, which processes a set number of carriers in each run, and a continuous type irradiator, which as the name implies, processes carriers on a continuous basis. Unlike ethylene oxide sterilization which is dedicated to the Customer, radiation sterilization allows many different Customers' products to be processed in the irradiator simultaneously.

Price setting for ethylene oxide sterilization is also based on cycle time. However, unlike the simple dose/density cycle time as defined for radiation, ethylene oxide sterilization cycle time is

defined as the time the product remains resident in the dedicated sterilization chamber during the sterilization process. In other words, cycle time for ethylene oxide is a summation of the time required to deliver each phase of the sterilization process from the time the door is closed on the vessel until the time it re-opens for product removal after the process.

To accurately estimate a price for ethylene oxide sterilization, the time for each phase must be estimated and the total time calculated from these estimates. Armed with this information, a cost estimate can be generated for a new or existing client.

Customer Specifications

To provide a price estimate for a client, a specification defining the cycle parameters is required. If the Customer specification is not available, contact STERIS's Isomedix Services, Ethylene Oxide Technology Center. At a minimum, the specification should contain a list of each phase of the sterilization process and the times associated with each phase.

Typical EO Specification

Table 1 is an example of a simple EO specification which, for discussion purposes, we will analyze and estimate a total cycle time.

Table 1

Cycle Phase		Setpoint	Tolerances
Chamber Temperature	a. Cycle Start Temperature	130°F	± 5°F
	b. Exposure Dwell Temperature	130°F	± 5°F
Initial Evacuation	a. Evacuation Pressure	1.0" HgA	± 0.5" HgA
	b. Evacuation Rate	2.0" HgA/minute	< /= 2.5 HgA/minute
Nitrogen Dilution (Pre-EO Exposure)	a. Injection Pressure	4.0" HgA	± 0.5" HgA
	b. Injection Rate	1.0" HgA/minute	N/A
	c. Evacuation Pressure	1.0" HgA	± 0.5" HgA
	d. Evacuation Rate	2.0" HgA/minute	< /= 2.5" HgA/minute
	e. Number of Repetitions	1	N/A
Humidity Injection & Humidity Dwell	a. Injection Pressure	3.8" HgA	± 0.5" HgA
	b. Humidity Dwell Control Pressure	3.8" HgA	± 0.5" HgA
	c. Dwell Time	60 minutes	-0,+15 minutes
Sterilant Injection & Exposure	a. Injection Rate	1.0" HgA/minute	N/A
	b. Sterilant Temperature	167°F	N/A
	c. Injection Pressure	15.1" HgA	± 0.5" HgA
	d. Dwell Time	240 minutes	-0,+0 minutes
Sterilant Removal	a. Evacuation Pressure	1.0" HgA	± 0.5" HgA
	b. Evacuation Rate	2.0" HgA/minute	< /= 2.5" HgA/minute
Nitrogen Wash (Post-EO Exposure)	a. Evacuation Pressure	20.0" HgA	± 0.5" HgA
	b. Evacuation Rate	2.0" HgA/minute	N/A
	c. Evacuation Pressure	1.0" HgA	± 0.5" HgA
	d. Evacuation Rate	2.0" HgA/minute	< /= 2.5" HgA/minute
	e. Vacuum Hold	15 minutes	N/A
	f. Number of Repetitions	3	N/A
Final Airbreak	a. In-bleed Pressure	Ambient	N/A
	b. In-bleed Rate	N/A	N/A

Cycle Phase Analysis

Chamber Temperature

- a. Cycle Start Temperature 130°F ± 5°F
- b. Exposure Dwell Temperature .. 130°F ± 5°F

Chamber Temperature becomes an issue if the requested temperature (130°F in this example) is outside the temperature normally used at the sterilizing facility. Many hours of sterilizer time may be consumed by heating and cooling the chambers. This must be taken into consideration when estimating a Customer's cycle price.

Initial Evacuation

- a. Evacuation Pressure 1.0" HgA ± 0.5" HgA
- b. Evacuation Rate 2.0" HgA/minute ≤ 2.5" HgA/minute

All processes delivered at STERIS's Isomedix Services are sub-atmospheric processes (vacuums). For analysis purposes, we will assume that atmospheric pressure is at 29" HgA (pronounced as 29 inches of Mercury absolute). Using the Evacuation Pressure requested (1.0" HgA), we calculate the Difference in pressure from atmospheric pressure (29" HgA) to the requested Initial Evacuation A pressure of 1.0" HgA. Also note the rate involved with the evacuation (2.0" HgA/minute). We will set the equipment at the requested rate.

NOTE: Due to limitations inherent in the vacuum system when operating in deep vacuums, a tailing in rate occurs after approximately 5.0" HgA is attained. When requested vacuums are below 5.0", as in this example, add an additional 5 minutes for vacuum pump efficiency losses.

Calculate:

Atmospheric Pressure =	29.0" HgA
Requested Evacuation Pressure =	1.0" HgA
Difference (Delta) =	28.0" HgA
Rate =	2.0" HgA/minute
Time Required (Delta/Rate) 28.0/2.0 =	14 minutes
Efficiency below 5.0" HgA Correction =	5 minutes
Total Time for Initial Evacuation A =	19 minutes

Nitrogen Dilution (Pre-EtO Exposure)

- a. Injection Pressure 4.0" HgA ± 0.5" HgA
- b. Injection Rate 1"HgA/minute N/A
- c. Evacuation Pressure ... 1.0" HgA ± 0.5" HgA
- d. Evacuation Rate ... 2.0"HgA/minute ... ≤ 2.5" HgA/minute
- e. Number of Repetitions 1 N/A

Nitrogen Dilution is a safety phase used at most facilities. In this example, nitrogen is injected to 4.0" HgA at a rate of 1" HgA/minute and evacuated back to 1.0" HgA at a rate of 2"/minute. This is performed one time per this specification.

Calculate:

Nitrogen Injection

Initial Evacuation Pressure =	1.0" HgA
Nitrogen Injection Pressure =	4.0" HgA
Difference (Delta) =	3.0" HgA
Inject Rate =	1.0" HgA/Minute
Time Required (Delta/Rate) = 3.0/1.0 =	3 minutes

Evacuation

Nitrogen Injection Pressure =	4.0" HgA
Initial Evacuation Pressure =	1.0" HgA
Difference (Delta) =	3.0" HgA
Evacuation Rate =	2.0" HgA/minute
Time Required (Delta/Rate) =	3.0/2.0 = 1.5 minutes
Efficiency below 5.0" HgA Correction =	5 minutes
Time for Initial Nitrogen Evacuation =	6.5 minutes
Total Time for Nitrogen Dilution =	9.5 minutes

Humidity Injection & Humidity Dwell

- a. Injection Pressure 3.8" HgA ± 0.5" HgA
- b. Humidity Dwell Control Pressure 3.8" HgA ± 0.5" HgA
- c. Dwell Time 60 minutes -0,+15 minutes

Humidification begins at the pressure remaining from the previous phase. Evacuation pressure was 1.0" HgA and we inject steam to 3.8" HgA and hold (dwell) it at that pressure for 60 minutes.

There is usually not a rate associated with this phase of the process. As a "rule of the thumb," allow 10 minutes for steam injection.

Time Required Steam Injection =	10 minutes
Time Required for Dwell =	60 minutes
Total Time for Humidity =	70 minutes

Sterilant Injection & Exposure

- a. Injection Rate 1.0" HgA/minute N/A
- b. Sterilant Temperature 167°F N/A
- c. Injection Pressure 15.1" HgA ± 0.5 " HgA
- d. Dwell Time 240 minutes -0,+0 minutes

Sterilant Injection and Exposure begins at the pressure remaining from the previous phase. Humidification pressure was 3.8" HgA, and we inject sterilant to 15.1" HgA and hold (exposure dwell) it at that pressure for 240 minutes.

Calculate:

Humidification Pressure =	3.8" HgA
Sterilant Injection Pressure =	15.1" HgA
Difference (Delta) =	11.3" HgA
Inject Rate =	1.0" HgA/minute
Time Required (Delta/Rate) =	$11.3/1.0 = 11.3$ minutes
Time Required Sterilant Injection =	11.3 minutes
Time Required for Dwell =	240 minutes
Total Time for Exposure =	251.3 minutes

Sterilant Removal

- a. Evacuation Pressure .. 1.0" HgA ± 0.5 " HgA
- b. Evacuation Rate .. 2.0" HgA/minute .. ≤ 2.5 " HgA/minute

Using the Evacuation Pressure requested (1.0" HgA), we calculate the Difference in pressure from the previous phase (15.1" HgA) to the requested Sterilant Removal Evacuation pressure of 1.0" HgA.

NOTE: The limitations inherent in the vacuum system when operating in deep vacuums are magnified during sterilant removal because of the high molecular weight of the ethylene oxide. We again experience a tailing in rate after approximately 5.0" HgA is attained. When requested vacuums for sterilant removal are below 5.0", as in this example, add an additional 20 minutes for vacuum pump efficiency losses.

Calculate:

Exposure Pressure =	15.1" HgA
Requested Evacuation Pressure =	1.0" HgA
Difference (Delta) =	14.1" HgA
Rate =	2.0" HgA/minute
Time Required (Delta/Rate) =	$14.1/2.0 = 7.0$ minutes
Efficiency below 5.0" HgA Correction =	20 minutes
Total Time for Sterilant Removal =	27 minutes

Nitrogen Wash (Post-EtO Exposure)

- a. Injection Pressure 20.0" HgA ± 0.5 " HgA
- b. Injection Rate 2.0" HgA/minute N/A
- c. Evacuation Pressure ... 1.0" HgA ± 0.5 " HgA
- d. Evacuation Rate 2.0" HgA/minute .. ≤ 2.5 " HgA/minute
- e. Vacuum Hold 15 minutes N/A
- f. Number of Repetitions 3 N/A

Nitrogen Wash is the phase designed to cleanse the product of residual ethylene oxide. It may be as simple as multiple nitrogen injects and vacuums or as complex as a steam sweep or flush coupled with hold times. For this example we will analyze a wash which incorporates three wash cycles, each with a 15-minute hold time.

Calculate:

Nitrogen Injection

Evacuation Pressure =	1.0" HgA
Nitrogen Injection Pressure =	20.0" HgA
Difference (Delta) =	19.0" HgA
Inject Rate =	2.0" HgA/minute
Time Required (Delta/Rate) =	$19.0/2.0 = 9.5$ minutes
Total Time for Three Injections =	$9.5 * 3 = 28.5$

Evacuation

Nitrogen Injection Pressure =	20.0" HgA
Initial Evacuation Pressure =	1.0" HgA
Difference (Delta) =	19.0" HgA
Inject Rate =	2.0" HgA/minute
Time Required (Delta/Rate) =	$19.0/2.0 = 9.5$ minutes
Efficiency below 5.0" HgA Correction =	15 minutes
Time for Each Nitrogen Evacuation =	24.5 minutes
Total Time for Three Evacuations =	73.5
Total Time for Three Vacuum Holds =	$15 * 3 = 45$ minutes
Total Time for Nitrogen Washes =	147 minutes

Final Airbreak

- a. In-bleed Pressure Ambient N/A
- b. In-bleed Rate N/A N/A

Final Airbreak allows air to enter the chamber until atmospheric pressure is attained and the door can be opened. In most applications this takes approximately 20 minutes, which we will use for this example.

Total Time for Final Airbreak = **20 minutes**

Putting It all Together!

Earlier we defined cycle time as the summation of the time required to deliver each phase of the ethylene oxide sterilization process. Thus, to estimate the total time, we add each phase as calculated above and get a total cycle time.

Total Time for Initial Evacuation A =	19 minutes
Total Time for Initial Nitrogen Dilution =	9.5 minutes
Total Time for Humidity =	70 minutes
Total Time for Exposure =	251.3 minutes
Total Time for Sterilant Removal =	27 minutes
Total Time for Nitrogen Washes =	147 minutes
Total Time for Final Airbreak =	20 minutes
Total Cycle time	543.8 / 60
Total Cycle Time	9.1 Hours

Caution

Many factors impact cycle time. The most accurate estimate is obtained from previous cycle records which reflect the actual time consumed. The above procedure will provide a ballpark estimate based on the assumptions made during the analysis.

For more information, please contact:

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