Compliance Assistance Tool for Clean Air Act Regulations: Subpart GGG of40 CFR NESHAPS for Source Category Pharmaceutical Production

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Chapter 10
Pollution Prevention

10.1 Overview

The pharmaceutical MACT rule allows the owner or operator of a manufacturing operation to use pollution prevention techniques to comply with the rule instead of installing traditional air pollution control devices. Essentially, the owner or operator demonstrates a 75% reduction (or a 50% with an additional 25% reduction achieved via traditional control devices) from a baseline amount, when adjusted for production. Rolling averages of the production-indexed consumption factor are calculated monthly and compared to the baseline value to confirm compliance with the pollution prevention standard.

Owners/operators of processes run in batch mode can demonstrate compliance with the pollution prevention standard on a schedule set according to the number of batches run per year. Any HAPs that are generated in the PMPU, and therefore not accounted for in the consumption factor, must be controlled according to the traditional standards for process vents, storage tanks, equipment leaks, and wastewater. The standard also contains restrictions regarding VOC consumption, as discussed further below, to avoid substituting VOC for HAP. The pollution prevention option is available only for existing sources; any unit which began production after April 2, 1997 is not eligible.

10.2 Structure of the Regulation

The pollution prevention standard is provided at §63.1252(e). The initial compliance demonstration requirements are described in §63.1257(f). These provisions describe how the baseline and annual factors are to be calculated for continuous and batch processes. In addition, these regulations describe the required elements for a pollution prevention (P2) demonstration summary, which must be submitted as part of the Precompliance Report (§63.1260(e)(4)). The monitoring requirements are contained in §63.1258(e) and pertain primarily to the calculation of rolling averages. Recordkeeping requirements are in §63.1259(b)(2).

10.3 Applicability

As mentioned in the Overview, the pollution prevention standard can be used only for existing sources. This is because it is impossible to calculate a baseline for a new source with no operating records. It makes sense to apply P2 planning concepts to new sources too, however.

The production-indexed consumption factor, on which the P2 standard is based, must be calculated at the PMPU level. The source should evaluate all components included in each PMPU to receive the maximum credit for emission reductions achieved within the PMPU. Additionally, the PMPU against which P2 is measured must begin with the same starting materials and end with the same products as the process for which the baseline was calculated. In other words, the source may not comply with the P2 option simply by eliminating steps by transferring the step off-site. For assistance in defining the PMPUs at a production site, the reader is referred to ° **Chapter 3 - Applicability**.

The owner or operator can choose to use the pollution prevention option for a series of processes, including situations where multiple processes are merged, as long as the processes were merged after the baseline period (single year no earlier than 1992) into an existing process or processes.

Definition of Baseline

To calculate the baseline annual consumption factor (kg HAP consumed per kg product made), the owner or operator must use consumption and production values averaged over the period from either:

1) startup of the process until the present time (if the process has been in operation for at least a year) OR
2) the first 3 years of operation (beginning no earlier than 1987), whichever is the **shorter time period**.

If the time period used is less than three years, the data must represent at least 1 year's worth of data.

10.4 Standards

The P2 regulations provide two options for the standard:

Pollution Prevention Options	
Option 1: Reduce the production-indexed consumption factor by at least **75%** from the baseline.	**Option 2**: Reduce the production-indexed consumption factor by at least **50%** from the baseline AND achieve additional reductions in emissions from control devices to yield at least a **75% overall reduction** in the consumption factor.

The difference in the two options is that traditional end-of-pipe emissions controls are being used to reach part of the 75% reduction in Option 2, while the 75% reduction in Option 1 is achieved entirely by using pollution prevention techniques.

The regulations specify which kinds of control devices may be used under Option 2. These are:

- combustion control devices such as incinerators, process flares, or process heaters,
- control devices such as condensers

and carbon adsorbers whose recovered product is destroyed or shipped offsite for destruction,
- any control device that does not allow for recycling of material back to the PMPU, or
- any control device for which the owner or operator can demonstrate that the use of the device will not affect the production-indexed consumption factor for the PMPU.

VOC Restrictions

To ensure that owner/operators do not achieve HAP emissions reductions merely by substituting VOC-containing materials for HAPs, the standard includes restrictions on VOCs. Therefore, if the HAP being reduced is classified as a VOC, then an equivalent reduction in the VOC consumption factor is also required. If a HAP being reduced is not also classified as a VOC, the VOC consumption factor cannot be increased.

Restriction on Generated HAP

If the manufacturing process itself generates HAP during the process, there is no way that these HAPs can be accounted for in the production-indexed consumption factor. Therefore, the owner or operator must control emissions of these “generated HAPs” according to the other, traditional standards for process vents, storage tanks, equipment leaks, and wastewater. Hydrogen halides that are generated as a result of control devices that use combustion must be controlled to 95% or to a concentration less than or equal to 20 ppmv.

Consumption

The definition of consumption in the regulations specifies that it is the quantity of all HAP raw materials entering a process in excess of the theoretical amount used as reactant, assuming 100 percent stoichiometric conversion. The raw materials include solvents and other additives as well as reactants. If the same HAP component is generated in the process as well as added as a raw material, consumption shall include the quantity generated in the process and the excess reactant, as calculated assuming 100 percent theoretical conversion. The pollution prevention option does not apply to HAPs used as reactants and totally consumed in the reaction.

10.5 Compliance Demonstration

For each process for which the P2 standard will be attempted, the owner or operator must:

1. **Calculate the baseline** as mentioned above in section 10.1, using at least one year’s worth of data, beginning no earlier than 1987. Divide the annual consumption of total HAPs (or VOCs) by the annual production rate:

Baseline HAP consumption factor =

$$\frac{annual\ kg\ total\ HAP\ consumed}{annual\ kg\ product\ made}$$

Baseline VOC consumption factor =

$$\frac{annual\ \ kg\ \ total\ \ VOC\ \ consumed}{annual\ \ kg\ \ product\ \ produced}$$

If more than one year of data will be used in calculating the baseline, take the average of the annual factors calculated.

2. **Calculate the annual consumption factor** after the implementation of P2 techniques as follows:

   For continuous processes - calculate the annual factor every 30 days for the 12-month period preceding the 30th day (i.e., calculate a 30-day rolling average).

   For batch processes - calculate the annual factor every 10 batches for the 12-month period preceding the 10th batch (10-batch rolling average) or a maximum of once per month, if the number of batches is greater than 10 batches per month..

3. **Demonstrate compliance** by showing that the baseline consumption factor has been reduced by 75% for Option 1. Case Study 1, on page 10-9 illustrates the use of the HAP consumption factor calculation, the VOC consumption factor calculation, and their evaluation to determine compliance. The case study is based upon a compilation of research and facility evaluations that EPA conducted in developing the rule and this plain English guide.

   If using Option 2 (add-on controls achieving balance of 75% reduction), the owner or operator must calculate the baseline HAP consumption factor and demonstrate a 50% reduction in consumption. In addition, the owner or operator must show that the yearly reduction achieved with the add-on controls (kg HAP/yr) is equal to or greater than the mass of HAP calculated using the following equation:

$$M=[kg/kg]_b \ x\ (0.75 - P_R)(M_{prod})$$

where:

$[kg/kg]_b$ =	the baseline production-indexed HAP consumption factor, in kg/kg
M_{prod} =	the annual production rate, in kg/yr
M =	the annual reduction required by add-on controls, in kg/yr
P_R =	the fractional reduction in the annual kg/kg factor achieved using pollution prevention where P_R \$0.5 and < 0.75.

The owner or operator must calculate the annual reduction achieved with the add-on devices using the methods described in §63.1257(d) in the process vents regulations (see ° **Chapter 8 - Compliance Demonstrations and Testing Procedures**).

To show that the add-on control devices used meet the criteria for allowable devices, the owner or operator must describe the control device and the material streams entering and exiting the control device.

Example Scenario for a Batch Operation - Using the same equipment, an operator follows an annual production cycle as shown below. All three processes use methanol in several wash cycles. The owner's pollution prevention strategy is two-fold: re-examine the process to determine if one of the wash cycles can be eliminated or done with a different material and install a closed-loop distillation unit to recover methanol, which will be reused in the same processes. The owner hopes to achieve a 75% reduction after implementation of his strategy. How does the owner determine whether he is in compliance with the standard?

	Process 1	**Process 2**	**Process 3**
production	5 batches	3 batches	4 batches
1. Determine baseline	20 kg methanol consumed/kg product produced	10 kg/kg	1 kg/kg
2. After installation of in-line methanol recovery device, calculate annual consumption factor	1kg/kg produced	.5 kg/kg	.5 kg/kg
3. Calculate percentage reduced	19/20 = 95 % reduction	9.5/10 = 95 % reduction	.5/1 = 50 % reduction
4. Was P2 goal achieved for process?	yes	yes	no; need to install additional controls to achieve 75% reduction

Note that the P2 goal must be assessed **for each process, not for the set of equipment**. Because each process has less than 10 batches per year, the annual consumption factor must be calculated with less than 10 batches. For purposes of calculating the baseline consumption factor and the annual consumption factor after implementation of the P2 plans, the operator must **track methanol consumption in each process separately**. To do this, the operator keeps a log book that tallies gallons of virgin methanol used in each process, on a daily, monthly, and annual basis. After the gallons of virgin methanol used per process is converted to kilograms, the operator can divide by the kilograms of finished product made per process. As a rough check on the virgin methanol figure, the operator could compare the annual consumption sums of the three processes to purchasing/inventory records that show how much methanol was purchased that year.

P2 Demonstration Summary

If an owner or operator uses the P2 option to achieve compliance with the MACT rule, he/she must prepare a P2 demonstration summary that contains:

- descriptions of the methodologies and forms used to measure and record daily consumption of HAP compounds
- descriptions of the methodologies and forms used to measure and record daily production of products
- supporting documentation for the descriptions above (e.g., operator log sheets, copies of daily, monthly, and annual inventories of materials and products)

10.6 Monitoring, Recordkeeping, and Reporting

Owners or operators electing to use the P2 option must prepare monthly calculations to demonstrate continued compliance with the P2 standard. The calculations are the same as those done to determine initial compliance. For continuous processes, the owner or operator must calculate monthly, on a rolling average basis, the HAP consumption factor and the VOC consumption factor. For batch processes, the owner or operator must calculate the annual factor every 10 batches, for the 12-month period preceding the 10th batch. The HAP consumption factor must be compared to the 75% or 50% reduction level (determined from the baseline) to confirm continued compliance. The VOC consumption factor must be compared to the baseline VOC consumption factor to confirm that it either does not go up (if the HAP being reduced is not a VOC) or that it is reduced (if the HAP being reduced is also a VOC). Each rolling average kg/kg consumption factor that exceeds the reduction value or the applicable VOC restriction is considered a violation of the emission limit.

Owners and operators must record the consumption, production, and rolling average values of the production-indexed HAP and VOC consumption factors used to demonstrate compliance with the pollution prevention standard. The P2 demonstration summary must be submitted as part of the precompliance report.

Q and A

Q. ***If an owner or operator makes changes to a process, such that it is considered a "new source," is that process no longer eligible for the pollution prevention option?***

A. *If the process is considered a "new source," it is not eligible for the pollution prevention option. (Please note that making changes to a process does not necessarily constitute a new source.)*

Q. ***If a process operates only six months of the year, how is the baseline calculated?***

A. *EPA's intent in using a year's worth of data to calculate the baseline is to ensure that the consumption and production figures are representative of the process and do not reflect anomalies and sensitivity in measurements. If the process routinely is conducted over a six-month period, however, and the operation is representative of how the process will be run in the future, it may be reasonable to calculate the baseline using the six-month period. In the P2 Demonstration Summary provided in the Precompliance Report, the owner/operator should describe why a baseline calculated with less than twelve months of data is legitimate for the intended purpose of calculated reductions achieved via pollution prevention.*

Q. ***What was EPA's rationale behind specifying the types of devices that can be used to achieve the balance of the 75% reduction in Option* 2?**

A. *EPA's intent is to ensure that control devices that allow recycling of solvent back into the process would not be used to make up the balance of the required 75% reduction, so that the results of using the control device aren't double-counted. For example, if a condenser's control efficiency is considered part of the reduction achieved by using add-on controls, the owner/operator should not also get credit for returning the recovered solvent back to the process. This would be double-counting the impact of the condenser.*

10.7 Examples

There are several different types of pollution prevention technologies applicable to the pharmaceutical manufacturing industry, including:

- material substitution - substituting raw materials to reduce the volume and/or toxicity of wastes,
- process modification - alteration of process or equipment to reduce wastes generated,
- good operating practices - adopting practices, such as employee training, improved maintenance programs, more rigorous inventory control, that will result in fewer material losses and generated wastes, and

- recycling, recovery, and reuse - in-process recycling of a material such that a smaller amount of the chemical is consumed and emissions are reduced.

Table 10-1 provides some examples of how different pollution prevention technologies have been applied successfully at pharmaceutical manufacturing plants. These examples are from the Sector Notebook prepared by EPA's Office of Compliance. Other examples of P2 in the pharmaceutical industry can be found in the sector notebook, *Profile of the Pharmaceutical Industry*, EPA 310-R-97-005, September, 1997.

For more reading on pollution prevention technologies, their application, and costing procedures for making decisions about using P2, the reader is referred to EPA's Enviroene website: http://es.epa.gov. The sector notebook referenced earlier in this chapter can be downloaded from this site:

http://es.epa.gov/comply/sector/index.html

Table 10-1. EXAMPLES OF POLLUTION PREVENTION EFFORTS

Pollution Prevention Examples		
Material Substitution	C	Riker Laboratories (Northbridge, CA) replaced several different organic solvent coating materials with a water-based coating materials, resulting in 24 tons per year reduction in organic solvent emissions.
	C	Glaxo-Wellcome eliminated the use of methylene chloride, isopropyl alcohol, methanol, and ethanol in a coating process by substituting aqueous-based materials. The new system reduced VOC emissions to the air from almost 15,000 pounds per year to zero.
Process Modification	C	To reduce the use of methanol in a cleanout process during product changeover, Hoffman La Rouche converted to a two-stage water -based cleaning system, before a final methanol rinse. This facility reduced the amount of methanol used from 110,000 gallons to 30,000 gallons per year.
	C	Merck replaced their steam jets used in a process vessel with liquid ring vacuum pumps. This reduced air emissions of dichloromethane which had been mixed with steam in the steam jets. Additional reductions in dichloromethane emissions were achieved by keeping the vacuum pump seal fluid at subzero temperatures such that the dichloromethane vapor was condensed and then reused.
	C	Sandoz Pharmaceutical Co. changed processes in its reactors to reduce solvent usage. In the new process, an inert atmosphere above the reaction mixture protects the reaction from exposure to oxygen. In the previous process, nitrogen flowed continuously over the mixture and carried away solvent vapors. The new system makes use of a non-flowing nitrogen layer that releases only a very small amount of nitrogen and solvent.
Good Operating Practices	C	A computerized inventory system in a central warehouse at a Schering-Plough Pharmaceuticals plant eliminates excess raw material wastes and ensures that only the exact amounts needed are used. Materials are weighed according to batch requirements, labeled, and sent to the appropriate process area.
Recycling, Recovery, and Reuse	C	Nycomed, Inc. Installed closed loop distillation units to recover all of its methanol from washes and methanol-containing wastewater. The recovered methanol is used in the same process. The company is reducing consumption of about one million pounds of methanol per year.
	C	A Pharmacia and Upjohn facility reuses more than 195 million pounds of solvent annually. The facility employs both in-process reuse and distillation. The company's efforts earned a National Performance Review Environmental Champion Award, given by Al Gore in 1995.

Case Study 1: 75% Reduction of HAP Consumption for and Existing Pharmaceutical Manufacturing Process Unit (PMPU)

The following case study is intended to illustrate the process for documenting compliance with the pollution prevention alternative standard. For this case, the manufacturer seeks to document that they have met the requirement for Option 1 (75% reduction) of the pollution prevention alternative standard.

Background:

Manufacturer A uses dichloromethane (methylene chloride) to produce an intermediate that is then processed elsewhere into a product. The intermediate manufacturing process is the only process that relies upon dichloromethane. Dichloromethane is used as a solvent in several steps of the manufacturing process. The entire intermediate manufacturing process is considered as single pharmaceutical manufacturing process unit (PMPU) that runs continuously throughout the year. The plant has the capacity to run several lines that all produce the same intermediate product. The data collected for the plant is inclusive off all lines running during the baseline period as well as subsequent monitoring.

Demonstrating Compliance:

Ø Manufacturer A reviews its dichloromethane consumption and intermediate production data to determine a baseline. The data is used to develop a Hazardous Air Pollutant (HAP) consumption factor. Since the process operates continuously, the manufacturer develops the baseline using monthly consumption and production rates and averages the HAP consumption factor over the three-year period.

The calculation is performed using the amounts of dichloromethane consumed by the process (i.e., recycled solvent is not included in the calculation if it is reused in the process). The HAP consumption factors are calculated for each year using the following equation and then averaged:

$HAP_{Consumption\ Factor}$ = $HAP_{Consumed}$ (kg)/Product (kg)

Sample Calculation:

1987: 6.2M kg $MeCl_2$ used 2.5M kg of product $HAP_{Consumption\ Factor}$ = 6.2/2.5 = 2.48kg/kg

1988: 5.9M kg $MeCl_2$ used 2.5M kg of product $HAP_{Consumption\ Factor}$ = 5.9/2.5 = 2.36kg/kg

1989: 6.4M kg $MeCl_2$ used 2.8M kg of product $HAP_{Consumption\ Factor}$=6.4/2.8 = 2.36kg/kg

The average $HAP_{Consumption\ Factor}$= 2.4kg of HAP consumed/kg of product

To document compliance, the manufacturer must also demonstrate that the total VOC consumed in this process does not increase as a result of pollution prevention alternatives that eliminate HAPs. As such, the manufacturer must also baseline and track total VOC consumption using a similar ratio of $VOC_{Consumption\ Factor}$ = $VOC_{Consumed}$ / Product. For our case, the $VOC_{Consumption\ Factor}$ ratios for 1987-89 are as follows:

1987: $VOC_{Consumption\ Factor}$ = 11.4M kg/2.5M kg = 4.56

1988: $VOC_{Consumption\ Factor}$ = 10.8M kg/2.5M kg = 4.32

1989: $VOC_{Consumption\ Factor}$ = 12.3M kg/2.8M kg = 4.39

The average $VOC_{Consumption\ Factor}$ for 1987-89 = 4.42kg VOC/kg of product

Pollution Prevention Approaches Selected

The manufacturer implemented the following pollution prevention alternatives over the period from 1987 through 1999:

1988 - install recyclable seal water vacuum pumps
1990 - initiate procedure to steam strip aqueous waste streams and process still bottoms to recovery dichloromethane.
1991-92 - test use of less dichloromethane in the process within FDA approved manufacturing limits. Test demonstrate that reductions in the amount of solvent used will not impact purity or quality. Reduction are implemented within FDA approved ranges.
1991-92 - Test and propose use of recycled dichloromethane in intermediate manufacturing process. Approval from FDA allows additional uses of recycled dichloromethane in manufacturing
1993-94 - upgrade carbon absorption system
1994 - map vents and attach all vents that receive dichloromethane to the carbon adsorption unit.
1995-96- change handling of intermediate products to ensure all volatilized dichloromethane is recovered.
1998-99 - segregate and capture all dichloromethane aqueous wastes and process through steam stripper and carbon absorption unit.

Ù Manufacturer A computes the monthly $HAP_{Consumption\ Factor}$ for the PMPU. The monthly values are averaged into an annual value. The values for 1997-99 for $HAP_{Consumption\ Factor}$ and $VOC_{Consumption\ Factor}$ are presented below.

1997: 2.48M kg $MeCl_2$ used 5.0 M kg of product $HAP_{Consumption\ Factor}$= 2.48/5.0 = 0.50kg/kg

1998: 3.52M kg $MeCl_2$ used 6.25M kg of product $HAP_{Consumption\ Factor}$= 3.52/6.25 = 0.56kg/kg

1999: 2.88M kg $MeCl_2$ used 7.0M kg of product $HAP_{Consumption\ Factor}$= 2.88/7.0 = 0.41kg/kg

The percent reduction of the $HAP_{Consumption\ Factor}$ is 79.2%, 76.6%, and 82.9% for 1997, 98, and 99, respectively. Manufacturer A must also demonstrate that their pollution prevention activities have not resulted in increased consumption of VOCs:

1997: $VOC_{Consumption\ Factor}$ = 21.5M kg/5.0M kg = 4.3

1988: $VOC_{Consumption\ Factor}$ = 25.5M kg/6.25M kg = 4.08

1999: $VOC_{Consumption\ Factor}$ = 28.7M kg/7.0M kg = 4.10

Each of these values is below the three-year average for the $VOC_{Consumption\ Factor}$ and meets the requirement. Having not increased VOC consumption, Manufacturer A has met the numeric reduction standard for $HAP_{Consumption\ Factor}$ of 75% to claim the pollution prevention alternate standard.

Ú To document and demonstrate on-going compliance, Manufacturer A must provide all of the information identified in the rule and summarized on page 10-6 of this document.