STATE OF NEW YORK
DEPARTMENT OF ENVIRONMENTAL CONSERVATION

In the Matter of the Petition of
Bristol-Myers Squibb Company for a
Declaratory Ruling

DECLARATORY RULING
DEC #19-10

INTRODUCTION

Bristol-Myers Squibb Company ("BMS") petitions, under 6 NYCRR §619, for a declaratory ruling as to whether the Department may require BMS to take certain actions requested by Department staff before it may employ coolant temperature monitoring of its condensers in implementing the process control requirements described in 6 NYCRR §233.3(a). Specifically, staff have requested that for each individual condenser that sometimes experiences negligible gas flow BMS (1) continue to monitor the condenser outlet gas temperature during those times when there is nonnegligible gas flow and (2) establish a correlation between the coolant temperature and the outlet gas temperature by either undertaking a particular type of "stack testing" or providing certain condenser design and engineering information.

DECLARATORY RULING

In resolving the issues raised in the petition, the Department makes the following determinations:

1. The Department has the authority to require BMS to monitor both the outlet gas temperature and the coolant temperature for any individual condenser that sometimes experiences negligible gas flow.

2. The Department lacks the authority to require BMS to undertake the specific requested correlation demonstration before BMS may ever use coolant temperature monitoring to comply with the control requirements of 6 NYCRR §233.3(a).

3. The Department has the authority to demand and obtain condenser design and engineering information for the condensers used by BMS.

4. The Department has the authority to require BMS to perform emissions testing to demonstrate compliance with any applicable statutory or regulatory requirement.

STATEMENT OF FACTS

For purposes of this declaratory ruling only, the Department will assume that the facts alleged in the petition are true. The Department may take official notice of any fact not subject to reasonable dispute if it is either generally known or can be accurately and readily verified. 6 NYCRR §619.2(b).

BMS operates a pharmaceutical manufacturing process within the meaning of 6 NYCRR §233.2(b)(8) at its Thompson Road facility in Syracuse, New York. Because BMS's facility has the annual potential to emit at least 50 tons of volatile organic compounds ("VOCs") from all sources regardless of process type, excluding combustion installations, it had to submit a compliance plan to the Department by November 15, 1993, containing a schedule of the steps necessary for the facility to achieve compliance with 6 NYCRR Part 233 and be in compliance by June 1, 1995. See 6 NYCRR §233.1(d)(4).

6 NYCRR §233.3 sets forth various control requirements that must be imposed on sources of VOC emissions at a facility of the type operated by BMS. To control emissions of VOCs from its process equipment, BMS employs surface condensers[1] pursuant to 6 NYCRR §233.3(a). This subdivision provides as follows:

> *Process equipment requirements.* The owner or operator of a pharmaceutical manufacturing process subject to this part must control the volatile organic compound emissions from reactors, extractors, distillation operations, crystallizers, centrifuges, and vacuum dryers which have an emission rate potential of more than 15 pounds per day as follows:
>
> (1) When surface condensers are used, the condenser outlet gas temperature must not exceed the allowable temperature limit described for each associated vapor pressure in the Table 1.

Table 1

VOC vapor pressure at 20 °C (psi)	*Allowable condenser outlet gas temperature (°C)*
) 5.8	*-25*
) 2.9	*-15*
) 1.5	*0*
) 1.0	*10*
) 0.5	*25*

[1] "Condenser" is defined as "[a] device which cools a gas stream to a temperature at which all or some of the vaporized volatile organic compounds in the gas stream will condense and will be removed." 6 NYCRR §233.2(b)(2).

(2) If the operation of a condenser at the exit temperature specified above results in freezing and consequent plugging of the condenser, the allowable exit temperature may be raised to a maximum of 2°C above the freezing point of the volatile organic compound.

(3) In cases where the condenser outlet gas temperature is not readily measurable due to negligible gas flow rate, the temperature of the condenser coolant may be used in lieu of condenser outlet gas temperature as long as the temperature of the condenser coolant does not exceed the allowable condenser outlet gas temperature shown in Table 1.

The monitoring requirements for air cleaning devices are set forth at 6 NYCRR §233.4(d) which provides as follows:

If an air cleaning device is used, continuous monitors for the following parameters must be installed, periodically calibrated, and operated at all times that the associated process equipment and control equipment are operating:

(1) an exhaust gas temperature of all incinerators;

(2) temperature rise across a catalytic incinerator bed;

(3) breakthrough of volatile organic compounds on a carbon adsorption unit; and

(4) outlet gas temperature of a refrigerated condenser;

(5) temperature of nonrefrigerated condenser coolant supply system; or

(6) any other continuous monitoring or recording device required by the commissioner for the purpose of demonstrating compliance with the control requirements of this Part.

Some of BMS's manufacturing operations are done on a batch basis rather than on a continuous basis. BMS estimates that its condensers experience negligible gas flow approximately 25-50% of the time that they are operating. If BMS were to rely solely on continuous monitoring of the outlet gas temperature at times of negligible gas flow, atmospheric air would occupy the area near the outlet and the temperature of this air would exceed the Table 1 values and mistakenly show a noncompliant condition.

Since July 1995, BMS and Region 7 staff have been engaged in discussions regarding how BMS will comply with the terms of 6 NYCRR Part 233. BMS and staff were unable to resolve the matter. At staff's suggestion, BMS submitted its petition for a declaratory ruling.

BMS contends that its condensers fall within the scope of 6 NYCRR §233.3(a)(3) and that it should be deemed in complete compliance with the control requirements of 6 NYCRR §233.3(a) so long as it can show that the coolant temperature of each individual condenser does not exceed the limits listed in Table 1. BMS claims that no showing of outlet gas temperature is required for any of these condensers that sometimes experience negligible gas flow. Because of the purported inapplicably of outlet gas temperature measurements for determining compliance with the terms of the 6 NYCRR §233.3(a) control requirements, BMS claims the applicable monitoring requirement for its condensers is set forth for at 6 NYCRR §233.4(d)(6) and not §233.4(d)(4).

Department staff contend that BMS may not be deemed to comply with the control requirements of 6 NYCRR §233.3(a) by measuring condenser coolant temperature alone. Staff read the regulation as (1) requiring monitoring of the outlet gas temperature during those time periods when the gas flow is nonnegligible and (2) allowing the use of coolant temperature monitoring during those time periods when the gas flow is negligible so long as a demonstration is made showing that there is a correlation between the coolant temperature and the outlet gas temperature. Under the first part of staff's interpretation, both the outlet gas temperature and coolant temperature must be monitored for each individual condenser. For each individual condenser, staff view the two monitoring methods as complementary rather than exclusive. Under the second part of staff's interpretation, BMS cannot be deemed to have properly employed the coolant temperature monitoring method unless it submits either certain "stack test" results or sufficient condenser design and engineering information proving the correlation with the outlet gas temperature. Staff further cite 6 NYCRR Part 202-1 (concerning the Department's authority to require a person to perform emissions testing, sampling and analytical determinations) as support for the request for a correlation demonstration.

RATIONALE

The Department has the authority to require BMS to monitor both the outlet gas temperature and the coolant temperature for any individual condenser that sometimes experiences negligible gas flow.

This determination depends primarily on the proper interpretation of the phrase "In cases where" found in 6 NYCRR §233.3(a)(3). Unfortunately, this phrase is ambiguous. It can be read either as relating to just those certain time periods when the gas flow past the condenser is negligible or it can be read as relating to the overall status of the gas flow without regard to individual temporal considerations. There is no definition in the regulation for the

word "case" and the dictionary definition is unhelpful.[2]

In construing administrative rules, the same canons of construction applicable to statutes are to be used. Cortland-Clinton, Inc. v. New York State Dept. of Health, 59 A.D.2d 228, 231, 399 N.Y.S.2d 492 (1977). When interpreting statutes, one must consider the purpose of the act and the objectives to be accomplished. People v. Cypress Hills Cemetery, 208 A.D.2d 247, 251, 622 N.Y.S.2d 300 (1995). The legislative intent is the great and controlling principle and the primary consideration in interpreting the statute is to ascertain and give effect to that intent. Id. Where the legislative intent of a statute cannot be determined from a literal reading, one may go outside the statute to try to find its true meaning. Id. Where there is ambiguity about the meaning and intent of a statute, it is proper to resort to its legislative history for clarification. Id. at 252. Every part of a statute must be given meaning and effect, and the various parts of the statute must be construed so as to harmonize with one another. Heard v. Cuomo, 80 N.Y.2d 684, 689, 594 N.Y.S.2d 695 (1993)(citing McKinney's Cons. Laws of N.Y., Book 1, Statutes §97); People v. Mobil Oil Corp., 48 N.Y.2d 192, 199, 422 N.Y.S.2d 33 (1979)(same). The general principle that a statute must be construed as a whole and that its particular parts, provisions or sections be considered together and with reference to each other has been applied in the construction of entire enactments such as the Tax Law or Workmen's Compensation Law. Comment to McKinney's Cons. Laws of N.Y., Book 1, Statutes §97. Although these enactments consist of hundreds of sections they have been construed as single acts. Id.

Based on a review of the rulemaking history and the statutory and regulatory context, it is apparent that the use of the phrase "In cases where" was intended to relate only to those times of negligible gas flow past a condenser.

Clean Air Act ("CAA") §184(a), 42 U.S.C.§7511c(a), established the interstate Ozone Transport Region of which all of New York State is a part. As such, the State was required to revise its State Implementation Plan ("SIP") by November 15, 1992 to require the implementation of reasonably available control technology ("RACT")[3] with respect to all sources of VOCs covered by a control techniques guideline ("CTG")[4] issued before or after the date of the enactment of the CAA Amendments of 1990 and all sources that have the potential

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[2] "Case" is defined as "a set of circumstances or conditions." Merriam-Webster's Collegiate Dictionary, 176 (10th ed. 1993).

[3] "Reasonably available control technology " is defined as "the lowest emission limit that a particular source is capable of meeting by application of control technology that is reasonably available, considering technological and economic feasibility." 6 NYCRR §200.1(bn).

[4] Control Technique Guidelines are guidance documents issued by the U.S. Environmental Protection Agency ("EPA") which define RACT to be applied to existing facilities that emit certain threshold quantities of air pollutants; they contain information both on economic and technological feasibility of available techniques. "Clean Air Act Amendments of 1990: Summary Materials - Glossary of Terms" Office of Air and Radiation, EPA, November 15, 1990.

to emit at least 50 tons per year of VOCs. CAA §184(b)(1)(B) and (b)(2), 42 U.S.C. §7511c(b)(1)(B) and (b)(2). The SIP revisions had to provide for the implementation of the RACT requirements by these sources by no later than May 31, 1995. CAA §182(b)(2), 42 U.S.C. §7511a(b)(2).

To comply with the CAA mandate to revise the SIP, the Department proposed revisions to Part 233 to incorporate RACT requirements for the pharmaceutical and cosmetic industries.[5] See NYS Register, September 2, 1992 at 16-19. As EPA had not issued a CTG for this precise category, the Department determined what constituted RACT by relying on what was prescribed by EPA in its December 1978 CTG entitled "Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products" as well as research concerning control strategies developed by other states.

The 1978 CTG is "intended to assist State and local air pollution control agencies develop regulations to reduce emissions of [VOCs] from existing sources within the pharmaceutical industry. Methodology described in [the CTG] represents the presumptive norm or [RACT] that can be applied to existing plants synthesizing pharmaceutical products." Id. at 1-1. The CTG indicates that condensers are applicable control devices for VOC emission sources including dryers, reactors, distillation units, filters, extractors, centrifuges, and crystallizers. Id. at 1-4. The CTG notes particularly that condensers work best on gas streams that are or nearly are saturated with condensable VOCs. Id. at 4-6. Regarding compliance testing methods and monitoring techniques, the CTG provides as follows:

> OBSERVATION OF CONTROL EQUIPMENT AND OPERATING PRACTICES
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> Regulations expressed as equipment and operating standards can be enforced by verifying that the equipment has been designed and installed properly and that it is being operated properly.
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> . . . .
>
> Condensation
>
> Temperature sensors can be placed in the exit gas stream from a condenser as an indicator of how well the condenser is operating. Indicated temperature can be checked against design temperature and conditions observed during tests.

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[5] The pre-1992 version of 6 NYCRR 233 applied only to emissions from synthesized pharmaceutical manufacturing processes with emission rates above certain thresholds. The 1992 revision added non-synthesized pharmaceutical manufacturing processes (e.g., manufacture of biological products from extraction of chemicals from vegetative materials) and cosmetic manufacturing processes.

Id. at 7-1.

In line with the direction provided in the CTG and the information received from other states, the Department included the outlet gas temperature monitoring requirement in the proposed 6 NYCRR Part 233 when it was presented for public comment during September 1992. In response to a comment by Eastman Kodak Company, the Department amended the proposed rule to include the language contained in 6 NYCRR §233.3(a)(3). See NYS Register, March 24, 1993 at 15 ("One commentator wanted an alternate method to measure the condenser outlet gas temperature, which was allowed."). The additional language constituted a verbatim adoption of the suggested text submitted by Eastman Kodak Company.[6]

The purpose of the monitoring of outlet gas temperature is to provide a measure of how well a properly designed and maintained condenser is operating. Put another way, this monitoring provides a measure of the control efficiency of the condenser assuming the condenser is appropriate to its particular use.[7] If an otherwise appropriate and properly operating condenser shows readings that remain within the corresponding vapor pressure and temperature values set forth at 6 NYCRR §233.3(a)(1), one can be satisfied that the use of the condenser constitutes the correct implementation of RACT for the particular VOC emission source.

Similarly, the monitoring of condenser coolant temperature is aimed at determining the efficiency of an otherwise appropriate and properly operating condenser. However, the monitoring of coolant temperature is not the preferred method of determining condenser efficiency. The 1978 CTG is the only relevant and applicable RACT directive from EPA available to date. This guidance provides for outlet gas temperature monitoring as the only means to determine the efficiency of a condenser. The Department's conditional allowance of coolant monitoring for determination of condenser efficiency was the next best expedient method to show a demonstration of condenser efficiency when the demonstration could not possibly be shown by the preferred method of outlet gas temperature monitoring. If the

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6 The comment of Eastman Kodak Company reads as follows:

Paragraph (a)(1): This paragraph establishes allowable condenser outlet gas temperature as a function of VOC vapor pressure. When non-condensibles (such as nitrogen) are not present in the reactor of gas, the condenser outlet gas flow rate may be negligible, making it impossible to measure outlet gas temperature to ensure compliance with this requirement. We propose that the condenser coolant temperature be used as an alternate allowable temperature limit in such cases. To accomplish this, we propose the addition of the following statement to 233.3(a)(1):

In cases where the condenser outlet gas temperature is not readily measurable due to negligible gas flow rate, the temperature of the condenser coolant may be used in lieu of condenser outlet gas temperature as long as the temperature of the condenser coolant does not exceed the allowable condenser outlet gas temperature shown in Table 1.

7 "If the relationship between VOC vapor pressure and temperature is known, the removal efficiency of a condenser can be estimated." 1978 CTG at 4-2.

Department had considered the use of coolant temperature monitoring as an equally effective measure of condenser efficiency, use of this monitoring method would not have been conditioned on the existence of negligible gas flow but would have been available to any person employing condensers to reduce VOC emissions in compliance with the control requirements of 6 NYCRR §233.3(a).

BMS cites a November 1993 draft CTG entitled "Control of Volatile Organic Compound Emissions from Batch Processes" for the proposition that EPA has concluded that condenser coolant temperature monitoring is an equally valid alternative monitoring method to demonstrate compliance with RACT control requirements for its sources.[8] EPA ultimately finalized this draft document as an Alternative Control Techniques Information Document ("ACT") during February 1994. No final CTG was ever issued by EPA.

These later EPA documents are not relevant to the determinations to be made in this matter. These documents were issued after the promulgation of 6 NYCRR Part 233 and were not relied on in the drafting of the regulation. As with a statute, a regulation is generally interpreted from the time it took effect. See McKinney's Cons. Laws of N.Y., Book 1, Statutes §93. Although matters arising subsequent to the regulation's promulgation may sometimes be considered, such as evidence of administrative intent furnished by subsequent regulations and administrative interpretations, id.(comment), the 1993 draft CTG was never finalized and does not constitute a RACT directive from EPA that must be implemented by the State. Unlike CTGs, ACTs do not prescribe RACT and nothing contained therein is binding on the State.[9] Even if the later EPA documents were relevant to the interpretation of 6 NYCRR Part 233, they do not, when read in their entirety, appear to permit monitoring of condenser coolant alone.[10] The 1978 CTG remains the only EPA directive concerning RACT for pharmaceutical manufacturing processes.

The intent of 6 NYCRR Part 233 in requiring monitoring of both outlet gas

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[8] BMS cites the following passage: "Monitoring can be relatively simple. Temperature monitors can be mounted at the coolant inlet to the vapor condenser or the gas outlet, and temperature can be recorded on a strip chart." November 1993 CTG at 7-11.

[9] The 1994 ACT reads, in pertinent part, as follows: "The purpose of this document is to provide information on alternative control techniques for volatile organic compound (VOC) emissions from batch operations. ... This document contains information on emissions, controls, control options, and costs that States can use in developing rules based on reasonably available control technology. The document presents options only, and does not contain a recommendation on reasonably available control technology." 1994 ACT at 1-1.

[10] The 1994 ACT is essentially a reissue of the 1993 CTG draft minus the RACT recommendation. Neither document addresses the situation of condenser monitoring during periods of negligible gas flow. Both documents recognize the essential requirement for monitoring of condenser outlet gas temperature to determine control efficiency. "The control efficiency attained by a condenser is a function of the outlet gas temperature." 1994 ACT at 4-2; 1993 draft CTG at 4-2. "To verify condenser efficiency, the outlet gas temperature is the only value that must be known in addition to the inlet conditions (including flowrate of noncondensables)." 1994 ACT at 4-4; 1993 draft CTG at 4-4).

temperature and coolant temperature for an individual condenser is further evident from an examination of 6 NYCRR §233.4(d). This subdivision states that "continuous monitors for the following parameters must be installed ..." The mandatory requirement of use of monitors is for all the listed parameters, not just any one of them.

6 NYCRR §233.4(d) contains two mistakes - one drafting error and one publication error - which should be addressed to clarify the meaning of the subdivision. The drafting error consists of the use of the word "or" following the text set forth at 6 NYCRR §233.4(d)(5). The use of the word "or" usually indicates that the statute or rule should be construed in an alternative sense. State v. Rock, 147 Misc.2d 231, 235, 555 N.Y.S.2d 584 [Sup Ct. 1990). However, the word "or" may be construed as meaning "and" when necessary to effectuate administrative intent. See McKinney's Cons. Laws of N.Y., Book 1, Statutes §365 and accompanying comment ("[W]hen the context of the statute and the surrounding circumstances indicate that the lawmakers have made an error in the choice of words, the courts will not hesitate to construe the statute so as to effectuate the intent of the lawmakers.").

The intent of the language of 6 NYCRR §233.4(d) was to list a number of cumulative monitoring requirements for any emission source for which the requirements are applicable rather than list alternative monitoring requirements for the source. This intent is evident from reviewing the administrative history of the subdivision as well as considering it in the context of other similar VOC RACT rules found in Subchapter A of Chapter III of 6 NYCRR (the regulations concerning the prevention and control of air contamination). The word "or" was incorrectly inserted in the final draft of the rule that was sent to the Secretary of State for publication. Notice of the final version of the rule was given on April 21, 1993. See NYS Register, April 21, 1993 at 15-16. The initial proposed draft and the interim amended draft both lacked this word, or any word for that matter, which connected the six paragraphs of subdivision (d) of 6 NYCRR §233.4. The use of this word to connect the paragraphs of this subdivision was mistaken and did not account for the intended cumulative nature of the monitoring requirements. This intent is apparent by the use of the word "and" just before the final paragraph of the subdivision concerning monitoring requirements as set forth in the pre-1992 version of 6 NYCRR Part 233 which read, in pertinent part, as follows:

> If an air cleaning device is used, continuous monitors for the following parameters shall be installed, periodically calibrated, and operated at all times that the associated process equipment is operating:
>
> (a) exhaust gas temperature of all incinerators handling volatile organic compounds;
>
> (b) temperature rise across catalytic incinerator bed;
>
> (c) breakthrough of volatile organic compound on a carbon adsorption unit; and

(d) any other continuous monitoring or recording device required by the commissioner.

Former 6 NYCRR §233.5 (emphasis added).

The appropriate use of "and" in this context is supported by review of similar provisions of other VOC RACT regulations. See e.g., 6 NYCRR §§228.5(g) and 234.4(c).

The publication error in 6 NYCRR §233.4(d) involves the publisher's failure to revise the text of the subdivision to follow exactly the text submitted to the Secretary of State. Apparently, the publisher neglected to remove the original "and" from its position after the third paragraph of the subdivision.

The Department concludes that 6 NYCRR §233.3(a) requires the owner or operator of a pharmaceutical manufacturing process which monitors the condenser coolant temperature during periods of negligible gas flow to also monitor the outlet gas temperature during all time periods when the gas flow is nonnegligible. The intent of 6 NYCRR §233.3(a) is to assure that RACT for the relevant VOC emission source is being properly implemented. This intent is carried out when the best possible efficiency of the air cleaning device is attained. Monitoring of both of the outlet gas temperature and coolant temperature for any individual condenser that sometimes experiences negligible gas flow is necessary to achieve the best overall measurements of condenser efficiency.

The Department lacks the regulatory authority to require BMS to undertake the specific requested correlation demonstration before BMS may ever use coolant temperature monitoring to comply with the control requirements of 6 NYCRR §233.3(a).

Although BMS must, for each individual condenser, monitor outlet gas temperature during periods of nonnegligible gas flow and monitor coolant temperature during periods of negligible gas flow, BMS is not required to undertake the particular testing or production of condenser design and engineering information requested by staff in order to show a correlation between outlet gas temperature and coolant temperature. The most reasonable and straightforward interpretation of the text of 6 NYCRR §233.3(a) is that the correlation is already assumed to exist for purposes of demonstrating that RACT has been implemented for the emission source. While use of coolant temperature monitoring as constituting RACT is less desirable than the preferred method of monitoring of outlet gas temperature, it represents a next best expedient form of monitoring during times of negligible gas flow. The regulation conditions the use of coolant temperature monitoring only on an adequate showing of the existence of the negligible gas flow.

The Department has the authority to demand and obtain condenser design and engineering information for the condensers used by BMS.

While BMS need not produce any condenser design or engineering information in order to demonstrate a correlation between the condenser outlet gas temperature and coolant temperature, this does not affect the Department's authority to require the production of such information for any legitimate purpose. Such a purpose may include the Department's overarching goal of ensuring that BMS's condensers are operating as designed and have the true capacity to reduce VOC emissions as the condenser designer or manufacturer may have claimed.

The Department is authorized to promulgate regulations aimed at preventing and controlling air pollution including requirements and standards for the approval of plans or specifications for air cleaning installations. See ECL §19-0301(1)(a) and (b). Concomitantly, the Department has the general authority to do things necessary to enforce the air pollution control regulations that it does promulgate. See ECL §19-0305(2)(*l*). Additionally, the Department has the specific authority to inspect any property, premise or place for the purpose of ascertaining compliance with any air pollution control regulation, ECL §19-0305(2)(a), and inspect any air cleaning installation for the purpose of ascertaining compliance with any plans or specifications, ECL §19-0305(2)(j).

6 NYCRR §201-5.3(c) provides, in pertinent part, that any person who owns or operates any stationary sources shall operate and maintain any required emission control device in compliance with any applicable regulations and laws. Failure to do so may constitute sufficient reason to revoke or deny a permit. See id. Under 6 NYCRR §200.7, any person who owns or operates an air contamination source which is equipped with an emission control device must operate such device and satisfactorily maintain and repair it in accordance with standards, practices and procedures, including the manufacturer's specifications, that are required to allow such device to operate effectively. In the present matter, the Department is unable to ensure compliance with 6 NYCRR §200.7 unless it has access to condenser design and engineering information.

The Department has the authority to require BMS to perform emissions testing to demonstrate compliance with any applicable statutory or regulatory requirement.

While BMS need not perform emissions testing in order to demonstrate a correlation between the condenser outlet gas temperature and coolant temperature, this does not affect the Department's authority to require emissions testing for any legitimate purpose. Such a purpose may include the Department's need to determine the control efficiency of the condensers.[11]

The Department's plenary authority to do things necessary to enforce the air pollution control regulations, see ECL §19-0305(2)(*l*), and powers of inspection, see ECL §§3-

[11] "Emission measurement tests of off-gas streams from ... condensers may occasionally be necessary to evaluate the control efficiency of a system." 1978 CTG at 7-2.

0301(2)(g), 19-0305(2)(a) and 19-0305(2)(j), provide statutory support for the Department's regulatory authority to perform emissions testing or require the performance of emissions testing by the source owner.

Under 6 NYCRR §202-1.1, the Department may require a person who owns any air contamination source to conduct an emissions test (commonly known as a "stack test"). An emissions test is defined as "[a]ny method of collecting stack samples or samples of emissions from an air contamination source and analyzing such samples for air contaminants." 6 NYCRR §200.1(v). An cleaning device may constitute an air contamination source. 6 NYCRR §200.1(f). Emissions consist of releases of air contaminants into the outdoor atmosphere, see 6 NYCRR §200.1(d) and (s).

BMS has expressed that "stack testing will not provide the necessary verification of VOC emission control by surface condensers in batch pharmaceutical manufacturing." BMS appears to interpret 6 NYCRR Subpart 202-1 to permit samples to be taken only at the end of a conventional "stack." BMS contends that temperature measurements taken at that point would be irrelevant for purposes of verification of VOC emissions control requirements. BMS's understanding of the type of testing allowed under this rule is too limited.

An emission test involves taking any sample of emissions and is not restricted to the taking of "stack samples." A sample may be taken at any point from which air contaminants are emitted without regard to the presence of a conventional stack. Thus, contrary to BMS's understanding, a stack sample need not be taken at the final opening of a channel transmitting contaminants from a condenser (the end of a conventional "stack"), but may be taken at the location of the initial outlet from the condenser. Even if the emissions test is referred to as a "stack test" this does not change the conclusion that the emissions test may be conducted at the initial outlet from the condenser. A "stack" from which a sample may be taken includes any opening of any kind arranged to conduct air contaminants to the outdoor atmosphere. 6 NYCRR §200.1(bw). A "stack sample" is collected at a location within a stack, see 6 NYCRR §200.1(bv), which may include the point at which air contaminants enter the stack.

To ensure that BMS's condensers are operating as designed and are being adequately maintained, the Department may need to know the control efficiency of the condensers. The Department may properly ascertain this by requiring BMS to conduct emissions testing to determine the amount of VOCs being emitted from the condensers.

John P. Cahill
General Counsel

Dated: December 11, 1996
Albany, New York