Project Name: **Experimental Model to Determine Potential Occupational Exposure to ETO**

Site: **Colorado**

Client: **Confidential**

Exposure Model

To select the best model to estimate the potential ETO occupational exposure we referenced the book Mathematical Models for Estimating Occupational Exposure to Chemicals, published by AIHA 2nd Edition. The model that best fits the desorption of gas from a solid was the exponentially decreasing emission rate formula.

The equation is shown below:

Equation 1

$$C(t) = \frac{\alpha M_0}{\alpha V - Q} \times \left[e^{\left(-\frac{Q}{V}t\right)} - e^{(-\alpha t)}\right]$$

With the following definitions of terms:

C = contaminant concentration (mg/m^3)
M_0 = initial contaminant mass in the source (mg)
α = emission rate (min^{-1})
Q = air supply rate (mg/m^3)
V = room volume m^3
t = time interval (min)

We simplified the equation to solve for α, the emission rate constant.

We constructed excel spreadsheets, containing the data and the appropriate equation to solve for α, the unknown emission rate constant for the product.

The emission value for each minute was calculated. Each calculated values were plotted and regressed to get a best fit line. The slope of the best fit line was used as the experimentally determined emission rate constant.

For modeling we selected the most conservative value for the emission rate constant.

Running Models

We employed an equation to determine when contaminant concentration would reach the maximum value at time t-peak

Using the selected rate constant, value of x.xx E -X and the peak time we then used equation 1 to calculate the C (expected concentration) for different scenarios. We used two extreme values of M_0 in the scenarios to see the effect.

The following are the scenarios run.

Scenario 1 Poorly ventilated closed

Scenario 2 Normal office space

Scenario 3 Laboratory

Conclusion

A method has been devised to measure the release of ETO from a new medical device. The method determined the concentration of ETO desorbed (off-gassed) in an enclosed system. ETO desorption concentration was tracked with time. Tables of concentration vs. time were created. The data was used with an appropriate equation to determine the exponentially decreasing emission rate. The data points were plotted and regressed to determine then emission rate constant for the product. The calculated emission rate constants were used in a dynamic model to determine the ETO concentrations likely to be found in an occupational setting. A review of the scenarios calculated ETO room concentrations were compared to occupational exposure limits. We were able o show that for the most conservative scenario (1) at the peak concentration time, the highest calculated ETO concentration levels were below the most conservative exposure limit, the NIOSH REL.

Therefore it is highly unlikely that any significant occupational exposure would occur as a result of the storage, handling or use of the product.