

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Parts 261 and 262**

[EPA-HQ-RCRA-2003-0012; FRL-8743-9]

RIN 2050-AG18

**Standards Applicable to Generators of Hazardous Waste; Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material at Laboratories Owned by Colleges and Universities and Other Eligible Academic Entities Formally Affiliated With Colleges and Universities****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA or the Agency) is finalizing an alternative set of generator requirements applicable to laboratories owned by eligible academic entities, as defined in this final rule. The rule provides a flexible and protective set of regulations that address the specific nature of hazardous waste generation and accumulation in laboratories at colleges and universities, as well as other eligible academic entities formally affiliated with colleges and universities. This final rule is optional and colleges and universities and other eligible academic entities formally affiliated with a college or university have the choice of managing their hazardous wastes in accordance with the new alternative regulations as set forth in this final regulation or remaining subject to the existing generator regulations.

**DATES:** This final rule is effective December 31, 2008.

**ADDRESSES:** EPA has established a docket for this action under Docket ID No. RCRA-2003-0012. All documents

in the docket are listed on the <http://www.regulations.gov> Web site. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the EPA RCRA Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the RCRA Docket is (202) 566-0270.

**FOR FURTHER INFORMATION CONTACT:** For further information regarding specific aspects of this notice, contact Kristin Fitzgerald, Office of Solid Waste, (703) 308-8286, [Fitzgerald.Kristin@epa.gov](mailto:Fitzgerald.Kristin@epa.gov); Patricia Mercer, Office of Solid Waste, (703) 308-8408, [Mercer.Patricia@epa.gov](mailto:Mercer.Patricia@epa.gov); or Jessica Biegelson, Office of Solid Waste, (703) 308-0026, [Biegelson.Jessica@epa.gov](mailto:Biegelson.Jessica@epa.gov). Mail inquiries may be directed to the Office of Solid Waste, (5304P), 1200 Pennsylvania Avenue NW., Washington, DC 20460.

**SUPPLEMENTARY INFORMATION:****I. General Information****A. Entities Potentially Affected by This Rule**

The rule establishes a new Subpart K within 40 CFR part 262. Entities potentially affected by this final action are colleges and universities; non-profit research institutes that are either owned by or have a formal written affiliation

agreement with a college or university; and teaching hospitals that are either owned by or have a formal written affiliation agreement with a college or university, that generate hazardous waste in laboratories. Today's final rule refers to these collectively as "eligible academic entities." This final action is optional for eligible academic entities. That is, eligible academic entities that are large quantity generators (LQGs), small quantity generators (SQGs), or conditionally exempt small quantity generators (CESQGs) may choose to have their laboratories be subject to 40 CFR part 262, Subpart K in lieu of the existing generator regulations. In States authorized to implement the RCRA program, Subpart K would only be available as an option once it has been adopted by the State in which the eligible academic entity is located.

Only eligible academic entities can participate under Subpart K for the laboratories they own. The following are examples of entities that are not eligible because they do not satisfy the definition of "eligible academic entity:" government facilities; commercial research and development (R&D) facilities; non-profit research institutes that are not owned by nor have a formal written affiliation agreement with a college or university; non-teaching hospitals; and teaching hospitals that are not owned by nor have a formal written affiliation agreement with a college or university. To determine whether the laboratories owned by an eligible academic entity are covered by this action, interested parties should examine 40 CFR part 262, Subpart K carefully. If there are questions regarding the applicability of the rule to a particular entity, consult your State, EPA Regional office, or the person(s) listed in the section of this preamble entitled, **FOR FURTHER INFORMATION CONTACT**.

**NAICS CODES OF ENTITIES POTENTIALLY AFFECTED BY THIS FINAL RULE**

NAICS codes	Description of NAICS code
<b>Colleges &amp; Universities</b>	
6112, 61121, 611210 .....	Junior Colleges.
6113, 61131, 611310 .....	Colleges, Universities, and Professional Schools.
6115, 61151 .....	Technical and Trade Schools.
611519 .....	Other Technical and Trade Schools.
61161, 611610 .....	Fine Arts Schools.
<b>Teaching Hospitals</b>	
54194, 541940 .....	Veterinary Services (Animal Hospitals).
622 .....	Hospitals.
6221, 62211, 622110 .....	General Medical and Surgical Hospitals.
6222, 62221, 622210 .....	Psychiatric and Substance Abuse Hospitals.
6223, 62231, 622310 .....	Specialty (except Psychiatric and Substance Abuse) Hospitals.

## NAICS CODES OF ENTITIES POTENTIALLY AFFECTED BY THIS FINAL RULE—Continued

NAICS codes	Description of NAICS code
<b>Non-profit Research Institutes</b>	
5417, 54171, 541710 .....	Research and Development in the Physical, Engineering, and Life Sciences.
54172, 541720 .....	Research and Development in the Social Sciences and Humanities.

## LIST OF ACRONYMS

APA .....	Administrative Procedures Act.
ACE .....	American Council on Education.
AAMC .....	Association of American Medical Colleges.
AIRI .....	Association of Independent Research Institutes.
BR .....	Biennial Report.
BMPs .....	Best Management Practices.
CAA .....	Central Accumulation Area.
CAS .....	Chemical Abstract Service.
CESQG .....	Conditionally Exempt Small Quantity Generator.
CFR .....	Code of Federal Regulations.
C2E2 .....	Campus Consortium for Environmental Excellence.
CSHEMA .....	Campus Safety Health and Environmental Management Association.
EH&S .....	Environmental Health and Safety.
HHMI .....	Howard Hughes Medical Institute.
HSWA .....	Hazardous and Solid Waste Amendments of 1984.
ICR .....	Information Collection Request.
LDR .....	Land Disposal Restrictions.
LMP .....	Laboratory Management Plan.
LQG .....	Large Quantity Generator.
NACUBO .....	National Association of College and University Business Officers.
NTTAA .....	National Technology Transfer Advancement Act.
OMB .....	Office of Management and Budget.
OSHA .....	Occupational Safety and Health Administration.
PRA .....	Paperwork Reduction Act.
Project XL .....	eXcellence and Leadership.
R&D .....	Research and Development.
RCRA .....	Resource Conservation and Recovery Act.
RFA .....	Regulatory Flexibility Act.
SAA .....	Satellite Accumulation Area.
SQG .....	Small Quantity Generator.
SWDA .....	Solid Waste Disposal Act.
TSDF .....	Treatment, Storage or Disposal Facility.
UMRA .....	Unfunded Mandates Reform Act.

**Outline****I. Statutory Authority****II. Background**

## A. History and Summary of the Proposed Rule

## B. Rationale of the Final Rule

## C. Summary of the Final Rule

## D. Effective Date of the Final Rule

**III. Detailed Discussion of the Final Rule**

## A. Scope of Eligible Academic Entities Covered Under the Final Rule

## 1. Hazardous Waste Generation Data

## 2. Laboratories Owned by Teaching Hospitals

## 3. Laboratories Owned by Non-profit Research Institutes

## 4. Laboratories Owned by Eligible Academic Entities that are Conditionally Exempt Small Quantity Generators (CESQGs)

## 5. Facilities with Laboratories Not Eligible to Participate in Subpart K

## a. Government Research Laboratories

## b. Commercial R&amp;D Laboratories

## 6. Non-laboratory Facilities at Eligible Academic Entities

## B. Discussion of Definitions

## 1. Definitions that Have Not Changed from the Proposed Rule

## 2. Definitions that Have Changed from the Proposed Rule

## 3. Definitions that Are New

## C. Specific Requirements of the Alternative Regulations

## 1. Notification

## 2. Labeling Standards

## 3. Container Standards

## 4. Training Requirements

## 5. Removal Frequency of Unwanted Materials

## a. Reactive Acutely Hazardous Unwanted Materials

## b. Transferring Unwanted Materials or Hazardous Wastes from the Laboratory to an On-site CAA or On-site TSDF

## c. On-site Consolidation Areas

## 6. Making the Hazardous Waste Determination

## 7. Laboratory Clean-outs

## a. Summary of the Proposed Laboratory Clean-out Provisions

## b. Changes Made to the Laboratory Clean-out Provisions

## c. Changes Not Made to the Laboratory Clean-out Provisions

## d. Clarifications About the Laboratory Clean-out Provisions

## 8. Laboratory Management Plan

## a. Part I of the LMP

## b. Part II of the LMP

## 9. How CESQGs Comply with Subpart K and How They Differ from LQGs and SQGs

## 10. Off-site Consolidation

## a. Off-site Consolidation by CESQGs

## b. Off-site Consolidation by CESQGs, SQGs, and LQGs

## 11. Topics that Are Outside the Purview of this Rulemaking

## D. Reporting and Recordkeeping

## 1. Reporting to the Biennial Report for Eligible Academic Entities that are LQGs

## 2. Recordkeeping

## E. Implementation and Enforcement

**IV. State Authorization**

## A. Applicability of Rules in Authorized States

## B. Effect on State Authorization

**V. Statutory and Executive Order Reviews**

## A. Executive Order 12866: Regulatory Planning and Review

## 1. Introduction to the Economic Assessment for the Final Rule

2. Baseline Specification
3. Analytical Methodology, Primary Data Sources, and Key Assumptions
4. Key Analytical Limitations
5. Findings
- B. Paperwork Reduction Act
- C. Regulatory Flexibility Act
- D. Unfunded Mandates Reform Act
- E. Executive Order 13132: Federalism
- F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
- G. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks
- H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Usage
- I. National Technology Transfer and Advancement Act
- J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
- K. Congressional Review Act

## I. Statutory Authority

These regulations are promulgated under the authority of §§ 2002, 3001, 3002, and 3004 of the Solid Waste Disposal Act (SWDA) of 1970, as amended by the Resource Conservation and Recovery Act (RCRA) of 1976, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6921, 6922, 6923, and 6924.

## II. Background

### A. History and Summary of the Proposed Rule

This rulemaking is a culmination of many years of investigation and participation by EPA in efforts designed to better understand the challenges that the academic community faces when managing hazardous wastes generated in laboratories under the hazardous waste regulations. As discussed at length in the preamble to the proposed rule (see 71 FR 29715), these efforts include two Reports to Congress; a project under EPA's eXcellence and Leadership program (Project XL) with three colleges and universities in New England; a pilot project led by the Howard Hughes Medical Institute (HHMI) to develop and implement a performance-based approach to the management of laboratory waste at ten colleges and universities; and a public meeting on June 18, 2003, sponsored by EPA to discuss the management of hazardous waste in research and/or academic laboratories. (See the announcement of the public meeting at 68 FR 33121, June 3, 2003. The comments submitted to EPA in response to the public meeting are included in the docket for today's rulemaking.)

As a result of these and other efforts, on May 23, 2006, EPA proposed

alternative generator requirements applicable to college and university laboratories that generate hazardous waste (71 FR 29712<sup>1</sup>). This preamble will refer to the alternative generator requirements as "Subpart K," because it establishes a new Subpart K of 40 CFR part 262. The proposed rule provided a flexible and protective set of regulations that addressed the specific nature of hazardous waste generation and accumulation in college and university laboratories. The proposed rule was optional and colleges and universities had the choice of managing their hazardous wastes in accordance with the proposed alternative Subpart K requirements or remaining subject to the existing generator regulations. Although the applicability of the proposed rule was limited to colleges and universities, the Agency requested comment on whether it would be appropriate to expand the applicability of the final rule to other organizations that also have research or teaching laboratories. In addition, since the Agency assumed that CESQs would not want to be subject to the increased burden of Subpart K, the proposed rule was limited to colleges and universities that are SQGs and LQGs. However, we solicited comments on whether CESQs should be allowed to be subject to Subpart K.

Throughout the years of working with academic institutions, EPA has heard consistently that the greatest challenge that academic institutions face in managing their laboratory hazardous wastes under the existing generator regulations is making the RCRA hazardous waste determination at the point of generation pursuant to 40 CFR 262.11 (i.e., determining whether their solid waste is hazardous waste and assigning the proper hazardous waste code(s) in the laboratory at the time the hazardous waste is generated). This is largely because the individuals in the laboratory generating the hazardous waste and other materials are students, who are often not trained to make a hazardous waste determination. We, therefore, proposed to remove the responsibility for the hazardous waste determination from the students in the laboratory and place it in the hands of trained environmental health and safety (EH&S) professionals. While the hazardous waste remains in the laboratory, we proposed that it would be referred to as "unwanted material," since the hazardous waste

determination had not yet been made and some portion of the unwanted materials may be unused and therefore still usable, or may not be hazardous waste when discarded. We proposed that while in the laboratory, the P-listed commercial chemical products that were listed for reactivity would be referred to as "reactive acutely hazardous unwanted materials." In lieu of making the hazardous waste determination at the point of generation, the Agency proposed that the hazardous waste determination must be made prior to removing the unwanted materials from the laboratory (but not at the time the unwanted materials are first generated), or within four calendar days of arriving at an on-site central accumulation area (CAA) or on-site interim status or permitted treatment, storage, or disposal facility (TSDF).

The Agency also proposed that the unwanted materials would be regulated in the laboratory by performance-based container labeling and container management standards. These performance-based standards for the management of unwanted materials in the laboratory were coupled with a requirement for a Laboratory Management Plan (LMP). This combination provided flexibility by allowing the college or university to specify in its LMP how it would comply with the performance-based standards. The Agency co-proposed two options regarding the enforceability of the contents of the individual LMPs that colleges and universities developed. One option was that the contents of the LMP would be enforceable; the second option was that the contents of the LMP would not be enforceable.

Additionally, we proposed that all containers of unwanted materials would have to be removed from the laboratory on a regular basis, not to exceed six months. However, if a laboratory accumulated more than 55 gallons of unwanted material before the regularly scheduled removal, then all containers of unwanted material would have to be removed from the laboratory within ten calendar days. Likewise, if a laboratory accumulated more than 1 quart of reactive acutely hazardous unwanted material prior to the regularly scheduled removal, then the reactive acutely hazardous unwanted materials would have to be removed from the laboratory within ten calendar days.

Finally, to address the problem of laboratories keeping old, unneeded, or expired chemicals (i.e., "legacy chemicals"), the Agency proposed regulatory provisions that would give colleges and universities incentives for conducting laboratory clean-outs: a

<sup>1</sup> Please see page 29716 of the preamble to the proposed rule for information on other EPA efforts to improve hazardous waste management at colleges and universities through compliance assistance centers and more.

laboratory clean-out could occur over a 30 day period, even if the 55-gallon limit of unwanted material was exceeded; and the hazardous waste generated during a laboratory clean-out would not have to be counted toward the college or university's generator status. However, we proposed that colleges and universities could only utilize the clean-out incentives once per 12 months per laboratory.

The comment period for the proposed rule was originally due to close on August 21, 2006. However, EPA received a request from the National Association of College and University Business Officers (NACUBO), on behalf of the American Council on Education (ACE), the Campus Safety Health and Environmental Management Association (CSHEMA), and the Campus Consortium for Environmental Excellence (C2E2) to extend the comment period for 45 days. On August 21, 2006, EPA extended the public comment period by 30 days (see 71 FR 48500). The comment period for the proposed rule closed on September 20, 2006.

The Agency received 111 comments on the proposed rule. Approximately two-thirds of the comments were from colleges and universities, or trade groups that represent colleges and universities. In general, colleges and universities were very supportive of the Agency's effort to address the challenges they face in complying with the RCRA hazardous waste regulations in their laboratories. However, many of these commenters also suggested specific changes to the rule. Thirteen States also submitted comments. Some States expressed support for the rule, while others were very skeptical of the need for the rule. Most of the rest of the comments were from organizations that were not eligible to participate in Subpart K, as proposed. These commenters, which included non-profit research organizations, commercial companies that conduct research and manufacture pharmaceuticals and other products, as well as several Federal governmental agencies, requested that the Agency expand the scope of the final rule to allow them to be subject to Subpart K. The more significant comments on the proposal are addressed later in this preamble, in section III, but all are addressed in the Response to Comments Document for today's final rule found in the docket at <http://www.regulations.gov> (EPA-HQ-RCRA-2003-0012).

#### *B. Rationale of the Final Rule*

In the proposal, the Agency discussed how the hazardous waste generation

and management practices at college and university laboratories differ from both industrial production and industrial laboratory operations in several meaningful ways (see 71 FR 29714). These differences, which were confirmed by many of the commenters, provide the rationale for today's final rule.

Specifically, the Agency identified four primary differences between laboratory operations at colleges and universities and typical industrial production facilities. First, laboratories at colleges and universities have a large number of points of generation (i.e., points where waste is originally generated), such as multiple laboratory benchtops within a single laboratory and laboratories located at several areas on a single campus. Second, these laboratories tend to generate relatively small volumes of each hazardous waste at each of these points of generation. Third, the hazardous wastes generated in these laboratories tend to vary over time, as areas of research change. In contrast, industrial generators tend to have a different hazardous waste generation pattern; they tend to generate a smaller number of predictable wastestreams in large quantities at relatively few generation points. Fourth, and of particular note, is that most individuals involved in hazardous waste generation activities at college and university laboratories are students. Students are inherently transient, which makes it more difficult to train them. This fourth difference sets college and university laboratories apart not only from typical industrial production facilities, but also from non-academic, government and commercial R&D laboratories. At both industrial production facilities and non-college or university, commercial laboratories, employees who generate hazardous waste are professionally trained in managing hazardous wastes and are held accountable due to their employee status.

The proposal addressed challenges faced by colleges and universities that result from these differences, and proposed to establish a new, optional Subpart K under 40 CFR part 262 for making the hazardous waste determination, and accumulating and removing unwanted materials from laboratories at colleges and universities. Comments from colleges and universities and their trade associations confirm EPA's conclusion that differences in hazardous waste generation and management activities at laboratories at academic institutions warrant this alternative set of requirements. Because of these

differences, the alternative generator requirements found in Subpart K are directed at the management of unwanted materials in the laboratory and not in other areas on the same site where hazardous waste may be generated or managed.

Therefore, today EPA is finalizing an alternative set of generator regulations for the management of hazardous waste generated in laboratories at specific types of academic facilities (i.e., eligible academic entities). Based on comments received on the proposed rule, as well as additional analysis, the Agency is finalizing the rule with some changes from the proposal. The Agency believes that today's final rule is better suited to the circumstances specific to these laboratories, and that it promotes environmental protection and public health through safer management of laboratory hazardous wastes.

#### *C. Summary of the Final Rule*

This section provides a brief overview of today's final rule and describes the major ways in which today's rule differs from the proposal. For a detailed description and justification of the changes in today's final rule, see Section III of today's preamble.

The final rule establishes a set of alternative generator regulations for laboratories owned by eligible academic entities under a new Subpart K in 40 CFR part 262. Eligible academic entities may choose to be subject to Subpart K in lieu of the existing generator requirements for the management of the hazardous waste generated in the laboratories that they own. Laboratories operating under Subpart K must comply with the performance-based standards, while the unwanted materials remain in the laboratory. The eligible academic entity also must develop an LMP that reasonably addresses the nine elements that are required to be part of the LMP and that describes how the eligible academic entity will comply with the performance-based standards. The final rule also provides incentives for eligible academic entities to conduct laboratory clean-outs of old, unneeded chemicals.

One of the major changes from the proposed rule found in today's final action is the Agency's decision to expand the applicability of the rule. Specifically, the scope of the final rule includes colleges and universities, non-profit research institutes that are owned by or have a formal written affiliation agreement with a college or university, and teaching hospitals that are owned by or have a formal written affiliation agreement with a college or university.

In addition, although the proposed rule specifically precluded laboratories

at colleges or universities that are CESQs from choosing to be subject to Subpart K, the final rule allows laboratories that are owned by eligible academic entities that are CESQs, SQGs or LQGs to operate under Subpart K. We also have modified the definition of laboratory, so that additional areas within an eligible academic entity, such as photo laboratories, field laboratories, and art studios are considered laboratories. In addition, chemical stockrooms and preparatory laboratories and other areas that provide a support function to research and teaching laboratories, are allowed to operate under Subpart K.

EPA recognizes that the details of hazardous waste management operations vary widely among campuses and some eligible academic entities have developed programs consistent with the existing generator regulations that have proven to be successful. Thus, these institutions may be reluctant to change from the generator regulations under which they are currently operating. Therefore, today's final rule, like the proposal, remains an optional, alternative set of requirements to the existing generator regulations and eligible academic entities may continue to manage their laboratory hazardous wastes under the current hazardous waste generator regulations. Eligible academic entities that would like the additional flexibility of today's rule may choose to manage their laboratory hazardous wastes according to the set of generator regulations we are finalizing today.

Public comments received on the proposed rule confirmed that the primary difficulty with managing laboratory hazardous wastes under current regulations is making the hazardous waste determination at the point of generation. As with the proposal, the final rule addresses this challenge by providing flexibility with regard to where and when the hazardous waste determination can be made (i.e., in the laboratory before it is removed from the laboratory, or within four calendar days of arriving at an on-site CAA, or on-site TSDF), provided all unwanted materials (as defined by the rule) that are generated in the laboratory are managed according to the requirements promulgated in today's rule.

EPA continues to stress that today's final rule does not alter or move the point of generation of any hazardous waste, but merely allows the hazardous waste determination to be made at an on-site CAA or on-site TSDF; or in the laboratory, but at a point in time after the initial generation of the waste. The

point of generation of the hazardous waste continues to be the location and time at which the hazardous waste is first generated. Therefore, the applicability of the land disposal restrictions (LDRs) to hazardous wastes generated in the laboratory are not affected by today's rule and continue to "attach" at the point of generation of the hazardous waste. In addition, RCRA's statutory inspection and enforcement authorities continue to apply in the laboratory, even though under Subpart K the hazardous wastes are referred to as "unwanted materials," while they remain in the laboratory.

Today's final rule maintains the proposed requirement that unwanted materials must be removed from the laboratory primarily on a time basis, and secondarily on a volume basis. That is, we are requiring that eligible academic entities conduct removals of unwanted materials from the laboratory on a regular basis, not to exceed six months, although we have included some additional flexibility. If a laboratory accumulates more than 55 gallons of unwanted material (including reactive acutely hazardous unwanted material) before the regularly scheduled removal, then all unwanted materials (including reactive acutely hazardous unwanted material) must be removed within ten calendar days. And if a laboratory accumulates more than 1 quart of reactive acutely hazardous unwanted material before the regularly scheduled removal, then the reactive acutely hazardous unwanted material must be removed from the laboratory within ten calendar days.

Another key issue identified by the academic community that we addressed in the proposal focused on incentives for discarding unneeded or expired chemicals that can accumulate in college and university laboratories and chemical store rooms. The academic community contends that the existing generator regulations result in discouraging laboratory clean-outs (because the increased quantities of hazardous waste generated can change the eligible academic entity's generator status) and therefore, laboratories often hold on to expired chemicals, some of which become dangerous over time. EPA believes that revising the regulations to encourage laboratories to remove legacy chemicals will result in greater protection of human health and the environment, as well as increased environmental compliance. Thus, an important part of this final rule is the laboratory clean-out provisions: once per 12 months per laboratory, a laboratory will have 30 days to conduct a clean-out and will not have to count

the hazardous waste that consists of unused commercial chemical products (either listed or characteristic) generated during those 30 days towards the eligible academic entity's generator status.

As in the proposed rule, today's final rule pairs a performance-based approach for management of unwanted materials in the laboratory with a requirement for the eligible academic entity to develop and implement an LMP. We believe that a performance-based approach will allow eligible academic entities greater flexibility by allowing them to tailor their laboratory waste management program with respect to container labeling, container management, and training, while ensuring better environmental results. Like the proposal, under today's final rule, the LMP must describe how an eligible academic entity will meet the required provisions (i.e., the performance-based standards) by reasonably addressing all the required elements. However, unlike the proposal, the LMP under today's final rule must include two distinct parts (Parts I and II). The eligible academic entity must comply with the specific contents it includes in Part I of its LMP, while Part II will comprise the institution's best management practices (BMPs). Thus, EPA and authorized States may take enforcement action against an institution if it fails to meet the specifics of Part I of its LMP. However, EPA and authorized States may not take enforcement action if an institution's actions vary from the specific procedures contained in Part II of its LMP, but may take enforcement action if the institution fails to reasonably address all the required elements in Part II of its LMP.

In summary, the Agency believes that today's rule will lead to the safe management of unwanted materials and greater environmental protection by requiring that the RCRA hazardous waste determination be performed by trained personnel, rather than by untrained students. We also believe that today's final rule will promote the protection of human health and the environment by ensuring that all unwanted materials which may, in whole or in part, be RCRA hazardous wastes, are safely managed while in the laboratory prior to the time that the hazardous waste determination is made. In addition, EPA believes that the requirement to develop and implement an LMP will improve the coordination and integration of hazardous waste management procedures and enhance environmental awareness among researchers and students at eligible

academic entities, leading to a transfer of good environmental management practices to the larger community.

#### *D. Effective Date of the Final Rule*

This final rule is effective on December 31, 2008 section 3010(b) of RCRA allows EPA to promulgate a rule with an effective date shorter than six months where the Administrator finds that the regulated community does not need additional time to come into compliance with the rule. This rule is optional for those eligible academic entities that choose to follow it. For those entities, this rule provides an alternative set of requirements that are intended to provide them flexibility from current applicable regulations. Therefore, the Agency finds that the regulatory community does not need six months to come into compliance.

### **III. Detailed Discussion of the Final Rule**

Today, EPA is publishing a final rule establishing alternative regulations (40 CFR part 262, Subpart K) for the management of unwanted materials generated in laboratories in eligible academic entities. This section discusses in detail the major features of the final rule and the rationale for the changes made from the proposal to today's final rule.

In today's final rule and preamble, we introduce and use several new terms. We are including here a brief description of how we will use the terminology in today's preamble. First, we will use the terms "choose to become subject to," "participate under," "operate under" and "opt in" to Subpart K interchangeably. Second, the regulations require that in order to be eligible to opt into Subpart K, a non-profit research institute must be owned by or have a formal written affiliation agreement with a college or university, and a teaching hospital must be owned by or have a formal written affiliation agreement with a college and university. In the preamble, we will generally refer to eligible academic entities other than colleges and universities as non-profit research institutes and teaching hospitals that are owned by or formally affiliated with a college or university.

Third, many eligible academic entities have multiple EPA Identification Numbers for different sections of the same "campus," typically because the sections of the eligible academic entity are separated by public roads. When referring to the individual sections of an eligible academic entity, we will use the term "site" or "EPA Identification Number." When referring collectively to all the sections of the eligible academic

entity, we will use the term, "campus," or "eligible academic entity," or "institution." As an example, when an eligible academic entity opts into Subpart K for its laboratories, it must notify the Agency for each EPA Identification Number on a campus that is opting in.

#### *A. Scope of Eligible Academic Entities Covered Under the Final Rule*

EPA proposed that this alternative set of generator regulations would apply only to laboratories at colleges and universities. As discussed in section II.A of today's preamble, EPA has had a long history of interaction with colleges and universities. From these interactions, the Agency has learned about the unique hazardous waste generation pattern in teaching and research laboratories at colleges and universities. However, EPA recognized that there may be additional types of facilities with laboratories that may fit the rationale for Subpart K. Thus, while the proposal was limited to colleges and universities, EPA solicited comment on whether to expand the scope of the final rule to other institutions that fit the rationale of Subpart K.

Public comments from trade groups, such as the Association of American Medical Colleges (AAMC), the Association of Independent Research Institutes (AIRI), the Campus Safety Health and Environmental Management Association (CSHEMA), and individual comments submitted by non-profit research institutes, teaching hospitals, private research and development companies, governmental research laboratories, and colleges and universities with teaching hospitals and/or non-profit research institutes all asserted that their research laboratories fit the hazardous waste generation pattern rationale of today's rule. That is, these commenters assert that given the nature of research, research laboratories share the same hazardous waste generation patterns, regardless of what type of institution they are found in. In addition, EPA has conducted site visits in various research laboratories at teaching hospitals and private R&D companies, among others, and has seen similar hazardous waste generation patterns and activities of these laboratories.

Based on the comments EPA received and additional research by EPA regarding the presence of students in laboratories at institutions other than colleges and universities, we have expanded the scope of the final rule to include specific additional entities that fit all aspects of the rationale for this rule. This rationale includes not only a

hazardous waste generation pattern that is similar to that found at college and university laboratories, but also a significant student population. EPA did not expand the scope of the final rule to include certain entities because they did not fit all aspects of the rationale for this rule. Therefore, today's final rule allows colleges and universities, teaching hospitals that are owned by or have a formal written affiliation agreement with a college or university, and non-profit research institutes that are owned by or have a formal written affiliation agreement with a college or university, to opt into Subpart K. This expansion includes laboratories at facilities that we and many commenters believe are closely integrated with laboratories at colleges and universities. Collectively, we are calling the entities that are eligible to opt into today's final rule, "eligible academic entities." Details on these entities are contained in the following sections. (For information regarding changes to the definition of laboratory, see section III.B.2 and § 262.200.)

#### **1. Hazardous Waste Generation Data**

In the preamble to the proposed rule, we stated that 9% of the hazardous waste generated at college and university LQGs was from laboratories. We received several comments from colleges and universities asserting that we erred in our estimates and that at their campuses, laboratory hazardous waste constituted a much higher percentage of their total hazardous waste. The Agency sent follow-up letters to several commenters requesting additional information in support of their comments. In response to our inquiries, many of the commenters supplied detailed information about their hazardous waste generation and one commenter provided a detailed analysis of our methodology for determining the percentage of laboratory hazardous waste, including specific suggestions on how to improve the methodology for the final rule. The follow-up letters and the responses are all included in the docket for today's rule.

As a result of these comments, EPA has significantly revised the methodology used in the proposal to determine the total quantity of hazardous waste and laboratory hazardous waste. Specifically, in the proposal, we used key-word searches of the description field on Biennial Report (BR) forms to identify laboratory hazardous waste as a percent of the total hazardous waste generated. Our revised methodology uses three source codes

from the BR to identify which hazardous wastes are from laboratories: (1) G11—Discarding off-specification or out-of-date chemicals or products (unused chemicals or products—corresponds to P and U hazardous waste codes);

(2) G22—Laboratory analytical wastes (used chemicals from laboratory operations), and

(3) G09—Other production or service-related processes from which the waste is a direct outflow or result. (Because hazardous waste from the source code G09 could also be generated in non-laboratory operations, these wastes were only considered laboratory wastes if the waste form codes indicated it was shipped in a lab pack (i.e., waste form codes W001 or W004)).

Additional laboratory wastes were identified using key-word searches of the description field. This revised method resulted in a much higher estimate for laboratory hazardous waste

as a percent of total hazardous waste at colleges and universities—73% under the revised methodology, compared to 9% under the original methodology used in the proposed rule. This revised methodology was used to calculate the amount of laboratory hazardous waste generated as a percent of the total hazardous waste generated for colleges and universities, as well as for other types of facilities with laboratories that we considered including in today's final rule: teaching hospitals, non-profit research institutes, governmental research laboratories, and commercial R&D laboratories. For a full explanation of the methodology used to determine the amounts of total hazardous waste and laboratory hazardous waste generated at colleges and universities, teaching hospitals, and non-profit research institutes, see the memo entitled, Lab Rule Data Analyses, from ICF International to Patricia Mercer, May 1, 2008; and for hazardous waste

information for LQG government research laboratories and LQG commercial R&D laboratories see the memo entitled, Final Analyses of College and University Laboratory Hazardous Waste, from ICF International to Patricia Mercer, August 17, 2007. Copies of both memos are in today's docket.

Below is a table of the hazardous waste data for eligible academic entities (i.e., those entities eligible to opt into Subpart K) that are LQGs. Using the revised methodology, we now estimate that for college and university LQGs, 73% of their total hazardous waste is from laboratories. The percent of hazardous waste coming from laboratories at teaching hospitals and non-profit research institutes is even higher—81% and 92%, respectively. Further, with all three types of eligible academic entities, nearly all LQGs generate laboratory hazardous waste.

	Colleges and universities	Teaching hospitals <sup>1</sup>	Non-profit research institutes <sup>2</sup>
# LQGs generating laboratory hazardous waste .....	286	104	8
# LQGs generating hazardous waste .....	293	109	8
% that generate laboratory hazardous waste .....	98	95	100
Tons of laboratory hazardous waste .....	6,530	1,712	119
Tons of all hazardous waste <sup>3</sup> .....	8,951	2,119	130
% of hazardous waste that is laboratory hazardous waste .....	73	81	92

<sup>1</sup> To be eligible to opt into Subpart K, a teaching hospital must be owned by or have a formal written affiliation agreement with a college or university

<sup>2</sup> To be eligible to opt into Subpart K, a non-profit research institute must be owned by or have a formal written affiliation agreement with a college or university

<sup>3</sup> Excludes remediation wastes because remediation wastes are not regularly generated hazardous wastes, but rather are hazardous wastes generated only when a clean-up or remediation project takes place.

As discussed above, based on EPA's observations, as well as comments that we have received and given the nature of teaching and research, activities conducted at teaching and research laboratories in colleges, universities, teaching hospitals, and non-profit research institutes are comparable and therefore share similar hazardous waste generation patterns. EPA identified challenges associated with the specific hazardous waste generation patterns, such as difficulty making hazardous waste determinations with a large variety of wastestreams. These difficulties, along with the difficulties associated with the presence of a significant student population, form the basis of this rule. Even at proposal, when we estimated that 9% of a college or university's hazardous waste was generated in the laboratory, we believed that these challenges were sufficient to warrant the development of Subpart K. With the revised estimates indicating that the percentage of hazardous waste

generated in laboratories by eligible academic entities being much higher, these specific challenges are shown to be even more pervasive and support the need for the flexibility offered by Subpart K for these particular entities.

Given that these types of organizations with research and teaching laboratories share similar hazardous waste generation patterns, we focused on the extent to which these entities had a significant student presence, which is a very important basis of today's rule. Because students are inherently transient, and generally have less accountability than professionals employed in laboratories, it is unlikely that they will make a proper hazardous waste determination which requires detailed knowledge of RCRA. The following discussion of which entities are and are not eligible to opt into today's rule focuses on whether there is a significant student presence. However, there are limited data readily available about the number of students

in laboratories even at colleges and universities much less for entities, such as teaching hospitals and non-profit research institutes. Thus, we used certain factors as indications that the organization did indeed have students in the laboratories. Examples of factors indicating student presence include programs for high school, undergraduate, or graduate students to conduct laboratory research, presence of medical residents/interns, co-sponsored degree programs with colleges or universities, or classes offered independent of the college or university.

## 2. Laboratories Owned by Teaching Hospitals

In the proposal, EPA specifically requested comment on whether laboratories in hospitals affiliated with colleges or universities should be included in the final rule. Previously, information about hospital laboratories led EPA to believe that their wastestreams are fairly routine and they

did not have the same challenges faced by college or university laboratories in training their workers. Through comments, EPA learned that many teaching hospitals owned by or formally affiliated with a college or university have research and teaching laboratories in addition to diagnostic laboratories dedicated to patient care. As stated earlier, research laboratories at teaching hospitals have similar hazardous waste generation patterns as research laboratories on a college or university campus. In addition, such teaching hospitals have students working in the laboratories to learn how to run various tests, how to operate equipment, or to conduct research with professors.

In fact, one commenter asserted that, “these types of laboratories [laboratories at college or university affiliated hospitals and other similar locations such as dental colleges, clinics and associated laboratories] are very similar to instructional and research laboratories. They are used by a large number of students; they are used for instructional and research purposes; while some processes are static and predictable, others are not; large numbers of different wastestreams are produced, but in relatively small quantities.” Another commenter wrote, “Research labs in a hospital are essentially the same as a research lab in a college or university and have similar waste generation patterns.”

Based on these comments, EPA conducted additional research into the types of laboratories that are present at teaching hospitals that are owned by or formally affiliated with a college or university. In particular, EPA identified three types of laboratories: (1) Clinical diagnostic laboratories that conduct typical laboratory tests related to patient care, (2) applied research laboratories that conduct clinical trials and (3) research laboratories that conduct basic medical research. While strictly speaking, clinical diagnostic laboratories may not exhibit the hazardous waste generation pattern identified in the rationale for this rule, we found that the setup in teaching hospitals makes it difficult to draw hard distinctions between the various types of laboratories. That is, each teaching hospital divides its laboratory space differently and oftentimes a single laboratory serves multiple functions, such as both diagnostic testing and research. Furthermore, in some cases, laboratory personnel perform multiple functions within a laboratory and are involved with both diagnostic and research activities. Thus, EPA has determined that it would be extremely difficult to implement a rule that made

a distinction between the various types of laboratories at such teaching hospitals.

The Agency also analyzed data from the BR which are sent to the Agency every other year by LQGs and housed in EPA's RCRAInfo database, to find out more about the universe of non-teaching and teaching hospitals owned by or formally affiliated with a college or university and their hazardous waste generation patterns. Notably, one of the main differences between the hazardous waste generation patterns at LQG teaching hospitals owned by or formally affiliated with a college or university and non-teaching hospitals is in the amount of laboratory hazardous waste as a percentage of the total amount of hazardous waste generated. Specifically, teaching hospitals showed approximately 80% of the total quantity of hazardous waste generated coming from laboratories, while non-teaching hospitals only had 13% of the total quantity of hazardous waste generated coming from laboratories. EPA attributes this disparity to be the result of the greater amount of research generally occurring in teaching hospitals owned by or formally affiliated with a college or university.

In terms of the transient students, EPA has learned from its research that teaching hospitals instruct a variety of students—interns, residents, nursing students, laboratory technicians, and more, in the hospital. Instruction of these students includes work in the laboratories to learn about the processes and tests conducted there, introducing similar difficulties as those encountered at colleges and universities in teaching and training transient students and making the hazardous waste determination. In fact, one commenter asserted that, “the amount of time a student spends at a teaching hospital is comparable to that of a graduate student in another laboratory discipline.” Also, medical research at a college and university oftentimes is shared between the college and university laboratories and teaching hospital laboratories. One commenter pointed out that professors, graduate students, and undergraduate students often go back and forth between laboratories at colleges and universities, and at teaching hospitals, to conduct research.

EPA recognizes that a teaching hospital that is owned by a college or university will instruct students from its medical school. However, due to the complex healthcare system, many times medical students or residents from a medical school will train in a teaching hospital that is affiliated with a college or university, but not owned by the

college or university. We do not want to preclude these teaching hospitals that are training students and have a significant transient student population from participating in Subpart K. Therefore, EPA looked for a way to define the concept of “affiliated teaching hospital.” We discovered that the Accreditation Council for Graduate Medical Education (ACGME) defines two types of agreements between a medical school and a teaching hospital: A master affiliation agreement and a program letter of agreement.<sup>2</sup> EPA has determined that the presence of both these agreements indicates that a teaching hospital is formally affiliated with a college or university.

Based on the evidence provided by commenters and additional EPA research, we have concluded that teaching hospitals owned by or formally affiliated with a college or university fit within all aspects of the rationale of today's final rule: many hazardous wastes that vary over time are generated in small quantities at many points of generation, and there is a significant and transient student population that is not familiar with the RCRA hazardous waste requirements. Therefore, EPA is allowing teaching hospitals, as defined in this final rule that are either owned by or have a formal written affiliation agreement with a college or university, to opt into Subpart K for their laboratories. (See section III.B.3 for a discussion of the definition of teaching hospital and formal written affiliation agreement or § 262.200.)

### 3. Laboratories Owned by Non-profit Research Institutes

EPA received many comments from representatives of non-profit research institutes, colleges and universities, and trade groups stressing the similarities between college and university laboratories and the laboratories at non-profit research institutes in terms of the hazardous waste generation pattern rationale identified in the rule and the student presence in the laboratories. As indicated above, a research laboratory at a non-profit research institute that is owned by or has a formal written affiliation agreement with a college or university shares the same hazardous waste generation pattern.

<sup>2</sup> The ACGME defines these terms in the “Glossary of Terms” that appears on its Web site at [http://acgme.org/acWebsite/about/ab\\_ACGMEglossary.pdf](http://acgme.org/acWebsite/about/ab_ACGMEglossary.pdf). The ACGME also describes these documents in more detail in a document called Frequently Asked Questions Related to Master Affiliation Agreements and Program Letters of Agreement that appears on its Web site at [http://acgme.org/acWebsite/about/ab\\_FAQAgreement.pdf](http://acgme.org/acWebsite/about/ab_FAQAgreement.pdf).



In terms of the presence of a significant transient student population, one commenter explained that as a non-profit research institute, it has close ties with the local university; they collaborate with the university on projects and faculty hold joint appointments. The commenter added that students and researchers often travel between the non-profit's laboratories and the local university's laboratories and that because the hazardous waste management requirements at both institutions are the same under the existing generator regulations, currently there are minimal differences in hazardous waste management for the students and researchers to learn when working at both institutions. Thus, the commenter requested that EPA add non-profit research institutes to the final rule in order to minimize confusion and training challenges under Subpart K.

In response to these comments, EPA conducted additional research and identified from the BR information housed in the RCRAInfo database, nine non-profit research institutes that are LQGs (see section III.A.1 for information on their hazardous waste generation). For all nine LGG non-profit research institutes, we were able to obtain readily available information on student populations and programs, as well as substantial evidence that non-profit research institutes are similar to colleges and universities in that they sometimes grant degrees of their own, co-sponsor degrees with colleges and universities, teach classes, and share faculty, funding sources, and laboratory space with colleges and universities. We determined that the information obtained is generally representative of the universe of laboratories at non-profit research institutes, because among the non-profits we researched, we found that their hazardous waste generation patterns and student programs were remarkably homogenous.

One commenter wrote, “\* \* \* the distinction between a research laboratory in a college and university and a research laboratory in an institution that is not a college and university has blurred considerably over the last decade.” As EPA conducted additional study into non-profit research institutes, it was difficult for the Agency to draw a hard line between college and universities and non-profit research institutes. For example, Memorial Sloan-Kettering Cancer Center (MSKCC) is a non-profit cancer research institute, a teaching hospital, a graduate school in biomedical sciences, and is in partnership with the Weill Cornell Graduate School of Medical Sciences

and Cornell University to train students in research and patient care. MSKCC also partners with New York-Presbyterian Hospital, the Hospital for Special Surgery, and the Rockefeller University. Via these partnerships, the majority of the faculty of the Weill Cornell Medical Graduate School of Medical Sciences has their research laboratories and other facilities located within the Weill Cornell Medical College-New York-Presbyterian Hospital Complex and the MSKCC's research laboratory buildings. Another outgrowth of this partnership is that MSKCC jointly administers a Ph.D. program with Cornell and Weill Medical College in computational biology and medicine. Finally, besides its own graduate school of biomedical sciences, MSKCC offers two certificate programs for students to learn cytotechnology and radiation therapy.

As shown in the example above, a non-profit research institute owned or formally affiliated with a college or university may be so closely associated with the college and university that excluding them will prevent colleges and universities from establishing one laboratory waste management system, introducing confusion among researchers working in laboratories at both institutions. In this situation, such non-profit research institutes are virtually identical to a college and university and their hazardous waste generation patterns and student presence fit within the rationale of this rule. This information made it clear to us that non-profit research institutes often are “academic” and should be eligible to opt into today's final rule, when they are owned by or formally affiliated with a college or university.

One commenter recommended that EPA expand the scope of the rule to any institution that has a formal affiliation with a college or university. While the Agency does not believe it should expand the scope of the rule to all institutions that have any kind of an affiliation with a college or university, we do believe it is appropriate to allow those non-profit research institutes that have a formal written affiliation agreement with a college or university to opt into Subpart K. In order to ensure that the formal written affiliation agreement between the two entities represents an affiliation that is longstanding, we believe that the affiliation must be at the institutional level, as opposed to an agreement between staff or professors at the two eligible academic entities. Of the nine non-profit research institutes that are identified as LQGs in the BR, we determined that eight had formal

affiliations with colleges and universities on an institutional level. For example, the Burnham Institute not only administers its own graduate program, it also has an institutional affiliation with the University of California at San Diego by participating in a joint graduate training program in molecular pathology (where approximately 30 graduate students a year obtain their primary scientific training at the Institute).

The reason we are requiring a formal written affiliation agreement at the institutional level is because having a formal affiliation at the institutional level with a college or university seemed to increase the likelihood that the non-profit research institutes would have students in their laboratories. The presence of a significant transient student presence is an important rationale of today's rule. Typically, a formal affiliation at the institutional level allows students at a college or university to conduct thesis research at the non-profit research institute, use non-profit researchers as mentors, and at times, take some of their degree classes at the non-profit research institute. Further, requiring a formal written affiliation agreement between the non-profit research institute and a college or university will assist the implementing agency verify that an affiliation at the institutional level exists. Thus, for these reasons, we decided to limit today's rule to those non-profit research institutes that have a formal written affiliation at the institutional level with a college or university. For a discussion of the definition of “formal written affiliation agreement,” see section III.B.3 of this preamble or § 262.200.

#### 4. Laboratories Owned by Eligible Academic Entities That Are Conditionally Exempt Small Quantity Generators (CESQGs)

EPA recognizes that laboratories at eligible academic entities that are CESQGs share the same hazardous waste generation patterns as laboratories at larger generators, except the eligible academic entities that are CESQGs generate smaller quantities of hazardous waste. However, while laboratories at CESQGs fit within the rationale used to define the scope of this rule, the proposal did not allow them to opt in. At the time of the proposal, we had thought CESQGs would not want to opt into Subpart K since they currently are not subject to the controls that apply to satellite accumulation areas (SAAs) and do not have to comply with most of the other requirements that apply to LQGs and SQGs. In fact, many of the

provisions in today's final rule would be more stringent than those to which they are currently subject under § 261.5. At proposal, we solicited comment on whether the final rule should include laboratories at CESQGs.

Numerous commenters indicated that we should provide CESQGs with the same opportunity as SQGs and LQGs to assess which set of generator regulations is most appropriate for their laboratories and that we should not prohibit them from opting into Subpart K.

Additionally, many comments from colleges and universities indicated that laboratory management would improve if their CESQG sites with laboratories could operate under this rule and follow the required LMP. Further, commenters explained that since colleges and universities often have CESQG sites, as part of a larger campus, a college or university may want to be able to manage all of its laboratories under one management system and that EPA should allow CESQGs to participate in Subpart K. This issue is particularly pertinent for urban college and university campuses that are divided by public roads. One campus can potentially include many separate generator sites, some LQGs, some SQGs, and some CESQGs. In light of the comments received, EPA agrees that it makes sense that at least some CESQGs would want to opt into Subpart K. Thus, EPA is allowing eligible academic entities to opt into Subpart K for their CESQG sites and is allowing stand-alone CESQGs to opt into Subpart K, as well. CESQG sites at an eligible academic entity may include field laboratories and small laboratories separated from the main campus by public roadways. In addition, we expect that some eligible academic entities that are themselves CESQGs (i.e., stand-alone CESQGs), such as small non-profit research institutes, may choose to opt into the rule to take advantage of the clean-out provisions.

Other commenters argued that the rule would encourage better environmental performance by extending the laboratory clean-out provisions to eligible academic entities that are themselves CESQGs or have CESQG sites without requiring them to comply with the rest of the Subpart K requirements. EPA agrees that stand-alone CESQGs and CESQG sites that are part of a larger eligible academic entity will benefit by removing legacy chemicals from the laboratory by taking advantage of the clean-out incentives of today's rule. However, EPA is not allowing a stand-alone eligible academic entity or a CESQG site that is part of a larger eligible academic entity to partake

only in the laboratory clean-out provisions and not the other Subpart K requirements because this would prevent CESQGs from taking advantage of the two main benefits of today's final rule. That is, if a CESQG site only participated in the laboratory clean-out provisions, it would not be able to take advantage of the flexibility in where and when to make the hazardous waste determination. Second, if a CESQG site that is part of a larger eligible academic entity only participated in the laboratory clean-out provisions, it would be unable to establish one hazardous waste management system in all the laboratories at the eligible academic entity. The ability to establish a unified hazardous waste management system for all laboratories is one of the priorities cited by academic commenters. Therefore, in order for a CESQG site at an eligible academic entity or an eligible academic entity that is itself a CESQG to take part in the laboratory clean-out incentives, the eligible academic entity must opt into Subpart K in its entirety and follow the management standards for unwanted materials in the laboratories.

#### 5. Facilities With Laboratories Not Eligible To Participate in Subpart K

As explained above, EPA solicited comment on whether to expand the scope of the rule beyond laboratories at colleges and universities to laboratories at other types of facilities. Many commenters supported expansion of the scope of the rule. We received comments from both government research laboratories and commercial R&D laboratories requesting to be included in this rulemaking. Overall, from the information available at this time, it appears that laboratories at both of these types of facilities have hazardous waste generation patterns similar to laboratories at colleges and universities—generating small quantities of many types of waste that vary over time at many points of generation—since they are research laboratories. However, information about the other key aspect of the rationale for today's rule, that is, significant student presence, has led EPA to determine that, at this time, laboratories at government research and commercial R&D facilities are not eligible to participate in Subpart K.

(a) Government Research Laboratories: We received comments from a number of governmental organizations that have research laboratories requesting that they be allowed to participate in (or opt into) Subpart K. These commenters, all from the Federal government, asserted that

they fit the hazardous waste generation pattern explained by EPA as part of the rationale for Subpart K. In addition to the public comments, EPA collected readily available information on hazardous waste generation patterns and student presence in government research laboratories. From EPA's BR on hazardous waste generated by LQGs, we identified 39 LQG government research laboratories. In addition, in its comments on the proposal, one Federal agency provided student numbers for ten of its laboratories, three of which we have identified as LQGs. We also acquired aggregated student numbers or estimates for three other Federal agencies. We were unable to obtain student population data at laboratories at the remaining government research laboratories, including State and local governmental laboratories. Based on this lack of available information, EPA has decided to defer our decision on government research laboratories and therefore, government research laboratories are not included in this final rulemaking. Rather, in 2009, EPA expects to prepare a **Federal Register** Notice soliciting additional information about government research laboratories, particularly the presence of students at such research laboratories in order to make a more informed decision regarding whether or not to allow them to opt into Subpart K in the future.

(b) Commercial R&D Laboratories: EPA requested comment on whether private laboratories fit within the rationale of Subpart K and received comments from pharmaceutical companies, engineering companies, and a utility solid waste activity group, all requesting to be included in Subpart K because their laboratories fit within the rationale of the hazardous waste generation pattern. Based on these comments and responses to follow-up letters to commercial research and development laboratories (copies of which are in today's docket), it appears that there is a similar hazardous waste generation pattern (i.e., small amounts of many different types of waste generated at multiple points of generation) as at laboratories at colleges and universities. However, there is little evidence of student presence in these laboratories as indicated in the follow-up responses from commenters and EPA's own research. Without the presence of students, commercial R&D laboratories do not have the same challenges in making hazardous waste determinations for their laboratory hazardous wastes and in training their laboratory personnel. Having similar hazardous waste generation patterns is

only one element in determining which entities should be eligible to opt into Subpart K. EPA believes that having a significant student presence in the laboratories (which increases the difficulty in training and in making hazardous waste determinations) is extremely important. Therefore, without meeting the rationale that a significant number of students must be present, EPA has decided not to allow commercial R&D laboratories to opt into Subpart K.

#### 6. Non-Laboratory Facilities at Eligible Academic Entities

The Agency received many comments requesting that the rule address all types of facilities at a college or university where hazardous waste is generated, rather than limiting the rule to teaching and research laboratories. Commenters requested that non-laboratory areas, such as vehicle maintenance shops, machine shops, maintenance shops, fabrication units, athletic departments, power plants/energy generation units, print shops, and facilities operations be included in the scope of the final rule. Some commenters suggested that we include these areas by modifying the definition of laboratory to include them. Other commenters stated that creating a dual regulatory system for hazardous waste management on college or university campuses would hinder their participation in Subpart K and ultimately be confusing.

While the Agency understands the concerns raised by the commenters, we also believe that the Subpart K requirements were developed to address specific concerns raised by the academic community as they relate to hazardous wastes generated in their laboratories—that is, the situations and challenges that exist in teaching and research laboratories are unique (e.g., having to identify which of the potentially hundreds of different wastestreams meet the definition of hazardous waste). The academic community has not raised such concerns about the hazardous wastes generated outside of the laboratories. For this reason, we believe it is inappropriate to expand the scope of the rule beyond laboratories at eligible academic entities.

#### B. Discussion of Definitions

All of the definitions that appear in today's final rule are only for the purposes of 40 CFR part 262, Subpart K. Therefore, the definitions are relevant only to the eligible academic entities that have laboratories and choose to be subject to the provisions of today's final rule. This section discusses: (1) Those

definitions that were proposed and have not changed since the proposal; (2) those definitions that were proposed, but have been modified based on comments received on the proposal; and (3) any new definitions that are being added, based on modifications to the final rule or comments on the proposed rule.

#### 1. Definitions That Have Not Changed From the Proposed Rule

The following definitions have not been changed from the proposal. In general, we received few comments on these definitions and the comments we received on these definitions were supportive. Refer to the preamble from the proposed rule for a detailed discussion of these definitions (71 FR 29722).

*College/University* means a private or public, post-secondary, degree-granting, academic institution, that is accredited by an accrediting agency listed annually by the U.S. Department of Education.

*Laboratory clean-out* means an evaluation of the inventory of chemicals and other materials in a laboratory that are no longer needed or that have expired and the subsequent removal of those chemicals or other unwanted materials from the laboratory. A clean-out may occur for several reasons. It may be on a routine basis (e.g., at the end of a semester or academic year) or as a result of a renovation, relocation, or change in laboratory supervisor/occupant. A regularly scheduled removal of unwanted material as required by § 262.208 does not qualify as a laboratory clean-out.

*Laboratory worker* means a person who handles chemicals and/or unwanted material in a laboratory and may include, but is not limited to, faculty, staff, post-doctoral fellows, interns, researchers, technicians, supervisors/managers, and principal investigators. A person does not need to be paid or otherwise compensated for his/her work in the laboratory to be considered a laboratory worker. Undergraduate and graduate students in a supervised classroom setting are not laboratory workers.

Commenters pointed out that the definition of "laboratory worker" in the preamble to the proposed rule differed slightly from the definition in the proposed regulatory text. In the definition included in the regulatory text, the last sentence of the definition included the words "Undergraduate and graduate" when referring to students. However, the definition included in the preamble discussion omitted the words "Undergraduate and graduate." Today,

we are finalizing the definition, as it was proposed, so that the final sentence reads, "Undergraduate and graduate students in a supervised classroom setting are not laboratory workers."

It is worth noting that EPA would consider undergraduate or graduate students in an unsupervised research setting to be laboratory workers. Additionally, any student performing duties of a trained professional, such as transferring unwanted materials and hazardous wastes outside of a laboratory, would be considered a trained professional, rather than a student.

#### 2. Definitions That Have Changed From the Proposed Rule

This section discusses comments on the definitions that were included in the proposed rule, as well as the changes that have been made to these definitions in today's final rule.

*Central accumulation area*—The Agency proposed to define "central accumulation area" as: an on-site hazardous waste accumulation area subject to either § 262.34(a) of this Part (large quantity generators) or § 262.34(d) of this Part (small quantity generators). A central accumulation area at a college or university that chooses to be subject to this subpart must also comply with § 262.211 when accumulating unwanted material.

The Agency has made three minor changes to the proposed definition of central accumulation area (CAA). First, we added a reference to the hazardous waste accumulation area regulations that are applicable to Performance Track members. There are currently three Performance Track members that would likely qualify as eligible academic entities (the MD Anderson Cancer Center, the University of Texas Medical Branch, and Washington State University), and we did not intend to imply that these eligible academic entities could not opt into Subpart K when we omitted a reference to the hazardous waste accumulation area regulations of § 262.34 that pertain to them.

The second change is to make more complete the reference to the hazardous waste accumulation area regulations for SQGs. The proposed definition referred only to § 262.34(d), which among other things, allows 180 days or less for the on-site accumulation of hazardous waste. However, SQGs also have the option of complying with § 262.34(e), which allows them to accumulate hazardous waste on-site for 270 days or less, if they must send their hazardous waste more than 200 miles for treatment, storage or disposal. In

addition, SQGs are subject to § 262.34(f), which states that if more than a total of 6000 kg of hazardous waste is accumulated on-site, the generator is a storage facility that is subject to the requirements for TSDFs. The third change was made to reflect the expansion of the applicability of the final rule beyond colleges and universities to eligible academic entities.

The definition of “central accumulation area” in the final rule is:

an on-site hazardous waste accumulation area subject to either § 262.34(a) (or 262.34(j) and (k) for Performance Track members) of this part (large quantity generators); or § 262.34(d)–(f) of this part (small quantity generators). A central accumulation area at an eligible academic entity that chooses to be subject to this subpart must also comply with § 262.211 when accumulating unwanted material and/or hazardous waste.

**Laboratory**—The Agency proposed to define “laboratory” as:

an area within a college or university where relatively small quantities of chemicals and other substances are used on a non-production basis for teaching or research purposes and are stored and used in containers that are easily manipulated by one person. An area where the same hazardous wastes are routinely generated, such as photo processing, is not a laboratory.

In response to comments and as a result of the expansion of scope of the final rule, the Agency has made several changes to the definition of laboratory. Specifically, the Agency has made two changes to reflect the expansion of scope, as discussed in section III.A of today's preamble. The first is to change the phrase “colleges and universities” to the phrase “eligible academic entities.” The second change is to indicate that clinical diagnostic laboratories at teaching hospitals are included within the scope of the final rule, as well as teaching and research laboratories at all eligible academic entities. This change is being made due to the expansion of the scope to include teaching hospitals.

As discussed in section III.A.2 of today's preamble, the Agency believes, and commenters have supported the conclusion, that it is the research laboratories at a teaching hospital that are most similar to laboratories at colleges and universities in their hazardous waste generation patterns. However, we realize that it would be confusing and difficult for institutions to implement today's rule if the research laboratories at a teaching hospital were allowed to operate under Subpart K, but diagnostic laboratories at the same teaching hospital were not allowed to operate under Subpart K. In fact, some commenters have indicated that in

many cases at teaching hospitals, it is not possible to distinguish a research laboratory from a clinical laboratory because they share physical space and staff. Therefore, the Agency has amended the definition of laboratory to include clinical diagnostic laboratories at teaching hospitals so that unwanted materials from all of the laboratories at a teaching hospital can be managed under the same management standards.

In addition, in response to numerous comments, the Agency has deleted the last sentence from the proposed definition of laboratory: “An area where the same hazardous wastes are routinely generated, such as photo processing, is not a laboratory.” The reason the Agency originally included this statement in the proposed definition is that part of our basis for proposing this rule is that laboratories at colleges and universities, unlike other types of hazardous waste generators, generate many different types of wastes that vary over time. However, based on the comments received, we believe it is no longer appropriate to include this sentence for the following reasons. First, comments indicated that some photo laboratories do, in fact, generate many wastestreams that vary over time—this is especially true when the photo laboratories are art studios where students may be experimenting with different photographic techniques, such as daguerreotype and calotype finishing.

Second, commenters pointed out that it is not unusual for an individual research laboratory to generate the same hazardous waste routinely for lengthy periods of time, as it focuses on a single area of research. Additionally, commenters pointed out that teaching laboratories can have an experiment that is part of the ongoing curriculum and that generates the same hazardous wastes each semester. We did not intend to create a system whereby some laboratories at the eligible academic entity would be eligible and some would not, based on the hazardous waste generation pattern of each individual laboratory. To the contrary, for ease of implementation and enforcement, if the eligible academic entity chooses to be subject to Subpart K, the Agency is requiring that all laboratories covered under an individual EPA Identification Number must operate under those provisions. Therefore, we believe that it is sufficient that an eligible academic entity's laboratories, as a category, rather than each laboratory, generate many different wastes every day.

Third, based on comments and follow-up discussion, we now understand that in many cases photo

processing takes place alongside teaching and research and that it would be difficult to regulate differently the various laboratory operations, as the same students and laboratory workers operate in both areas. Therefore, we have revised the definition of laboratory to include photo laboratories.

The Agency also received many comments suggesting that the definition of laboratory should include chemical stockrooms, preparatory laboratories and other areas ancillary to the laboratory. EPA agrees with these commenters that the definition of laboratory should include chemical stockrooms and preparatory laboratories and other areas that provide a support function to teaching or research laboratories (or diagnostic laboratories at teaching hospitals). The reason for this change is that the operation of these areas is well integrated with the operation of the laboratories; that is, they are often in close proximity to the laboratories, and share laboratory personnel, and thus should properly be viewed as part of the laboratory. Chemical stockrooms that are not associated with laboratory operations would not, however, be eligible to operate under Subpart K. For example, a chemical stockroom that stores cleaning chemicals or pesticides for maintenance at the facility would not be providing a support function to a laboratory and would not be considered a laboratory that is allowed to operate under Subpart K.

The Agency also agrees with commenters that field laboratories should be considered laboratories because we agree that field laboratories, like other laboratories under this rule, exhibit similar hazardous waste generation patterns. By considering field laboratories as laboratories, laboratory workers would thus only need to operate under one set of hazardous waste regulations. However, if the field laboratory is off-site and/or has a separate EPA Identification Number from the rest of the campus, the eligible academic entity must notify separately that the field laboratory will be subject to Subpart K. In the proposal, we stated that we expected many field laboratories to be CESQGs, which under the proposal were not eligible to opt into Subpart K. Commenters confirmed that many field laboratories are, indeed, CESQGs. Therefore, with the modifications that the Agency is making in today's rule regarding the eligibility of CESQGs and the definition of “laboratory,” field laboratories, whether they are located on-site or off-site from the rest of the eligible academic entity, would be allowed to operate under the

Subpart K requirements. See Section III.C.9 regarding the implementation of Subpart K at CESQG sites.

Furthermore, a number of commenters agreed with the Agency's position that art studios at eligible academic entities should be considered laboratories, despite the fact that they are rarely referred to as laboratories. These commenters confirmed that art studios have similar hazardous waste generation patterns as scientific laboratories, and, like other classroom settings, have students generating much of the hazardous waste. Therefore, the definition has been changed to clarify that the Agency considers art studios to be laboratories for the purposes of Subpart K.

Finally, we proposed that a "laboratory" is "an area within a college or university \* \* \*" We received comments suggesting that we modify the definition of laboratory to be "an area under the administrative or managerial control of a college or university \* \* \*" However, this terminology is not currently used or defined under RCRA. The Agency agrees that the definition should be more specific and we have incorporated into today's definition of "laboratory" a similar concept as suggested by the commenters. However, we have relied on terminology that is already used and defined in RCRA. Specifically, under today's final rule, a laboratory is "an area that is owned by an eligible academic entity \* \* \*" Therefore, in today's preamble and final rule, when we use the term laboratory, we are referring to laboratories that are owned by an eligible academic entity.

To be eligible to opt into today's final rule, an institution first must meet the definition of "eligible academic entity." That is, it must be a college or university, or a non-profit research institute or teaching hospital that is owned by or has a formal written affiliation agreement with a college or university, as these terms are defined in today's rule. Second, an eligible academic entity may opt into Subpart K for the laboratories that it owns. Therefore, government facilities with laboratories that are operated by colleges and universities (such as many of the Department of Energy's laboratories) would not be eligible to opt into Subpart K, because the government facility is not an eligible academic entity and the laboratories are not owned by an eligible academic entity.

For the reasons discussed above, today's final rule defines "laboratory" as follows:

an area owned by an eligible academic entity where relatively small quantities of chemicals and other substances are used on a non-production basis for teaching or research (or diagnostic purposes at a teaching hospital) and are stored and used in containers that are easily manipulated by one person. Photo laboratories, art studios, and field laboratories are considered laboratories. Areas such as chemical stockrooms and preparatory laboratories that provide a support function to teaching or research laboratories (or diagnostic laboratories at teaching hospitals) are also considered laboratories.

*Reactive acutely hazardous unwanted material*—The Agency proposed to define "reactive acutely hazardous unwanted material" as:

an unwanted material that is one of the acutely hazardous commercial chemical products listed in § 261.33(e) for reactivity and toxicity.

At proposal, the Agency intended to maintain more stringent regulations in the laboratory for the "P-listed" commercial chemical products that are listed for reactivity because of their high potential for causing immediate harm. In the preamble to the proposed rule, we provided a list of seven commercial chemical products that we believed met this definition:

- (1) P006 (CAS Number: 20859-73-8) Aluminum phosphide;
- (2) P009 (CAS Number: 131-74-8) Ammonium picrate; Pheno, 2,4,6-trinitro-, ammonium salt;
- (3) P042 (CAS Number: 51-43-4) 1,2-Benzenediol, 4-[1-hydroxy-2-(methylamino)ethyl];
- (4) P065 (CAS Number: 628-86-4) Fulminic Acid, mercury(2+) salt; Mercury fulminate;
- (5) P081 (CAS Number: 55-63-0) Nitroglycerine; 1,2,3-Propanetriol, trinitrate;
- (6) P112 (CAS Number: 509-14-8) Methane, tetranitro-; Tetranitromethane; and
- (7) P122 (CAS Number: 1314-84-7) Zinc phosphide  $Zn_3P_2$  when present at concentrations greater than 10%.

Many commenters correctly pointed out that P042 (CAS Number 51-43-4) 1,2-Benzenediol, 4-[1-hydroxy-2-(methylamino)ethyl]-, which is actually Benzenediol, 4-[1-hydroxy-2-(methylamino)ethyl]-, (R)-, (and is also known as epinephrine) is not listed on the "P-list" because of reactivity. They pointed out that the (R)- following the listing for P042 refers to the R enantiomer of the chemical and does not refer to the reactivity characteristic. The Agency acknowledges that the commenters are, indeed, correct, and if epinephrine were an unwanted material in a laboratory, it would not meet the

definition of reactive acutely hazardous unwanted material. EPA's acknowledgment is simply a matter of clarification and does not affect the definition as proposed.<sup>3</sup>

Many commenters also correctly pointed out that three of the chemicals on the list above are listed only for reactivity (P009, P081, P112), and not for toxicity and, therefore, do not meet the definition of reactive acutely hazardous unwanted material, as proposed. While the commenters are correct that P009, P081, and P112 are listed only for reactivity, we believe that the proposal was clear as to the Agency's intent—that a "reactive acutely hazardous unwanted material" includes those chemicals included on the P-list for reactivity, and that *some* of those chemicals were listed for toxicity, as well. The wording of the proposed definition, however, did not convey that clearly. Therefore, we are revising the definition of "reactive acutely hazardous unwanted material" to be consistent with the intent discussed in the preamble, by omitting the reference to toxicity, as follows:

an unwanted material that is one of the acutely hazardous commercial chemical products listed in § 261.33(e) for reactivity.

*Trained professional*—The Agency proposed to define a "RCRA-trained individual" as:

a person who has completed the applicable RCRA training requirements of § 265.16 for large quantity generators, or § 262.34(d)(5)(iii) for small quantity generators. A RCRA-trained individual may be an employee of the college/university or may be a contractor or vendor.

The Agency is replacing the term "RCRA-trained individual" with "trained professional." This does not affect the substance of the definition, but is merely a change in terminology since Subpart K is part of the RCRA hazardous waste regulations and including "RCRA" as part of the term is unnecessary and may, in fact, imply that anyone who is trained under Subpart K is not "RCRA" trained.

In addition, because the final rule has been expanded to include eligible academic entities that include CESQG sites or that are themselves CESQGs, we have added to the definition of "trained professional" a requirement that a trained professional at an eligible academic entity that is a CESQG must be trained in accordance with the SQG training requirements of

<sup>3</sup> The Agency has recently issued a memo clarifying that the scope of the P042 listing does not include epinephrine salts (see memo from Hale to EPA Regions, October 15, 2007, RCRA Online # 14778).

§ 262.34(d)(5)(iii). As discussed in more detail in Section III.C.4 of today's preamble, the hazardous waste determination and on-site transfers of unwanted materials outside the laboratory must be performed by trained professionals (also see § 262.207). The proposed definition of "RCRA-trained individual" (which is re-named "trained professional" in today's final rule) relied on references to the existing generator training requirements, which vary based on generator status. The existing CESQG regulations, however, do not include training requirements. It would be counter to the intent of today's rule to allow CESQGs opting into Subpart K to have untrained personnel making the hazardous waste determination and transferring unwanted materials outside the laboratory. Therefore, today's final rule requires that trained professionals at eligible academic entities that are CESQGs must be trained in accordance with the SQG training requirements.

Finally, because the applicability of the final rule has been broadened beyond colleges and universities, the Agency has modified the definition of "trained professional" accordingly, as follows:

a person who has completed the applicable RCRA training requirements of § 265.16 for large quantity generators, or is knowledgeable about normal operations and emergencies in accordance with § 262.34(d)(5)(iii) for small quantity generators and conditionally exempt small quantity generators. A trained professional may be an employee of the eligible academic entity or may be a contractor or vendor who meets the requisite training requirements.

**Unwanted material**—The Agency proposed to define "unwanted material" as:

means any chemical, mixtures of chemicals, products of experiments or other material from a laboratory that are no longer needed, wanted or usable in the laboratory and that are destined for hazardous waste determination by a RCRA-trained individual. Unwanted material includes reactive acutely hazardous unwanted materials. Unwanted material includes material that may eventually be determined not to be solid waste pursuant to § 261.2 or a hazardous waste, pursuant to § 261.3.

The Agency has made two changes to the definition of unwanted material. The first is to reflect the change from the term "RCRA-trained individual" to "trained professional." The second change is to reflect the additional flexibility that we have added to the final rule that allows an eligible academic entity the option of using another "equally effective term" in lieu of the term "unwanted material." In the

preamble and the regulations, the Agency continues to use the term, "unwanted material," but an eligible academic entity that opts into Subpart K may use another term if it chooses, provided the term is used consistently and is identified in its LMP. Regardless of the term that is used, however, it will have the same meaning as found in the definition for unwanted material, and it will be subject to the same requirements under Subpart K. This additional flexibility allowed for using another term in lieu of "unwanted material" is discussed in more detail in preamble section III.C.2 (also see § 262.206).

For the reasons discussed above, today's final rule defines "unwanted material" as:

any chemical, mixtures of chemicals, products of experiments or other material from a laboratory that is no longer needed, wanted or usable in the laboratory and that is destined for hazardous waste determination by a trained professional. Unwanted materials include reactive acutely hazardous unwanted materials and materials that may eventually be determined not to be solid waste pursuant to § 261.2, or a hazardous waste pursuant to § 261.3. If an eligible academic entity elects to use another equally effective term in lieu of "unwanted material," as allowed by § 262.206(a)(1)(i), the equally effective term has the same meaning and is subject to the same requirements as "unwanted material" under this subpart.

### 3. Definitions That Are New

The definitions discussed in this section of today's preamble are those definitions that have been developed and added since the proposal. All new definitions, except one, pertain to the expansion of the scope to other eligible academic entities.

**Eligible academic entity**—Today's final rule defines "eligible academic entity" as:

a college or university, or a non-profit research institute that is owned by or has a formal written affiliation agreement with a college or university, or a teaching hospital that is owned by or has a formal written affiliation agreement with a college or university.

Since we have expanded the scope of the final rule to allow non-profit research institutes and teaching hospitals that are either owned by or have a formal written affiliation agreement with a college or university to opt into Subpart K, we believe it is appropriate to add a new term to refer to these types of institutions collectively.

Incorporated in the definition above is the concept that teaching hospitals and non-profit research institutes must be either owned by or have a formal

written affiliation agreement with a college or university. As explained in section III.A. of today's preamble, we are requiring a formal written affiliation agreement with a college or university because the affiliation indicates that an entity is integrated with the college or university and that the entity has a significant transient student presence. Our research also demonstrated that in some instances, a teaching hospital or non-profit research institute is owned by a college or university. We assume that if a non-profit research institute is owned by a college or university it would not have a formal written affiliation agreement. Similarly for teaching hospitals, we assume that a formal written affiliation agreement, defined below for teaching hospitals as a master affiliation agreement and program letter of agreement, would not exist when the teaching hospital is owned by the college or university. Thus, this definition allows teaching hospitals and non-profit research institutes that are located on-campus or off-campus to opt into this rule, provided they are owned by or have a formal written affiliation agreement with a college or university.

**Formal written affiliation agreement**—Today's final rule defines "formal written affiliation agreement" as:

for a non-profit research institute means a written document that establishes a relationship between institutions for the purposes of research and/or education and is signed by authorized representatives, as defined by § 260.10, from each institution. A relationship on a project-by-project or grant-by-grant basis is not considered a formal written affiliation agreement. A formal written affiliation agreement for a teaching hospital means a master affiliation agreement and program letter of agreement, as defined by the Accreditation Council for Graduate Medical Education, with an accredited medical program or medical school.

For non-profit research institutes, "formal written affiliation agreement" is defined in a manner to reflect the importance of having an official legal written agreement documenting the affiliation, partnership, collaboration, or association between the non-profit research institute and a college or university. In order for a non-profit research institute to be eligible to opt into Subpart K, it must have this documentation.

The Agency is requiring that this agreement be signed by authorized representatives with the authority to obligate the institution as a whole. The term "authorized representative" is already defined in 40 CFR 260.10 as "the person responsible for the overall

operation of a facility or an operational unit (i.e., part of a facility), e.g., the plant manager, superintendent, or person of equivalent responsibility.” The Director or Chief Executive Officer (CEO) of a non-profit research institute and the President or Dean of a college or university, among others, would be considered authorized representatives.

The Agency also stresses that the formal written affiliation agreement must be between the institutions: The non-profit research institute and the college or university. This agreement is intended to represent a long-standing collaboration between the two institutions rather than simply a relationship between two principal investigators or researchers, working jointly for the duration of a particular project or grant. An example of what we would consider to be an affiliation at the institutional level includes being a member of a research consortium with colleges and universities. For instance, the Southwest Research Institute is a member of the Southwest Research Consortium which combines the research capabilities of nine research and educational organizations, including the University of Texas at San Antonio, Trinity University, and St. Mary's University. Another example of what we would consider an institutional-level affiliation agreement is when there are joint faculty appointments on a departmental or other large-scale basis. For instance, Seattle Biomedical Research and the University of Washington have a formal affiliation where all researchers at Seattle Biomedical Research are also faculty members at the University of Washington. A third example of what we would consider an institutional-level affiliation agreement is when a non-profit co-sponsors degrees with a college or university. For instance, Fred Hutchinson Cancer Research Center and the University of Washington jointly administer or co-sponsor a Ph.D. program in Molecular and Cellular Biology. Thus, EPA developed this definition to be broad to encompass the various working situations that we understand to be currently in existence.

For the definition of formal written affiliation agreement for teaching hospitals, EPA researched definitions and terms to describe the concept of “affiliated teaching hospitals,” such as “academic health centers,” “major teaching hospital,” and “university teaching hospital.” We quickly discovered that an industry-wide standard term for referring to teaching hospitals affiliated with colleges and universities does not exist. Without a standard definition, we looked into how

college or university medical schools are linked with hospitals. We learned that the ACGME has established a mechanism for medical schools to send residents to hospitals that are not part of the medical school. In such cases, ACGME requires a master affiliation agreement and a program letter of agreement between the medical school and the teaching hospital. Since the ACGME defines these two types of agreements and requires them in certain arrangements between teaching hospitals and colleges and universities, and since the industry already follows and understands these agreements, we have decided to refer to these agreements in the definition of “formal written affiliation agreement” for teaching hospitals in this rule.

*Non-profit research institute*—Today's final rule defines “non-profit research institute” as:

an organization that conducts research as its primary function and files as a non-profit organization under the tax code of 26 U.S.C. 501(c)(3).

EPA's definition, which refers to a well-known, existing definition under the tax code of 26 U.S.C. 501(c)(3), is intended to make the definition as clear as possible, as well as easy for implementers and inspectors to verify. We are emphasizing through this definition that not every non-profit organization is eligible to opt into the Subpart K requirements. Rather, the non-profit must conduct research as its primary function. We require this because, as explained in sections II.B and III.A of this preamble, research laboratories, as a category of laboratories, have a hazardous waste generation pattern that fits within the rationale of today's final rule. Further, as discussed above, the non-profit research institute must either be owned by a college or university or have a formal written affiliation agreement with a college or university in order to be eligible to opt into this rule.

*Teaching hospital*—Today's final rule defines “teaching hospital” as:

a hospital that trains students to become physicians, nurses or other health or laboratory personnel.

EPA believes it is important to capture the basic purpose of a teaching hospital in this definition: training students in medicine. A teaching hospital will train nursing students, medical residents, technicians, and others in the laboratories at the hospital's facilities ensuring that teaching hospitals fit within a key aspect of the rationale of today's rule: a significant transient student presence in the laboratories. In addition, the

teaching hospital must either be owned by a college or university or have a formal written affiliation agreement with a college or university in order to be eligible to opt into this rule.

*Working container*—The Agency did not include a definition of “working container” in the proposed rule. In the preamble to the proposed rule, however, we did discuss a possible definition for working container and solicited comment on whether the final rule should include such a provision. The definition of “working container” in the preamble to the proposed rule was:

A small container (of one gallon or less), managed under the control of a laboratory worker and used at a bench or work station, whose contents are emptied into a container of unwanted material at the end of the procedure.

There generally was broad support among commenters for including a definition of working container in the final rule. A number of commenters suggested, however, that the Agency increase the maximum size limit of a working container to five gallons. Since one gallon is equal to 3.78 liters, the one-gallon limit discussed in the preamble to the proposed rule would have precluded the use of four-liter solvent bottles as working containers. The Agency believes that a 5-gallon limit for working container is too large to be appropriate despite suggestions from commenters. Given that water weighs 8.34 pounds per gallon, a full 5-gallon container would weigh in excess of 40 pounds, which may be pushing the limits of what can be easily manipulated by one person (without the aid of equipment or other devices). This is especially true considering that the contents of many working containers will be transferred to other containers for disposal.

Nevertheless, the Agency does agree that since 4-liter solvent bottles are commonly used as collection containers in laboratories and are easily manipulated by one person, even if full, the Agency believes a two-gallon limit for working containers is more appropriate. Furthermore, two gallons is consistent with an interpretive letter signed by both Region I and the State of Massachusetts (September 2004; a copy of which is in today's docket), that originally introduced the concept of a working container under RCRA. Therefore, in response to these comments, the Agency has increased the maximum size of a working container to two gallons. The Agency is not limiting the type of containers that can be used as working containers. Thus, the types of containers that we would expect to be



used as working containers are beakers, flasks, bottles, and other types of containers typically used in a teaching or research laboratory.

The Agency also has deleted from the definition of working container that appeared in the preamble to the proposed rule the requirement for the contents of a working container to be emptied into a container of unwanted material at the end of a procedure. We believe it is more appropriate to include any management standards for working containers in § 262.206(b), which addresses the management standards for all containers.

Finally, the Agency has added to the definition that working containers are those that are used to collect “unwanted material.” The Agency believes that this modification is necessary in order to distinguish “working containers” from other containers used during an experiment or procedure that may contain product and are not subject to the RCRA Subtitle C regulations. See section III.C.3 of today’s preamble for a detailed discussion of the container management standards that apply to working containers (also see § 262.206).

The definition of “working container” in today’s final rule is:

a small container (i.e., two gallons or less) that is in use at a laboratory bench, hood, or other work station, to collect unwanted material from a laboratory experiment or procedure.

### *C. Specific Requirements of the Alternative Regulations*

Today’s final Subpart K regulations will allow laboratories at eligible academic entities to send unwanted materials that are generated in the laboratory to an on-site CAA or an on-site TSDF before making the hazardous waste determination for the unwanted materials, or to make the hazardous waste determination in the laboratory prior to its removal. However, the eligible academic entity must meet certain requirements such as notifying, complying with performance-based standards in the laboratory, and developing and implementing an LMP with nine required elements as described in the sections below.

#### **1. Notification**

Because today’s final rule provides eligible academic entities the option to manage their hazardous wastes from laboratories under the existing generator regulations or their laboratories’ unwanted materials under today’s provisions, it is important that EPA, or the authorized State, know to which set of regulations an eligible academic entity’s laboratories are subject.

Therefore, this rule requires that an eligible academic entity choosing to manage its unwanted materials in compliance with the alternative set of generator requirements being promulgated today submit a one-time notification to the appropriate EPA Regional Administrator or, when appropriate, State Director in authorized States that have adopted the final rule. Should an eligible academic entity decide not to opt into Subpart K, it will continue to operate under the existing generator regulations and there is no need to notify.

EPA proposed that the notification be provided by letter, but requested comment on whether the RCRA Subtitle C Site Identification Form (EPA Form 8700–12; or Site Identification Form) should be used to provide this notice, and whether the form should be modified to include a checkbox to indicate that a college or university is choosing to be subject to Subpart K. One commenter pointed out the advantage to using a letter would be to allow a college or university to submit one notice for several sites with different EPA Identification Numbers. However, most commenters supported the option of using the Site Identification Form to notify EPA (or the authorized State) regarding their decision to manage laboratory hazardous waste under the Subpart K requirements. The commenters noted that the regulated community is already familiar with this form and the form requires much of the necessary information required by the notification requirement that was proposed under Subpart K, such as name of the facility, address, and EPA Identification Number. Further, most commenters agreed that by using the Site Identification Form, there would be increased consistency in reporting. When eligible academic entities notify by Site Identification Form, the information is included in the RCRAInfo database, which provides an additional benefit of being able to monitor the extent to which eligible academic entities are taking advantage of this new Subpart.

Based on these comments, EPA is requiring the use of the Site Identification Form for notification of opting into, as well as withdrawing from Subpart K. In order to use this form for this purpose, we will be modifying the Site Identification Form to include a checkbox for an eligible academic entity to indicate what type of entity it is (i.e., a college or university, or a teaching hospital or a non-profit research institute that is either owned by or has a formal written affiliation agreement with a college or university) and that it

is choosing to be subject to the 40 CFR part 262, Subpart K requirements.<sup>4</sup> There is also a checkbox for an eligible academic entity to indicate that it is withdrawing from the Subpart K requirements, if after having decided to be subject to Subpart K, it determines it would prefer to be regulated under the existing hazardous waste generator standards.

Since we are requiring the use of the Site Identification Form, an eligible academic entity will have to submit one Site Identification form for each EPA Identification Number, or site as defined by RCRA.<sup>5</sup> Thus, if the eligible academic entity is composed of multiple sites (i.e., it has multiple EPA Identification Numbers) and all its sites will operate under Subpart K, separate Site Identification Forms must be submitted for each site. For example, if an urban college or university composed of multiple sites divided by public roads wants all of its laboratories to operate under Subpart K, the college or university must notify the appropriate authority that each of its sites is going to be subject to 40 CFR part 262, Subpart K by submitting a Site Identification Form for each distinct site (i.e., EPA Identification Number) opting into today’s rule.

As indicated in the example above, an eligible academic entity can be composed of multiple sites because of the way RCRA defines “on-site.” We believe that where this is the case, the eligible academic entity will choose to have all its sites at a single campus opt into Subpart K. This would allow eligible academic entities to have a unified institution-wide hazardous waste management system for all its laboratories on campus, which is one of the highest priorities for Subpart K cited by the academic community in their public comments. However, since a campus or institution opts in for each individual site, via EPA Identification Number, there is nothing in today’s rule

<sup>4</sup> If an eligible academic entity chooses to opt into Subpart K prior to the completion of the revisions to the Site Identification Form (8700–12), it should indicate in the comment field of the form what type of eligible academic entity it is and that it is opting into Part 262 Subpart K.

<sup>5</sup> RCRA 40 CFR part 260.10 defines, “on-site” to mean the same or geographically contiguous property which may be divided by public or private right-of-way provided the entrance and exit between the properties is at a cross-roads intersection, and access is by crossing as opposed to going along, the right-of-way. Non-contiguous properties owned by the same person, but connected by a right-of-way which he controls and to which the public does not have access, is also considered on-site property. For further interpretations, see Memo, Shapiro to Wojdyla; May 1, 1996, (RCRA Online #14031), a copy of which is in today’s docket.



that requires an eligible academic entity to have all of its separate sites opt into the Subpart K requirements. Thus, by not requiring that all the sites with different EPA Identification Numbers at an eligible academic entity opt into this rule together, we are providing additional flexibility for the eligible academic entity to determine the best hazardous waste management practices for its facility.

Teaching hospitals and non-profit research institutes, as defined in this rule, may be located on a college or university campus or located nearby. In rare instances, they may even be located in a separate State from the college or university with which they are affiliated. Since eligible academic entities opt in by filling out the Site Identification Form, a teaching hospital or non-profit research institute that has a separate EPA Identification Number from a college or university must decide independently whether it wants to opt into today's final rule. When a teaching hospital or non-profit research institute is owned by or formally affiliated with a college or university and located on campus, it does not have to opt in when the college or university opts in, if it is a separate site or has a separate EPA Identification Number, although, as noted above, we believe that teaching hospitals and non-profit research institutes will likely opt into Subpart K, if the colleges or universities with which they are affiliated opt in, to create a more integrated laboratory waste management system on campus.

As explained above, while not all the sites of an eligible academic entity must choose to be subject to today's rule, we continue to stress that all laboratories owned by the eligible academic entity within one EPA Identification Number must comply with the same set of regulations. In other words, the alternative approach cannot be applied to only one or a few laboratories within that EPA Identification Number, but rather must apply to all laboratories or no laboratories. The reason for this is that EPA believes it would be difficult for an eligible academic entity to keep track of which set of generator regulations apply to which laboratory or group of laboratories. Moreover, it would be extremely difficult, if not impossible, for the States or Regions to keep track of the applicable set of regulations if, within a single EPA Identification Number, different laboratories were choosing to be regulated under different requirements. No mechanism currently exists at EPA or the States to track such distinctions.

The required notice must be submitted to the appropriate EPA

Regional Administrator (or State Director in authorized States that adopt the final rule). At all times, an eligible academic entity's laboratories must comply with either the existing hazardous waste generator regulations or the Subpart K regulations. Once an eligible academic entity notifies by Site Identification Form that it is opting into Subpart K, EPA expects that the site will be in compliance with the Subpart K requirements. Therefore, we strongly suggest that an eligible academic entity prepare its LMP and ready its facilities for the Subpart K laboratory hazardous waste management system before it submits a Site Identification Form to the EPA Regional Authority (or State Director in authorized States). Further, an eligible academic entity may, for example, want to train its employees in the Subpart K labeling requirements and container management standards before notifying. In addition, an eligible academic entity may want to contact its hazardous waste vendors to prepare the vendor for the eligible academic entity's switch to Subpart K.

It is also possible that after an eligible academic entity has chosen to manage its unwanted materials under the Subpart K regulations and has gained some experience with the program, it may decide that this approach is not meeting its needs, and that it would prefer to return to regulation under the now existing applicable generator regulations, 40 CFR part 262 (or 40 CFR 261.5 for CESQGs). Under this final rule, an eligible academic entity that chooses to end its participation in the Subpart K program would be required to submit another Site Identification Form to the EPA Regional Administrator (or State Director in authorized States) checking the box for withdrawing from 40 CFR part 262, Subpart K. Then, the eligible academic entity's laboratories would no longer be subject to Subpart K and would be subject to the existing applicable generator regulations. Once the Agency receives the Site Identification Form from the eligible academic entity indicating that it is withdrawing from the Subpart K program, the Agency expects that the eligible academic entity will be in compliance with the 40 CFR part 262 applicable generator requirements (or 40 CFR 261.5 for CESQGs).

Finally, EPA sought comment on whether the Regional Administrator (or State Director in authorized States) should provide the eligible academic entity with a written receipt of the one-time notice before it could manage its unwanted materials in accordance with the Subpart K requirements. Most commenters did not want to wait for

EPA or the State to provide a written receipt of the one-time notice before managing their unwanted materials under these alternative generator requirements; they argued that it would cause delay and confusion. Other commenters pointed out that many States already respond in writing when the Site Identification Form is received. Therefore, we are not requiring that the Regional Administrator (or State Director in authorized States) provide a written receipt of the one-time notice before the eligible academic entity can manage its unwanted materials under the Subpart K requirements. (For more information on how CESQGs notify, see section III.C.9 and § 262.203.)

## 2. Labeling Standards

Because today's rule provides laboratories owned by eligible academic entities with flexibility in where and when to make the hazardous waste determination, labeling requirements for unwanted materials in the laboratory are needed. For example, labeling is critical to ensure that non-laboratory personnel, such as firefighters can quickly ascertain the hazardous materials that are in the laboratory in case of an emergency. In order to provide the necessary information to laboratory personnel, EH&S staff, inspectors, emergency responders, and others, today's rule includes performance-based labeling requirements that are informative, yet flexible to fit the varying situations at eligible academic entities.

The labeling requirements in the proposed rule consisted of two sets of performance-based labels. First, the proposal required that a label be affixed to or physically accompany the container of unwanted material. This label was intended to convey the most essential information that one needs to know about the contents of the container in an emergency situation. It also was intended to convey the notion that "unwanted material" was no longer wanted in the laboratory. Thus, the proposal required that this label include the words "unwanted material," as well as sufficient information to alert emergency response personnel to the container's hazards or contents.

The second part of the proposed labeling requirements provided flexibility by allowing information to be "associated with the container." We proposed that this label contain sufficient information for the RCRA-trained professional (which has been changed to trained professional in today's final rule) to make the hazardous waste determination. At a minimum, the information "associated" with containers of unwanted materials

was intended to ensure that a hazardous waste determination of the contents can be made by a trained professional. Additionally, the proposal required that the date when the unwanted materials first began accumulating in the container be associated with the container, so that EH&S staff or other trained professionals would know when to remove the containers of unwanted materials from the laboratory. The preamble to the proposed rule indicated that the accumulation start date and information sufficient to make a hazardous waste determination could be on the label that is affixed to or physically accompanies the container, but must, at a minimum, be associated with the container.

In the preamble to the proposed rule, we discussed examples of how the required information might be "associated" with a container. One example is that laboratory personnel could number containers of unwanted material and create an accompanying spreadsheet containing sufficient information to identify the material for each numbered container of unwanted material that would be given to the trained professional to make the hazardous waste determination. Another example is that laboratories could affix a bar code to each container of unwanted material that when scanned would provide the necessary information to make the hazardous waste determination of the unwanted material. Alternatively, laboratory personnel might choose to include a printed inventory of the unwanted materials and the associated information for each container that would provide the necessary information for a trained professional to make the hazardous waste determination.

The Agency received a large number of comments from academia in support of the performance-based labeling requirements in lieu of prescriptive requirements. In keeping with the original intent of the rulemaking, today's final rule maintains the performance-based two-tiered labeling structure; however, we have revised the labeling requirements to take into account public comments received on the proposal.

Specifically, we have revised the proposed labeling requirements in today's final rule to clarify that the first part of the labeling requirement requires the label to be "affixed or attached to" the container of unwanted material rather than be "affixed to or physically accompany" the container. We believe this modified language provides clarity and ensures that, during the accumulation period in the laboratory or

during on-site transfer, the identifying information will not be inadvertently separated from a container of unwanted material and thus the contents of any container can be quickly identified in an emergency situation. Examples of labels that are "affixed or attached to" containers of unwanted materials are stickers that have been affixed on the container by adhesive, or labels that are attached to a small container of unwanted material (i.e., too small for an adhesive label) by wire or a piece of tape.

Many commenters expressed concern about the proposed requirement to label containers with the words "unwanted material," preferring a more flexible labeling requirement. As one commenter stated, "The purpose of adding an additional label [unwanted material] to a reagent chemical container, for instance, is to differentiate it from others that a lab still wants or needs in their work so that the pickup crew or contractor knows which containers to take. The exact terminology is not important to meeting this goal." In response to this and other similar comments, in the final rule, we are requiring that containers be labeled with the words "unwanted material" or another "equally effective term" that is used consistently by the eligible academic entity and is identified in Part I of the eligible academic entity's LMP. Examples of an "equally effective term" include, but are not limited to, "laboratory waste" or "chemical lab waste." We believe this approach is responsive to the comments in that it provides each eligible academic entity with flexibility, yet conveys the basic information that the material is no longer needed or wanted in the laboratory. To this end, if an eligible academic entity elects to use another equally effective term in lieu of "unwanted materials," that term must address and have the same meaning as "unwanted material," and is subject to the same requirements in Subpart K for "unwanted material." Additionally, if an eligible academic entity chooses to use an equally effective term instead of "unwanted materials," the eligible academic entity must use the term consistently in all its laboratories that are covered by its LMP. It would not be acceptable for each laboratory at an eligible academic entity to be free to use its own term of choice because the use of different terms at the same eligible academic entity would cause confusion for implementers and enforcers.

A number of commenters opposed the proposed requirement that the label that is "affixed to or physically accompany" the container provide sufficient

information to alert emergency responders to the contents or the hazards of the container, arguing that the requirement is unnecessary and burdensome.<sup>6</sup> EPA disagrees with these comments and believes that maintaining this information is necessary to protect the safety of workers, students, emergency responders, and others that may come into contact with containers of unwanted materials. For safety purposes, emergency responders need to have a quick way to assess the contents of a container. However, we understand that at least part of the concern was the use of the term "hazards," in that it caused some confusion among commenters, many of whom thought that the Agency was proposing to require Department of Transportation (DOT) hazard classes or National Fire Protection Agency (NFPA) chemical hazard labels to be on the label that must be "affixed to or attached to" the container. This was not the Agency's intent. To address this misunderstanding in today's final rule, we have clarified the requirement that the label contain sufficient information to alert emergency responders to the contents of the container. This performance-based standard could be met by including information, such as the name of the chemical(s) in the container or, alternatively, a descriptive phrase, such as "inorganic solvents," "halogenated organic solvents," or "water reactive chemicals." This requirement is flexible, yet provides sufficient information to emergency responders in an easily understandable manner that would allow them to ascertain the potential dangers associated with the contents of containers in the laboratory, while being protective of health and safety.

As proposed, today's final rule requires that each container of unwanted material must have associated with the container the date that the unwanted material begins accumulating and information sufficient to make a hazardous waste determination. We are allowing this information to be "associated with" the container, as opposed to requiring that it be "affixed or attached to" the container, in order to facilitate the use of technology in conveying this information. This could be done using an electronic spreadsheet, a bar code, or some other printed inventory of containers (see previous examples of "affixed or attached to" or

<sup>6</sup> As discussed previously, the requirement that the label be "affixed to or physically accompany" the container has been changed in the final rule to that the label must be "affixed or attached to" the container.

“associated” labels). We also point out that this labeling requirement maintains the flexibility of the proposed rule, such that an eligible academic entity can use the container labeling approach that works best for the institution. That is, while it is acceptable to have the accumulation start date and information sufficient to make a hazardous waste determination “associated with” the container, some eligible academic entities may prefer to have all required container labeling information in a single place. Therefore, it is also acceptable to place the accumulation start date and the information sufficient to make a hazardous waste determination on the label that is “affixed or attached to” the container. We have reworded the container labeling regulations accordingly to reflect the intended flexibility and to indicate that, at a minimum, the accumulation start date and information sufficient to make a hazardous waste determination must be “associated with” the container, but that it can be on the label that is “affixed or attached” to the container, if that is preferred.

Many commenters had concerns about the burden imposed by the requirement to associate the accumulation start date with containers of unwanted material because it is not required in the current satellite accumulation area regulations. We maintain that this requirement is necessary to ensure that accumulation time limits in the laboratory are complied with for containers of unwanted material. Some commenters argued that alternatively, EPA should add a requirement to log regular removals from each laboratory in lieu of the container “dating” requirement. We disagree with this comment because we believe that the suggested method would not provide the information necessary to verify that a particular container had not been accumulating unwanted material for more than six months in the laboratory and, therefore, would not allow EPA or an authorized State to determine whether the laboratory was in compliance with Subpart K. Therefore, the dating requirement for each container of unwanted material has been retained in today’s final rule.

Finally, we have retained the requirement from the proposal that the label associated with the container must contain information sufficient to make a hazardous waste determination. As discussed above, this requirement provides flexibility to eligible academic entities in that this information can be on the label that is “affixed or attached to” the container, but it must at least be

on the label that is “associated with” the container. However, we stress that “information sufficient” to make a hazardous waste determination, whether that information is “associated with” or “affixed or attached to” containers of unwanted materials, must ensure that a hazardous waste determination of the contents can be made. Examples of information sufficient to make a hazardous waste determination include, but are not limited to: the name and/or description of the chemical contents or composition of the unwanted material, or, if known, the product of the chemical reaction, whether the unwanted material has been used or is unused, and a description of the manner in which the chemical was processed, if applicable.

In summary, today’s rule finalizes the proposed performance-based two-tiered labeling structure, but has modified it to address a number of comments received on the proposal. The first part of the final labeling requirement consists of information that must be “affixed or attached to” the container. The information must consist of the words “unwanted material” or another equally effective term that is used consistently by the eligible academic entity and is identified in Part I of the eligible academic entity’s LMP. Additionally, the label must contain sufficient information to alert emergency responders to the contents of the container. The second part of the final labeling requirement consists of information that must be “associated with” the container in some manner, which could include affixing or attaching it to the container. The information required includes the date that unwanted material first begins accumulating in the container, and information sufficient to allow trained professionals to determine whether the unwanted material is a solid and hazardous waste, as well as assign the proper hazardous waste code(s), pursuant to § 262.11. For more detail on specific labeling requirements for when volume limits are exceeded in the laboratory and after hazardous waste determinations are made, see section III.C.5, Removal Frequency of Unwanted Materials and Section III.C.6, Making the Hazardous Waste Determination, respectively.

### 3. Container Standards

When accumulating unwanted materials in the laboratory, proper container management is essential to protect human health and the environment. We proposed performance-based container management standards, requiring that

the containers be stored to prevent leaks, spills, emissions to the air, adverse chemical reactions, and to avoid dangerous situations that may result in harm to human health and the environment. The proposed container management standards also included two specific standards as a means to achieve these goals: (1) Containers must be kept in good condition and damaged containers must be replaced; and (2) containers must be compatible with their contents.

In the preamble to the proposed rule, we solicited comment on two alternative approaches for container management. First, we requested comment as to whether the rule should include more specific container management requirements in the regulations, potentially going beyond what was proposed. In the preamble, we included some examples of specific requirements we were considering, such as secondary containment and imposing a minimum safe distance for the storage of incompatibles. Another example that was discussed in the preamble was requiring that containers of unwanted material always be closed during storage, except for cases of in-line collection. An in-line collection system is a piece of laboratory equipment, such as a high performance liquid chromatograph (HPLC) that is directly connected to a container that collects unwanted material, including hazardous waste, typically by tubing. The tube carries the waste from the equipment directly into the container.

The second alternative approach for container management that we requested comment on was the concept of a “working container.” In the preamble to the proposal, a working container was defined as a small container (one gallon or less), managed under the control of a laboratory worker and used at a bench or work station, whose contents are emptied into a container of unwanted material at the end of the procedure. Similar to the previous alternative, we indicated that if we added “working container” to the final rule, we would also add a more specific requirement that any container of unwanted material that does not fit the definition of working container, be closed at all times, except when necessary to add or remove unwanted materials.

We received many comments on the proposed container management standards. Most commenters were supportive of the performance-based container management standards in lieu of the more prescriptive standards. Commenters argued that performance-based container management standards

would allow them the flexibility to tailor the standards to laboratory-specific operations. On the other hand, a few State commenters preferred more prescriptive container management standards as they found them easier to enforce than performance-based standards. However, we decided to maintain the performance-based container standards because we believe they are protective of human health and the environment, while providing flexibility to eligible academic entities.

Today's rule finalizes the proposed container management standards with one minor change and adds a new requirement. The requirement that eligible academic entities must properly manage containers of unwanted material to assure safe storage of the unwanted materials, to prevent leaks, spills, emissions to the air, adverse chemical reactions, and dangerous situations that may result in harm to human health or the environment has remained the same from proposal. Similarly, containers must be compatible with their contents. A minor clarification was added to the requirement that damaged containers be replaced. Several commenters requested that the Agency add language clarifying that replacing damaged or degraded containers is not the only method of reducing their threat. We agree and have added the requirement in the final rule that damaged or degraded containers be replaced, overpacked, or repaired, in order to prevent releases of the container's contents into the environment. An example of overpacking a container is taking a damaged container of unwanted materials and placing it into a second container in good condition and then packing the second container with absorbent filler similar to the practice of lab-packing. An example of repairing a damaged container would be if a small leak appears in the cap of a container of unwanted material, and a laboratory worker covered the broken cap with a polymer film.

Many commenters also provided comments in support of the concept of a "working container," although a few commenters were opposed to allowing a "working container" in the final rule. Opponents believed that the approach is not protective of the environment, while supporters felt that the prescriptive requirement that containers be kept closed, except when adding or removing waste, which we said would be added if a working container provision were added to the final rule, is easier to enforce. In addition, commenters in support of adding a working container wrote that this concept "recognizes the fact that many unwanted laboratory

materials are actively accumulated in small containers at a bench, work station, or fume hood." Academic and State commenters supported the inclusion of a working container provision because it allows containers that are in use for collecting unwanted materials to be open while the experiment is running, while at the same time it provides protection by requiring that non-working containers be closed at all times, except when adding, removing, or consolidating unwanted materials.

After evaluating all of the comments, we have decided to include a provision in the final rule allowing laboratories to use "working containers." As discussed in the definition section above (section III.B.3), a working container is defined in the final rule as a small container (i.e., two gallons or less) that is used at a laboratory bench, hood, or other work station in order to collect unwanted material from a laboratory experiment or procedure. We have added to the container management standards a requirement that a working container may be open until the end of the procedure or work shift, or until it is full, whichever comes first, at which time it must either be closed or the contents must be emptied into a container that is closed after the contents of the working container are added.

In reference to the other containers of unwanted materials in the laboratory (i.e., non-working containers), several commenters opposed the requirement that these non-working containers remain closed, except to add or remove unwanted material. We disagree with these commenters. We believe that the requirement that containers remain closed, except when adding, removing, or consolidating unwanted material is straightforward and is protective of human health and the environment. Requiring that containers remain closed, except in certain instances, will prevent or mitigate accidents in the laboratory that could otherwise lead to spills or releases.

Commenters identified two additional situations (besides working containers) where they believed a requirement to keep containers closed is problematic. One commenter stated, " \* \* \* tightly capping containers after addition of waste is sometimes impractical and dangerous. Capping systems should be allowed which preclude excessive evaporation while providing for displacement of air while filling from in-line systems such as an HPLC or allow pressure relief from wastes which have not fully reacted." The comment about "in-line" collection of unwanted

materials is consistent with what the Agency has heard over the years through our Project XL with the three New England colleges and universities, as well as through public meetings. In many cases, automated laboratory equipment will shut down if air is not able to escape from an in-line collection system because of a build-up of pressure. Another commenter stated, " \* \* \* that the closed container rule may also have a negative effect by creating a compromised container in certain situations. Chemical reaction residues may react slowly over several days, thus building up pressure in a container. The semiconductor etching solution known as "piranha solution" is one example. Proper management of these solutions requires that the container be able to safely vent the excess pressure."

In response to the two public comments above, we have modified the container management regulations to add these two additional situations (besides working containers) in which containers are not required to be completely closed, because in these two situations keeping a container of unwanted materials closed may be problematic. Specifically, the final rule allows containers to be vented when it is necessary (1) for the operation of laboratory equipment, such as in-line collection, and (2) to avoid dangerous situations, such as the build-up of extreme pressure. Thus, as we have explained, we have determined that a combination of both performance-based and prescriptive approaches (as it relates to whether containers must be kept closed) is more protective of human health and the environment than performance-based requirements alone. The Agency believes it is preferable to maintain the requirement that containers remain closed, except when adding, removing or consolidating unwanted material in most instances, while allowing for a few specific instances in which it is not appropriate, rather than to eliminate the requirement for closed containers altogether. This is because such an approach provides the flexibility in specific situations where commenters have shown that requiring closed containers is inappropriate and does not compromise protection for all the other containers of unwanted materials that have no cause to be open. Furthermore, this approach is simpler for an eligible academic entity to implement and is more easily enforceable.

In summary, today's final rule contains container management standards that require that containers be managed to assure the safe storage of the

unwanted material to prevent leaks, spills, emissions to the air, adverse chemical reactions, and dangerous situations that may result in harm to human health or the environment. Specifically, today's final rule requires that containers be maintained and kept in good condition and that damaged containers be replaced, overpacked, or repaired. Additionally, containers must be compatible with their contents to avoid reactions between the contents and the container and must be made of, or lined with, material that is compatible with the unwanted material so that the container's integrity is not impaired. Finally, containers of unwanted material must be kept closed at all times, with three exceptions: (1) When adding, removing or consolidating unwanted material, (2) when using working containers, which may be open until the end of the procedure or work shift, or until they are full, whichever comes first, and (3) allowing containers to be vented if necessary for the proper operation of laboratory equipment, such as with in-line collection, or to prevent dangerous situations, such as build-up of extreme pressure.

#### 4. Training Requirements

The Agency intends to provide flexibility in the content and method of training for laboratory workers and students, while ensuring that unwanted materials are properly managed and that an eligible academic entity is in full compliance with the Subpart K requirements. Thus, EPA has included performance-based standards in today's final rule for training of laboratory workers and students.

EPA proposed that under Subpart K a college or university be required to provide training or instruction to all individuals working in the laboratory. Specifically, the proposal required that laboratory workers be trained commensurate with their duties so they understand the requirements of Subpart K and can implement them to ensure the laboratories' compliance with the requirements of the rule. In addition, we proposed that students in a laboratory where unwanted material is generated must receive instruction relevant to their activities in the laboratory. We proposed that instruction may include proper container labeling, collection procedures for unwanted material, and emergency response procedures. Further, the proposal required that on-site transfers of unwanted materials (which ultimately may prove to be hazardous wastes) and the hazardous waste determination could only be conducted by RCRA-trained individuals

(called "trained professionals" in the final rule). The proposal indicated that a college or university could provide training and instruction for laboratory workers and students in a variety of ways, including, but not limited to, instruction by the professor or laboratory manager before or during an experiment, formal classroom training, electronic or written training, on-the-job training, or written or oral exams. Finally, the proposal required that a college or university that is an LQG must maintain training records for the laboratory workers that are sufficient to determine whether such workers have been trained.

Many commenters expressed general or partial support for the proposed performance-based training and instruction requirements, in lieu of prescriptive training requirements. However, many commenters requested that the training requirements be made more performance-based and include greater flexibility in training approaches (e.g., use of postings and signs). In contrast, a few commenters expressed support for a more prescriptive approach to training and instruction, including a clear and concise required curriculum for RCRA training in order to make the Subpart K requirements more meaningful.

We maintain that performance-based training requirements are appropriate for laboratory workers and students. Eligible academic entities should have the flexibility to offer training to laboratory workers and students through their choice of an effective method, provided the information is sufficient and thorough enough to ensure proper management of the unwanted materials by laboratory personnel in order to avoid dangerous situations. However, EPA disagrees that merely posting a sign would adequately instruct laboratory workers and students on the proper and safe management of unwanted materials, believing that some active training is necessary to ensure that all laboratory personnel fully comprehend their duties and assignments with respect to unwanted materials management. As stipulated in the proposal and supported by comments, today's final rule maintains that training methods may consist of a variety of approaches, including formal classroom or electronic on-line training, on-the-job training, or instruction by a professor or manager. Use of postings or signs may supplement and serve as a reminder of the more formal training, but does not itself constitute "training" for the purposes of today's final rule. While we do not believe the use of postings or signs alone constitute "training," EPA

believes that the use of signs and postings to supplement and reinforce the knowledge gained from the required training program would be beneficial. Training must be sufficient to enable individual laboratory workers and students in the laboratory to conduct their duties in an environmentally safe manner and in accordance with all applicable regulations.

Many commenters stated that all training and instruction should be commensurate with the duties and activities of the personnel, irrespective of their status as students or laboratory workers. We concur with these commenters and thus the final rule has been modified to reflect that principle. Therefore, as opposed to the proposed rule, which distinguished between training for laboratory workers and instruction for students, today's final rule requires that both laboratory workers and students be trained commensurate with their duties. Therefore, commensurate training constitutes training aligned with an individual's assigned duties and the degree of involvement with the management of the unwanted materials. EPA believes that training commensurate with ones duties should correspond with the level of knowledge or practical application needed by individuals to perform their assigned functions or fulfill their job or enrollment classification (i.e., professor, researcher, graduate student, undergraduate student) within an eligible academic entity.

We believe that training commensurate with the duties for students constitutes familiarization or transference of knowledge to perform tasks and assignments in the laboratory in a safe and environmentally sound manner for unwanted materials handling, in accordance with the Subpart K requirements. Specifically, students conducting experiments will come in contact with and use a variety of chemicals which may potentially become hazardous waste following experimentation or may react adversely if incorrectly stored or managed. Students in a supervised classroom setting generally would require less training than students in a research setting. In a teaching laboratory, containers for the unwanted materials that are generated during an experiment are typically pre-labeled by the laboratory instructor. Therefore, students in a supervised classroom setting should be trained to place the products of experiments in the appropriate containers of unwanted materials. On the other hand, students conducting research where such

containers are not provided should be trained to store unwanted materials in containers to minimize risk and label containers with the words "unwanted materials," or another equally effective term, so that EH&S staff know that the containers are not longer wanted, as well as the contents of the container and the accumulation start date. There is also the potential for dangerous or hazardous situations, such as explosions, fires, spills, or other hazards from mishandling chemicals of unwanted materials which would require emergency response actions by qualified personnel. It is not necessary that students have the capability of an emergency response coordinator or other qualified individual to respond and perform emergency procedures and other remedial actions. Rather, it is sufficient for students to know how to correctly handle and manage unwanted materials to avoid dangerous or hazardous situations and in case of an emergency, know the correct information or procedures to follow, such as how to contact emergency responders and when to evacuate the laboratory.

Training commensurate with the duties for laboratory workers and graduate students working as laboratory workers may be more formalized or technical instruction whereby upon completion of training, personnel are qualified to perform the functions of their job descriptions or assigned duties. For the purpose of Subpart K, laboratory workers must receive training or technical instruction in direct correlation to their individual job description or assignments. Under Subpart K, the definition of "laboratory worker" includes a broad array of job classifications with different duties, such as supervisor or manager of a laboratory, faculty, staff, researcher, post-doctoral fellows, interns, technicians and principal investigators. Examples of training for laboratory workers commensurate with ones duties include, but are not limited to, training to perform their duties to comply with the Subpart K labeling and container management standards, supervising students in the laboratory, preparing containers for transport, emergency response duties, and/or other duties, as appropriate.

Several commenters expressed concern about the requirement that personnel conducting on-site transfers of unwanted materials be RCRA-trained. The commenters stated that this requirement is unnecessary and does not recognize that these entities have been safely transferring hazardous waste on-site for years and that a person can

safely transfer unwanted materials with appropriate safety training. In contrast, the Agency heard from one commenter stating that students and non-RCRA trained staff should not transfer hazardous wastes outside of the laboratory. We believe that the person transferring unwanted materials on-site must be a "trained professional" according to the definition in § 262.200, which requires that the individual complete the applicable RCRA training requirements of § 265.16 for LQGs, or § 262.34(d)(5)(iii) for SQGs and CESQGs. Despite the fact that commenters stated otherwise, this requirement is consistent with the Agency's existing interpretation for on-site transfers of hazardous waste (see memo March 17, 2004, Springer to Regions, RCRA Online #14703). Furthermore, we believe that this level of training is "commensurate" with the duties of the individual transferring the unwanted materials on-site, which are to transfer the materials safely, to avoid spills or releases, and to respond properly to any releases, among other things. Specifically, we believe that the on-site transfer of unwanted materials outside of the laboratory should be conducted by an individual who has received the full complement of RCRA training in accordance with the eligible academic entity's generator status, to ensure that that individual is knowledgeable about the RCRA requirements, especially with regard to the compatibility of chemicals, spill prevention, and emergency response. This is especially important considering that the unwanted materials from many individual laboratories will often be collected together during the on-site collection and transfer of those materials.

We also heard from two commenters who emphasized the importance of training for personnel who make the hazardous waste determination at an eligible academic entity. We agree with the commenters, and, as proposed, require in today's final rule that the individual making the hazardous waste determination, whether it is in the laboratory, at the on-site CAA or on-site TSDF, be a trained professional who has the full complement of RCRA training in accordance with the eligible academic entity's generator status (SQG status for CESQGs). Individuals making the hazardous waste determination must be aware of all applicable RCRA requirements in order to complete their duties, which are to classify the unwanted materials properly as solid and/or hazardous wastes and to apply the correct hazardous waste code(s).

Thus, we are continuing to require that the person making the hazardous waste determination be a "trained professional" according to the definition set out in § 262.200.

Therefore, today's final rule maintains the requirement that trained professionals make the hazardous waste determination and transfer unwanted materials (or hazardous wastes, if the hazardous waste determination is made in the laboratory) outside the laboratory and that the trained professionals must meet the existing RCRA generator training requirements applicable to the eligible academic entity's generator status. In addition, today's final rule has added the requirement that trained professionals at CESQGs must receive RCRA training in accordance with the training requirements for SQGs, at a minimum (see definition of "trained professional" in Section III.B.2 of today's preamble, as well as § 262.200).

Several commenters described other regulatory bodies (e.g., DOT; U.S. Nuclear Regulatory Commission (NRC); Occupational Safety and Health Administration (OSHA)) that require training on hazardous chemicals, emphasizing that Subpart K's training requirements should avoid redundancy with other required training. Some of these commenters stated that they would use OSHA training to satisfy the proposed Subpart K training requirements. In contrast, we heard from one commenter expressing concern that there are no other appropriate regulatory requirements for training specific enough to be appropriate for RCRA because they do not effectively cover the RCRA hazardous waste determination. The Agency believes that neither the "traditional" RCRA generator regulations nor Subpart K prohibits the use of other training programs to satisfy the training requirements of Subpart K, provided the other training program(s) address the relevant RCRA requirements for trained professionals, and the relevant Subpart K requirements to train laboratory workers and students commensurate with their duties.

Several commenters argued that eligible academic entities should be able to provide evidence of training, in lieu of training records, which they believe are too burdensome to keep. Furthermore, a few commenters advocated eliminating the proposed recordkeeping requirements for LQGs, arguing that such requirements would be more burdensome than the existing requirements for satellite accumulation areas, which do not require documented training for personnel. The Agency recognizes that the satellite

accumulation area regulations do not require documented training for personnel and is not requiring that records be retained for training of students in the laboratory. However, we believe it is appropriate that eligible academic entities that are LQGs retain the records for training of laboratory workers in order to demonstrate that the laboratory worker received the necessary training. The records that are required for laboratory workers at LQGs are the same that are required for trained professionals at eligible academic entities that are LQGs (and which they are subject to today), both of which reference the current LQG training regulations in § 265.16.

Finally, we heard from a few commenters who stated that the maintenance of training records for trained professionals or laboratory workers at SQGs is unnecessary. We did not propose to require such recordkeeping for training of laboratory workers or trained professionals at SQGs, nor has the Agency included such a requirement in today's final rulemaking.

In summary, under today's final rule, eligible academic entities managing their laboratory hazardous wastes under Subpart K must provide training for laboratory workers and students, and the training must provide sufficient information so that laboratory workers and students can understand and implement the requirements of Subpart K, commensurate with their duties. An eligible academic entity can provide training and instruction for laboratory workers and students in a variety of ways, including, but not limited to, instruction by the professor/manager before or during an experiment, formal classroom training, electronic/written training, on-the-job training, or written or oral exams. LQGs managing their laboratory waste under Subpart K must maintain documentation demonstrating that the training has been provided to laboratory workers and trained professionals. Documentation demonstrating training can include, but is not limited to, sign-in or attendance sheet(s) for training session(s), syllabi for training session(s), certificate(s) of completion, or test results. Finally, the training requirements in today's final rule restrict who may conduct certain activities under Subpart K. Specifically, only "trained professionals," as defined in § 262.200, may transfer unwanted materials on-site and make the hazardous waste determination, pursuant to § 262.11, for unwanted material.

#### 5. Removal Frequency of Unwanted Materials

Currently, most laboratories operate under what is commonly referred to as the satellite accumulation area (SAA) regulations (see 40 CFR 262.34(c)). At SAAs, removal of hazardous waste is dependent on the volume of hazardous waste that is accumulated in each SAA. That is, once more than 55 gallons of hazardous waste (or more than 1 quart of acutely hazardous waste) is accumulated in an SAA, a generator has three days to remove the excess of 55 gallons (or excess of 1 quart of acutely hazardous waste) from the SAA and transfer it to an on-site CAA or TSDF, or transport it off-site.

In large part because colleges and universities explained to us that they rarely accumulate 55 gallons of hazardous waste in a laboratory, except during a laboratory clean-out, in Subpart K we proposed to require the removal of unwanted materials from laboratories based primarily on time, and secondarily by the volume of unwanted materials. Specifically, we proposed that all unwanted materials, including reactive acutely hazardous unwanted materials (as defined in the proposal), generated in laboratories must be removed from the laboratory at a regular interval that is specified in the entity's LMP, and that such interval for routine removals must not exceed six months. College and university representatives had told EPA that tying the removal of laboratory wastes with the academic calendar would facilitate removal of laboratory wastes that accumulate during the course of the semester with a minimum of disruption. Therefore, the Agency believed that six months was an appropriate length of time to allow colleges and universities to schedule routine removals of unwanted materials at the end of each semester.

We also proposed that if a laboratory accumulates more than 55 gallons of unwanted materials (including reactive acutely hazardous unwanted materials) prior to the regularly scheduled removal specified in the entity's LMP, then all of the unwanted materials, including the reactive acutely hazardous unwanted materials, must be removed from the laboratory within ten calendar days of exceeding 55 gallons, or at the next regularly scheduled removal, whichever occurs first. For reactive acutely hazardous unwanted materials, we proposed that if a laboratory accumulates more than 1 quart prior to the regularly scheduled removal, then the reactive acutely hazardous unwanted materials would have to be

removed from the laboratory within ten calendar days of exceeding 1 quart, or at the next regularly scheduled removal, whichever occurs first. The Agency proposed that the reactive acutely hazardous unwanted materials be subject to the 1-quart volume limit for accumulation in the laboratory, instead of the 55-gallon limit, because when these reactive chemicals are stored for long periods, they can become unstable, posing an extreme danger because these reactive chemicals have the potential to cause significant harm to laboratory personnel and property.

Many commenters generally supported the shift to the time-driven removal of unwanted materials from laboratories. However, they also requested that the maximum time between regularly scheduled removals be lengthened from six months to a year, or an "academic year," which commenters defined as "the 11–13 month period that corresponds to a college or university's annual teaching and research activities." Some commenters argued that six months was too frequent because some laboratories generate very small quantities of unwanted material in that time period. While some laboratories may generate small quantities of unwanted material, we have determined, based on all the available information, to keep six months as the maximum time between regularly scheduled removals.

We have retained six months as the maximum time between regularly scheduled removals of unwanted materials from the laboratory for several reasons. First, we believe that implementing regular removals on the basis of an "academic year" could be confusing. Second, as we indicated in the preamble to the proposed rule, our goal is to have unwanted materials removed from laboratories at least once each semester. One commenter indicated that a schedule that allows removals on a semester basis is preferred by stating, "colleges and universities generally use the semester's end to encourage laboratory workers and students to have unwanted materials removed from their laboratories before leaving campus. This practice reduces the risk that unknown materials will be left behind by a student or laboratory worker who does not return the following semester. Also it limits the amount of waste material stored in laboratories during the break, when fewer people are around to monitor or be aware of the conditions in the laboratory." Finally, as discussed in the proposal, we do not believe that allowing unwanted materials to accumulate for longer than six months



would reduce risk to laboratory personnel and provide the benefits to human health and the environment to the same extent and therefore the anticipated benefits from moving to a time-driven rather than a volume-driven approach would be diminished.

We realize that some laboratories will not generate any unwanted materials during a six month period and we do not intend for EH&S personnel or other staff or contractors to make a trip to the laboratory if they know that the laboratory does not have any unwanted materials. The eligible academic entity must describe in Part II of its LMP how it will determine whether a removal of unwanted material is necessary at each individual laboratory. For example, a form or an e-mail could be sent to each laboratory asking whether the laboratory has any unwanted material accumulating and the EH&S could respond accordingly. Eligible academic entities have flexibility with respect to how they intend to comply with the requirements for regular removals of unwanted materials. However, each eligible academic entity is responsible for ensuring that it meets the time-driven requirement (i.e., every six months) for the method it has selected for removing unwanted materials from the laboratory. The accumulation start date associated with each container (or affixed or attached to each container, if that is preferred) of unwanted material is intended to be used as the mechanism for determining compliance with regularly scheduled removals. Of course, unwanted materials may always be picked up with greater frequency than specified in either the regulations or the eligible academic entity's LMP.

A number of commenters expressed concern over the requirement to remove "all" containers of unwanted materials from the laboratory either during a regularly scheduled removal or when the volumes have been exceeded, because this would require partially-filled containers to be removed from the laboratory, which could require the use of more containers. Many of these commenters requested that EPA modify the requirement to remove "all" unwanted material from the laboratory to require that only full containers of unwanted material have to be removed from the laboratory.

We recognize the commenters' concerns regarding the requirement to remove "all" unwanted materials from the laboratory during regularly scheduled removals or when volumes have been exceeded. However, we do not consider the alternative suggested by commenters—to require that only full containers of unwanted material

have to be removed from the laboratory—to be practical. It would be easy to circumvent the intent of the regulations for regular systematic removals of unwanted materials from the laboratory by simply not completely filling containers of unwanted materials. In this scenario, the removal of unwanted materials from the laboratory would be based primarily on volume, rather than based on EPA's preferred approach of time. We prefer the time-driven approach, with the maximum volumes as a backup because, for most laboratories, it is rare to accumulate 55 gallons of unwanted material. Without a time limit, unwanted materials could remain in the laboratory for extended periods of time. As for the concern about using too many containers, consolidation of compatible materials is allowed within in a laboratory, as well as at an on-site CAA or on-site TSDF, which could then return some or most of the reusable containers for use in collecting unwanted material.

One commenter suggested adopting a system that mirrors the Universal Waste system for tracking the amount of time that unwanted materials remain in the laboratory. This commenter suggested that a laboratory should be allowed to demonstrate the length of time that each container has been accumulating unwanted material and that EPA should base the removal on how long each container is in the laboratory. We also heard from many commenters that we should be more flexible in the removal provisions.

In response to these comments, there are now two alternative approaches allowed for regular removals of unwanted materials. The first approach is the one that was proposed. That is, all containers of unwanted material must be removed from the laboratory on a regular basis, not to exceed six months. Under this approach, however, it is possible that a container that began accumulating unwanted materials the day before the regularly scheduled removal would be required to be removed. This approach is easy to implement, as all containers of unwanted material would be removed from the laboratory, regardless of when they began accumulating unwanted materials.

The second alternative being added today allows the removal of containers of unwanted material using a "rolling" six months approach. That is, no individual container of unwanted material could remain in the laboratory for more than six months. We believe this alternative approach provides additional flexibility that many commenters sought by adding a choice

of implementation methods for the removal of unwanted materials, while maintaining the intent of the regulations by requiring regular, systematic, time-driven removals of unwanted materials. Since there is already a requirement that all containers have an accumulation start date associated with them, this approach would rely on checking the dates associated with each container in order to determine which containers would have to be removed from the laboratory. Individual containers could potentially remain in the laboratory longer than under the other alternative approach and therefore, would be more likely to be full or nearly full. On the other hand, this approach would likely require more frequent removals from the laboratory to ensure that no container accumulating unwanted materials remains in the laboratory longer than six months.

Each eligible academic entity choosing to be subject to Subpart K must select and identify in Part I of its LMP, the approach it chooses for complying with regular removals of unwanted materials from the laboratory. In Part II of its LMP, the eligible academic entity must describe how it plans to comply with the approach it has chosen for regular removal of unwanted materials from the laboratory.

Under the SAA regulations of § 262.34(c), if the maximum volumes are exceeded, the excess of 55 gallons of hazardous waste (or 1 quart of acutely hazardous waste) must be removed from the area within three days. We have frequently heard that the three-day time limit was problematic, especially during long weekends and holidays. Under Subpart K, we proposed to extend from three days to ten calendar days the removal of unwanted materials from the laboratory when the maximum volumes are exceeded. Many commenters supported this change, although a few commenters believed that three days was sufficient. One State commenter suggested that laboratories should remove their unwanted materials before the maximum volumes are reached, which would remove the need for providing additional time for the removal of unwanted materials from the laboratory. We have decided to retain ten calendar days for removing unwanted materials from the laboratory when the maximum volumes are exceeded. We believe that ten calendar days will provide sufficient flexibility to respond to the occasions when 55 gallons of unwanted material (or 1 quart of reactive acutely hazardous unwanted material) is exceeded, while maintaining protection to human health and the environment.



With regard to which unwanted materials must be removed from the laboratory when maximum volumes are exceeded, we proposed that when a laboratory exceeds 55 gallons of unwanted material, it must remove all unwanted materials—including the reactive acutely hazardous materials. This is because all reactive acutely hazardous materials are unwanted materials and should be considered in calculating whether the 55 gallons has been exceeded. On the other hand, we proposed that when a laboratory exceeds 1 quart of acutely reactive unwanted material, it must remove only the reactive acutely hazardous unwanted material, not all containers of unwanted material, because not all unwanted materials are reactive acutely hazardous unwanted materials, and therefore should not be subject to the lower accumulation limits in the laboratory. We have retained these requirements in today's final rule, with some minor rewording to clarify our intent. Of course, in the case where a laboratory exceeds 1 quart of reactive acutely hazardous unwanted material, an eligible academic entity may choose to remove all unwanted materials from the laboratory. If a trained professional has to make a trip to the laboratory to remove reactive acutely hazardous unwanted materials in excess of 1 quart, it may be more efficient to remove all unwanted materials at the same time, even if they are not required to be removed at that time.

We proposed that if a laboratory accumulates more than 55 gallons of unwanted material, then all containers of unwanted materials (including reactive acutely hazardous unwanted materials) must be dated with the date the 55 gallons is exceeded. We also proposed that if a laboratory accumulates more than 1 quart of reactive acutely hazardous unwanted material, then all containers of reactive acutely hazardous unwanted materials must be dated with the date the 1 quart is exceeded. This date is necessary to determine whether the ten calendar days had elapsed and, therefore, when the containers must be removed from the laboratory. In the proposed regulations, we did not specify which label this date must go on—the label that is “affixed to or physically accompanies” (which has been changed to “affixed or attached to” in the final rule) the container, or the label that is “associated with” the container. However, in the preamble to the proposed rule, we did indicate that, as with the requirement to date containers with their accumulation start date, this

date may be included on either label—the label that is “affixed or physically accompanies” the container, or the label that is “associated with” the container (see 71 FR 29730). In today's final rule, we have revised the regulatory text to be consistent with the preamble discussion from the proposed rule. Therefore, when 55 gallons of unwanted material (or 1 quart of reactive acutely hazardous unwanted material) is exceeded in a laboratory, the date that the maximum volume is exceeded may be added to either type of label. That is, it may be added to the label that is “affixed or attached to” the container, but at a minimum it must be added to the label that is “associated with” the container.

One commenter pointed out that if an eligible academic entity does not have an on-site CAA and one of its laboratories exceeds the specified volume limits, the generator must be prepared to have a vendor ship the unwanted materials from the laboratory to an off-site TSDF within 10 calendar days. We agree with the commenter's assessment and point out that this is an increase in the time allowed under the current SAA regulations, under which the same generator would have only three days in which to ship the hazardous waste off-site (or come into compliance with the requirements for 90/180/270-day generator accumulation areas).

One commenter suggested that in order to be consistent with the SAA regulations, the 55-gallon limit should be on a “per wastestream” basis, rather than a “total volume” basis. We disagree with the commenter and find the commenter's interpretation of the SAA regulations to be incorrect. To the contrary, EPA has consistently interpreted the SAA regulations such that 55 gallons is based on a total volume of all wastestreams combined (see memo from Robert Springer, Director, OSW to EPA Regional Directors, March 17, 2004, RCRA Online #14703). Thus, Subpart K is consistent with the SAA regulations with respect to this provision.

#### a. Reactive Acutely Hazardous Unwanted Materials

Under the SAA regulations of § 262.34(c), if more than 1 quart of an acutely hazardous waste listed in § 261.33(e) is accumulated, the excess of 1 quart must be removed from the SAA within three days and taken either to an on-site CAA or TSDF, or transported off-site. Section 261.33(e), which is commonly referred to as the “P list” of hazardous wastes, currently comprises 124 chemicals. The P-list is a list of commercial chemical products that are

considered acutely hazardous waste when discarded because they are considered hazardous even when managed in small quantities. Under Subpart K, the Agency is reducing the number of chemicals that are subject to removal from the laboratory at the 1-quart threshold from all 124 chemicals on the P-list to the six chemicals that are on the P-list because they are reactive. We focused on the reactive chemicals on the P-list because, as reactive chemicals, they have the potential to cause significant and immediate harm to individuals and property. We are finalizing this provision as proposed, along with the change to the definition of reactive acutely hazardous unwanted material that was previously discussed in section III.B.2 of today's preamble (also see § 262.200).

We also would like to clarify that this regulatory revision—that is, the number of P-listed chemicals that are subject to removal from the laboratory if they exceed the 1-quart threshold—does not impact other aspects of the hazardous waste regulations. That is, we have not changed the regulations with respect to which chemicals are identified as acutely hazardous wastes or the 1 kg/month threshold for becoming an LQG. Therefore, the entire P-list must be considered when a trained professional makes the hazardous waste determination for unwanted materials. If an eligible academic entity generates more than 1 kg/month of acutely hazardous waste, it is an LQG for that calendar month, except if the acutely hazardous waste is from a laboratory clean-out conducted in accordance with § 262.213 of today's rule, in which case it need not be counted toward the eligible academic entity's generator status. See section III.C.7 of today's preamble for a discussion of the laboratory clean-out provisions, as well as § 262.213.

#### b. Transferring Unwanted Materials or Hazardous Wastes From the Laboratory to an On-site CAA or On-site TSDF

To ensure that unwanted materials removed from the laboratory are brought promptly to their next destination, such as an on-site CAA or TSDF, the Agency proposed to require that when unwanted materials (or hazardous wastes, if the hazardous waste determination was made in the laboratory) are removed from a laboratory, they must be brought “directly” from the laboratory(ies) to an on-site CAA or TSDF. We sought comment on whether it was necessary to define “directly” or to replace it with a more specific time-frame, such as a same day requirement.

We received several comments in support of defining the term “directly.” Other commenters, however, stated that it was not necessary to define the term, especially given our preamble discussion in the proposed rule. In reviewing the comments, we have decided not to add a regulatory definition of “directly” and will simply reiterate and expand upon the preamble discussion from the proposed rule.

In general, if the unwanted material is sent from the laboratory or laboratories to the on-site CAA or TSDF within the same work day, this would meet the intent of the regulation. We realize that many eligible academic entities will collect unwanted materials from many laboratories at a time, in series, and will deliver all the unwanted materials to an on-site CAA or TSDF at the end of the collection process. This would be an acceptable practice under today’s regulations, provided the unwanted materials are in continuous custody of the trained professional that is collecting and transferring the unwanted materials and they are delivered to the on-site CAA or TSDF at the end of the work shift. It is not necessary to bring the unwanted material from each individual laboratory directly to the on-site CAA or TSDF and then in a separate trip bring the unwanted materials from the next laboratory. Such an arrangement would only increase the amount of time that trained professionals would spend in removing unwanted materials from laboratories and that unwanted materials would spend in transport, with no benefit. On the other hand, if unwanted materials were left on a cart in the hallway overnight, this would not be an acceptable practice and would not meet the intent of the regulation.

#### c. On-site Consolidation Areas

Under the existing regulations, generators may accumulate hazardous waste in two types of areas without having a permit or interim status: (1) An SAA or (2) an on-site generator accumulation area ( $\leq 90$ ,  $\leq 180$  or  $\leq 270$  day areas).<sup>7</sup> Under Subpart K, eligible academic entities also may accumulate

unwanted materials and hazardous wastes in two types of areas without having a permit or interim status: (1) Laboratories (in lieu of SAAs) and (2) an on-site CAA (“CAA” is a term that has been defined under Subpart K, but is the same as what has sometimes been called “generator accumulation areas” or “90/180/270-day areas”).

At proposal, we solicited comment on whether an additional accumulation area beyond what is already allowed in the rules should be created to allow for the consolidation of unwanted materials after they have been removed from the laboratory. We received many comments in favor of establishing a consolidation area as a new type of area for the accumulation of unwanted materials after such material has been removed from the laboratory. Some commenters even included suggested regulatory text for how these new consolidation areas would be regulated, including specific requirements for labeling/dating, container management, training, removal frequency, hazardous waste determinations, inspections, spill response, signage, and documentation in the LMP. A few commenters, however, opposed the creation of another type of accumulation area, primarily because they were concerned that the addition of another accumulation area would cause confusion.

After analyzing the comments and considering the flexibility that is already provided in the regulations, we have decided not to establish a “consolidation area” as another type of accumulation area for unwanted materials. We agree with the commenters that argued that adding another type of accumulation area with another set of standards would be confusing for implementers and enforcers with little, if any, benefit. We believe that the flexibility that is already in Subpart K can provide the benefits of a consolidation area, without establishing a new regulatory category for them.

It has been EPA’s regulatory interpretation that hazardous wastes can not be moved from one SAA to another (see memo from Robert Springer, Director, OSW, to EPA Regional Directors; March 17, 2004, RCRA Online #14703). One reason for this prohibition is that it would be easy to circumvent the 55-gallon limit in an SAA by moving hazardous wastes from one SAA to another SAA and thus remain below the volume limits, allowing hazardous wastes to remain in the SAA indefinitely.

In today’s rule, however, the removal of unwanted materials is based on time

primarily, and volume secondarily. Containers must be marked with the date that unwanted materials first begin to accumulate. This requirement is necessary in order to verify that unwanted materials are being removed from the laboratory on a regular basis. The requirement for a date to be associated with each container provides laboratories with additional flexibility that does not exist in SAAs. That is, under Subpart K, unwanted materials can be safely consolidated within an on-site laboratory, such as in a chemical stockroom. As with all on-site transfers of unwanted material outside of a laboratory, the transfer of unwanted materials between laboratories must be accompanied by a trained professional. Further, any laboratory in which unwanted materials are consolidated from other laboratories is subject to the time and volume limits for all laboratories that are subject to Subpart K (i.e., if the laboratory accumulates more than 55 gallons of unwanted material (or 1 quart of reactive acutely hazardous unwanted material), the unwanted material must be removed from the laboratory within 10 calendar days). In addition, the date that an unwanted material first begins to accumulate in a container would remain the same, regardless of where the container is moved. In other words, no re-dating of a container would be permitted if it were moved to another laboratory or chemical stockroom. If the contents of two or more containers with compatible materials are combined into one container; however, the earliest date associated with the original containers must be used. The date that is associated with each container will allow inspectors to verify that containers are being removed from the laboratory on a routine basis not to exceed six months, as required. The 55-gallon volume limit will ensure that large quantities of unwanted materials are not consolidated without the additional protections required at CAAs.

We envision this flexibility to be particularly useful for eligible academic entities that do not have on-site CAAs. Commenters have indicated that by consolidating their unwanted materials in a laboratory or chemical stockroom themselves prior to a vendor’s arrival, they can save money because the vendor will be able to collect unwanted materials from fewer laboratories, thus spending less time on-site. In such a situation, if an eligible academic entity (or the vendor) makes the hazardous waste determination in the laboratory, the eligible academic entity does not have to make the hazardous waste

<sup>7</sup> LQGs may accumulate hazardous waste for 90 days or less on-site without a permit or interim status, provided the provisions of § 262.34(a) (or § 262.34(g)–(i) for F006 recyclers; or § 262.34(j)–(k) for Performance Track members) are met. SQGs may accumulate hazardous waste for 180 days or less on-site without a permit or interim status, provided the provisions of § 262.34(d) and (f) are met. SQGs that must send their hazardous waste more than 200 miles for off-site treatment, storage, or disposal are allowed to accumulate hazardous waste for 270 days or less on-site without a permit or interim status, provided the provisions of § 262.34(d) and (f) are met (see § 262.34(e)).

determination when the unwanted material is removed from the first laboratory. Rather, the hazardous waste determination may be made when the unwanted material is removed from the final laboratory where the unwanted materials are consolidated, before it is sent off-site. Consolidating unwanted materials from multiple laboratories will provide another opportunity to consolidate unwanted materials that are compatible with one another, thereby allowing containers to be reused. We emphasize that trained professionals must transfer unwanted materials between laboratories and that any laboratory where unwanted materials are consolidated also is subject to the Subpart K requirements, including the time and volume limits.

#### 6. Making the Hazardous Waste Determination

One of the primary benefits that Subpart K provides over the existing generator regulations is flexibility in where and when to make the hazardous waste determination. The Agency has consistently interpreted the existing generator regulations to require that the hazardous waste determination be made at the point of generation. We now recognize that making the hazardous waste determination at the point of generation is difficult and impractical in teaching and research laboratories, because of the high number of individual wastes, the variability in such wastes, and the transient nature of those generating many of the wastes, namely students. Therefore, in Subpart K, we proposed to allow the hazardous waste determination to be made in the laboratory before the unwanted materials are removed from the laboratory, or within four calendar days of arriving at an on-site CAA or interim status or permitted TSDF. We proposed that when the hazardous waste determination is made in the laboratory, it does not have to be made at the initial time that the hazardous waste is generated, as is required under the existing generator regulations, only that it must be made before the unwanted materials are removed from the laboratory. This alternative approach ensures that the hazardous waste determination is made by a trained professional, rather than by students, who would likely lack the necessary training, and allows much greater flexibility in where and when to make the hazardous waste determination.

In general, we received favorable comments about the flexibility provided by Subpart K with regard to making the hazardous waste determination. Today, we are finalizing the regulations

pertaining to where and when the hazardous waste determination must be made with some minor changes to address the expansion of the applicability of the final rule to include eligible academic entities that are CESQGs. Eligible academic entities that are LQGs or SQGs will continue to have the choice of making the hazardous waste determination in the laboratory before the unwanted material is removed from the laboratory, or within four calendar days of arriving at an on-site CAA or interim status or permitted TSDF. Because CESQGs would not have an on-site CAA or TSDF, CESQGs are required to make the hazardous waste determination in the laboratory before the unwanted material is removed from the laboratory. See section III.C.9 of today's preamble for further discussion of how Subpart K is implemented at CESQGs.

At the time of the proposal, the Agency was aware that many smaller eligible academic entities contract with outside vendors to make the hazardous waste determination on their behalf. We expected that the smaller eligible academic entities, which do not have on-site CAAs or on-site TSDFs, would be relying on vendors to make the hazardous waste determination in the laboratory(ies) prior to the hazardous waste being brought off-site. As proposed, the regulations of Subpart K, specifically § 262.210, allowed for this scenario.

From comments, we learned that even eligible academic entities with on-site CAAs contract with vendors to make and/or confirm their hazardous waste determinations. Thus, we received many comments arguing against the requirement that the hazardous waste code(s) be placed on the container within four days of arriving at the on-site CAA because this essentially would preclude these entities from using vendors to make the hazardous waste determinations for them. These commenters believe that placing the words "hazardous waste" on the container is sufficient to indicate that a hazardous waste determination has been made and that they should be allowed to delay putting the hazardous waste code(s) on the container until the vendor comes to ship the hazardous wastes off-site.

We agree with these commenters that the practice of using vendors to make the hazardous waste determination should not be limited to those eligible academic entities that make the hazardous waste determination in the laboratory. Eligible academic entities that make the hazardous waste determination in an on-site CAA or

interim status or permitted TSDF also should be able to use vendors to assist them with their hazardous waste determination. In today's final rule, therefore, the hazardous waste determination must still be made within four calendar days of arriving at an on-site CAA or TSDF, and for those unwanted materials that are hazardous waste, the words "hazardous waste" still must be added to the label that is affixed or attached to the container within those four calendar days. However, the Agency is amending the final rule so that eligible academic entities may delay assigning the hazardous waste code(s) until immediately prior to shipping the hazardous waste(s) off-site. When containers of unwanted materials arrive at an on-site CAA, they are subject to the CAA regulations appropriate to the site's generator status, including dating of the containers to calculate the 90/180/270 days that the containers may be accumulated on-site, and the container management standards. Likewise, when containers of unwanted materials arrive at an on-site TSDF, the unwanted material becomes subject to the terms of the facility's hazardous waste permit or interim status, as soon as it arrives. Therefore, since the containers must be managed as hazardous waste upon arriving at an on-site CAA or TSDF, we believe there is no decrease in protection of human health and the environment by delaying the addition of the hazardous waste code(s). The hazardous waste code(s) are necessary for determining the LDR regulations that apply to the hazardous wastes, but do not provide additional protection while the hazardous wastes are being accumulated on-site. We emphasize that, in all cases, regardless of generator status, or where the eligible academic entity chooses to make the hazardous waste determination, the hazardous waste determination must be made on-site before the unwanted material can be treated at an on-site CAA, or treated or disposed at an on-site TSDF, or sent off-site.

Many commenters stated that four calendar days was not sufficient to make the hazardous waste determination in an on-site CAA or TSDF. However, given that (1) the hazardous waste determination is usually required to be made at the point of generation and that the Agency is providing considerable flexibility in Subpart K for where and when to make the hazardous waste determination and (2) the initial hazardous waste determination should be more straightforward without the addition of the hazardous waste code(s),

we are not providing additional time. Thus, under today's final rule, the hazardous waste determination must be made within four calendar days of arriving at an on-site CAA or TSDF. Commenters also gave various suggestions for changing "calendar" days to "working" or "business" days. We believe that this would be confusing because not everyone shares the same "working" or "business" days. By relying on "calendar" days, we are providing consistency and clarity in calculating the timeframes within the rule.

The Agency solicited comment on whether the four calendar days should be included within the 90/180/270 day timeframe allowed for accumulation in an on-site CAA or whether it should be separate from these timeframes. Most commenters preferred the proposed option of including the four calendar days for making the hazardous waste determination as part of the 90/180/270 days allowed for the on-site accumulation of hazardous wastes. They expressed this preference, in large part, to avoid additional dating of containers that would be necessary if the four days were separate from, and additional to, the 90/180/270 days of accumulation time. Therefore, under today's final rule, a container's date of arrival at an on-site CAA will be used for two purposes: (1) Calculating the four calendar days allotted for making the hazardous waste determination and (2) calculating the maximum accumulation time in the CAA.

Many commenters objected to the proposed requirement that the hazardous waste code(s) be placed on the label that is affixed to or physically accompanies the container (as previously discussed, today's final rule changes this requirement so that the label must be "affixed or attached" to the container). They pointed out that the majority of hazardous wastes generated in a laboratory are lab-packed when they are transported off-site and that putting the hazardous waste code(s) on the label that is affixed to the container, then placing the container inside of a lab pack is of no value because the hazardous waste code(s) would not be able to be seen. The commenters suggested allowing the hazardous waste code(s) to be placed on the label that is "associated with the container" rather than the label that is "affixed or physically accompanies the container." We had proposed that, as part of the hazardous waste determination, the hazardous waste code(s) must be placed on the containers within four days of arriving at an on-site CAA or interim status or permitted TSDF. In this

instance, the hazardous waste code(s) on the container label would have been visible during accumulation in an on-site CAA or storage in an on-site TSDF. However, since the final regulations have been revised so that the hazardous waste code(s) do not need to be added until just before the hazardous waste is transported off-site and since most containers will be lab-packed, we agree that placing the hazardous waste code(s) on the container label that is affixed or attached to the container provides no value. Therefore, we have revised the regulatory language in §§ 262.210(b)(2), 262.211(e)(2), and 262.212(e)(2) to allow the appropriate hazardous waste code(s) to be placed on the container label that is associated with the container. This will allow the practice of putting hazardous waste code(s) on a packing slip or inventory list for a lab pack to continue.

One commenter expressed concern about the statement in the preamble to the proposed rule (see 71 FR 29735) that, " \* \* \* regardless of whether an employee or non-employee makes the hazardous waste determination, the college or university could (emphasis added) still be responsible if the hazardous waste determination is not made correctly and for any mismanagement of hazardous waste." The commenter was concerned "that such wording could be used to contradict current RCRA requirements that the generator is always responsible for the proper waste determination regardless of who does the actual designation." We did not intend this language to suggest the potential interpretation for which the commenter expressed concern. Indeed, we agree with the commenter that making the proper hazardous waste determination is, and always has been, the responsibility of the generator (as described in 40 CFR 262.11), which in this case, would be the eligible academic entity, and did not intend to suggest otherwise.

Another commenter requested that the Agency clarify that the hazardous waste determination can be made in "any" of the three areas, rather than in "one" of the three areas identified in § 262.209(a). We agree with the commenter and have changed the regulatory language to reflect the comment. For LQs and SQGs, it is not necessary for the eligible academic entity to limit itself to making the hazardous waste determination in the same place all the time. We realize that this could change depending upon circumstances. For instance, during typical operations, an eligible academic entity may choose to make the

hazardous waste determination in its on-site CAA. However, during a laboratory clean-out, the hazardous waste determination might be made in the laboratory. Eligible academic entities that are CESQs, however, are limited by regulation to making the hazardous waste determination in the laboratory before the unwanted materials are removed from the laboratory and sent off-site.

Several commenters requested that the Agency clarify the status of chemicals or unwanted materials that can be redistributed to other laboratories. It has always been the case under existing RCRA regulations, and continues to be the case under Subpart K, that chemicals that are fit for continued use are not solid or hazardous wastes (see § 261.2(e)(1)) and can be transferred between SAAs, laboratories, and chemical stockrooms. Under Subpart K, we realize that some chemicals that are initially identified as unwanted materials will turn out not to be solid or hazardous wastes. If, for example, an unwanted material is brought to an on-site CAA or TSDF for a hazardous waste determination, and it is determined that such unwanted material can be reused, then it is not a solid or hazardous waste and is not subject to Subpart K or the Subtitle C hazardous waste regulations, once the determination is made. That is, if a chemical is initially labeled as an unwanted material and then it is subsequently discovered that it can continue to be used, the chemical can be returned to a laboratory or chemical stockroom for redistribution. EPA selected the term "unwanted material" over "laboratory waste," in part to indicate that the material may still be useable.

Sometimes laboratories end up discarding chemicals for which little or no identifying information is available. We recognize that, in some cases, chemicals will be managed in the laboratory and that when those chemicals are eventually disposed, it may not be possible to identify the chemicals. This sometimes happens when a researcher retires and leaves unlabeled chemicals behind. In addition, some laboratories synthesize new compounds as part of their research. When these "unknowns" are disposed of, it may not be possible to make a hazardous waste determination without analysis. A few commenters requested that the Agency address more specifically how to handle the hazardous waste determination for such unknown chemicals. As a result, we have added a requirement that an eligible academic entity must develop,

in Part II of its LMP, procedures for the timely and reliable characterization of unknown chemicals. See section III.C.8, of today's preamble for more detail, as well as § 262.214.

#### 7. Laboratory Clean-outs

##### a. Summary of the Proposed Laboratory Clean-out Provisions

EPA inspections and enforcement cases have revealed that used and unused chemicals that are clearly no longer useable, have in some cases remained in laboratories at academic institutions for years and even decades. Sometimes these chemicals have not been discarded because the eligible academic entity did not want to change its RCRA generator status. In fact, one of EPA's goals in promulgating Subpart K has been to provide incentives for eligible academic entities to remove such "legacy" chemicals from their laboratories. We proposed to provide two incentives for conducting voluntary laboratory clean-outs. First, we proposed that a college or university would have 30 days to conduct a laboratory clean-out. It is during a laboratory clean-out that a laboratory is most likely to accumulate more than 55 gallons of unwanted material (or 1 quart of reactive acutely hazardous unwanted material). If a laboratory accumulates more than 55 gallons, the current SAA regulations require that the excess of 55 gallons of hazardous waste (or 1 quart of acutely hazardous waste) be removed within three days. Under Subpart K, we proposed that if a laboratory accumulates more than 55 gallons of unwanted material, all unwanted material, including reactive acutely hazardous unwanted material, must be removed within ten calendar days, and if a laboratory accumulates more than 1 quart of reactive acutely hazardous unwanted material then all reactive acutely hazardous unwanted material must be removed from the laboratory within ten calendar days. In a laboratory clean-out conducted under Subpart K, however, a laboratory has 30 days from the starting date of the laboratory clean-out to complete the laboratory clean-out without being required to remove the assembled unwanted materials from the laboratory, even if the laboratory exceeds 55 gallons of unwanted material (or 1 quart of reactive acutely hazardous unwanted material). This incentive provides flexibility by giving an extension in the time allowed for removal of the unwanted material over the three days allowed in the satellite accumulation area regulations, as well as the ten days allowed in Subpart K for

unwanted materials that are routinely generated.

Second, we proposed that unwanted materials that are generated during the 30 days of a laboratory clean-out and that are hazardous wastes do not need to be counted toward the facility's generator status. However, with this "no counting" incentive, we were and remain concerned about inadvertently encouraging eligible academic entities to retain unwanted materials that are generated in the laboratory on a routine basis and to remove them only during a laboratory clean-out, thereby improperly manipulating their generator status. Two provisions in the proposal were intended to safeguard against this. First was the proposed requirement for the college or university to identify the start date of the laboratory clean-out in its records. This, in combination with the proposed labeling requirement for each container to have an accumulation start date associated with it, provides a method of verification to ensure that any container of unwanted material that has a date that pre-dates the onset of the laboratory clean-out would not be considered to be from the laboratory clean-out and the unwanted material would have to be counted toward calculating the facility's generator status, assuming it is determined to be hazardous waste. The second safeguard that was proposed was that each laboratory at an eligible academic entity could take advantage of the laboratory clean-out incentives only once per 12 month period. Given that each laboratory is required to have a regularly scheduled removal of unwanted material at least every six months, this was intended to ensure that each laboratory would have at least one regularly scheduled removal during a calendar year between laboratory clean-outs.

We received a large number of comments, covering all aspects of the laboratory clean-out provisions. In general, there was overwhelming support for the concept of the laboratory clean-out incentives, although there was opposition expressed by some commenters, as well. Based on these comments, in today's final rule, we have made some revisions to the proposed laboratory clean-out provisions. Below, we discuss the revisions to the proposed laboratory clean-out provisions, as well as the aspects of the laboratory clean-out provisions that are being finalized as proposed, and we provide clarifications regarding the laboratory clean-out provisions.

##### b. Changes Made to the Laboratory Clean-Out Provisions

Many commenters expressed support for the laboratory clean-out incentive that allowed them not to count their laboratory clean-out hazardous wastes toward their generator status. On the other hand, several commenters expressed concern that the Agency was creating a system that would encourage laboratories to hold onto their routinely generated unwanted materials until a laboratory clean-out, in order to manipulate their generator status. We share the commenters' concerns and have changed the provision of the laboratory clean-out incentive so that only laboratory clean-out hazardous wastes that are unused commercial chemical products are not counted toward the eligible academic entity's generator status. Unused commercial chemical products include chemicals that are discarded P- or U-listed commercial chemical products, and unused discarded chemicals that are hazardous waste because they exhibit one or more characteristics. Any unwanted material that has been used and is a hazardous waste must be counted toward the eligible academic entities generator status, even if it is removed during the 30-day period of a laboratory clean-out. We intend for routinely generated unwanted materials to be removed from the laboratory during regularly scheduled removals, and we expect that the bulk of these routinely generated unwanted materials will be used chemicals. We do not consider these used, routinely generated unwanted materials to be laboratory clean-out wastes and thus, they must be counted toward the eligible academic entity's generator status. Therefore, we have revised the regulatory language to be consistent with our intent and to safeguard against the potential for abuse of the laboratory clean-out incentive. This change will also emphasize that the purpose of the laboratory clean-out is to remove unneeded or unusable chemicals from the laboratory's inventory in order to increase safety within the laboratory.

We will rely on existing regulations and guidance for defining what is considered a used or unused commercial chemical product. For example, the P- or U-listings of § 261.33(e) and (f) apply only to unused commercial chemical products. Therefore, a P- or U-listed hazardous waste generated during a laboratory clean-out would not have to be counted toward the eligible academic entity's generator status, because, by definition, it would be unused. An unused

chemical that is a hazardous waste because it exhibits one or more characteristics also would not have to be counted toward the eligible academic entity's generator status if it were generated during a laboratory clean-out. In a memo dated June 14, 1990, (Bussard to Wilson, RCRA Online #11523), the Agency answered a series of specific questions relating to the definition of "used." In summary, the memo states that dissolving or diluting P- or U-listed chemicals in water, acids, bases, preservatives, or solvents to make laboratory standards (in lieu of buying such solutions) does not constitute use of these chemicals. In addition, any unused, leftover chemical (either P- or U-listed, or characteristic) in an original container, either unopened or opened, or that has been transferred to another container, such as a squirt bottle, for use would also be considered unused.

Some commenters were concerned about the possibility that as a result of the laboratory clean-out provision that allows some hazardous waste not to count toward the eligible academic entity's generator status, some eligible academic entities that are typically CESQGs but would become either SQGs or LQGs as a result of a laboratory clean-out (absent Subpart K), would be able to maintain their CESQG status. If this were the case, the commenter was concerned that hazardous wastes that should normally be managed as hazardous waste would be eligible to be disposed of in a municipal solid waste landfill, which is allowed under the CESQG regulations of § 261.5. The Agency shares the commenter's concern. In fact, in the preamble to the proposed rule we stated, "any hazardous waste that is not counted toward generator status during a laboratory clean-out is still a hazardous waste and is subject to all applicable regulations, including the land disposal regulations, and the regulations for on-site and off-site management, transportation, and treatment and disposal of hazardous waste. The incentive that the Agency is proposing to provide for hazardous wastes generated during a laboratory clean-out affects only the length of time that hazardous wastes are stored on-site and other associated regulations of 40 CFR 262.34 pertaining to generator status, such as biennial reporting and contingency plans" (see 71 FR 29739).

Nevertheless, we believe that for clarity it is appropriate to revise the regulatory language of § 262.213 to reflect the intent of the rule as stated in the preamble to the proposed rule. This is made all the more necessary by the expansion of the final rule to include

eligible academic entities that are CESQGs. If an SQG avoided LQG status as the result of a laboratory clean-out incentive, the hazardous waste would still be regulated as hazardous waste once it is taken off-site, since both SQGs and LQGs must comply with the same transportation and disposal regulations. With the inclusion of CESQGs into the final rule, however, if a CESQG avoided becoming an SQG or LQG as the result of a laboratory clean-out incentive, then potentially regulated hazardous waste would be allowed to be disposed of at a municipal solid waste landfill. Therefore, we are modifying the language of § 262.213(a)(2) to indicate that the effect of not counting hazardous wastes that are unused commercial chemical products toward the eligible academic entity's generator status is limited to the *on-site accumulation* of the hazardous waste. In tandem, we also are including a new paragraph, § 262.213(a)(3), to indicate that for the purposes of *off-site management*, if an eligible academic entity generates more than the monthly CESQG limits (i.e., >1 kg of acutely hazardous waste, or >100 kg of hazardous waste), then the eligible academic entity must manage its hazardous waste according to all applicable hazardous waste regulations for SQGs and LQGs. When determining whether these monthly limits have been exceeded, the eligible academic entity must count all of its hazardous wastes, including those generated during laboratory clean-outs. In other words, even when hazardous wastes are not counted toward the site's generator status, if they are generated in excess of the CESQG monthly limits, they are regulated as hazardous waste when they are transported, treated, stored or disposed of off-site. EPA intended to create an incentive to conduct laboratory clean-outs by relieving the generator of some of the additional burden that would be incurred by changing generator status. However, we did not intend to allow regulated hazardous waste in excess of the CESQG monthly limits to be disposed of in municipal solid waste landfills.

We illustrate how this would work by providing an example of a likely scenario. An eligible academic entity that is normally a CESQG conducts a laboratory clean-out. As a result of the laboratory clean-out, the eligible academic entity generates 5 kg of P-listed hazardous waste. Because P-listed hazardous wastes are all acute hazardous wastes, the eligible academic entity generates more than 1 kg of acute hazardous waste that month. Normally, this would mean that the eligible

academic entity would become subject to the LQG regulations for that month. However, because the laboratory clean-out provisions allow the eligible academic entity not to count the 5-kg of P-listed hazardous waste from the laboratory clean-out toward its generator status, the eligible academic entity will remain a CESQG under § 261.5 for the purposes of on-site accumulation of its hazardous waste, including the acute hazardous waste. However, once the hazardous waste is sent off-site, the eligible academic entity would not be allowed to send its hazardous waste to a non-hazardous waste facility, such as a municipal solid waste landfill, as allowed by the CESQG regulations of § 261.5. Instead, because the eligible academic entity generated acute hazardous waste in excess of the CESQG monthly limits (i.e., >1 kg acute hazardous waste), the hazardous waste would have to be managed as hazardous wastes when sent off-site. This means, for example, that the hazardous waste would have to be manifested, comply with the LDRs, and be either recycled or treated and disposed of at a hazardous waste TSDF.

A number of commenters expressed support for extending the laboratory clean-out incentives to ancillary spaces, such as stockrooms and laboratory preparatory rooms. As discussed in the preceding section on the definition of laboratory (see Section III.B.2 and § 262.200), these ancillary spaces would be considered laboratories, whether they support individual laboratories or the laboratories of a department, and thus would be eligible to take advantage of the laboratory clean-out provisions. In fact, since these ancillary areas typically store chemicals for use by nearby or surrounding laboratories, we believe the clean-out provisions are especially important for these ancillary areas.

Two commenters pointed out an inconsistency between the preamble and the regulatory text with respect to how long records of laboratory clean-outs must be kept. The preamble to the proposed rule stated that records must be kept "for as long as the college or university operates under this new subpart" (see 71 FR 29739), while the proposed regulatory text stated that records pertaining to laboratory clean-outs must be kept "for a period of three years from the date the clean-out ends." The proposed regulatory text reflects what we intended for record retention pertaining to laboratory clean-outs. Thus, the final rule makes clear that records for laboratory clean-outs must be kept for three years from the date the clean-out ends.

#### c. Changes Not Made to the Laboratory Clean-Out Provisions

Many commenters expressed support for the 30-day timeframe for conducting laboratory clean-outs, believing that 30 days is sufficient time to conduct a laboratory clean-out. About the same number of commenters, however, requested a longer timeframe for conducting laboratory clean-outs. Suggestions ranged from 60 days to 180 days. One commenter indicated that "60 days is a more reasonable length of time to arrange for and mobilize a hazardous waste contractor for on-site lab-packing services, especially if the clean-out was unexpected or the institution is in a remote location." We anticipate that in most instances, laboratory clean-outs will be planned events. Therefore, we continue to believe that 30 days is sufficient time to conduct a thorough laboratory clean-out and we are finalizing the time limit for laboratory clean-outs, as proposed.

Commenters asked the Agency when the 30 days of a laboratory clean-out would begin—while the inventory of laboratory chemicals is being sorted or when they are discarded? The definition of "laboratory clean-out" in today's final rule is:

an evaluation of the inventory of chemicals and other materials in a laboratory that are no longer needed or that have expired and the subsequent removal of those chemicals or other unwanted materials from the laboratory. A clean-out may occur for several reasons. It may be on a routine basis (e.g., at the end of a semester or academic year) or as a result of a renovation, relocation, or change in laboratory supervisor/occupant. A regularly scheduled removal of unwanted material as required by § 262.208 does not qualify as a laboratory clean-out.

Therefore, the 30 days of a laboratory clean-out starts when a trained professional or laboratory personnel begins sorting through and evaluating the inventory of laboratory chemicals, making decisions about whether they are unwanted materials or not. Once it has been determined that a chemical is, indeed, an unwanted material, as opposed to a chemical or other material that can be kept in the laboratory for further use, then the unwanted material becomes subject to the requirements of Subpart K. We realize that a laboratory clean-out can involve considerable planning before the laboratory clean-out begins. Advanced planning for a laboratory clean-out prior to sorting and evaluating a laboratory's chemical inventory is not considered the start of the 30 days allowed for a laboratory clean-out.

At the conclusion of the laboratory clean-out, all unwanted materials (or

hazardous waste, if the hazardous waste determination is made in the laboratory) must be removed from the laboratory. Note that, as with routinely generated unwanted materials, unwanted materials from a laboratory clean-out can be taken to an on-site CAA or TSDF to make the hazardous waste determination. Eligible academic entities without an on-site CAA, or on-site interim status or permitted TSDF will have to make the hazardous waste determination for unwanted materials generated during a laboratory clean-out in the laboratory before they are removed from the laboratory and will have to be prepared to send the hazardous wastes off-site at the conclusion of the 30-day clean-out.

Finally, although a few commenters suggested that the Agency require that eligible academic entities conduct laboratory clean-outs, the Agency has decided not to do so. Rather, we believe that the laboratory clean-out provisions are attractive enough to eligible academic entities such that they will avail themselves of the clean-out provisions without EPA forcing them to do so through a mandate.

#### d. Clarifications About the Laboratory Clean-Out Provisions

The Agency wants to reiterate the point that we view laboratory clean-outs to be distinct from routine, regularly scheduled removals of unwanted materials. In the course of normal laboratory operations, many chemicals are used and will become unwanted materials and ultimately may be determined to be hazardous wastes. This can occur as a result of teaching or research activities or, in the case of teaching hospitals, as a result of clinical or diagnostic activities. We expect that these routinely generated wastestreams will comprise the bulk of the unwanted materials that are removed from the laboratory during regularly scheduled removals. On the other hand, a laboratory often can accrue a large number of unused chemicals in its inventory, some of which can become dangerous over time, developing the potential to cause significant harm. It has been our observation that it is unusual for laboratories to remove unused chemicals from their inventories on any regular basis. We have developed the laboratory clean-out provisions to provide incentives for laboratories to assess their inventory and remove chemicals from the laboratory that are either dangerous or have the potential to become dangerous, or are unlikely to be used in the future, regardless of the reason. We anticipate that many eligible academic entities will

take advantage of the laboratory clean-out provisions when a researcher or faculty member retires or moves, or when a building is renovated. However, we are not limiting the use of the laboratory clean-out provisions to these events because we would like to encourage laboratories to develop the practice of more frequent reviews and removals of their unneeded or unusable chemicals. However, the laboratory clean-out incentives (i.e., having 30 days to conduct a laboratory clean-out and not counting toward the eligible academic entity's generator status the hazardous waste that consists of unused commercial chemical products) is still limited to once per laboratory per 12 month period.

Two commenters asked for clarification about the labeling and container management standards that apply to laboratory clean-out wastes. During the course of a laboratory clean-out, some chemicals will be considered unwanted materials and ultimately hazardous wastes, while others will not. Those laboratory clean-out chemicals that become unwanted materials are subject to all the same labeling and container management standards—as well as all other applicable requirements of Subpart K—as any other unwanted material in the laboratory, with the exceptions noted in § 262.213(a)(1)–(4). On the other hand, those chemicals that can continue to be used in the same laboratory would be considered products, not unwanted materials, and would not be subject to the labeling and container management standards of Subpart K. If a clean-out chemical from one laboratory can be used in a different laboratory, we can envision two probable scenarios. If the determination is made in the laboratory that a chemical can be used in another laboratory, it would not be considered an unwanted material; rather, it would be considered a product and thus not regulated under RCRA. If, on the other hand, the determination that the chemical can be used in another laboratory is made after it is removed from the laboratory, in an on-site CAA or TSDF, the clean-out chemical would be regulated as an unwanted material until it is redistributed from the CAA to another laboratory for further use.

Several commenters were concerned that if hazardous wastes generated as a result of a laboratory clean-out do not have to be counted toward the eligible academic entity's generator status, fewer generators will have to submit a BR and the result would be under-reporting of hazardous wastes from those eligible academic entities that choose to be subject to the Subpart K requirements.



We acknowledge that there may be fewer generators reporting hazardous waste generation as a result of the laboratory clean-out provisions not to count hazardous waste that consists of unused commercial chemical products toward the eligible academic entity's generator status because under the Federal regulations, only LQGs have to submit the BR. Nevertheless, we anticipate that even after subtracting laboratory clean-out wastes when calculating their generator status, many eligible academic entities will still generate enough hazardous waste to be LQGs, based on their routinely generated laboratory waste, as well as their non-laboratory hazardous wastes, in which case they will still be required to submit the BR. Moreover, some States require SQGs to submit a BR. For information on how to submit the BR with respect to hazardous wastes generated during laboratory clean-outs, see Section III.D.1.

#### 8. Laboratory Management Plan

Today's final rule requires that eligible academic entities choosing to be subject to the Subpart K requirements must develop an LMP. As EPA explained in the preamble to the proposed rule, the goal of the LMP is for a college or university to plan carefully how it is going to implement Subpart K's performance-based requirements for safely managing the unwanted materials generated in laboratories. We believe that the LMP provides a necessary supplement to the flexibility provided in this rule and will ultimately work to increase environmental performance and protection. EPA received positive feedback from commenters about requiring the LMP. Many commenters explained that requiring an LMP along with a performance-based approach will help make it possible for eligible academic entities to achieve their environmental goals, such as regulatory compliance, pollution prevention and laboratory safety.

Some commenters misinterpreted EPA's intent for the LMP. One commenter believed that each laboratory within a college or university had to develop an LMP. That is not the case at all. Rather, EPA intended that the eligible academic entity—a college or university, or non-profit research institute or teaching hospital that is owned by or has a formal written affiliation agreement with a college or university—would create one LMP for all its laboratories that are operating under Subpart K. In addition, if an eligible academic entity has multiple EPA Identification Numbers or sites, then it can develop one LMP to cover

operations for all laboratories at all sites operating under the Subpart K requirements. Also, a number of commenters suggested that an eligible academic entity should list in its LMP which laboratories would be covered under Subpart K and its LMP. The commenters go on to state that each eligible academic entity should be allowed to determine which of its laboratories will operate under Subpart K and document this in its LMP. In response, and as described earlier in the preamble, if multiple sites with separate EPA Identification Numbers operate under one LMP, the LMP must identify which sites are covered by the LMP. However, there is no requirement to identify each laboratory within each site, as all laboratories at a participating eligible academic entity within that site or covered by an EPA Identification Number must operate under Subpart K (see section III.C.1, Notification and § 262.203). Nevertheless, should an eligible academic entity choose to list all its laboratories that are participating in Subpart K, it could be a valuable tool to manage removals of unwanted material, as well as assist EPA and State inspectors in determining compliance with the Subpart K requirements.

Another commenter argued that requiring an LMP would be redundant documentation since laboratories are required to have a Chemical Hygiene Plan under OSHA's Laboratory Standard. We disagree. As the proposal clearly explained, a college or university (and now eligible academic entities) can take an existing plan, such as the Chemical Hygiene Plan and revise it to include the additional necessary information or procedures required by today's rule.

Two requirements for the LMP are remaining the same in today's final rule. First, an eligible academic entity must make its LMP "available" to laboratory workers, students, and anyone requesting the LMP at the eligible academic entity. Examples may include, but are not limited to, posting the LMP on the Web site of the participating eligible academic entity or keeping a copy of the LMP at each individual site of the eligible academic entity that is participating in Subpart K. Second, since the LMP is a document to plan how an eligible academic entity will meet the performance-based standards of Subpart K, EPA requires the LMP to be reviewed and updated, as needed, so that it is current with the waste management practices at the eligible academic entity's laboratories.

Most of the comments received about the LMP centered on the two options EPA co-proposed regarding the

enforceability of the contents of the LMP. Both proposed options required development of an LMP that addressed how the college or university would achieve the performance-based standards of the rule. The difference between the two options was in the enforceability of the contents of the LMP. Under one proposed option, compliance with the performance-based regulations was enforceable, but the contents of the LMP were not enforceable. In the other proposed option, the contents of the LMP were enforceable, as well as compliance with the performance-based regulations.

EPA received comments supporting both options. There was a strong belief from some commenters that if the EPA did not make the LMP's contents enforceable, then the LMP would not be a meaningful document and would not be followed. On the other side, commenters argued that the LMP should not be enforceable; these commenters believed that an enforceable LMP would compel colleges or universities to develop vague, minimum procedures and that an enforceable LMP would be contrary to the goals of a performance-based regulation.

Reviewing the Agency's reasons for proposing the requirement for an LMP, EPA wanted colleges and universities to give careful thought regarding the management of unwanted materials and hazardous waste generated in their laboratories. Moreover, we wanted to encourage colleges or universities to go above and beyond the regulations and to think holistically about waste management on campus by planning and developing best management practices (BMPs) in the LMP. We continue to believe strongly that the LMP is necessary in order to provide the planning component for implementing the provisions of this rule. Based on our views regarding the purpose of the LMP and the comments we received, we have decided to split the LMP into two parts—with the contents of one part enforceable and the contents of the other part not enforceable, although in order to be in compliance with Subpart K, an eligible academic entity must address all nine elements in its LMP.

Thus, under the final rule, the LMP must be comprised of two parts with a total of nine elements as specified in 40 CFR 262.214. The specific contents in Part I of the LMP are enforceable, while the specific contents in Part II of the LMP are not enforceable. Below is a discussion of the required elements in the two Parts of the LMP. If an element has remained the same as proposed, it is simply enumerated without discussion.



#### a. Part I of the LMP

As a way to incorporate more flexibility into the regulations, while maintaining the accountability in this Subpart, the contents of Part I of the LMP are enforceable. This part of the LMP contains necessary information for inspectors and other officials about what options within Subpart K the eligible academic entity is exercising. The two elements of Part I of the LMP are explained here:

1. Describe procedures for container labeling in accordance with § 262.206(a), including

i. Identifying whether the eligible academic entity will use the term “unwanted material” on the containers in the laboratory. If not, identify the equally effective term that will be used in lieu of “unwanted material” and consistently by the eligible academic entity. The equally effective term, if used, has the same meaning and is subject to the same requirements as “unwanted material.”

ii. Identifying the manner in which information that is “associated with the container” will be imparted.

The first sub-element allows flexibility in using different terminology other than “unwanted materials.” Many commenters wrote that they disliked the term “unwanted materials” because it was overbroad and would cause confusion. While we do not necessarily agree with these commenters, EPA does not object to including additional flexibility concerning the terminology that can be used in the laboratory instead of “unwanted materials.”<sup>8</sup>

However, in order for an eligible academic entity to take advantage of this option, it must identify another equally effective term (e.g., laboratory waste) in the first element of Part I of its LMP. This equally effective term must be used consistently in all of its laboratories operating under Subpart K (see Section III.C.2 and § 262.206(a)(1)(i)).

The second sub-element of the first element of Part I of the LMP in today’s final rule requires eligible academic entities to describe the manner in which information associated with the container will be provided. For example, if an eligible academic entity chooses to use barcodes and a computer tracking system to meet the requirement to have information associated with a container, it must describe this in the enforceable Part I of the LMP, so that inspectors know where the associated container information resides.

<sup>8</sup> If an eligible academic entity elects to use another equally effective term in lieu of “unwanted material,” in compliance with § 262.206(a)(1)(i), the equally effective term will have the same meaning as “unwanted material.” In addition, the equally effective term shall be subject to all of the same requirements in this rule that apply to unwanted materials.

2. Identify whether the eligible academic entity will comply with § 262.208(a)(1) or § 262.208(a)(2) for regularly scheduled removals of unwanted material from the laboratory.

In the second element of Part I of the LMP, an eligible academic entity must describe which method it will exercise for the removal of unwanted materials. Today’s final rule adds another option for the removal of unwanted materials, as described in Section III.C.5 of today’s preamble, in order to increase the flexibility for eligible academic entities. However, with the added flexibility, we require that the eligible academic entity documents which removal method it chooses to use. For example, if an eligible academic entity elects to comply with 40 CFR 262.208(a)(2), where it must remove containers of unwanted material from each laboratory within six months of each container’s accumulation start date, then the eligible academic entity must record this choice in Part I of the LMP. If the eligible academic entity elects to comply with the other approach, that must be documented in Part I of the LMP.

#### b. Part II of the LMP

As with Part I of the LMP, Part II of the LMP is required and must reasonably address the seven required elements. EPA envisions that eligible academic entities will use this section to capture BMPs for holistic waste management within laboratories. In order to encourage the development of BMPs, the specific contents of Part II of the LMP are not enforceable. For example, should an eligible academic entity explain that it will train students commensurate with their duties by showing a video, but instead provides classroom instruction because the video is broken, then the eligible academic entity is not in violation of its LMP. The following are the seven elements that an eligible academic entity must address in Part II of its LMP; discussed in the order in which they appear in the regulations.

- The first three elements of Part II of the LMP are essentially the same as proposed.

The second element includes a minor change that was necessary because of the change in the training and instruction requirements for laboratory workers and students. Under the proposed rule, training was required for laboratory workers, while instruction was required for students. Today’s final rule requires that for both laboratory workers and students, training be commensurate with their duties.

Elements one, two, and three of Part II of the LMP are below:

1. Describe its intended best practices for container labeling and management standards, including how the eligible academic entity will manage containers used for in-line collection of unwanted materials, such as with high performance liquid chromatographs and other laboratory equipment (see the required standards at § 262.206).

2. Describe its intended best practices for providing training for laboratory workers and students commensurate with their duties (see the required standard at § 262.207(a)).

3. Describe its intended best practices for providing training to ensure safe on-site transfers of unwanted material by trained professionals (see the required standard at § 262.207(d)(1)).

- The fourth element of Part II of the LMP has changed since proposal.

The fourth element of Part II of the LMP concerns the procedures of regularly removing unwanted materials from the laboratory. While EPA is not adding anything to this element, the regulatory language has been modified to clarify what the Agency intends as part of this element. That is, we have included two different types of removals of unwanted materials from laboratories—regularly scheduled removals, and removals when maximum volumes are exceeded—because they require different procedures. This clarification will ensure that an eligible academic entity develops a method to communicate with EH&S personnel or vendors when laboratories exceed the maximum volume and a pickup of the unwanted materials is needed. See the fourth element below:

4. Describe its intended best practices for removing unwanted material from the laboratory, including:

a. For regularly scheduled removals—Develop a regular schedule for identifying and removing unwanted materials from its laboratories (see the required standards at § 262.208(a)(1) and § 262.208(a)(2)).

b. For removals when maximum volumes are exceeded

A. Describe its intended best practices for removing unwanted materials from the laboratory within 10 calendar days when unwanted materials have exceeded their maximum volumes (see the required standards at § 262.208(d)).

B. Describe its intended best practices for communicating that unwanted materials have exceeded their maximum volumes.

- The fifth and sixth elements of Part II of the LMP have remained essentially the same as proposed. The second part of element six reflects one minor change. In the preamble to the proposed rule and as finalized today, one of the requirements for a laboratory clean-out is that an eligible academic entity must document its clean-out activities (see section III.D.2 or § 261.213(a)(4)). Because we are not mandating that an

eligible academic entity document its laboratory clean-out in a particular format or media, we are requiring that an eligible academic entity develop procedures for documenting it as part of element six of Part II of the LMP. See elements five and six below:

5. Describe its intended best practices for making hazardous waste determinations, including specifying the duties of the individuals involved in the process (see the required standards at § 262.11 and §§ 262.209–262.212).

6. Describe its intended best practices for laboratory clean-outs if the eligible academic entity plans to use the incentives for laboratory clean-outs provided in § 262.213, including:

a. Procedures for conducting laboratory clean-outs (see the required standards at § 262.213(a)(1)–(3)) and

b. Procedures for documenting laboratory clean-outs (see the required standards at § 262.213(a)(4)).

• The seventh element of Part II of the LMP has changed since proposal.

The seventh element has been expanded in the final rule based on several comments about the characterization of unknown chemicals and chemicals that degrade over time. The proposed rule required colleges and universities to develop emergency prevention, notification, and response procedures appropriate to the hazards in the laboratory, and the final rule keeps this requirement as the first sub-element of element seven. In comments, however, we were informed that laboratories face issues with chemicals that expire and/or become dangerous as they degrade. A good example of this is picric acid, which becomes explosive if it becomes dehydrated/crystallized. Because of the threat some chemicals may pose, the final rule requires that the seventh element of Part II of the LMP includes a list of chemicals that the eligible academic entity has or is likely to have that can degrade over time and become more dangerous with age; the list of chemicals is intended to facilitate the removal of these chemicals before a problem develops. The third sub-element requires eligible academic entities to develop procedures to dispose of these chemicals safely.

Finally, a number of commenters suggested that eligible academic entities should develop procedures in their LMPs for identifying and characterizing unknown chemicals in a timely manner. Since transporters and TSDFs often will not accept unknown chemicals, the unknown chemicals tend to remain on-site for extended periods. We agree with the commenters and believe this requirement will assist in the timely removal of these unknown chemicals and in emergency prevention for

laboratories. Thus, we have added it as the fourth sub-element of the seventh element of Part II of the LMP. See the seventh element below:

7. Describe its intended best practices for emergency prevention, including:

a. Procedures for emergency prevention, notification, and response, appropriate to the hazards in the laboratory, and

b. A list of chemicals that the eligible academic entity has, or is likely to have, that become more dangerous when they exceed their expiration date and/or as they degrade, and

c. Procedures to safely dispose of chemicals that become more dangerous when they exceed their expiration date and/or as they degrade, and

d. Procedures for the timely characterization of unknown chemicals.

In summary, an eligible academic entity must develop an LMP with two parts covering a total of nine elements. The contents of the two elements in Part I of the LMP are enforceable. Part II of the LMP is intended to encourage eligible academic entities to develop BMPs for their laboratories. While the contents of Part II of the LMP are not enforceable, eligible academic entities must reasonably address the seven required elements.

#### 9. How CESQGs Comply With Subpart K and How They Differ From LQGs and SQGs

In most respects, an eligible academic entity that opts into Subpart K is regulated the same, regardless of whether the eligible academic entity is a CESQG, SQG, or LQG. However, because CESQGs are regulated differently than SQGs and LQGs under the existing generator regulations, we have had to tailor some sections of the Subpart K requirements to reflect their inclusion. This section discusses how the Subpart K requirements will be implemented for CESQGs.

Specifically, Subpart K provides an alternative set of requirements for generators of laboratory hazardous waste. For SQGs and LQGs, Subpart K provides an alternative to §§ 262.11 and 262.34(c) (the SAA regulations). For CESQGs, however, the Subpart K requirements provide an alternative to the conditional exemption in § 261.5(b), which exempts hazardous waste from regulation under 40 CFR Parts 124, 262–266, 268, 270, and the notification requirements of RCRA section 3010, provided the CESQG complies with the conditions of the exemption. Thus, by choosing to become subject to Subpart K, an eligible academic entity relinquishes its conditionally exempt status and becomes subject to the requirements of 40 CFR part 262, Subpart K, while managing its

unwanted materials and hazardous wastes in its laboratories. However, a CESQG also will be able to take advantage of the two main benefits of the alternative standards: Making the hazardous waste determination before the unwanted materials are removed from the laboratory (but at a time after the initial generation) and the laboratory clean-out provisions.

As with other eligible academic entities, an eligible academic entity that is a CESQG and that opts into Subpart K must notify EPA of its intended participation using the Site Identification Form (EPA Form 8700–12). One of the fields on the Site Identification Form asks for the site's EPA Identification Number. We realize that most CESQGs will not have EPA Identification Numbers when they submit their notifications for Subpart K and they are not required to apply for one, although some States may choose to assign an Identification Number once a Site Identification Form is submitted. If an eligible academic entity that opts into Subpart K is a CESQG and does not have an EPA Identification Number, all of the laboratories owned by the eligible academic entity and that are on-site (as opposed to under the same EPA Identification Number) will be subject to Subpart K.

Many college and university commenters informed the Agency that they have multiple EPA Identification Numbers (or sites) within a single campus. When a campus is divided into numerous sites, each site has its own generator status, based on its monthly generation of hazardous waste. Therefore, a single campus may be comprised of sites that are CESQGs, SQGs, and LQGs. Some other commenters also indicated that they have field laboratories, which may not be on campus, that are typically CESQGs, and which may not be on campus, but that laboratory personnel often work in both the campus laboratories and the field laboratories. Commenters requesting that CESQGs be allowed to be subject to Subpart K argued that it would be to their benefit to have the same management standards for the hazardous wastes generated in all of their laboratories. The Agency agrees and is clarifying that when eligible academic entities that are CESQGs choose to be subject to the Subpart K requirements, their laboratories must follow the same container labeling, container management, training requirements and all other management standards for the management of their unwanted materials in the laboratory as other generators operating under Subpart K.

Since CESQGs will not have an on-site CAA or TSDF, CESQGs must make the hazardous waste determination in the laboratory before the unwanted materials may be removed from the laboratory (but at a time after the initial generation of the unwanted materials). We realize that a CESQG may be part of a larger "main" campus that has a CAA and that the eligible academic entity may want to bring the unwanted materials from the CESQG site to the main campus's CAA to make the hazardous waste determination. However, today's rule does not allow for this and all hazardous waste determinations must be made on-site before the unwanted material may be treated or disposed of on-site or transported off-site. Today's rule does not allow for off-site consolidation of unwanted materials or hazardous wastes, with two exceptions that are discussed in section III.C.10 of today's preamble. As discussed previously, eligible academic entities, including CESQGs, may consolidate unwanted materials on-site in another laboratory (see section III.C.5.c of today's preamble for more detail).

Once the hazardous waste determination is made in accordance with § 262.11, the eligible academic entity must count the unwanted materials that are hazardous wastes toward calculating its monthly generator status and it must remove the hazardous waste from the laboratory directly. If the total quantity of hazardous waste for the month for the site is below the CESQG limits (i.e., <1 kg of acutely hazardous waste and <100 kg of hazardous waste), the hazardous waste may be managed as CESQG hazardous waste when removed from the laboratory. That is, the hazardous waste may be managed at any of the types of facilities listed in § 261.5(f)(3) for acute hazardous waste, or § 261.5(g)(3) for hazardous waste:

- (i) Permitted under 40 CFR part 270.
- (ii) In interim status under 40 CFR parts 265 and 270.
- (iii) Authorized to manage hazardous waste by a State with a hazardous waste management program approved under 40 CFR part 271.
- (iv) Licensed, registered or permitted by the State to manage municipal solid waste, and if managed in a solid waste landfill is subject to 40 CFR part 258.
- (v) Licensed, registered or permitted by the State to manage non-municipal non-hazardous waste, and if managed in a non-municipal non-hazardous waste disposal unit is subject to 40 CFR 257.5–257.30.
- (vi) Beneficially uses, reuses, legitimately recycles or reclaims its waste; or treats its waste prior to

beneficial use, reuse, legitimate recycling or reclamation, or

- (vii) For universal waste, a universal waste handler or destination facility subject to the requirements of 40 CFR part 273.

Eligible academic entities that are CESQGs or have CESQG sites also will be able to take advantage of the laboratory clean-out provisions in the final rule. That is, CESQGs can have up to 30 days to conduct a laboratory clean-out and not be required to count hazardous wastes that are unused commercial chemical products and that are generated during a laboratory clean-out toward calculating their generator status. Thus, we believe that the laboratory clean-out incentives will now provide a considerable benefit to generators that are typically CESQGs, but become LQGs on an episodic or periodic basis when they discard unused commercial chemical products (either listed or characteristic) from their laboratories. As discussed in section III.B.7 of today's preamble, even if the laboratory clean-out incentives allow an eligible academic entity to maintain its conditionally exempt status, if the eligible academic entity generates hazardous waste in quantities in excess of the CESQG monthly limits, the hazardous waste is fully regulated as hazardous waste when it is transported, treated, stored or disposed of off-site (also see § 262.213).

#### 10. Off-site Consolidation

##### a. Off-site Consolidation by CESQGs

Several commenters suggested that the Agency allow the off-site consolidation of unwanted materials at a centralized, off-site location. These commenters generally suggested this as part of their request to expand the applicability of the final rule to include CESQGs. The current generator regulations, for any generator status, provide limited opportunities for a generator to accept off-site shipments of another generator's hazardous waste. Under both the existing generator regulations, as well as under today's final rule, there are two situations that allow for a generator to receive hazardous waste from another, off-site generator.

The first situation applies to the off-site consolidation of hazardous waste generated only by CESQGs. Under § 261.5, in order to qualify as a CESQG, a CESQG must ensure delivery of its acute hazardous waste and hazardous waste to one of the seven types of facilities listed in § 261.5(f)(3) and 261.5(g)(3):

- (i) Permitted under 40 CFR part 270.

(ii) In interim status under 40 CFR Parts 265 and 270.

(iii) Authorized to manage hazardous waste by a State with a hazardous waste management program approved under 40 CFR part 271.

(iv) Licensed, registered or permitted by the State to manage municipal solid waste, and if managed in a solid waste landfill is subject to 40 CFR part 258.

(v) Licensed, registered or permitted by the State to manage non-municipal non-hazardous waste, and if managed in a non-municipal non-hazardous waste disposal unit is subject to 40 CFR 257.5 through 257.30.

(vi) Beneficially uses, reuses, legitimately recycles or reclaims its waste; or treats its waste prior to beneficial use, reuse, legitimate recycling or reclamation, or

(vii) For universal waste, a universal waste handler or destination facility subject to the requirements of 40 CFR part 273.

If a CESQG that generates hazardous waste wants to send its hazardous waste to an off-site consolidation area for centralized collection, it must send its hazardous waste to a collection site that would qualify as one of the above mentioned facilities in order to still qualify as a CESQG. Thus, a receiving generator could be an acceptable collection site if it qualified as one of the seven categories of facilities above. For example, a CESQG could send its hazardous waste to an eligible academic entity if such receiving entity was an interim status or permitted TSDF or was authorized by the State to manage hazardous waste under the State approved program. If the CESQG that generates hazardous waste sends it to another generator that does not qualify as one of the facilities specified above, the generating CESQG would not meet the conditions of the CESQG exemption and would be subject to the applicable generator regulations of 40 CFR part 262 (see Q&A dated April 4, 1987; RCRA Online #12894).

##### b. Off-site Consolidation by CESQGs, SQGs, and LQGs

The second situation applies to all generator categories. A generator can send its hazardous waste to another generator's site if the receiving site qualifies as a transfer facility (see Q&A dated April 4, 1987; RCRA Online #12894). Under § 263.12, hazardous waste may be stored in containers at a transfer facility for ten days or less without requiring interim status or a permit. A transfer facility is defined in 40 CFR 260.10 as " \* \* \* any transportation related facility including loading docks, parking areas, storage

areas, and other similar areas where shipments of hazardous waste are held during the normal course of transportation." It is possible that a generator may qualify as a transfer facility, as long as the hazardous waste it receives is not stored on-site for more than ten days. As stated previously, the hazardous waste determination must be made for all unwanted materials prior to transporting them off-site, regardless of whether the off-site transportation includes a stop at a transfer facility.

#### 11. Topics That Are Outside the Purview of This Rulemaking

EPA has consistently interpreted our existing hazardous waste regulations to allow generators to non-thermally treat the hazardous waste they generate on-site in their accumulation tanks and containers, without needing to obtain a RCRA permit or having interim status (51 FR 10168, March 24, 1986). Examples of treatment that may be conducted in accumulation tanks and containers without a permit or interim status include precipitating heavy metals from solutions and oxidation/reduction reactions. A permit or interim status would be required to store and/or treat hazardous waste that is consolidated from off-site locations or if the treatment was thermal treatment.

Many commenters suggested that the Subpart K requirements should specifically address treatment of hazardous waste by generators in laboratories. In the proposal to Subpart K, the Agency did not specifically identify a regulatory approach for the treatment of hazardous waste by generators in laboratories. Therefore, because the Agency did not provide notice and an opportunity for public comment on this subject, it is outside the scope of this rulemaking and EPA does not intend to add any such provisions to the final rule. While today's final rule does not specifically address the treatment of hazardous waste in laboratories, it also does not change EPA's interpretation of its existing regulations.

We have also often been informed, and commenters confirmed, that it is not uncommon for an eligible academic entity to have numerous EPA Identification Numbers per "campus." Typically, this is because the campus is intersected by public roads so that not all areas of the campus are considered "on-site," as defined by RCRA. We received several comments encouraging EPA to allow a single EPA Identification Number per campus. We did not specifically identify in the proposal to Subpart K a regulatory approach for allowing one EPA Identification

Number per campus. Therefore, because the Agency did not provide notice and an opportunity for public comment on this subject, it is outside the scope of this rulemaking and EPA does not intend to add any such provisions to the final rule.

#### D. Reporting and Recordkeeping

##### 1. Reporting to the Biennial Report for Eligible Academic Entities That Are LQGs

Under the existing generator regulations, LQGs are required to submit information about their hazardous waste generation and management activities in the BR. The data are prepared and submitted to the EPA Regions (or authorized States) in even-numbered years (e.g., 2006) and must include waste information from the previous, odd-numbered year (e.g., 2005). The data submitted for the BR is retained in the RCRAInfo System. When developing rulemakings, the Agency often relies on data submitted for the BR to inform us about various aspects of the hazardous waste activities, such as identifying generators of hazardous wastes and waste generation and management activities (i.e., number of hazardous waste generators and volume of hazardous waste being generated and managed). When analyzing data in the RCRAInfo System to support the development of this rulemaking, it became clear to the Agency that there are a variety of ways in which similar entities with similar hazardous waste generation patterns report data for the BR. The Agency recognizes the differences in reporting may be situational; however, we offer suggestions here for reporting future laboratory hazardous waste activities to the BR that will assist the Agency in analyzing data in a more consistent and accurate manner.

On the Generation and Management (GM) form of the BR, we suggest the use of the Source Code G22 (Laboratory analytical wastes (used chemicals from laboratory operations)) would be appropriate in most cases for hazardous wastes that are generated in the laboratory and that are not from a laboratory clean-out. When G22 is not applicable, but the hazardous wastes are generated in a laboratory, the generator should indicate in the comment field (when provided by the State) that the hazardous waste originated in a laboratory. In addition, the Form Codes W001 (Lab packs from any source not containing acute hazardous waste) and W004 (Lab packs from any source containing acute hazardous waste) should be used when applicable.

If an eligible academic entity submits a BR that includes hazardous waste from laboratory clean-outs, the Agency's guidance on preparing the GM Form of the BR is to use the Source Code G11, for the discarding of off-specification or out-of-date chemicals or products. If the State's version of the GM form provides a comment section, we suggest the eligible academic entity indicate that the hazardous waste is from a Subpart K laboratory clean-out.

##### 2. Recordkeeping

Today's final rule requires that eligible academic entities choosing to comply with the Subpart K requirements maintain certain records. Specifically, eligible academic entities must maintain the following records: (1) Notification(s) to the appropriate EPA Regional Administrator (or State Director, in authorized States) of its participation in or subsequent withdrawal from Subpart K (using the EPA Site Identification Form (EPA Form 8700-12)); (2) non-profit research institutes and teaching hospitals that are not owned by a college or university must keep the formal written affiliation agreement on file; (3) training records for laboratory workers defined in 40 CFR 262.200 of this Subpart at participating LQG eligible academic entities; (4) documentation of laboratory clean-out activities identifying the laboratory being cleaned out, the date the clean-out begins and is completed, and the volume of hazardous waste generated during the clean-out that is conducted in accordance with § 262.213; and (5) an LMP (an existing plan may be modified to address the specific requirements of this alternative regulation).

EPA is not requiring that a participating eligible academic entity keep all required records, such as notifications, training records, formal written affiliation agreements and the LMP together. However, EPA believes filing all required records together, if practicable, may enhance the ease of accessibility by those individuals needing access to the records at any given time. Additionally, having the records located in one central location may help increase efficiency of inspections by reducing the amount of time expended to locate records that may be kept in several different locations at a participating institution (e.g., training records might normally be filed with personnel files and the LMP might normally be kept at the EH&S department).

EPA is requiring that an eligible academic entity maintain a copy of its notification to participate in this

Subpart on file in-house (i.e., at the participating eligible academic entity) for the duration that the institution remains subject to the Subpart K requirements. Additionally, an eligible academic entity must maintain a copy of its notification to withdraw from Subpart K on file for three years from the date of the notification of withdrawal from the Subpart K requirements.

Because of the expansion in scope of today's final rule, the Agency has added recordkeeping for teaching hospitals and non-profit research institutes, as defined in the final rule. In order to document that a non-profit research institute or a teaching hospital is eligible to opt into Subpart K, the non-profit research institute or teaching hospital must keep on file for the duration that the institution remains subject to the Subpart K requirements a copy of the formal written affiliation agreement that it has with the college or university. For a teaching hospital, the formal written affiliation agreement must consist of a master affiliation agreement and program letter of agreement with the medical college or school with which it is affiliated.

We reiterate that today's final rule does not change the existing recordkeeping requirements for documenting training of trained professionals at LQGs. Under the existing hazardous waste generator regulations, LQGs must comply with the recordkeeping requirements found at 40 CFR 265.16(e). Since this rule simply refers to the existing applicable training requirements pertaining to an eligible academic entity's generator status, training records for trained professionals (i.e., individuals conducting the hazardous waste determination or transferring unwanted materials on-site) must be maintained at LQGs. SQG training requirements at 40 CFR 262.34(d)(5)(iii) do not require retention of training records; therefore, Subpart K does not require training records to be kept for trained professionals at SQGs. Likewise, training records are not required for trained professionals at CESQGs. Furthermore, training records for students are not required for LQGs, SQGs or CESQGs.

In addition, as proposed, today's final rule requires that LQG eligible academic entities maintain documentation that demonstrates that laboratory workers have been trained commensurate with their duties. As with trained professionals, these records must be kept for the duration specified in § 265.16(e). Thus, these training records must be kept until the institution closes

or for three years after the departure of a trained professional or laboratory worker.

Additionally, as proposed, today's final rule includes a recordkeeping provision for laboratory clean-out events at participating eligible academic entities. Section 262.213(a)(4) of today's rule requires eligible academic entities to document their clean-out activities. EPA is not mandating a particular record format or media. Instead, participating institutions may determine the most appropriate type of record that best suits their individual capabilities and recordkeeping systems (e.g., filed hard copy, electronic copy). However, the documentation must contain certain information and be retained at the eligible academic entity for three years from the date the laboratory clean-out ends. Specifically, this documentation must identify the particular laboratory that is being cleaned out, the date the clean-out began and ended, and the volume of hazardous waste generated during the clean-out. This documentation is particularly relevant since a laboratory may only utilize the laboratory clean-out provision incentives (i.e., not counting hazardous wastes that are unused commercial chemical products toward its generator status and the 30-day allowance for removal) once per 12-month period per laboratory.

Also, EPA is requiring that a copy of a participating eligible academic entity's LMP be retained on file at the participating institution for the duration that it is regulated under 40 CFR part 262, Subpart K. Furthermore, we recommend that the LMP be dated. While EPA is not requiring that a copy of the LMP at a participating eligible academic entity be kept at each individual site with a unique EPA Identification Number that has opted in, we do require that the LMP is "available" by anyone involved in the management of unwanted materials (e.g., students in the laboratory, faculty, inspectors and other relevant regulatory authorities). The participating eligible academic entity will determine how best to meet the requirements of making the LMP available since EPA envisions that an LMP will be revised periodically. Examples of "available" may include, but are not limited to, posting the LMP on the participating eligible academic entities Web site or other universally accessible electronic system, or keeping a copy of the LMP at each individual site that has opted in.

Today's rule strives to reduce or minimize additional recordkeeping requirements on eligible academic entities participating in Subpart K. As

an example, we believe some participating eligible academic entities will revise their current required planning documents, such as the Chemical Hygiene Plan (CHP), which is required by OSHA's Laboratory Standard regulations at 29 CFR 1910.1450. In such cases, there would be minimal additional recordkeeping associated with an LMP. However, we also understand that this may not be true in all cases. When planning documents don't already exist, an additional recordkeeping requirement would be associated with maintaining an LMP since eligible academic entities will need to develop this document to comply with this Subpart.

We solicited comment on whether there should be a requirement to retain records of the labels associated with containers. The information on the label associated with containers, such as the accumulation start date and information sufficient to make a hazardous waste determination, was assumed to be either electronic, via spreadsheets and bar codes, or written logs and in the proposed rule EPA considered requiring that this information be retained on file as a record. However, commenters noted that records of container labels should not be retained because it would be too burdensome and unnecessary. We agree with the commenters and believe that other recordkeeping requirements sufficiently document the information necessary for inspections of laboratories at eligible academic entities. Therefore, the final rule does not require that records be kept for labeling information associated with containers, beyond the time that a hazardous waste determination is made for the contents.

EPA also solicited comment in the proposal on whether maintenance of any other records or reporting requirements should be required under today's Subpart K regulations for purposes of improving implementation, compliance monitoring and assistance by the relevant regulatory authority or for program implementation. Comments submitted by the academic community stated, "do not add recordkeeping." These comments noted that the proposed recordkeeping or documentation requirements for notification, labeling, laboratory clean-outs and the LMP are sufficient to ensure compliance and measure success. We agree with these commenters that additional recordkeeping or reporting requirements beyond what was included in the proposal are unnecessary to ensure compliance with today's rule. Therefore, in today's final rule, we are not including any new or additional

recordkeeping or reporting requirements to the final rule.

#### *E. Implementation and Enforcement*

Subpart K blends traditional regulatory requirements with performance-based standards to maximize flexibility and enable better environmental compliance at eligible academic entities. Subpart K also offers greater flexibility in implementation than the existing generator requirements. As such, we are highlighting some points on compliance for a few of the more flexible requirements of Subpart K.

First, only eligible academic entities, as defined in this final rule, may participate in Subpart K. As this rule is optional, eligible academic entities must at all times comply with either the existing generator regulations or with today's Subpart K requirements. Specifically, under today's final rule, an eligible academic entity must decide under which set of standards (existing generator standards or Subpart K) it will operate all of its laboratories that are covered by the same EPA Identification Number (or that are on-site) and notify EPA if it chooses to opt into Subpart K. Eligible academic entities may have several sites with unique EPA Identification Numbers, and each site may have laboratories. It is important to note that eligible academic entities operating laboratories with different EPA Identification Numbers may elect which laboratories will opt into or withdraw from Subpart K on a site-by-site basis.

Second, since this rule is for laboratories only, it is likely that participating eligible academic entities will be subject to two different sets of requirements for hazardous waste management: 40 CFR part 262, Subpart K for unwanted materials generated in its laboratories, and existing generator requirements for all other hazardous wastes generated at these institutions. As a result, implementers (eligible academic entities and compliance and enforcement individuals) will need to determine whether the laboratories at an eligible academic entity are operating under Subpart K (i.e., under different generator regulations) from the remainder of the site for compliance monitoring and assistance.

Third, because the enforcement of the contents of the LMP differs for Part I and Part II, and participating entities may modify an existing plan to meet the LMP requirements, we reiterate the requirements relating to the different parts below (see preamble section III.C.8 or § 262.214 of today's final rule for all requirements related to the LMP). We

also remind eligible academic entities that if they choose to modify an existing plan in order to meet the LMP requirements under Subpart K, today's rule does not supersede or otherwise affect the requirements related to that existing plan.

For Part I of the LMP, the eligible academic entity must implement and comply with the specific contents for all the elements they develop for Part I. For example, if an eligible academic entity chooses to use another "equally effective term" for "unwanted material," then it must identify the term in Part I of its LMP and must use this equally effective term consistently. In addition, the equally effective term is subject to all requirements of this rule that apply to unwanted materials. If the eligible academic entity uses another term, but fails to identify the equally effective term in Part I of its LMP, or uses a different term not identified in Part I of its LMP, then the eligible academic entity would be considered in violation of Subpart K.

While an eligible academic entity's LMP must include, and reasonably address, the required elements in Part II of its LMP, if the eligible academic entity does not meet or implement the specific contents of the elements in Part II of its LMP, an enforcement action would not be brought against it for such deviations. For example, an eligible academic entity must describe in Part II of its LMP how it will provide training for laboratory workers and students commensurate with their duties. If the institution describes a training program that specifies the number of hours of classroom training for laboratory workers or students in its LMP, but they receive either a different number of hours, or a different type of training, such as video instruction, the participating institution would not be in violation of Subpart K, provided the laboratory workers and students are trained commensurate with their duties.

Finally, today's rule would not affect a participating eligible academic entity's obligation to respond promptly to any releases of hazardous wastes that may occur, including releases of unwanted materials in the laboratory. Any management of released unwanted material not in compliance with applicable Federal and State hazardous waste requirements could result in an enforcement action. For example, if a spill or release of hazardous waste occurred and was not immediately cleaned up, the participating eligible academic entity could potentially be subject to enforcement for illegal disposal of the hazardous waste. In addition, solid and hazardous waste

releases could potentially be addressed through enforcement orders, such as orders under RCRA sections 3013 and 7003.

#### **IV. State Authorization**

##### *A. Applicability of Rules in Authorized States*

Under section 3006 of RCRA, EPA may authorize a qualified State to administer its own hazardous waste programs within the State in lieu of the Federal program. Following authorization, EPA retains enforcement authority under Sections 3008, 3013, and 7003 of RCRA, although authorized States have primary enforcement responsibility. The standards and requirements for State authorization are found at 40 CFR part 271.

Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final RCRA authorization administered its hazardous waste program entirely in lieu of EPA administering the Federal program in that State. The Federal requirements no longer applied in the authorized State, and EPA could not issue permits for any facilities in that State, since only the State was authorized to issue RCRA permits. When new, more stringent Federal requirements were promulgated, the State was obligated to enact equivalent authorities within specified time frames. However, the new Federal requirements did not take effect in an authorized State until the State adopted the Federal requirements as State law.

In contrast, under RCRA section 3006(g) (42 U.S.C. 6926(g)), which was added by HSWA, new requirements and prohibitions imposed under HSWA authority take effect in authorized States at the same time that they take effect in unauthorized States. EPA is directed by the statute to implement these requirements and prohibitions in authorized States, including the issuance of permits, until the State is granted authorization to do so. While States must still adopt HSWA related provisions as State law to retain final authorization, EPA implements the HSWA provisions in authorized States until the States do so.

Authorized States are required to modify their programs only when EPA enacts Federal requirements that are more stringent or broader in scope than the existing Federal requirements. RCRA section 3009 allows the States to impose standards more stringent than those in the Federal program (see also 40 CFR 271.1). Therefore, authorized States may, but are not required to, adopt Federal regulations, both HSWA

and non-HSWA, that are considered less stringent than previous Federal regulations.

#### B. Effect on State Authorization

Today's rule finalizes regulations that are not being promulgated under the authority of HSWA. Thus, the standards finalized today would be applicable on the effective date only in those States that do not have final authorization of their base RCRA programs. Moreover, authorized States are required to modify their programs only when EPA promulgates Federal regulations that are more stringent or broader in scope than the authorized State regulations. For those changes that are less stringent or reduce the scope of the Federal program, States are not required to modify their program. This is a result of section 3009 of RCRA, which allows States to impose more stringent regulations than the Federal program. However, today's final rule is considered to be neither more nor less stringent than the current standards. Therefore, authorized States would not be required to modify their programs to adopt regulations consistent with and equivalent to today's standards. Nevertheless, because EPA believes that today's rule will increase the ability of eligible academic entities to comply with the RCRA hazardous waste generator regulations which would likely lead to greater environmental protection, EPA strongly encourages States to adopt today's rule. Eligible academic entities located in authorized States wishing to be subject to Subpart K do not have this option until their State has adopted the final rule.

### V. Statutory and Executive Order Reviews

#### A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action is a "significant regulatory action" since this action may raise novel legal or policy issues [3(f)(4)]. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866. Any changes made in response to OMB recommendations have been documented in the docket for this action.

This rule is projected to result in benefits to society in the form of cost savings. The aggregate cost savings for all eligible academic entities that are projected to take advantage of the final rule is estimated to be \$396,000 per year. This figure is significantly below

the \$100 million threshold<sup>9</sup> established under part 3(f)(1) of the Order. Thus, this rule is not considered to be an "economically significant action." However, in an effort to comply with the spirit of the Executive Order, we have prepared an economic assessment in support of today's action. This document is entitled: *Assessment of Potential Costs, Benefits and Other Impacts for the Revised Standards Applicable to Generators of Hazardous Waste; Subpart K—Laboratories Owned by Eligible Academic Entities*. This document is otherwise referred to as the "Economic Assessment." The docket established for today's rulemaking maintains a copy of this *Economic Assessment* for public review. For a more detailed discussion regarding the comments received on the economic assessment for the proposed rule, refer to the Response to Comments Document which can be found in the docket for today's final rule.

#### 1. Introduction to the Economic Assessment for the Final Rule

The value of any regulatory action is traditionally measured by the net change in social welfare that it generates. The Agency's economic assessment conducted as part of EPA's obligations under Executive Order 12866 evaluates costs, cost savings (benefits), waste quantities affected, and other impacts, such as environmental justice, children's health, unfunded mandates, regulatory takings, and small entity impacts. To conduct this analysis, we prepared a baseline characterization, developed and implemented a methodology for examining impacts, and followed appropriate guidelines and procedures for examining equity considerations, children's health, and other impacts.

#### 2. Baseline Specification

Proper baseline specification is vital to the accurate assessment of incremental costs, benefits, and other economic impacts associated with any rulemaking. The baseline essentially describes the world absent today's final rulemaking. The incremental impacts of today's final rule are evaluated by assessing anticipated post-rule responses with respect to baseline conditions and actions. The baseline, as applied in this analysis, reflects the practices and requirements of eligible academic entities under the existing hazardous waste generator regulations. A full discussion of the baseline

specification is presented in the *Economic Assessment*.

#### 3. Analytical Methodology, Primary Data Sources, and Key Assumptions

The first step in the methodology for the economic assessment of today's final rule was to use data from EPA's 2005 *National Biennial Report* database and other sources to estimate the number of eligible academic entities that generate laboratory hazardous wastes and may be affected by the final rule. Several of the comments submitted to EPA expressed concern that in the proposed rule, EPA underestimated the fraction of hazardous waste generated in teaching and research laboratories at colleges and universities compared to total hazardous waste generated at colleges and universities. In contrast to the 9 percent estimate used by EPA for its economic analysis for the proposed rule, these commenters stated that in their experience, laboratory hazardous waste represents a much larger portion (60 to 95 percent) of a college or university's total hazardous waste stream. Several commenters provided detailed data on their hazardous waste generation especially laboratory hazardous waste. To address this concern, a more refined methodology for estimating the quantity of hazardous waste generated by laboratories at eligible academic entities was developed. For more details about the methodology changes, see section III.A.1 of today's preamble or the economic assessment for today's final rule.

Since today's final rule is equally as stringent as the existing Federal hazardous waste regulations, authorized States are not required to adopt Subpart K. Thus, once the number of eligible academic entities was determined, for purposes of the rule's *Economic Assessment*, EPA estimated how many States would adopt Subpart K. EPA assumed that States which have historically adopted at least 85 percent of RCRA's rule changes over a five-year period will adopt Subpart K. Thus, 29 States and Puerto Rico are projected to adopt today's final rule, while 21 States are assumed to not adopt today's rule.

In order to model the various scenarios at eligible academic entities, we employed four factors to categorize eligible academic entities: institution type, laboratory system size, hazardous waste generator status, and whether an eligible academic entity operates a CAA. Using these categorizations, the *Economic Assessment* examines the costs and savings of this rule's new requirements, such as recordkeeping, reporting, training, laboratory clean-outs, etc., compared to the existing

<sup>9</sup> The \$100 million threshold applies to both costs, and cost savings.



hazardous waste generator requirements, to determine the net overall cost or cost savings of Subpart K which includes all of these factors.

Finally, a specific annualized before-tax cost analysis was conducted for each affected entity. Before-tax incremental compliance costs were used because they represent a resource or social cost of the rulemaking. A discount rate (real rate of return) of 7 percent was used covering the estimated period of service or life of the product. All costs are adjusted to year 2008 dollars using the Implicit Price Deflator for Gross Domestic Product.

#### 4. Key Analytical Limitations

The Agency was not able to complete a formal RCRA Section 3007 survey of laboratories at colleges and universities, and non-profit research institutes and teaching hospitals that are either owned by or have a formal written affiliation agreement with a college or university. Consequently, for this assessment, it was necessary to rely on publicly available data. The key analytical limitations associated with these data are briefly summarized in the bullets below. Additional limitations and assumptions related to the economic analysis are discussed in more detail in the *Economic Assessment*.

- The analysis relies heavily on information generated in 2005 through a survey by NACUBO and, while this survey represents the best available source of data, the facilities captured by the survey may not be representative of the colleges and universities impacted by the rule.

- This analysis relies on BR data which includes hazardous waste quantity data for a limited number of SQGs and CESQGs. Thus, the number of entities within the universe of potentially eligible academic entities is uncertain.

- Data were not available to estimate the number of laboratories at non-profit research institutes and teaching hospitals. College and university data and Web-based internet information were used to estimate the number of laboratories at these sites.

- The cost impact analysis is very sensitive to the number and size of containers requiring labeling in the laboratory. The analysis assumes that one-third of the containers are pint-size, one-third are quart-size and one-third are gallon-size.

- An eligible academic entity can develop a single LMP that can cover all its laboratories regardless of whether they are located in sites with separate EPA Identification Numbers. Data limitations prevented us from

determining which sites generating laboratory hazardous waste may choose to operate under the same LMP.

#### 5. Findings

The findings presented here reflect a number of analytical assumptions and limitations, as touched on above, and as described in more detail in the *Economic Assessment*. Furthermore, we have analyzed additional scenarios and conducted sensitivity analyses that are not presented in today's preamble. Readers wanting to gain a full understanding of our analytical methodology, data, findings, assumptions, and limitations are encouraged to read the *Economic Assessment* document prepared in support of this final rule.

In summary, we have identified a total of 1,580 facilities in operation in the U.S., which generate laboratory hazardous wastes and are eligible academic entities as defined under today's rulemaking. Of this total, 397 are LQGs, 759 are SQGs, and the remaining 424 are CESQGs. However as stated above, we assume the States which have historically adopted at least 85 percent of RCRA's rule changes over a five-year period will adopt Subpart K; thus the universe of eligible academic entities located in these States is 169 LQGs, 323 SQGs and 181 CESQGs (673 facilities in total). Out of this number of eligible academic entities located in the States that adopt Subpart K, we assumed for this analysis that eligible academic entities that experience cost savings by opting into Subpart K will be the only eligible academic entities that participate in the final rule. Thus, the final rule would provide annual aggregate net cost savings of approximately \$396,000. These savings would be realized by the estimated 112 eligible academic entities that we project would choose to operate under Subpart K. The greatest savings would accrue to the 25 LQGs projected to elect to be regulated under Subpart K; the analysis estimates average annual cost savings of approximately \$12,200 per LQG opting into the rule. Lesser savings would be realized by the 87 SQGs that are projected to elect to be regulated under Subpart K; for each SQG opting into Subpart K, we estimate average annual cost savings of approximately \$1,000. Under this *Economic Assessment*, all CESQG eligible academic entities demonstrated cost increases by operating under Subpart K, so we assumed that CESQGs would not opt into the final rule. Overall, average annual savings for eligible academic entities operating under Subpart K are

estimated at approximately \$3,500 per entity.

An important benefit of Subpart K for some eligible academic entities will be the opportunity to maintain their typical RCRA generator status because of today's rule's laboratory clean-out provisions (see § 262.213). Eligible academic entities that are able to maintain their normal generator status rather than episodically increasing their generator status by generating laboratory clean-out waste can realize savings in reporting, planning, and overall administrative costs when operating under Subpart K. Another significant portion of the cost savings achieved reflects a reduction in the number of off-site hazardous waste shipments, thereby reducing shipment costs, particularly among colleges, universities, and research institutes that are able to maintain their typical generator status from LQG to SQG as a result of the laboratory clean-out provisions. Such a change allows for longer accumulation times and increased efficiencies in the number of laboratories visited per day for entities without CAAs, in order to remove unwanted materials. In addition to reduced shipments, much of the benefits of the rule include reduced costs for on-site travel. This largely reflects the stipulation that a hazardous waste determination for unwanted material in the laboratory may occur at any time before it is removed from the laboratory or within four days of arrival at an on-site CAA or TSDF, unlike the existing generator regulations that stipulate that the hazardous waste determination must be made at the point of generation.

The overall goal of today's action is to promote environmental protection and public health through safer management of laboratory hazardous waste at eligible academic entities. The Agency has not monetized or quantitatively estimated the human health or environmental benefits. However, this rule is expected to result in numerous environmental benefits. The structured nature of the LMP is expected to result in safer laboratory practices and increased awareness of hazardous waste management. This will minimize exposure of humans and the environment to hazardous wastes. Ultimately, LMPs are expected to improve the way eligible academic entities coordinate and integrate their hazardous waste management activities and enhance awareness about proper laboratory waste handling techniques. In addition to the LMP, the rule specifies streamlined, yet cost-neutral training requirements that are expected to increase awareness of waste hazards



and so reduce the potential for mismanagement of the hazardous waste generated in laboratories. Also, the Agency included incentives in today's final rule to encourage more frequent laboratory clean-outs of unwanted and unused reagents, thus reducing the potential for accidental releases of these chemicals into the environment. Further, EPA expects to see a benefit from allowing CESQGs to opt into the rule, because those hazardous wastes generated above CESQGs' monthly volume limits during a laboratory clean-out will be managed within the Subtitle C system, as opposed to being managed as a non-hazardous waste. Finally, we anticipate additional non-quantified economic gains through improved hazardous waste management practices, waste minimization, and waste coordination activities.

#### *B. Paperwork Reduction Act*

The information collection requirements in this final rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by EPA has been assigned EPA ICR Number 2317.01.

The Paperwork Reduction Act requires that EPA estimate the burden (time, effort, financial resources) on respondents to comply with all actions that involve the collection of information, such as recordkeeping, reporting, or disclosure requirements or other information collection activities required by this rulemaking. Below is a description of the information collection activities required by today's rulemaking.

Since this rule establishes an alternative set of hazardous waste generator requirements for eligible academic entities' laboratories, it is important that EPA or the authorized States know to which set of regulations an eligible academic entity is subject. Therefore, EPA has determined at 40 CFR 262.203 and 262.204 that it is necessary to require an eligible academic entity to submit a notification to the EPA Regional Administrator (or State Director in authorized States) indicating that it is electing to be subject to or withdrawing from Subpart K for all laboratories under the same EPA Identification Number (or on the same site, in the absence of an EPA Identification Number). The Site Identification Form must be used by eligible academic entities to notify the appropriate authority of its participation in or withdrawal from Subpart K. Under 40 CFR 262.206, 262.208, 262.10,

262.11, and 262.12 of Subpart K, an eligible academic entity must label containers of unwanted materials, as specified. These labeling requirements are necessary to: Demonstrate compliance with Subpart K, alert individuals handling the containers of their contents to ensure proper management, assist trained professionals in making the hazardous waste determination and assigning the appropriate hazardous code(s), ensure emergency responders can quickly ascertain and assess the contents of a container in case of an emergency, and utilize for enforcement and monitoring purposes.

Part 40 CFR 262.207 of Subpart K requires training, commensurate with duties, for all students and laboratory workers working in a laboratory. This training is necessary to ensure that unwanted materials are handled safely and in an environmentally sound manner and in compliance with Subpart K. In addition, eligible academic entities that are LQGs must maintain the training records for laboratory workers.

Under 40 CFR 262.313, eligible academic entities must develop and maintain documentation of laboratory clean-outs to ensure compliance with Subpart K. Also under 40 CFR 262.214, eligible academic entities are required to develop, implement and maintain an LMP to document their practices for complying with the performance-based requirements of Subpart K.

Section 3007(b) of RCRA and 40 CFR part 2, Subpart B, defines EPA's general policy on public disclosure of information, and contains provisions for confidentiality. However, the Agency does not anticipate that eligible academic entities will assert any claims of confidentiality in association with the final rule. If such a claim were asserted, EPA must and will treat the information in accordance with the regulations cited above. EPA also will assure that this information collection complies with the Privacy Act of 1974 and OMB Circular 108.

According to the estimates provided in the ICR for this final rule, the average annual incremental burden of new paperwork requirements to respondents as a result of today's final rule is approximately 12,557 hours and \$461,632. These estimates are a total net burden to respondents meaning that the burden relief to eligible academic entities under the existing regulations was subtracted from the new paperwork requirements of Subpart K. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal

agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The Agency received one consolidated comment representing six commenters on the ICR for the proposed rule. The comment on burden estimates focused on the notification requirement for Subpart K. In general, the commenters believe the burden estimates for notifying the appropriate authority of an eligible academic entity's decision to opt into or out of Subpart K (see §§ 262.203 and 262.204) were fairly accurate and supported use of the Site Identification Form as the mechanism to be used for notification. The comment specifically stated, “\* \* \* burden for the college to notify appears to be accurate and would be the same regardless of whether a letter or Site Identification Form is used. However, the burden for the implementer for clerical time should be cut in half, from 0.5 to 0.25.” In addition the comment stated, “\* \* \* the proposed notification requirement discussed on **Federal Register** notice page 29727 under section B.3 could be met by using the Site Identification Form (EPA form 8700-12).” A vast majority of the comments received supported the use of the Site Identification Form over the use of a letter for notification purposes. Thus, the Agency has chosen to finalize the requirement for eligible academic entities to use the Site Identification Form for notification.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9. When this ICR is approved by OMB, the Agency will publish a technical amendment to 40 CFR part 9 in the **Federal Register** to display the OMB control number for the approved information collection requirements contained in this final rule.

### C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act, or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

The RFA provides default definitions for each type of small entity. Small entities are defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. Under the final rule, no small eligible academic entities are projected to adopt the regulation unless they expect to experience a net decrease in costs associated with managing their laboratory hazardous waste. Based on these findings, we do not believe that this rule will result in significant economic impacts on a substantial number of small entities.

### D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, Local, and Tribal governments and the private sector. Under § 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, Local, and Tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, Section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives

of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's final rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, Local, or Tribal governments or the private sector. The UMRA generally excludes from the definition of "Federal intergovernmental mandate," duties that arise from participation in a voluntary Federal program. This rule is a voluntary program because the States are not required to adopt these requirements as a condition of authorization (or otherwise). Furthermore, EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, Local, and Tribal governments, in the aggregate, or the private sector in any one year. The total net benefits (cost savings) of this action are estimated to be \$396,000 per year. Finally, EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments.

### E. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and Local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" are defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and

responsibilities among the various levels of government."

Today's rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in the Order. The rule focuses on a set of alternative generator requirements for eligible academic entities generating laboratory hazardous wastes, without affecting the relationships between Federal and State governments. Thus, Executive Order 13132 does not apply to this rule.

### F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by Tribal officials in the development of regulatory policies that have Tribal implications." This final rule does not have Tribal implications, as specified in Executive Order 13175. EPA has concluded that this rule may have Tribal implications only to the extent that qualifying academic institutions could be affected if they have laboratories that are in some way affiliated with Tribal lands. However, this rule will neither impose substantial direct compliance costs on Tribal governments nor preempt Tribal law.

EPA did not consult directly with representatives of Tribal governments in the process of developing this rule. However, EPA did conduct an extensive outreach process with States and potentially affected entities. Furthermore, we received no comments from any Tribal governments on the proposed rule. Thus, we believe we have captured the concerns that would have been expressed by representatives of Tribal governments.

### G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria,

the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

Today's final rule is not subject to the Executive Order because it is not economically significant and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

*H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Usage*

This rule is not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)) because it is not an economically significant action under Executive Order 12866. This rule will not seriously disrupt energy supply, distribution patterns, prices, imports or exports. Furthermore, this rule is designed to improve economic efficiency by streamlining the management of laboratory hazardous wastes.

*I. National Technology Transfer and Advancement Act*

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104-113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

*J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

Executive Order 12898 (59 FR 7629 (Feb. 16, 1994)) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent

practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. This final action is designed to ensure more effective and efficient management of laboratory hazardous wastes.

*K. Congressional Review Act*

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A Major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective December 31, 2008.

**List of Subjects**

*40 CFR Part 261*

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

*40 CFR Part 262*

Environmental protection, Exports, Hazardous materials transportation, Hazardous waste, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

Dated: November 18, 2008.

**Stephen L. Johnson,**  
*Administrator.*

■ For the reasons set out in the preamble, Parts 261 and 262 of title 40, chapter I of the Code of Federal Regulations are amended as follows:

**PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE**

■ 1. The authority citation for part 261 continues to read as follows:

**Authority:** 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y), and 6938.

■ 2. Section 261.5 is amended by removing the period at the end of paragraph (c)(6) and adding in its place a "semicolon" and by adding paragraph (c)(7) to read as follows:

**§ 261.5 Special requirements for hazardous waste generated by conditionally exempt small quantity generators.**

\* \* \* \* \*

(c) \* \* \*

(7) Is a hazardous waste that is an unused commercial chemical product (listed in 40 CFR part 261, subpart D or exhibiting one or more characteristics in 40 CFR part 261, subpart C) that is generated solely as a result of a laboratory clean-out conducted at an eligible academic entity pursuant to § 262.213. For purposes of this provision, the term eligible academic entity shall have the meaning as defined in § 262.200 of Part 262.

\* \* \* \* \*

**PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE**

■ 3. The authority citation for part 262 continues to read as follows:

**Authority:** 42 U.S.C. 6906, 6912, 6922–6925, 6937, and 6938.

**Subpart A—General**

■ 4. Section 262.10 is amended by adding paragraph (l) to read as follows:

**§ 262.10 Purpose, scope, and applicability.**

\* \* \* \* \*

(l) The laboratories owned by an eligible academic entity that chooses to be subject to the requirements of Subpart K of this part are not subject to (for purposes of this paragraph, the terms "laboratory" and "eligible academic entity" shall have the meaning as defined in § 262.200 of Subpart K of this part):

(1) The requirements of § 262.11 or § 262.34(c), for large quantity generators and small quantity generators, except as provided in Subpart K, and

(2) The conditions of § 261.5(b), for conditionally exempt small quantity generators, except as provided in Subpart K.

■ 5. Part 262 is amended by adding Subpart K to read as follows:

**Subpart K—Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities**

Sec.

262.200 Definitions for this subpart.

262.201 Applicability of this subpart.

262.202 This subpart is optional.

- 262.203 How an eligible academic entity indicates it will be subject to the requirements of this subpart.
- 262.204 How an eligible academic entity indicates it will withdraw from the requirements of this subpart.
- 262.205 Summary of the requirements of this subpart.
- 262.206 Labeling and management standards for containers of unwanted material in the laboratory.
- 262.207 Training.
- 262.208 Removing containers of unwanted material from the laboratory.
- 262.209 Where and when to make the hazardous waste determination and where to send containers of unwanted material upon removal from the laboratory.
- 262.210 Making the hazardous waste determination in the laboratory before the unwanted material is removed from the laboratory.
- 262.211 Making the hazardous waste determination at an on-site central accumulation area.
- 262.212 Making the hazardous waste determination at an on-site interim status or permitted treatment, storage or disposal facility.
- 262.213 Laboratory clean-outs.
- 262.214 Laboratory management plan.
- 262.215 Unwanted material that is not solid or hazardous waste.
- 262.216 Non-laboratory hazardous waste generated at an eligible academic entity.

**Subpart K—Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities**

**§ 262.200 Definitions for this subpart.**

The following definitions apply to this subpart:

*Central accumulation area* means an on-site hazardous waste accumulation area subject to either § 262.34(a) (or 262.34(j) and (k) for Performance Track members) of this part (large quantity generators); or § 262.34(d)–(f) of this part (small quantity generators). A central accumulation area at an eligible academic entity that chooses to be subject to this subpart must also comply with § 262.211 when accumulating unwanted material and/or hazardous waste.

*College/University* means a private or public, post-secondary, degree-granting, academic institution, that is accredited by an accrediting agency listed annually by the U.S. Department of Education.

*Eligible academic entity* means a college or university, or a non-profit research institute that is owned by or has a formal written affiliation agreement with a college or university, or a teaching hospital that is owned by or has a formal written affiliation agreement with a college or university.

*Formal written affiliation agreement* for a non-profit research institute means a written document that establishes a relationship between institutions for the purposes of research and/or education and is signed by authorized representatives, as defined by § 260.10, from each institution. A relationship on a project-by-project or grant-by-grant basis is not considered a formal written affiliation agreement. A *formal written affiliation agreement* for a teaching hospital means a master affiliation agreement and program letter of agreement, as defined by the Accreditation Council for Graduate Medical Education, with an accredited medical program or medical school.

*Laboratory* means an area owned by an eligible academic entity where relatively small quantities of chemicals and other substances are used on a non-production basis for teaching or research (or diagnostic purposes at a teaching hospital) and are stored and used in containers that are easily manipulated by one person. Photo laboratories, art studios, and field laboratories are considered laboratories. Areas such as chemical stockrooms and preparatory laboratories that provide a support function to teaching or research laboratories (or diagnostic laboratories at teaching hospitals) are also considered laboratories.

*Laboratory clean-out* means an evaluation of the inventory of chemicals and other materials in a laboratory that are no longer needed or that have expired and the subsequent removal of those chemicals or other unwanted materials from the laboratory. A clean-out may occur for several reasons. It may be on a routine basis (e.g., at the end of a semester or academic year) or as a result of a renovation, relocation, or change in laboratory supervisor/occupant. A regularly scheduled removal of unwanted material as required by § 262.208 does not qualify as a laboratory clean-out.

*Laboratory worker* means a person who handles chemicals and/or unwanted material in a laboratory and may include, but is not limited to, faculty, staff, post-doctoral fellows, interns, researchers, technicians, supervisors/managers, and principal investigators. A person does not need to be paid or otherwise compensated for his/her work in the laboratory to be considered a laboratory worker. Undergraduate and graduate students in a supervised classroom setting are not laboratory workers.

*Non-profit research institute* means an organization that conducts research as its primary function and files as a non-

profit organization under the tax code of 26 U.S.C. 501(c)(3).

*Reactive acutely hazardous unwanted material* means an unwanted material that is one of the acutely hazardous commercial chemical products listed in § 261.33(e) for reactivity.

*Teaching hospital* means a hospital that trains students to become physicians, nurses or other health or laboratory personnel.

*Trained professional* means a person who has completed the applicable RCRA training requirements of § 265.16 for large quantity generators, or is knowledgeable about normal operations and emergencies in accordance with § 262.34(d)(5)(iii) for small quantity generators and conditionally exempt small quantity generators. A trained professional may be an employee of the eligible academic entity or may be a contractor or vendor who meets the requisite training requirements.

*Unwanted material* means any chemical, mixtures of chemicals, products of experiments or other material from a laboratory that is no longer needed, wanted or usable in the laboratory and that is destined for hazardous waste determination by a trained professional. Unwanted materials include reactive acutely hazardous unwanted materials and materials that may eventually be determined not to be solid waste pursuant to § 261.2, or a hazardous waste pursuant to § 261.3. If an eligible academic entity elects to use another equally effective term in lieu of “unwanted material,” as allowed by § 262.206(a)(1)(i), the equally effective term has the same meaning and is subject to the same requirements as “unwanted material” under this subpart.

*Working container* means a small container (i.e., two gallons or less) that is in use at a laboratory bench, hood, or other work station, to collect unwanted material from a laboratory experiment or procedure.

**§ 262.201 Applicability of this subpart.**

(a) Large quantity generators and small quantity generators. This subpart provides alternative requirements to the requirements in §§ 262.11 and 262.34(c) for the hazardous waste determination and accumulation of hazardous waste in laboratories owned by eligible academic entities that choose to be subject to this subpart, provided that they complete the notification requirements of § 262.203.

(b) Conditionally exempt small quantity generators. This subpart provides alternative requirements to the conditional exemption in § 261.5(b) for

the accumulation of hazardous waste in laboratories owned by eligible academic entities that choose to be subject to this subpart, provided that they complete the notification requirements of § 262.203.

**§ 262.202 This subpart is optional.**

(a) Large quantity generators and small quantity generators: Eligible academic entities have the option of complying with this subpart with respect to its laboratories, as an alternative to complying with the requirements of §§ 262.11 and 262.34(c).

(b) Conditionally exempt small quantity generators. Eligible academic entities have the option of complying with this subpart with respect to its laboratories, as an alternative to complying with the conditional exemption of § 261.5(b).

**§ 262.203 How an eligible academic entity indicates it will be subject to the requirements of this subpart.**

(a) An eligible academic entity must notify the appropriate EPA Regional Administrator in writing, using the RCRA Subtitle C Site Identification Form (EPA Form 8700–12), that it is electing to be subject to the requirements of this subpart for all the laboratories owned by the eligible academic entity under the same EPA Identification Number. An eligible academic entity that is a conditionally exempt small quantity generator and does not have an EPA Identification Number must notify that it is electing to be subject to the requirements of this subpart for all the laboratories owned by the eligible academic entity that are on-site, as defined by § 260.10. An eligible academic entity must submit a separate notification (Site Identification Form) for each EPA Identification Number (or site, for conditionally exempt small quantity generators) that is electing to be subject to the requirements of this subpart, and must submit the Site Identification Form before it begins operating under this subpart.

(b) When submitting the Site Identification Form, the eligible academic entity must, at a minimum, fill out the following fields on the form:

- (1) Reason for Submittal.
- (2) Site EPA Identification Number (except for conditionally exempt small quantity generators).
- (3) Site Name.
- (4) Site Location Information.
- (5) Site Land Type.
- (6) North American Industry Classification System (NAICS) Code(s) for the Site.
- (7) Site Mailing Address.
- (8) Site Contact Person.

(9) Operator and Legal Owner of the Site.

(10) Type of Regulated Waste Activity.

(11) Certification.

(c) An eligible academic entity must keep a copy of the notification on file at the eligible academic entity for as long as its laboratories are subject to this subpart.

(d) A teaching hospital that is not owned by a college or university must keep a copy of its formal written affiliation agreement with a college or university on file at the teaching hospital for as long as its laboratories are subject to this subpart.

(e) A non-profit research institute that is not owned by a college or university must keep a copy of its formal written affiliation agreement with a college or university on file at the non-profit research institute for as long as its laboratories are subject to this subpart.

**§ 262.204 How an eligible academic entity indicates it will withdraw from the requirements of this subpart.**

(a) An eligible academic entity must notify the appropriate EPA Regional Administrator in writing, using the RCRA Subtitle C Site Identification Form (EPA Form 8700–12), that it is electing to no longer be subject to the requirements of this subpart for all the laboratories owned by the eligible academic entity under the same EPA Identification Number and that it will comply with the requirements of §§ 262.11 and 262.34(c) for small quantity generators and large quantity generators. An eligible academic entity that is a conditionally exempt small quantity generator and does not have an EPA Identification Number must notify that it is withdrawing from the requirements of this subpart for all the laboratories owned by the eligible academic entity that are on-site and that it will comply with the conditional exemption in § 261.5(b). An eligible academic entity must submit a separate notification (Site Identification Form) for each EPA Identification Number (or site, for conditionally exempt small quantity generators) that is withdrawing from the requirements of this subpart and must submit the Site Identification Form before it begins operating under the requirements of §§ 262.11 and 262.34(c) for small quantity generators and large quantity generators, or § 261.5(b) for conditionally exempt small quantity generators.

(b) When submitting the Site Identification Form, the eligible academic entity must, at a minimum, fill out the following fields on the form:

- (1) Reason for Submittal.

(2) Site EPA Identification Number (except for conditionally exempt small quantity generators).

(3) Site Name.

(4) Site Location Information.

(5) Site Land Type.

(6) North American Industry Classification System (NAICS) Code(s) for the Site.

(7) Site Mailing Address.

(8) Site Contact Person.

(9) Operator and Legal Owner of the Site.

(10) Type of Regulated Waste Activity.

(11) Certification.

(c) An eligible academic entity must keep a copy of the withdrawal notice on file at the eligible academic entity for three years from the date of the notification.

**§ 262.205 Summary of the requirements of this subpart.**

An eligible academic entity that chooses to be subject to this subpart is not required to have interim status or a RCRA Part B permit for the accumulation of unwanted material and hazardous waste in its laboratories, provided the laboratories comply with the provisions of this subpart and the eligible academic entity has a Laboratory Management Plan (LMP) in accordance with § 262.214 that describes how the laboratories owned by the eligible academic entity will comply with the requirements of this subpart.

**§ 262.206 Labeling and management standards for containers of unwanted material in the laboratory.**

An eligible academic entity must manage containers of unwanted material while in the laboratory in accordance with the requirements in this section.

(a) Labeling: Label unwanted material as follows:

(1) The following information must be affixed or attached to the container:

(i) The words “unwanted material” or another equally effective term that is to be used consistently by the eligible academic entity and that is identified in Part I of the Laboratory Management Plan, and

(ii) Sufficient information to alert emergency responders to the contents of the container. Examples of information that would be sufficient to alert emergency responders to the contents of the container include, but are not limited to:

(A) The name of the chemical(s),

(B) The type or class of chemical, such as organic solvents or halogenated organic solvents.

(2) The following information may be affixed or attached to the container, but

must at a minimum be associated with the container:

(i) The date that the unwanted material first began accumulating in the container, and

(ii) Information sufficient to allow a trained professional to properly identify whether an unwanted material is a solid and hazardous waste and to assign the proper hazardous waste code(s), pursuant to § 262.11. Examples of information that would allow a trained professional to properly identify whether an unwanted material is a solid or hazardous waste include, but are not limited to:

(A) The name and/or description of the chemical contents or composition of the unwanted material, or, if known, the product of the chemical reaction,

(B) Whether the unwanted material has been used or is unused,

(C) A description of the manner in which the chemical was produced or processed, if applicable.

(b) Management of Containers in the Laboratory: An eligible academic entity must properly manage containers of unwanted material in the laboratory to assure safe storage of the unwanted material, to prevent leaks, spills, emissions to the air, adverse chemical reactions, and dangerous situations that may result in harm to human health or the environment. Proper container management must include the following:

(1) Containers are maintained and kept in good condition and damaged containers are replaced, overpacked, or repaired, and

(2) Containers are compatible with their contents to avoid reactions between the contents and the container; and are made of, or lined with, material that is compatible with the unwanted material so that the container's integrity is not impaired, and

(3) Containers must be kept closed at all times, except:

(i) When adding, removing or consolidating unwanted material, or

(ii) A working container may be open until the end of the procedure or work shift, or until it is full, whichever comes first, at which time the working container must either be closed or the contents emptied into a separate container that is then closed, or

(iii) When venting of a container is necessary.

(A) For the proper operation of laboratory equipment, such as with in-line collection of unwanted materials from high performance liquid chromatographs, or

(B) To prevent dangerous situations, such as build-up of extreme pressure.

#### **§ 262.207 Training.**

An eligible academic entity must provide training to all individuals working in a laboratory at the eligible academic entity, as follows:

(a) Training for laboratory workers and students must be commensurate with their duties so they understand the requirements in this subpart and can implement them.

(b) An eligible academic entity can provide training for laboratory workers and students in a variety of ways, including, but not limited to:

(1) Instruction by the professor or laboratory manager before or during an experiment; or

(2) Formal classroom training; or

(3) Electronic/written training; or

(4) On-the-job training; or

(5) Written or oral exams.

(c) An eligible academic entity that is a large quantity generator must maintain documentation for the durations specified in § 265.16(e) demonstrating training for all laboratory workers that is sufficient to determine whether laboratory workers have been trained. Examples of documentation demonstrating training can include, but are not limited to, the following:

(1) Sign-in/attendance sheet(s) for training session(s); or

(2) Syllabus for training session; or

(3) Certificate of training completion; or

(4) Test results.

(d) A trained professional must:

(1) Accompany the transfer of unwanted material and hazardous waste when the unwanted material and hazardous waste is removed from the laboratory, and

(2) Make the hazardous waste determination, pursuant to § 262.11, for unwanted material.

#### **§ 262.208 Removing containers of unwanted material from the laboratory.**

(a) Removing containers of unwanted material on a regular schedule. An eligible academic entity must either:

(1) Remove all containers of unwanted material from each laboratory on a regular interval, not to exceed 6 months; or

(2) Remove containers of unwanted material from each laboratory within 6 months of each container's accumulation start date.

(b) The eligible academic entity must specify in Part I of its Laboratory Management Plan whether it will comply with paragraph (a)(1) or (a)(2) of this section for the regular removal of unwanted material from its laboratories.

(c) The eligible academic entity must specify in Part II of its Laboratory Management Plan how it will comply

with paragraph (a)(1) or (a)(2) of this section and develop a schedule for regular removals of unwanted material from its laboratories.

(d) Removing containers of unwanted material when volumes are exceeded.

(1) If a laboratory accumulates a total volume of unwanted material (including reactive acutely hazardous unwanted material) in excess of 55 gallons before the regularly scheduled removal, the eligible academic entity must ensure that all containers of unwanted material in the laboratory (including reactive acutely hazardous unwanted material):

(i) Are marked on the label that is associated with the container (or on the label that is affixed or attached to the container, if that is preferred) with the date that 55 gallons is exceeded; and

(ii) Are removed from the laboratory within 10 calendar days of the date that 55 gallons was exceeded, or at the next regularly scheduled removal, whichever comes first.

(2) If a laboratory accumulates more than 1 quart of reactive acutely hazardous unwanted material before the regularly scheduled removal, then the eligible academic entity must ensure that all containers of reactive acutely hazardous unwanted material:

(i) Are marked on the label that is associated with the container (or on the label that is affixed or attached to the container, if that is preferred) with the date that 1 quart is exceeded; and

(ii) Are removed from the laboratory within 10 calendar days of the date that 1 quart was exceeded, or at the next regularly scheduled removal, whichever comes first.

#### **§ 262.209 Where and when to make the hazardous waste determination and where to send containers of unwanted material upon removal from the laboratory.**

(a) Large quantity generators and small quantity generators—an eligible academic entity must ensure that a trained professional makes a hazardous waste determination, pursuant to § 262.11, for unwanted material in any of the following areas:

(1) In the laboratory before the unwanted material is removed from the laboratory, in accordance with § 262.210;

(2) Within 4 calendar days of arriving at an on-site central accumulation area, in accordance with § 262.211; and

(3) Within 4 calendar days of arriving at an on-site interim status or permitted treatment, storage or disposal facility, in accordance with § 262.212.

(b) Conditionally exempt small quantity generators—an eligible academic entity must ensure that a trained professional makes a hazardous

waste determination, pursuant to § 262.11, for unwanted material in the laboratory before the unwanted material is removed from the laboratory, in accordance with § 262.210.

**§ 262.210 Making the hazardous waste determination in the laboratory before the unwanted material is removed from the laboratory.**

If an eligible academic entity makes the hazardous waste determination, pursuant to § 262.11, for unwanted material in the laboratory, it must comply with the following:

(a) A trained professional must make the hazardous waste determination, pursuant to § 262.11, before the unwanted material is removed from the laboratory.

(b) If an unwanted material is a hazardous waste, the eligible academic entity must:

(1) Write the words “hazardous waste” on the container label that is affixed or attached to the container, before the hazardous waste may be removed from the laboratory; and

(2) Write the appropriate hazardous waste code(s) on the label that is associated with the container (or on the label that is affixed or attached to the container, if that is preferred) before the hazardous waste is transported off-site.

(3) Count the hazardous waste toward the eligible academic entity’s generator status, pursuant to § 261.5(c) and (d), in the calendar month that the hazardous waste determination was made.

(c) A trained professional must accompany all hazardous waste that is transferred from the laboratory(ies) to an on-site central accumulation area or on-site interim status or permitted treatment, storage or disposal facility.

(d) When hazardous waste is removed from the laboratory:

(1) Large quantity generators and small quantity generators must ensure it is taken directly from the laboratory(ies) to an on-site central accumulation area, or on-site interim status or permitted treatment, storage or disposal facility, or transported off-site.

(2) Conditionally exempt small quantity generators must ensure it is taken directly from the laboratory(ies) to any of the types of facilities listed in § 261.5(f)(3) for acute hazardous waste, or § 261.5(g)(3) for hazardous waste.

(e) An unwanted material that is a hazardous waste is subject to all applicable hazardous waste regulations when it is removed from the laboratory.

**§ 262.211 Making the hazardous waste determination at an on-site central accumulation area.**

If an eligible academic entity makes the hazardous waste determination,

pursuant to § 262.11, for unwanted material at an on-site central accumulation area, it must comply with the following:

(a) A trained professional must accompany all unwanted material that is transferred from the laboratory(ies) to an on-site central accumulation area.

(b) All unwanted material removed from the laboratory(ies) must be taken directly from the laboratory(ies) to the on-site central accumulation area.

(c) The unwanted material becomes subject to the generator accumulation regulations of § 262.34(a) (or § 262.34(j) and (k) for Performance Track members) for large quantity generators or § 262.34(d)–(f) for small quantity generators as soon as it arrives in the central accumulation area, except for the “hazardous waste” labeling requirements of § 262.34(a)(3) (or § 262.34(j)(6) for Performance Track members).

(d) A trained professional must determine, pursuant to § 262.11, if the unwanted material is a hazardous waste within 4 calendar days of the unwanted materials’ arrival at the on-site central accumulation area.

(e) If the unwanted material is a hazardous waste, the eligible academic entity must:

(1) Write the words “hazardous waste” on the container label that is affixed or attached to the container, within 4 calendar days of arriving at the on-site central accumulation area and before the hazardous waste may be removed from the on-site central accumulation area, and

(2) Write the appropriate hazardous waste code(s) on the container label that is associated with the container (or on the label that is affixed or attached to the container, if that is preferred) before the hazardous waste may be treated or disposed of on-site or transported off-site, and

(3) Count the hazardous waste toward the eligible academic entity’s generator status, pursuant to § 261.5(c) and (d) in the calendar month that the hazardous waste determination was made, and

(4) Manage the hazardous waste according to all applicable hazardous waste regulations.

**§ 262.212 Making the hazardous waste determination at an on-site interim status or permitted treatment, storage or disposal facility.**

If an eligible academic entity makes the hazardous waste determination, pursuant to § 262.11, for unwanted material at an on-site interim status or permitted treatment, storage or disposal facility, it must comply with the following:

(a) A trained professional must accompany all unwanted material that is transferred from the laboratory(ies) to an on-site interim status or permitted treatment, storage or disposal facility.

(b) All unwanted material removed from the laboratory(ies) must be taken directly from the laboratory(ies) to the on-site interim status or permitted treatment, storage or disposal facility.

(c) The unwanted material becomes subject to the terms of the eligible academic entity’s hazardous waste permit or interim status as soon as it arrives in the on-site treatment, storage or disposal facility.

(d) A trained professional must determine, pursuant to § 262.11, if the unwanted material is a hazardous waste within 4 calendar days of the unwanted materials’ arrival at an on-site interim status or permitted treatment, storage or disposal facility.

(e) If the unwanted material is a hazardous waste, the eligible academic entity must:

(1) Write the words “hazardous waste” on the container label that is affixed or attached to the container (or on the label that is affixed or attached to the container, if that is preferred) within 4 calendar days of arriving at the on-site interim status or permitted treatment, storage or disposal facility and before the hazardous waste may be removed from the on-site interim status or permitted treatment, storage or disposal facility, and

(2) Write the appropriate hazardous waste code(s) on the container label that is associated with the container (or on the label that is affixed or attached to the container, if that is preferred) before the hazardous waste may be treated or disposed of on-site or transported off-site, and

(3) Count the hazardous waste toward the eligible academic entity’s generator status, pursuant to § 261.5(c) and (d) in the calendar month that the hazardous waste determination was made, and

(4) Manage the hazardous waste according to all applicable hazardous waste regulations.

**§ 262.213 Laboratory clean-outs.**

(a) One time per 12 month period for each laboratory, an eligible academic entity may opt to conduct a laboratory clean-out that is subject to all the applicable requirements of this subpart, except that:

(1) If the volume of unwanted material in the laboratory exceeds 55 gallons (or 1 quart of reactive acutely hazardous unwanted material), the eligible academic entity is not required to remove all unwanted materials from the laboratory within 10 calendar days



of exceeding 55 gallons (or 1 quart of reactive acutely hazardous unwanted material), as required by § 262.208. Instead, the eligible academic entity must remove all unwanted materials from the laboratory within 30 calendar days from the start of the laboratory clean-out; and

(2) For the purposes of on-site accumulation, an eligible academic entity is not required to count a hazardous waste that is an unused commercial chemical product (listed in 40 CFR part 261, subpart D or exhibiting one or more characteristics in 40 CFR part 261, subpart C) generated solely during the laboratory clean-out toward its hazardous waste generator status, pursuant to § 261.5(c) and (d). An unwanted material that is generated prior to the beginning of the laboratory clean-out and is still in the laboratory at the time the laboratory clean-out commences must be counted toward hazardous waste generator status, pursuant to § 261.5(c) and (d), if it is determined to be hazardous waste; and

(3) For the purposes of off-site management, an eligible academic entity must count all its hazardous waste, regardless of whether the hazardous waste was counted toward generator status under paragraph (a)(2) of this section, and if it generates more than 1 kg/month of acute hazardous waste or more than 100 kg/month of hazardous waste (i.e., the conditionally exempt small quantity generator limits of § 261.5), the hazardous waste is subject to all applicable hazardous waste regulations when it is transported off-site; and

(4) An eligible academic entity must document the activities of the laboratory clean-out. The documentation must, at a minimum, identify the laboratory being cleaned out, the date the laboratory clean-out begins and ends, and the volume of hazardous waste generated during the laboratory clean-out. The eligible academic entity must maintain the records for a period of three years from the date the clean-out ends; and

(b) For all other laboratory clean-outs conducted during the same 12-month period, an eligible academic entity is subject to all the applicable requirements of this subpart, including, but not limited to:

(1) The requirement to remove all unwanted materials from the laboratory within 10 calendar days of exceeding 55 gallons (or 1 quart of reactive acutely hazardous unwanted material), as required by § 262.208; and

(2) The requirement to count all hazardous waste, including unused hazardous waste, generated during the laboratory clean-out toward its

hazardous waste generator status, pursuant to § 261.5(c) and (d).

#### **§ 262.214 Laboratory management plan.**

An eligible academic entity must develop and retain a written Laboratory Management Plan, or revise an existing written plan. The Laboratory Management Plan is a site-specific document that describes how the eligible academic entity will manage unwanted materials in compliance with this subpart. An eligible academic entity may write one Laboratory Management Plan for all the laboratories owned by the eligible academic entity that have opted into this subpart, even if the laboratories are located at sites with different EPA Identification Numbers. The Laboratory Management Plan must contain two parts with a total of nine elements identified in paragraphs (a) and (b) of this section. In Part I of its Laboratory Management Plan, an eligible academic entity must describe its procedures for each of the elements listed in paragraph (a) of this section. An eligible academic entity must implement and comply with the specific provisions that it develops to address the elements in Part I of the Laboratory Management Plan. In Part II of its Laboratory Management Plan, an eligible academic entity must describe its best management practices for each of the elements listed in paragraph (b) of this section. The specific actions taken by an eligible academic entity to implement each element in Part II of its Laboratory Management Plan may vary from the procedures described in the eligible academic entity's Laboratory Management Plan, without constituting a violation of this subpart. An eligible academic entity may include additional elements and best management practices in Part II of its Laboratory Management Plan if it chooses.

(a) The eligible academic entity must implement and comply with the specific provisions of Part I of its Laboratory Management Plan. In Part I of its Laboratory Management Plan, an eligible academic entity must:

(1) Describe procedures for container labeling in accordance with § 262.206(a), including:

(i) Identifying whether the eligible academic entity will use the term "unwanted material" on the containers in the laboratory. If not, identify an equally effective term that will be used in lieu of "unwanted material" and consistently by the eligible academic entity. The equally effective term, if used, has the same meaning and is subject to the same requirements as "unwanted material."

(ii) Identifying the manner in which information that is "associated with the container" will be imparted.

(2) Identify whether the eligible academic entity will comply with § 262.208(a)(1) or (a)(2) for regularly scheduled removals of unwanted material from the laboratory.

(b) In Part II of its Laboratory Management Plan, an eligible academic entity must:

(1) Describe its intended best practices for container labeling and management, including how the eligible academic entity will manage containers used for in-line collection of unwanted materials, such as with high performance liquid chromatographs and other laboratory equipment (see the required standards at § 262.206).

(2) Describe its intended best practices for providing training for laboratory workers and students commensurate with their duties (see the required standards at § 262.207(a)).

(3) Describe its intended best practices for providing training to ensure safe on-site transfers of unwanted material and hazardous waste by trained professionals (see the required standards at § 262.207(d)(1)).

(4) Describe its intended best practices for removing unwanted material from the laboratory, including:

(i) For regularly scheduled removals—Develop a regular schedule for identifying and removing unwanted materials from its laboratories (see the required standards at § 262.208(a)(1) and (a)(2)).

(ii) For removals when maximum volumes are exceeded:

(A) Describe its intended best practices for removing unwanted materials from the laboratory within 10 calendar days when unwanted materials have exceeded their maximum volumes (see the required standards at § 262.208(d)).

(B) Describe its intended best practices for communicating that unwanted materials have exceeded their maximum volumes.

(5) Describe its intended best practices for making hazardous waste determinations, including specifying the duties of the individuals involved in the process (see the required standards at § 262.11 and §§ 262.209 through 262.212).

(6) Describe its intended best practices for laboratory clean-outs, if the eligible academic entity plans to use the incentives for laboratory clean-outs provided in § 262.213, including:

(i) Procedures for conducting laboratory clean-outs (see the required standards at § 262.213(a)(1) through (3)); and

(ii) Procedures for documenting laboratory clean-outs (see the required standards at § 262.213(a)(4)).

(7) Describe its intended best practices for emergency prevention, including:

(i) Procedures for emergency prevention, notification, and response, appropriate to the hazards in the laboratory; and

(ii) A list of chemicals that the eligible academic entity has, or is likely to have, that become more dangerous when they exceed their expiration date and/or as they degrade; and

(iii) Procedures to safely dispose of chemicals that become more dangerous when they exceed their expiration date and/or as they degrade; and

(iv) Procedures for the timely characterization of unknown chemicals.

(c) An eligible academic entity must make its Laboratory Management Plan

available to laboratory workers, students, or any others at the eligible academic entity who request it.

(d) An eligible academic entity must review and revise its Laboratory Management Plan, as needed.

**§ 262.215 Unwanted material that is not solid or hazardous waste.**

(a) If an unwanted material does not meet the definition of solid waste in § 261.2, it is no longer subject to this subpart or to the RCRA hazardous waste regulations.

(b) If an unwanted material does not meet the definition of hazardous waste in § 261.3, it is no longer subject to this subpart or to the RCRA hazardous waste regulations, but must be managed in compliance with any other applicable regulations and/or conditions.

**§ 262.216 Non-laboratory hazardous waste generated at an eligible academic entity.**

An eligible academic entity that generates hazardous waste outside of a laboratory is not eligible to manage that hazardous waste under this subpart; and

(a) Remains subject to the generator requirements of §§ 262.11 and 262.34(c) for large quantity generators and small quantity generators (if the hazardous waste is managed in a satellite accumulation area), and all other applicable generator requirements of 40 CFR part 262, with respect to that hazardous waste; or

(b) Remains subject to the conditional exemption of § 261.5(b) for conditionally exempt small quantity generators, with respect to that hazardous waste.

[FR Doc. E8-27863 Filed 11-28-08; 8:45 am]

**BILLING CODE 6560-50-P**