WEST VIRGINIA
SECRETARY OF STATE
JOE MANCHIN, III
ADMINISTRATIVE LAW DIVISION

Form #5

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OFFICE OF WEST VIRGINIA SECRETARY OF STATE

NOTICE OF AGENCY ADOPTION OF A PROCEDURAL OR INTERPRETIVE RULE OR A LEGISLATIVE RULE EXEMPT FROM LEGISLATIVE REVIEW

AGENCY: WV DEP - Division of Air Quality TITLE NUMBER: 45

CITE AUTHORITY: W.Va.Code§§22-5-1et seq; 45CSR13

RULE TYPE: PROCEDURAL _____ INTERPRETIVE X

EXEMPT LEGISLATIVE RULE _____

CITE STATUTE(s) GRANTING EXEMPTION FROM LEGISLATIVE REVIEW

_____

AMENDMENT TO AN EXISTING RULE: YES ____ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

_____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 13B

TITLE OF RULE BEING PROPOSED: "The Permitting of Laboratory Facilities Under 45CSR13"

_____

THE ABOVE RULE IS HEREBY ADOPTED AND FILED WITH THE SECRETARY OF STATE. THE EFFECTIVE DATE OF THIS RULE IS March 30, 2002

Authorized Signature

TITLE 45
INTERPRETIVE RULE
DEPARTMENT OF ENVIRONMENTAL PROTECTION
DIVISION OF AIR QUALITY

SERIES 13B
THE PERMITTING OF LABORATORY FACILITIES UNDER 45CSR13

§45-13B-1. General.

1.1. Scope. -- It is the purpose of this rule to provide guidance and clarification regarding the permitting of laboratory facilities under 45CSR13, while ensuring compliance with all applicable requirements and at the same time providing operational flexibility.

1.2. Authority.-- W. Va. Code §§22-5-1 et seq. and WV 45CSR13.

1.3. Filing Date. – February 28, 2002.

1.4. Effective Date. – March 30, 2002.

§45-13B-2. Definitions.

2.1. "Bench-scale laboratory equipment" means:

2.1.a. Bench-scale laboratory testing equipment and quality control testing equipment used exclusively for chemical or physical analysis, including vacuum-producing devices;

2.1.b. Activities associated with the equipment or devices described in subdivision 2.1.a, including sample preparation, handling, and disposal activities; or

2.1.c. Laboratory process emission sources conducted at private, public or vocational educational institutions, where the emissions are the result of teaching or training exercises, and the institution is not generally engaged in the manufacture of products for commercial sale.

2.2. "Bench-scale research and development equipment" means laboratory facilities not covered under subsection 2.1 and the primary purpose of which is at least one of the following:

2.2.a. To conduct "scale-up" from laboratory or bench-scale studies for the purpose of collecting information and data for engineering and design of a commercial facility;

2.2.b. To evaluate process changes in connection with pollution prevention efforts (including improved process efficiencies);

2.2.c. To develop data for correction of manufacturing facility operational problems and customer product quality concerns; or

2.2.d. To produce products for commercial sale for the purpose of customer evaluation, market development or testing, provided that such activity is not the principal purpose of the facility.

2.3. Other words and phrases used in this rule, unless otherwise indicated, shall have the meaning ascribed to them in 45CSR13 and W. Va. Code §22-5-2.

§45-13B-3. Facilities Exempt from Permitting.

3.1. Facilities defined as "bench-scale laboratory equipment" under subsection 2.1 shall be exempt from permitting requirements under 45CSR13 as de minimus sources included in No. 7 of Table 45-13B of 45CSR13.

3.2. The owner or operator of bench-scale research and development equipment designed to have a total input of no more than twenty-five (25) pounds of material which could be emitted into the air (excluding water, steam, nitrogen, hydrogen, oxygen, and chemicals which are not capable of being emitted as regulated air pollutants under 45CSR13) per any calendar day, including vacuum-producing devices, and any associated devices to capture and collect emissions from any such equipment or devices, shall be exempt from permitting requirements under 45CSR13. A demonstration of eligibility for this exemption shall be made by the owner or operator of such equipment in the following manner:

3.2.a. Make a case-specific demonstration of eligibility describing how total input of materials will be determined, which demonstration may include limitations on operating practices, training, engineering or administrative controls; or

3.2.b. Make an alternative demonstration of eligibility describing how total input of materials will be determined, which demonstration may include the kind of limitations and controls described in subdivision 3.2.a.

3.3. Case-specific determinations of eligibility under subdivision 3.2.a shall be maintained on-site at all times that the laboratory is relying on the demonstration and for at least an additional two (2) years thereafter and shall be available to the Secretary upon request. Alternative demonstrations of eligibility under subdivision 3.2.b shall be maintained on-site at all times that the laboratory is relying on the alternative demonstration and for at least an additional two (2) years thereafter and shall be available to the Secretary upon request.

§45-13B-4. Additional Facilities Exempt from Permitting.

4.1. The owner or operator of a laboratory that does not qualify for the exemption set forth in section 3 shall be exempt from the permitting requirements under 45CSR13 provided the owner or operator meets all of the following conditions:

4.1.a. Laboratory activities shall be conducted in accordance with a written Good Laboratory Practices Plan, developed and implemented by the source, which sets forth procedures, equipment, and work practices which (with respect to regulated air pollutants):

4.1.a.1. Are capable of protecting the environment from activities occurring at that particular operation;

4.1.a.2. Include standard operating procedures relevant to environmental considerations to be followed when research and development work involves the emission of regulated air pollutants; and

4.1.a.3. Include, where appropriate, the following control measures that will be used to minimize the emission of regulated air pollutants:

4.1.a.3.A Procedures to minimize emissions of regulated air pollutants from equipment vents;

4.1.a.3.B. Procedures to minimize emissions of regulated air pollutants from equipment leaks;

4.1.a.3.C. Containers which have the potential to emit regulated air pollutants shall be kept closed when not in use; and

4.1.a.3.D. Procedures to estimate and record the actual emissions of regulated air pollutants, including supporting calculations and the date and duration of emissions, unless alternative procedures are approved in writing by the Secretary;

4.1.b. The Good Laboratory Practices Plan shall be maintained on-site at all times and be made available to the Secretary upon request;

4.1.c. The Secretary has made no determination that the laboratory facility causes statutory air pollution;

4.1.d The specific laboratory operation shall be located at least 100 feet from any public recreational area or private residence unless waived by the owner thereof or waived in an easement that runs with the land on which such residence or recreation area is located;

4.1.e. The total input of materials to the laboratory facility (excluding water, steam, nitrogen, hydrogen, oxygen and chemicals which are not capable of emitting regulated air pollutants under 45CSR13), taking into account actual planned operating hours and conditions, does not exceed the following criteria:

4.1.e.1. One hundred forty-four (144) pounds per any rolling 24-hour time period; or

4.1.e.2 Five hundred (500) pounds per day, provided the actual emissions of regulated air pollutants do not exceed any threshold amounts under subdivisions 2.17 or 2.24 of 45CSR13; and

4.1.f. The owner or operator shall make a case-specific demonstration describing how total input of materials will be determined, which demonstration may include limitations on operating practices, training, engineering or administrative controls. The owner or operator may submit the demonstration to the Secretary for approval. Records of the demonstration shall be maintained on-site at all times that the laboratory facility is relying on such demonstration and for at least an additional two (2) years thereafter and shall be available to the Secretary upon request.

§45-13B-5. Effect on Other Rules.

5.1. For application of the exemptions for particulate matter and mineral acids provided by section 10 of 45CSR7 and of the exemptions for sulfur dioxide provided by section 4 of 45CSR10, actual emissions will be regarded the same as potential to emit.

Union Carbide Corporation
A Subsidiary of The Dow Chemical Company
PO Box 8004
437 McCorkle Avenue SW
South Charleston, WV 25303
U.S.A.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 16, 2001

Mr. John A. Benedict, Deputy Chief
WV Division of Air Quality
7012 MacCorkle Avenue, SE
Charleston, WV 25304

Subject: Division of Air Quality Proposed Interpretative Rules
Comments Regarding Series 13A and Series 13B

Dear Mr. Benedict,

We have reviewed the WV Division of Air Quality Proposed Interpretative Rules – Series 13A the Permitting of Research and Development Activities Under 45 CSR 13 and Series 13B The Permitting of Laboratory Facilities. We believe proposed regulatory changes will result in a more effective air permitting program for laboratory and research activities while ensuring that air quality is protected. However, some of the proposed regulatory provisions are overly stringent and may be impractical for implementation. We request that the following concerns be addressed in final regulations.

Series 13A – The Permitting of Research and Development (R&D) Activities Under 45CSR13

Section 2.1 identifies activities that are considered research and development. It is requested that new items 2.1.d and 2.1.e be added which read as follows:

"2.1.d. to conduct scale-up of laboratory or bench-scale studies to evaluate equipment, technology, etc. in support of commercial production, or

2.21.e. to provide technical support to commercial facilities, or to obtain data, information or knowledge to support design engineering or process optimization."

Section 4.3 provides that R&D equipment may be considered as permanently shutdown unless the equipment is not operated at least 500 hours in a 12-month period. This section is unnecessary and should be deleted. It is not unusual for R&D equipment to remain idle for many

months. In fact, equipment may be operated for only minimal hours over a number of years as necessary to address research needs. To maintain a record identifying operating hours and dates is impractical and unnecessary.

If the Agency is unwilling to delete Section 4.3, it is requested that the provision be changed to shutdown of a facility.

Series 13B – The Permitting of Laboratory Facilities Under 45CSR13.

Section 4.1.a.3.d provides that the Good Laboratory Practices Plan must include "Procedures to estimate and record actual emissions of regulated pollutants, including supporting calculations and the date and duration of emissions."

It is requested that the language supporting Good Laboratory Practices Plan be revised to read as follows:

"Procedures to estimate, record and report actual emissions as needed to satisfy air emission inventory regulatory requirements and as appropriate, other applicable requirements."

The requirement to record the date and duration of emissions (no matter how miniscule) does not add value due to the small amounts of materials handled. Adoption of the above revised provision will ensure that proper information is recorded while allowing emission calculations to be conducted using techniques and at frequencies that will not disrupt research and development work.

If there are any questions concerning this correspondence, please contact Freddie Sizemore of my staff at 747-3713.

Sincerely yours,

J. L. Blatt
Responsible Care® Leader
West Virginia Operations

Cc: Mr. John Pitner, Chairman
WVMA Air Issues

Mr. David M. Flannery, Esq.
Jackson and Kelly

October 17, 2001

Mr. John Benedict
Deputy Chief
Division of Air Quality
West Virginia Department of Environmental Protection
7012 MacCorkle Avenue S.E.
Charleston, West Virginia 25304

Re: 45 CSR 13 B "The Permitting of Laboratory Facilities Under 45 CSR 13"

Dear Deputy Chief Benedict:

The West Virginia Chamber of Commerce and the West Virginia Manufacturers Association are particularly pleased that DEP has proposed the issuance of an interpretive rule adding long needed and important guidance and clarification identifying the circumstances under which permits are required for laboratory facilities under West Virginia's minor source permitting program, 45 CSR 13.

It has been our pleasure to have worked with the Division of Air Quality for nearly two years in the development of a regulatory program to address laboratories. We commend DEP for its commitment to this project, and we strongly support the finalization of an appropriate interpretive rule on this subject at the earliest possible date. We would like to remind DAQ that the results of our joint working group resulted in a document dated May 4, 2001 in which the results of our discussions were captured. That document is in part the basis of our comments to follow.

45 CSR 13 recognizes that certain sources known as "de minimus sources" should be exempt from permitting and many other requirement of 45 CSR 13. The criteria for a "de minimus source" is set forth at 45 CSR 13. 2.6 and includes the following:

> "A "de-minimus source" is deemed to have insignificant emissions and/or is not usually a source of quantifiable emissions which can be practically regulated in determining potential to emit or actual emissions for the purpose of determining whether a permit is required under this rule."

While Table 45-13B of 45 CSR 13 contains a list of sources which the rule itself deems to be insignificant, 45 CSR 13.2.6.c. authorizes a petition to be filed with the Director for a determination of regulatory applicability for a particular activity to be deemed a de minimus source. The West Virginia Chamber of Commerce and the West Virginia Manufacturers Association hereby petition the Director for a determination that the sources described in these comments are "de minimus sources" and therefore are not subject to the requirements of 45 CSR 13.

While there is much about DEP proposed rule that we support, several areas require further revision. These comments will address the rule on a section-by-section basis, pointing out the areas in which we urge that the rule be revised before it is finally adopted:

1. Associated Devices - Sections 2.1.a. and 2.1.d. define "bench-scale laboratory equipment" which are to be excluded from permitting. The definition does not, however, include language that was contained in the last draft of the working group involved in this issue. This language would have extended the definition, and therefore the exemption to "any associated devices to capture and collect emissions from any such equipment or devices." We encourage DEP to include capture and collection devices within the definition of the source exemption to be certain that the regulation does not create a "catch-22" by having the source itself exempt from the regulation, but not the capture and collection devices. In the alternative, DEP should explain in its response to comments that failing to include these devices within the terms of the exemption does not narrow the exemption.

2. Calendar Day – Our further review of the provision contained in Section 2.1.d. causes us to believe that it is necessary to determine the 25 pounds of total input on a calendar day basis rather than on the basis of any rolling 24 hour period. From the view point of either the regulated community or the agency, one of the primary objectives of this rule should be the ease of its implementation. Using a calendar day basis for the rule would add an element of simplicity by significantly reducing the number of time periods over which data would need to be collected and analyzed. Accordingly, we urged that in this section the words "any rolling 24-hour time period " be changed to "calendar day." In addition, as is set forth in the following section, the provisions of Section 2.1.d. should be moved to Section 3.2.

3. "Bench-scale Laboratory Equipment" Exemption - Paragraph 3.1 of the proposed rule creates confusion in that it combines the broad exemption for all the types of laboratories contained in the definition of "bench-scale laboratory equipment" set forth in Section 2.1 of the rule, with a demonstration that must be made with respect to that subset of those laboratories that are defined in Section 2.1.d., namely, laboratories used for R & D purposes. We suggest that these two concepts be moved into separate sections. We urge that Section 3.1 of the rule be revised to exempt bench scale laboratory equipment and should read in its entirety as follows:

> 3.1. Facilities defined as "bench-scale laboratory equipment" under subsection 2.1 shall be exempt from permitting requirements under 45 CSR Section 13 as de minimus sources included in No. 7 of Table 45-13B of 45 CSR 13.

We then propose that the remainder of Section 3.1 as it was proposed be moved into a new Section 3.2. and it be combined with Section 2.1.d. all as set forth in the following comment.

4. R & D Exemption – The proposal which has been advanced by DEP has fundamentally changed the structure of the policy negotiated by the working group by applying a program intended for R & D facilities to laboratories and by applying a program intended for laboratories to R & D facilities. Specifically, the exemption for activities involving 25 pounds or less of total input, was specifically intended to apply to "bench scale research and development equipment." DEP's proposal inappropriately applies this 25 pound exemption to "bench scale laboratory equipment." DEP also inappropriately applies an exemption intended for applicability to other laboratories to R & D laboratories, instead (See Section 4 of the proposed rule). We strongly urge that this provision be changed and restored to the working group proposal.

In addition, the proposal with respect to making a case-specific demonstration of eligibility for determining whether a bench-scale research and development equipment has a total output of no more than 25 pounds of material, has been modified from the version negotiated by the working group to allow that demonstration to include limitations on operating practices, training, engineering or administrative controls. We believe the type of demonstration which relies on operating practices, training, engineering or administrative controls is the type of demonstration that would more fairly be included within the alternative demonstration set forth in subsection b. of this Section. We also believe the section is much more logical if the definition set forth in Section 2.1.d. is incorporated into this Section.

Accordingly, we would urge that this Section related to laboratories used for R & D purposes be revised and renumbered to read as follows:

> 3.2. The owner or operator of bench-scale research and development equipment designed to have a total input of no more than twenty-five (25) pounds of material which could be emitted into the air (excluding water, steam, nitrogen, hydrogen, oxygen, and chemicals which are not capable of being emitted as regulated air pollutants under 45 CSR 13) per any calendar day, including vacuum producing devices, and any associated devices to capture and collect emissions from any such equipment or devices, shall be exempt from permitting requirements under 45 CSR 13 as de minimus sources included in No. 7 of table 45-13B of 45 CSR 13. A demonstration of eligibility for this exemption shall be made by the owner or operator of such equipment in the following manner:
>
> 3.2.a. Make a case-specific demonstration of eligibility describing how total input of materials will be determined; or

3.2.b. Make an alternative demonstration of eligibility which demonstration may include limitations on operating practices, training, engineering or administrative controls.

A conforming amendment, deleting Section 2.1.d. also need to be made. An additional conforming amendment would need to be made to renumber proposed Section 3.2 to 3.3.

In addition, the term defined in Section 2.2. of the proposed rule should be changed to "bench-scale research and development equipment" instead of "laboratory facilities associated with research and development activities." We also suggest that the recognition of "scale-up" as an appropriate R&D function should be linked to gathering data to design of a commercial facility.

5. Other Laboratories – As stated above, DEP's proposal fundamentally changes the scope of the exemption that needs to be contained in Section 4. As originally conceived by the working group on this rule, the Section 4 provisions are to be applicable to laboratories that do not meet the de minimus test set forth in Section 3. The proposal advanced by DEP inappropriately limits the Section 4 exemption to "laboratories facilities associated with research and development activities. We believe this section must extend to any laboratory that does not qualify for the exemptions set forth in Section 3 (related to quality control labs, educational labs, and R&D labs with 25 pounds of input, or less).

Section 4 should be made applicable to laboratories that are not covered under Section 3. This can be accomplished by revising Section 4.1. to read as follows:

4.1. "The owner or operator of a laboratory that does not qualify for the exemption set forth in section 3 of this rule shall be exempt from the permitting requirements under 45 CSR §13 provided the owner or operator meets all the following conditions:"

6. Regulated Air Pollutants - While the term regulated air pollutants is used throughout the document as a means of indicating the limitation of the scope of the rule, there are two sections of the rule where the term has been incorrectly written as "regulated pollutants." For consistency with the remainder of the document, we urge that in Section 4.1.a.3.B. and in Section 4.1.a.3.D. the term be corrected to read "regulated air pollutants" or in the case of our proposal with respect to Section 4.1.a.3.D., that the term be deleted.

7. Estimating Actual Emissions – As part of the working group negotiations, we supported the need for a Good Laboratory Practices Plan as a condition for exempting certain larger labs from coverage under 45 CSR 13. We also supported having such a Plan set forth procedures, equipment and work practices "to estimate, record and report emissions." Elsewhere, we agreed as part of the working group deliberations to a provision that provides that in absence of the contemporaneous calculation of emissions,

it would be appropriate to allow the use of operating practices, training, engineering or administrative controls to estimate the amount of total input to the laboratory.

DEP's proposal (Section 4.1.a.3.D) alters this basic concept by inappropriately requiring that estimates of emissions be supported by "supporting calculations and the date and duration of emissions." We submit that this additional requirement is overly burdensome for laboratories to maintain. We urge that the owners and operators of laboratories be allowed to use alternative means to estimate, record and report actual emissions.

We have reviewed the comment letter and proposal of Mr. Blatt of Dow Chemical on this point and support revising Section 4.1.A.3.D. to read as follows:

> "Procedures to estimate, record and report actual emissions as needed to satisfy air emission inventory regulatory requirements, and, if appropriate, other applicable requirements.

8. Information Available to the Director - While Sections 3.2 and 4.1.f. place obligations on an owner or operator to make documents available to the Director upon request, this concept is treated inconsistently in Section 4.1.b. We urge that 4.1.b. be revised to make it clear that the good laboratory practices plan required by that section shall be maintained on site at all times and available "to the Director" upon request.

9. Buffer Zone - In Section 4.1.d, there has been an unwarranted expansion of the buffer zone that must surround laboratory facilities before those facilities can be exempt from permitting. In the negotiations of the working group, this provision had been carefully negotiated so as to be limited to facilities located at least 100 feet from any public recreation area or private residence. The expansion of this buffer zone to a distance of 300 feet and extending it to any business, public building, school, church, community or institutional building significantly limits the scope and availability of this provision. It is particularly troublesome that the provision does not even limit the expansion of this provision to those buildings or areas when occupied. We urge that this provision be revised to read as follows:

> The specific laboratory operation is located at least 100 feet from any public recreational area or private residence, unless waived by the owner thereof or waived in an easement that runs with the land on which such residence or recreation area is located.

It is necessary to allow any waiver of this provision to be embodied in an easement that runs with the land to assure that a mechanism exists by which subsequent owners of the adjacent property are bound by any commitments made by their predecessors in the chair of title.

10. Throughput Exemption – We are also concerned about Section 4.1.e.1. This Section was intended to provide a straight-forward exemption based on throughput if the laboratory can demonstrate that no more than 144 pounds of total input was involved. DEP has proposed that this throughput exemption can be relied upon only "where actual emissions cannot be reasonably estimated." We believe that the addition of this language defeats the very purpose of having a throughput exemption, namely, to create a threshold throughput that was low enough to allow laboratory operators to avoid the need to collect and record actual emission data. We believe that in the context of this regulation, there should be a straight-forward throughput exemption that can be satisfied by doing nothing more than examining the material that is being utilized as input to the process. By deleting this additional language related to actual emissions, the throughput exemption contained in Section 4.1.e.1. would be made comparable to similar language involving a comparable exemption that appears in Section 2.1.d. related to bench-scale laboratory equipment. Accordingly, Section 4.1.e.1 should read as follows:

> 4.1.e.1. One hundred forty-four (144) pounds per day; or

11. Effect on Other Rules – As has been proposed in 45 CSR 13A, we urge DEP to include within 45 CSR 13B a provision that states that actual emissions from facilities subject to this rule will be regarded as potential to emit to the extent that any of these facilities are subject to other applicable rule. We urge that a new Section 5 be added to the rule to read as follows:

> §45-13B-5. Effect on Other Rules.
>
> 5.1 To the extent that any facility subject to the exemption authorized by this rule is also subject to the exemptions for particulate matter and mineral acids provided by Section 10 of 45 CSR 7 and of the exemptions for sulfur dioxide provided by Section 4 of 45 CSR 10, actual emissions will be regarded the same as potential to emit.

We appreciate the opportunity to comment on this rule. We encourage DEP to move forward with making appropriate revisions to this rule as soon as possible and to the finalization of the rule so that it can be applied to all qualifying facilities. A revision to the proposed rule which incorporates these changes is attached.

The current circumstances involving the application of West Virginia's minor source permitting regulation to facilities of this kind creates difficult and burdensome regulatory requirements without commensurate environmental benefit. A properly

revised rule of this kind will go a long way towards reducing the unnecessary impact of this rule on these facilities.

Very truly yours,

David M. Flannery
Chair, Environmental Committee
West Virginia Chamber of Commerce

John K. Pitner
Team Leader, Air Team
Environmental, Safety & Health Committee
West Virginia Manufacturers Association

Industry Markup 10.17.01

TITLE 45
INTERPRETIVE RULE
DEPARTMENT OF ENVIRONMENTAL PROTECTION
DIVISION OF AIR QUALITY

SERIES 13B
THE PERMITTING OF LABORATORY FACILITIES UNDER 45CSR13

§45-13B-1. General.

1.1. Scope. -- It is the purpose of this rule to provide guidance and clarification regarding the permitting of laboratory facilities under 45CSR13, while ensuring compliance with all applicable requirements and at the same time providing operational flexibility.

1.2. Authority.-- W. Va. Code §§22-5-1 et seq. and WV 45CSR13.

1.3. Filing Date. --

1.4. Effective Date. --

§45-13B-2. Definitions.

2.1. "Bench-scale laboratory equipment" means:

2.1.a. Bench-scale laboratory testing equipment and quality control testing equipment used exclusively for chemical or physical analysis, including vacuum-producing devices and any associated devices to capture and collect emissions from any such equipment of devices.

2.1.b. Activities associated with the equipment or devices described in subdivision 2.1.a, including sample preparation, handling, and disposal activities;

2.1.c. Laboratory process emission sources conducted at private, public or vocational educational institutions, where the emissions are the result of teaching or training exercises, and the institution is not generally engaged in the manufacture of products for commercial sale; or

~~2.1.d. Bench-scale laboratory equipment designed to have a total input of no more than twenty-five (25) pounds of material which could be emitted into the air (excluding water, steam, nitrogen, hydrogen, oxygen, and chemicals which are not capable of being emitted as regulated air pollutants under 45CSR13) per any rolling 24-hour time period, including vacuum-producing devices.~~

2.2. "~~Laboratory facilities associated with research and development activities~~""Bench-scale research and development equipment" means laboratory facilities not covered under subsection 2.1 and the primary purpose of which is at least one of the following:

2.2.a. to conduct "scale-up" from laboratory or bench-scale studies for the purpose of collecting information and data for engineering and design of a commercial facility;

2.2.b. to evaluate process changes in connection with pollution prevention efforts (including improved process efficiencies);

2.2.c. to develop data for correction of manufacturing facility operational problems and customer product quality concerns; or

2.2.d. to produce products for commercial sale for the purpose of customer evaluation, market development or testing, provided that such activity is not the principal purpose of the facility.

2.3. Other words and phrases used in this rule, unless otherwise indicated, shall have the meaning ascribed to them in 45CSR13 and W. Va. Code §22-5-2.

§45-13B-3. Facilities Exempt from Permitting as De Minimis Sources.

3.1. Facilities defined as "bench-scale laboratory equipment" under subsection 2.1 shall be exempt from permitting requirements under 45CSR13 as de minimis sources included in No. 7 of Table 45-13B of 45CSR13.~~, provided that the owner or operator of bench-scale equipment defined in subdivision 2.1.d shall demonstrate eligibility for the permitting exemption in the following manner:~~

3.2 The owner or operator of bench-scale research and development equipment designed to have a total input of no more than twenty-five (25) pounds of material which could be emitted into the air (excluding water, steam, nitrogen, hydrogen, oxygen, and chemicals which are not capable of being emitted as regulated air pollutants under 45CSR13) per any calendar day, including vacuum-producing devices, and any associated devices to capture and collect emissions from any such equipment or devices, shall be exempt from permitting requirements under 45CSR13 as de minimus sources included in No. 7 of Table 45-13B of 45CSR13. A demonstration of eligibility for this exemption shall be made by the owner or operator of such equipment in the following manner:

3.~~1~~2.a. Make a case-specific demonstration of eligibility describing how total input of materials will be determined, ~~which demonstration may include limitations on operating practices, training, engineering or administrative controls;~~ or

3.~~1~~2.b. Make an alternative demonstration of eligibility ~~providing at a minimum such information as required in subdivision 3.1.a.~~ which demonstration may include limitations on operating practices, training, engineering or administrative controls.

3.~~2~~3. Case-specific determinations of eligibility under subdivision 3.~~1~~2.a shall be maintained on-site at all times that the laboratory is relying on the demonstration and for at least an additional two (2) years thereafter and shall be available to the Director upon request. Alternative demonstrations of eligibility under subdivision 3.~~1~~2.b shall be maintained on-site at all times that the laboratory is relying on the alternative demonstration and for at least an additional two (2) years thereafter and shall be available to the Director upon request.

§45-13B-4. Additional Facilities Exempt from Permitting.

4.1. ~~Facilities defined as "laboratory facilities associated with research and development activities" under subsection 2.2 shall be exempt from permitting requirements under 45CSR13, provided that the owner or operator meets all of the following conditions~~ The owner or operator of a laboratory that does not qualify for the exemption

set forth in Section 3 of this rule shall be exempt from the permitting requirements under 45CSR13 provided the owner or operator meets all the following conditions:

4.1.a. Laboratory activities shall be conducted in accordance with a written Good Laboratory Practices Plan, developed and implemented by the source, which sets forth procedures, equipment, and work practices which (with respect to regulated air pollutants):

4.1.a.1. Are capable of protecting the environment from activities occurring at that particular operation;

4.1.a.2. Include standard operating procedures relevant to environmental considerations to be followed when research and development work involves the emission of regulated air pollutants;

4.1.a.3. Include, where appropriate, the following control measures that will be used to minimize the emission of regulated air pollutants:

4.1.a.3.A Procedures to minimize emissions of regulated air pollutants from equipment vents;

4.1.a.3.B. Procedures to minimize emissions of regulated air pollutants from equipment leaks;

4.1.a.3.C. Containers which have the potential to emit regulated air pollutants shall be kept closed when not in use; and

4.1.a.3.D. Procedures to estimate, and record and report the actual emissions as needed to satisfy air emission inventory regulatory requirements, and if, appropriate, other applicable requirements of regulated pollutants, including supporting calculations and the date and duration of emissions.

4.1.b. The Good Laboratory Practices Plan shall be maintained on-site at all times and available to the Director upon request.

4.1.c. The Director has made no determination that the laboratory facility causes statutory air pollution.

4.1.d. The specific laboratory operation is facility shall be located at least 300 100 feet from any public recreational area or private residence occupied dwelling or business, public building, school, church, community, institutional building or public park unless waived by the owner thereof or waived in an easement that runs with the land on which such residence or recreation area is located.

4.1.e. The total input of materials to the laboratory facility (excluding water, steam, nitrogen, hydrogen, oxygen and chemicals which are not capable of emitting regulated air pollutants under 45CSR13), taking into account actual planned operating hours and conditions, does not exceed the following criteria:

4.1.e.1. One hundred forty- four (144) pounds per day where actual emissions cannot be reasonably estimated; or

4.1.e.2. Five hundred (500) pounds per day, provided the actual emissions of regulated air pollutants do not exceed any threshold amounts under subdivisions 2.17 or 2.24 of 45CSR13.

4.1.f. The owner or operator shall make a case-specific demonstration describing how total input of materials will be determined, which demonstration may include limitations on

operating practices, training, engineering or administrative controls. The owner or operator may submit the demonstration to the Director for approval. Records of the demonstration shall be maintained on-site at all times that the laboratory facility is relying on such demonstration and for at least an additional two (2) years thereafter and shall be available to the Director upon request.

§45-13B-5. Effect on Other Rules.

5.1. To the extent that any facility subject to the exemption authorized by this rule is also subject to the exemptions for particulate matter and mineral acids provided by Section 10 of 45CSR7 and of the exemptions for sulfur dioxide provided by Section 4 of 45CSR10, actual emissions will be regarded the same as potential to emit.

45CSR13B

THE PERMITTING OF LABORATORY FACILITIES UNDER 45CSR13

RESPONSE TO COMMENTS

On September 14, 2001 the West Virginia Department of Environmental Protection's Division of Air Quality (DAQ) commenced a public comment period to accept comments on the proposed interpretive rule, 45 CSR 13B. Written comments as well as electronically submitted comments were accepted through 5:00 PM on Wednesday, October 17, 2001, which the DAQ addresses below.

I. COMMENTERS: West Virginia Chamber of Commerce and West Virginia Manufacturers Association (submitted joint comments)

COMMENT A: *45 CSR 13 recognizes that certain sources known as "de minimus sources" should be exempt from permitting and many other requirements of 45 CSR 13. 45 CSR 13.2.6.c authorizes a petition to be filed with the Director for a determination of regulatory applicability for a particular activity to be deemed a de minimus source. The commenters petition the Director for a determination that the sources described in these comments are "de minimus sources" and therefore are not subject to the requirements of 45 CSR 13.*

RESPONSE A: DAQ disagrees with the commenters' suggestion/petition that all sources addressed under these interpretive rules be considered "de minimus" sources as defined in 45 CSR 13. Of the emissions and sources addressed under both interpretive rules, only certain "bench-scale" laboratory emissions are truly "de minimus" in DAQ's opinion, because other emissions covered in these rules can be almost as high as the threshold limits under 45 CSR 13. It is appropriate, however, to exempt all these sources from the permit requirement, as long as the conditions specified in the interpretive rules are satisfied.

COMMENT B: *Associated Devices - Sections 2.1.a and 2.1.d do not include the language "any associated devices to capture and collect emissions from any such equipment or devices." The commenters encourage DAQ to include capture and collection devices within the definitions.*

RESPONSE B: DAQ disagrees. The reason these associated devices were not included in this section is that they are expressly excluded from the list of "de minimus"

sources under No. 7 of Table 45-13B in 45 CSR 13. The interpretive rule cannot conflict with the underlying legislative rule. However, to address the commenters' concern, the DAQ has added language in section 3.2 which will allow these sources to be exempted if the total input of materials is less than twenty-five (25) pounds and the source provides a demonstration to that effect.

COMMENT C: *Calendar Day - It is necessary to determine the 25 pounds of total input on a calendar day basis rather than on the basis of any rolling 24 hour period. Using a calendar day basis for the rule would add an element of simplicity by significantly reducing the number of time periods over which data would need to be collected and analyzed.*

RESPONSE C: DAQ agrees with the comment because these emissions are relatively small and has revised the rule accordingly.

COMMENT D: *"Bench-scale Laboratory Equipment" Exemption - Paragraph 3.1 of the proposed rule creates confusion in that it combines the broad exemption for all the laboratories contained in the definition of "bench-scale laboratory equipment" set forth in Section 2.1 of the rule, with a demonstration that must be made with respect to that subset of those laboratories that are defined in Section 2.1.d. The commenters suggest that these two concepts be moved into separate sections.*

RESPONSE D: DAQ agrees with the comment and has revised the rule accordingly.

COMMENT E: *R & D Exemption - The proposal which has been advanced by DAQ fundamentally changed the structure of the policy negotiated by the working group by applying a program intended for R & D facilities to laboratories and by applying a program intended for laboratories to R & D facilities. Specifically, the exemption for activities involving 25 pounds or less of total input, was specifically intended to apply to "bench scale research and development equipment." DAQ's proposal inappropriately applies this 25 pound exemption to "bench scale laboratory equipment." DAQ also inappropriately applies an exemption intended for applicability to other laboratories to R & D laboratories, instead.*

The proposal with respect to making a case-specific demonstration of eligibility has been modified to allow that demonstration to include limitations on operating practices, training, engineering or administrative

controls. The commenters believe the type of demonstration which relies on operating practices, training, engineering or administrative controls is the type of demonstration that would more fairly be included within the alternative demonstration set forth in subsection b. of this Section.

In addition, the term defined in Section 2.2 of the proposed rule should be changed to "bench-scale research and development equipment" instead of "laboratory facilities associated with research and development activities." The commenters also suggest that the recognition of "scale-up" be linked to gathering data to design of a commercial facility.

RESPONSE E: DAQ disagrees that it has fundamentally changed the structure of the two policies drafted by the working group. As originally drafted, the two policies were unclear in their scope of coverage and, in fact, blended the two types of source categories, laboratory, and research and development emissions. It was not clear which exemptions and criteria were applicable to which sources. DAQ believes it is important that the two rules be clear as to which type of emissions are covered under which rule and under what conditions.

Regarding the specific comment about the exemption for activities involving 25 pounds or less of total input, it is true the proposed rule used "bench-scale laboratory equipment" as the operative term instead of "bench-scale research and development equipment." However, even the commenters' suggested language in section 2.2 states " 'bench-scale research and development equipment' means laboratory facilities . . . , " preserving the distinction DAQ was attempting to make. The commenters' last point in the first paragraph regarding inappropriately applying an exemption intended for "other laboratories" to "R & D laboratories" is one with which DAQ agrees, and the rule has been revised accordingly. See Response I.F. below.

With respect to the case-specific and alternative demonstrations of eligibility, the proposed rule provides that whether it is a case-specific or an alternative demonstration, a source may use limitations on operating practices, training, engineering or administrative controls. The DAQ envisions that case-specific determinations for determining input may, on occasion, rely upon limitations on operating practices, training, engineering or administrative controls and views this language as expanding the requirement rather than restricting it. DAQ has, however, revised the language pertaining to the alternative demonstration to make it more broad.

With respect to the suggestion to expand the scope of the "scale-up" exemption, DAQ agrees and has revised the rule accordingly.

COMMENT F: *Other Laboratories - The proposal advanced by DAQ inappropriately limits the Section 4 exemption to "laboratory facilities associated with research and development activities." The commenters believe this section must extend to any laboratory that does not qualify for the exemptions set forth in Section 3.*

RESPONSE F: DAQ agrees with the comment and has revised the rule accordingly.

COMMENT G: *Regulated Air Pollutants - There are two sections of the rule where the term has been incorrectly written as "regulated pollutants." For consistency, the commenters urge that the term be corrected to read "regulated air pollutants."*

RESPONSE G: DAQ agrees with the comment and has revised the rule accordingly.

COMMENT H: *Estimating Actual Emissions - DAQ's proposal (Section 4.1.a.3.D) inappropriately requires that estimates of emissions be supported by "supporting calculations and the date and duration of emissions." The commenters submit that this additional requirement is overly burdensome for laboratories to maintain and urge that the owners and operators of laboratories be allowed to use alternative means to estimate, record and report actual emissions.*

RESPONSE H: The proposed rule language at section 4.1.a.3.D is more precise and more meaningful as a monitoring and record-keeping requirement than the one stated in the original policy drafted by the working group. DAQ believes estimating emissions is an important condition which must be satisfied before these relatively large sources of laboratory emissions can be exempted from permitting obligations. (DAQ would point out that section 5.14 of 45CSR13 requires sources to maintain records of emissions, even when emissions are below the threshold levels in the rule). DAQ does, however, recognize there may be some instances where maintaining supporting calculations and the date and duration of emissions is not feasible, and the rule has been revised to allow the agency to approve alternative procedures for such instances.

COMMENT I: *Information Available to the Director - The commenters urge for consistency sake that 4.1.b be revised to make it clear that the good*

laboratory practices plan required by that section shall be maintained on site at all times and available "to the Director" upon request.

RESPONSE I: DAQ agrees with the comment and has revised the rule accordingly.

COMMENT J: *Buffer Zone - In Section 4.1.d, there has been an unwarranted expansion of the buffer zone that must surround laboratory facilities before those facilities can be exempt from permitting. The expansion of this buffer zone to a distance of 300 feet and extending it to any business, public building, school, church, community or institutional building significantly limits the scope and availability of this provision. It is particularly troublesome that the provision does not even limit the expansion of this provision to those buildings or areas when occupied.*

RESPONSE J: DAQ agrees with the comment and has revised the rule accordingly.

COMMENT K: *Throughput Exemption - Section 4.1.e.1 was intended to provide a straightforward exemption based on throughput if the laboratory can demonstrate that no more than 144 pounds of total input was involved. DAQ has proposed that this throughput exemption can be relied upon only "where actual emissions cannot be reasonably estimated." The commenters believe that the addition of this language defeats the very purpose of having a throughput exemption, namely, to create a threshold throughput that was low enough to allow laboratory operators to avoid the need to collect and record actual emission data.*

RESPONSE K: DAQ agrees with the comment and has revised the rule to remove the language "where actual emissions cannot be reasonably estimated." This will, as the commenters suggested, allow the 144 pounds per day criterion to function as a straightforward throughput exemption without the need to collect and record actual emissions data. Such sources will, however, be required to make a case-specific demonstration under section 4.1.f of the rule describing how total input of materials is determined.

Additionally, DAQ has revised the rule to specify that the 144 pounds per day criterion is to be determined on a rolling 24-hour basis. Unlike the small bench-scale emissions, which under section 3.2 of the revised rule are limited to 25 pounds of material, this particular criterion allows up to 144 pounds of material. The DAQ believes it is more appropriate to base this limit on a rolling 24-hour time period rather than on a calendar day basis, as was done

for the smaller emissions in section 3.2 of the rule.

COMMENT L: *Effect on Other Rules - As has been proposed in 45 CSR 13A, the commenters urge DAQ to include within 45 CSR 13B, a provision that states that actual emissions from facilities subject to this rule will be regarded as potential to emit to the extent that any of these facilities are subject to another applicable rule.*

RESPONSE L: DAQ agrees with the comment and has revised the rule accordingly.

II. COMMENTER: Union Carbide Corporation, a subsidiary of Dow Chemical Company

COMMENT A: *Section 4.1.a.3.d provides that the Good Laboratory Practices Plan must include "Procedures to estimate and record actual emissions of regulated pollutants, including supporting calculations and the date and duration of emissions." It is requested that the language supporting Good Laboratory Practices Plan be revised.*

The requirement to record the date and duration of emissions (no matter how minuscule) does not add value due to the small amounts of materials handled.

RESPONSE A: See Response I.H. above. With regard to the commenter's statement concerning the requirement to record the date and duration of emissions (no matter how minuscule), DAQ points out that this requirement is found under section 4 of the rule, which pertains to the larger laboratories, not the smaller bench-scale labs and those with inputs less than 25 pounds per day.