

Form #2

OFFICE WEST VIRGINIA
SECRETARY OF STATE

**BUREAU OF ENVIRONMENT
DEPARTMENT OF ENVIRONMENTAL PROTECTION**

BRIEFING DOCUMENT

Rule Title: 45CSR13B - "The Permitting of Laboratory Facilities Under 45CSR13"

A. AUTHORITY: W.Va. Code §§22-5-1 et seq. and 45CSR13

B. SUMMARY OF RULE:

This interpretive rule provides that certain laboratory facilities, both those considered de minimis and those larger, are exempt from permitting requirements under 45CSR13 as long as they demonstrate how total input of materials will be determined and keep records, and in the case of larger laboratories, stay below a fixed amount of total input of materials and meet other conditions such as ensuring that control measures are used to minimize emissions.

C. STATEMENT OF CIRCUMSTANCES WHICH REQUIRE RULE:

This interpretive rule is necessary to provide guidance and clarification regarding the circumstances under which a permit is required for laboratory facilities under 45CSR13, the agency's minor source preconstruction permitting rule. The interpretive rule will result in the streamlining of permitting requirements and increased operational flexibility for these sources.

5

Rule Title: 45CSR13B - "The Permitting of Laboratory Facilities Under 45CSR13"

Agency: Division of Air Quality

Address: 7012 MacCorkle Avenue, SE

Charleston, WV 25304-2943

1. Effect of Proposed rule:

	ANNUAL FISCAL YEAR				
	INCREASE	DECREASE	CURRENT	NEXT	THEREAFTER
ESTIMATED TOTAL COST	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0
PERSONAL SERVICES	0	0	0	0	0
CURRENT EXPENSE	0	0	0	0	0
REPAIRS & ALTERATIONS	0	0	0	0	0
EQUIPMENT	0	0	0	0	0
OTHER	0	0	0	0	0

2. Explanation of Above Estimates:

The proposed Interpretive Rule will have minimal effect on the costs to the Division of Air Quality and implementation will be absorbed into the existing work environment. Costs are covered under previous budget estimates.

3. Objectives of These Rules:

The objective of this rule is to provide guidance to sources with laboratory facilities regarding the permitting requirements under 45CSR13.

Rule Title: "The Permitting of Laboratory Facilities Under 45CSR13"

4. Explanation of Overall Economic Impact of Proposed Rule:

A. Economic Impact on State Government:

See section 2.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens:

There will be no economic impact on political subdivisions or the regulated community in West Virginia resulting from the Interpretive Rule contained herein. There may, in fact, be a beneficial effect on the regulated community due to clarifications in the underlying legislative rule, 45CSR13.

C. Economic Impact on Citizens/Public at Large.

There will be no economic impact on the citizens or public at large in West Virginia resulting from the Rule contained herein.

Date: _____

Signature of Agency Head or Authorized Representative:

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

FILED

2001 SEP 12 A 10:29

SERIES 13B
THE PERMITTING OF LABORATORY FACILITIES
UNDER 45CSR13

OFFICE WEST VIRGINIA
SECRETARY OF STATE**§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.

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" 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;

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:

3.1.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.b. Make an alternative demonstration of eligibility providing at a minimum such information as required in subdivision 3.1.a.

3.2. Case-specific determinations of eligibility under subdivision 3.1.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.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:

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 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 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 upon request.

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

4.1.d. The laboratory facility shall be located at least 300 feet from any occupied dwelling or business, public building, school, church, community, institutional building or public park unless waived by the owner thereof.

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.