SUPPORTING STATEMENT FOR
INFORMATION COLLECTION REQUEST NUMBER 2317.01
"GENERATOR STANDARDS APPLICABLE TO LABORATORIES OWNED BY ELIGIBLE ACADEMIC ENTITIES"
(Final Rule)

November 2008

Office of Solid Waste
United States Environmental Protection Agency
Washington, D.C. 20460

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1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title and Number of the Information Collection

This Information Collection Request (ICR) is entitled "Generator Standards Applicable to Laboratories Owned by Eligible Academic Entities (Final Rule)," EPA ICR Number 2317.01.

1(b) Short Characterization

The U.S. Environmental Protection Agency (EPA) has finalized an alternative set of generator requirements applicable to laboratories owned by eligible academic entities, as defined in the final rule. The rule, which establishes a new Subpart K within 40 *CFR* Part 262, provides a flexible and protective set of regulations that address the specific nature of hazardous waste generation and accumulation in laboratories owned by colleges and universities, and teaching hospitals and non-profit research institutes that are either owned by or formally affiliated with a college or university. In addition, the final rule allows colleges and universities and these other eligible academic entities formally affiliated with a college or university the discretion to determine the most appropriate and effective method of compliance with these requirements by allowing them the choice of managing their hazardous wastes in accordance with the new alternative regulations as set forth in Subpart K or remaining subject to the existing generator regulations.

In Sections 1 through 5 of this document, EPA presents a comprehensive description of the information collection requirements in the final rule. In Section 6, EPA estimates the total annual hour and cost burden to respondents associated with these new paperwork requirements. In addition, EPA estimates the total annual burden impacts to respondents for being relieved of some existing requirements.

In the following paragraphs, EPA describes the information collection requirements in the final rule.

(1) Notification of Intent to Comply with Subpart K and Recordkeeping of Agreements

40 *CFR* 262.203(a) provides that 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 Subpart K 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 Subpart K for all the laboratories owned by the eligible academic entity that are on-site. 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 Subpart K.

When submitting the Site Identification Form, the eligible academic entity must, at a minimum, fill out the fields on the form that are specified at section 262.203(b)(1)-(11).

Section 262.203(c) provides that 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 Subpart K.

Section 262.203(d) provides that 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 Subpart K.

Section 262.203(e) provides that 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 Subpart K.

(2) Notification of Withdrawal from Subpart K

40 *CFR* 262.204(a) provides that 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 Subpart K 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 withdrawing from the requirements of Subpart K for all the laboratories owned by the eligible academic entity that are on-site. 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 Subpart K.

When submitting the Site Identification Form, the eligible academic entity must, at a minimum, fill out the fields on the form that are specified at section 262.204(b)(1)-(11).

Section 262.204(c) provides that 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.

(3) Labeling of Containers of Unwanted Material in the Laboratory

40 *CFR* 262.206 provides that an eligible academic entity must label and manage containers of unwanted material while in the laboratory in accordance with the requirements in section 262.206.

Section 262.206(a)(1) requires that the following information must be affixed or attached to the container: 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 (262.206(a)(1)(i)), and sufficient information to alert emergency responders to the contents of the container (262.206(a)(1)(ii)).

Section 262.206(a)(2) provides that the following information may be affixed or attached to the container, but must at a minimum associated with the container: the date that the unwanted material first began accumulating in the container (262.206(a)(2)(i)) and 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 section 262.11 (262.206(a)(2)(ii)).

(4) Training

40 *CFR* 262.207 provides that an eligible academic entity must provide training to all individuals working in a laboratory at that eligible academic entity, as specified.

Section 262.207(a) requires that training for laboratory workers and students must be commensurate with their duties so they understand the requirements in Subpart K and can implement them.

Section 262.207(b) provides that an eligible academic entity can provide training for laboratory workers and students in a variety of ways (e.g., instruction by the professor or laboratory manager before or during an experiment, formal classroom training, electronic/written training).

Section 262.207(c) provides that an eligible academic entity that is a large quantity generator must maintain documentation demonstrating training for all laboratory workers. Section 262.207(c) requires that the information must be sufficient to determine whether laboratory workers have been trained and must be retained for the durations specified in section 265.16(e). Sections 262.207(c)(1)-(4) provides examples of documentation demonstrating training.

(5) Removing Containers of Unwanted Material from the Laboratory

40 *CFR* 262.208(a) establishes standards for removing containers of unwanted material on a regular schedule. An eligible academic entity must either: remove all containers of unwanted material from each laboratory on a regular interval, not to exceed 6 months (262.208(a)(1)); or remove containers of unwanted material from each

laboratory within 6 months of each container's accumulation start date (262.208(a)(2)).

Section 262.208(b) requires that the eligible academic entity must specify in Part I of its Laboratory Management Plan whether it will comply with section 262.208(a)(1) or (a)(2) for the regular removal of unwanted material from its laboratories.

Section 262.208(c) requires that the eligible academic entity must specify in Part II of its Laboratory Management Plan how it will comply with section 262.208(a)(1) or (a)(2) and develop a schedule for regular removals of unwanted material from its laboratories.

Section 262.208(d) establishes standards for removing containers of unwanted material when maximum volumes are exceeded. Section 262.208(d)(1) provides that, if a laboratory accumulates more than 55 gallons of unwanted material (including reactive acutely hazardous unwanted material) before the regularly scheduled removal, the eligible academic entity must ensure that all containers of unwanted material (including reactive acutely hazardous unwanted material): must have the date that 55 gallons is exceeded on the label that is associated with the container (262.208(d)(1)(i)); and 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 (262.208(d)(1)(ii)).

Section 262.208(d)(2) provides that, 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: must have the date that 1 quart is exceeded on the label that is associated with the container (262.208(d)(2)(i)); and 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 (262.208(d)(2)(ii)).

(6) Where and When to Make the Hazardous Waste Determination and Where to Send Containers of Unwanted Material

40 *CFR* 262.209(a) establishes standards for when and where large quantity generators and small quantity generators may make the hazardous waste determination. An eligible academic entity must ensure that a trained professional makes a hazardous waste determination, pursuant to section 262.11, for unwanted material in any of the following areas:

- In the laboratory before the unwanted material is removed from the laboratory, in accordance with section 262.210.
- Within 4 calendar days of arriving at an on-site central accumulation area, in accordance with section 262.211.
- Within 4 calendar days of arriving at an on-site treatment, storage

or disposal facility, in accordance with section 262.212.

Section 262.209(b) establishes standards for when and where conditionally exempt small quantity generators may make hazardous waste determinations. An eligible academic entity must ensure that a trained professional makes a hazardous waste determination, pursuant to section 262.11, for unwanted material in the laboratory before the unwanted material is removed from the laboratory, in accordance with 262.210.

(7) Making the Hazardous Waste Determination in the Laboratory

40 CFR 262.210 provides that, if an eligible academic entity makes the hazardous waste determination, pursuant to section 262.11, for unwanted material in the laboratory before the unwanted material is removed from the laboratory, it must comply with the specified requirements.

Section 262.210(a) requires that a trained professional must make the hazardous waste determination, pursuant to section 262.11, before the unwanted material is removed from the laboratory.

Section 262.210(b) provides that, if an unwanted material is a hazardous waste, the eligible academic entity must 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 (262.210(b)(1)) and the appropriate hazardous waste codes(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 may be transported off-site (262.210(b)(2)). [Note: OMB guidance indicates that, if a person is requested or directed to post a label disclosing information completely defined by a Federal agency, the information collection is exempted from OMB review and approval. For this reason, in this ICR, the addition of the words "hazardous waste" to the container label is not considered an information collection and thus is not examined in the remainder of this document.]

(8) Making the Hazardous Waste Determination in an On-site Central Accumulation Area

40 CFR 262.211 provides that, if an eligible academic entity makes the hazardous waste determination, pursuant to section 262.11, for unwanted material at an on-site central accumulation area, it must comply with requirements in 262.211:

Section 262.211(d) requires that 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.

Section 262.211(e) provides that, if the unwanted material is a hazardous waste, the eligible academic entity must 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 (262.211(e)(1)) and 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 on-site or transported off-site (262.211(e)(2)). [Note: OMB guidance indicates that, if a person is requested or directed to post a label disclosing information completely defined by a Federal agency, the information collection is exempted from OMB review and approval. For this reason, in this ICR, the addition of the words "hazardous waste" to the container label is not considered an information collection and thus is not examined in the remainder of this document.]

(9) Making the Hazardous Waste Determination at an On-site Interim Status or Permitted Treatment, Storage, or Disposal Facility

40 CFR 262.212 provides that, if an eligible academic entity makes the hazardous waste determination, pursuant to section 262.11, for unwanted material at an on-site interim status or permitted treatment, storage or disposal facility, it must comply with the requirements in section 262.212.

Section 262.212(d) requires that a trained professional must determine, pursuant to section 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/permitted treatment, storage or disposal facility.

Section 262.212(e) provides that, if the unwanted material is a hazardous waste, the eligible academic entity must 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 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 (262.212(e)(1)) and 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 on-site or transported off-site (262.212(e)(2)). [Note: OMB guidance indicates that, if a person is requested or directed to post a label disclosing information completely defined by a Federal agency, the information collection is exempted from OMB review and approval. For this reason, in this ICR, the addition of the words "hazardous waste" to the container label is not considered an information collection and thus is not examined in the remainder of this document.]

(10) Laboratory Clean-outs

40 *CFR* 262.213(a) provides that one time per 12 month period per laboratory, an eligible academic entity may opt to conduct a laboratory clean-out that is subject to all the applicable requirements of Subpart K, except as specified otherwise in section 262.213(a).

Section 262.213(a)(4) requires that an eligible academic entity must document the activities of the laboratory clean-out, as specified. The eligible academic entity must maintain the records for a period of three years from the date the clean-out ends.

(11) Laboratory Management Plan

40 *CFR* 262.214 provides that 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 comply with Subpart K. An eligible academic entity may write one Laboratory Management Plan for all the laboratories owned by the eligible academic entity that have opted into Subpart K, 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 section 262.214(a) and (b). In Part I of its Laboratory Management Plan, an eligible academic entity must describe its procedures for each of the elements listed in section 262.214(a). 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 section 262.214(b). 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 Subpart K. An eligible academic entity may include additional elements and best management practices in Part II of its Laboratory Management Plan if it chooses.

Section 262.214(c) provides that 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.

Section 262.214(d) requires that an eligible academic entity must review and revise its Laboratory Management Plan, as needed.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need and Authority for the Collection

The final regulations are promulgated under the authority of Sections 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).

EPA believes there is a clear need for the final rule. The Agency has identified four primary differences between laboratory operations at colleges, universities, and other eligible academic entities and typical industrial production facilities. These differences provide the rationale for the rule. First, laboratories owned by colleges, universities and, teaching hospitals and non-profit research institutes that are either owned by or formally affiliated with a college or university 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 generate a relatively 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 eligible academic entity laboratories are students. Students are inherently transient, which makes it more difficult to train them. This fourth difference sets eligible academic entity laboratories apart not only from typical production facilities, but also from non-academic, commercial laboratories. At industrial production facilities and non-academic, commercial laboratories, employees who generate hazardous waste are professionally trained in managing hazardous wastes and are held accountable due to their employee status.

(1) Notification of Intent to Comply with Subpart K and Recordkeeping of Agreements

Because the rule provides eligible academic entities the option to manage their hazardous wastes from laboratories under the existing hazardous waste generator regulations or their laboratories' unwanted materials under Subpart K, it is important that EPA, or the authorized State, know which set of regulations apply to an eligible academic entity's laboratories. Therefore, the rule requires that an eligible academic entity choosing to manage its unwanted materials in compliance with the alternative set of generator requirements of Subpart K to submit a Site Identification Form on a one-time basis 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 existing regulations and it does not need to notify.

EPA believes the Site Identification Form will simplify this notification process in

comparison with other types of notification methods. Regulated entities and authorized States are already familiar with the form because it must be submitted under other RCRA provisions (e.g., RCRA 3010 Notifications, Hazardous Waste Report). Further, some eligible academic entities may have retained a copy that they had completed and submitted under another provision. A pre-populated form will greatly ease the process of completing the form to opt into Subpart K.

(2) Notification of Withdrawal from Subpart K

It is 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 standard 40 *CFR* Part 262 applicable generator regulations. Under the final rule, an eligible academic entity that chooses to end its participation in the Subpart K program will 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 will no longer be subject to Subpart K and would be subject to the existing applicable generator regulations.

(3) Labeling of Containers of Unwanted Material in the Laboratory

Eligible academic entities must label containers of unwanted materials managed in a laboratory, as specified. These labeling requirements are necessary to demonstrate compliance with the rule and alert anyone handling the containers of unwanted materials of what is enclosed in the container so that proper handling may occur. The labeling requirements also would assist trained professionals in properly identifying whether an unwanted material is a hazardous waste and to assign the appropriate hazardous waste code(s).

(4) Training

Eligible academic entities must train all individuals working in a laboratory commensurate with their duties. This training is necessary to ensure that individuals perform their duties in a way that ensures compliance with the Subpart K requirements. It also will enable individuals to manage unwanted materials safely and in an environmentally sound manner, while in the laboratory.

In addition, eligible academic entities that are large quantity generators (LQGs) must maintain training records for laboratory workers. These records are necessary to ensure compliance with the Subpart K training requirements.

(5) Removing Containers of Unwanted Material from the Laboratory

Eligible academic entities must label containers with the date the 55 gallons of unwanted material, or the 1 quart of acutely reactive unwanted material, is exceeded. This information is needed for enforcement and monitoring purposes.

(6) Where and When to Make the Hazardous Waste Determination and Where to Send Containers of Unwanted Material

The rule specifies three on-site locations at which a hazardous waste determination can be made:

- In the laboratory before the unwanted material is removed from the laboratory, in accordance with section 262.210.
- Within 4 calendar days of arriving at an on-site central accumulation area, in accordance with section 262.211.
- Within 4 calendar days of arriving at an on-site interim status or permitted treatment, storage or disposal facility, in accordance with section 262.212.

This provision is needed to clarify where and when the hazardous waste determination must be made. Without time limits, EPA would not be able to ensure that eligible academic entities were making their determinations in a timely manner and managing their hazardous waste in accordance with the hazardous waste regulations.

(7) Making the Hazardous Waste Determination in the Laboratory

As provided at section 262.210, if an unwanted material meets the definition of hazardous waste per 40 *CFR* 261.3, the appropriate hazardous waste code(s) must be placed on the container label that is associated with the container. This information is needed to alert anyone handling the container that hazardous waste is enclosed in the container so that proper handling may occur.

(8) Making the Hazardous Waste Determination in an On-site Central Accumulation Area

As provided at section 262.211, if an unwanted material meets the definition of hazardous waste per 40 *CFR* 261.3, the appropriate hazardous waste code(s) must be placed on the container label that is associated with the container. This information is needed to alert anyone handling the container that hazardous waste is enclosed in the container so that proper handling may occur.

(9) Making the Hazardous Waste Determination at an On-site Interim Status or Permitted Treatment, Storage, or Disposal Facility

As provided at section 262.212, if an unwanted material meets the definition of hazardous waste per 40 *CFR* 261.3, the appropriate hazardous waste code(s) must be placed on the container label that is associated with the container. This information is needed to alert anyone handling the container that hazardous waste is enclosed in the container so that proper handling may occur.

(10) Laboratory Clean-outs

Eligible academic entities must develop and maintain documentation on laboratory clean-outs. This information is needed to ensure compliance with the laboratory clean-out requirements. For example, the documentation must show the dates when the clean-out began and ended. This information will hold the eligible academic entity accountable for adhering to the 30-day clean-out time limit, as well as other stipulations in the final rule.

(11) Laboratory Management Plan

Performance-based standards set the framework for managing unwanted materials generated in laboratories owned by eligible academic entities. The Laboratory Management Plan required under 40 *CFR* 262.214 is the mechanism for implementing the alternative program. This plan is needed to ensure that eligible academic entities seeking flexibility in managing the unwanted materials from their laboratories will do so in a thoughtful manner by documenting their practices.

2(b) Practical Utility and Users of the Data

(1) Notification of Intent to Comply with Subpart K and Recordkeeping of Agreements

Because the rule establishes an alternative set of generator requirements that is self-implementing, EPA has determined that it is necessary to require eligible academic entities to submit a one-time notification to the appropriate EPA Regional Administrator or State Director indicating that they are electing to be subject to the Subpart K requirements as specified. EPA and States will use this information to identify the entities and sites subject to the Subpart K requirements and ensure that all of these sites are managing their unwanted materials in a manner that is protective of human health and the environment.

(2) Notification of Withdrawal from Subpart K

Eligible academic entities that elected to comply with the Subpart K requirements may elect, at any time, to withdraw from the Subpart K program. Because a site's withdrawal would be self-implementing (i.e., done at its own discretion), EPA has

determined that it is necessary to require entities to submit a one-time withdrawal notification to the appropriate EPA Regional Administrator indicating that they will again begin to manage their hazardous waste pursuant to section 262.34(c) (or section 261.5 for conditionally exempt small quantity generators). EPA and States will use this information to identify the sites subject to the Subpart K requirements and ensure that all of these sites are managing their unwanted materials in a manner that is protective of human health and the environment.

(3) Labeling of Containers of Unwanted Material in the Laboratory

The labeling requirements are necessary to alert anyone handling the containers of unwanted materials of what is enclosed in the containers so that proper handling or inspection may occur. The labeling requirements also assist RCRA-trained individuals in properly identifying whether an unwanted material is a hazardous waste and to assign the appropriate hazardous waste code(s).

(4) Training

Eligible academic entities must train all individuals working in a laboratory commensurate with their duties. This training will enable individuals to manage unwanted materials safely and in an environmentally sound manner, while in the laboratory.

In addition, LQGs must maintain training records for laboratory workers. Entities will use this information to demonstrate compliance with the Subpart K requirements. EPA will use the information during inspections and for enforcement purposes.

(5) Removing Containers of Unwanted Material from the Laboratory

Eligible academic entities will use the information on the date the 55 gallons of unwanted material, or the 1 quart of acutely reactive unwanted material, was exceeded to maintain compliance with Subpart K. EPA will use the information during inspections and for enforcement purposes.

(6) Where and When to Make the Hazardous Waste Determination and Where to Send Containers of Unwanted Material

The rule clarifies where the hazardous waste determinations can be made, as well as the timing of them. Eligible academic entities will follow these procedures to ensure that they are making their determinations in a timely manner and managing their hazardous wastes in accordance with the hazardous waste regulations.

(7) Making the Hazardous Waste Determination in the Laboratory

Eligible academic entities will use the hazardous waste code information to ensure that the hazardous waste is managed in a manner that is protective of human

health and the environment.

(8) Making the Hazardous Waste Determination in an On-site Central Accumulation Area

Eligible academic entities will use the hazardous waste code information to ensure that the hazardous waste is managed in a manner that is protective of human health and the environment.

(9) Making the Hazardous Waste Determination at an On-site Interim Status or Permitted Treatment, Storage, or Disposal Facility

Eligible academic entities will use the hazardous waste code information to ensure that the hazardous waste is managed in a manner that is protective of human health and the environment.

(10) Laboratory Clean-outs

Eligible academic entities must develop and maintain documentation on laboratory clean-outs. They will use this information to demonstrate compliance with the Subpart K requirements. EPA will use the information during inspections and for enforcement purposes.

(11) Laboratory Management Plan

Eligible academic entities must develop, implement, and retain a Laboratory Management Plan. They will use the Laboratory Management Plan to document their practices for complying with the performance-based requirements of Subpart K.

3. NONDUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a) Nonduplication

None of the information required by the final rule is duplicative with any information required by the existing Federal regulations.

3(b) Public Notice

On May 23, 2006, EPA proposed alternative generator requirements applicable to college and university laboratories (71 *FR* 29712). To assist the public in commenting on the proposal, EPA raised a number of issues in the preamble to the proposed rule and asked for the public to comment on them. EPA received 111 comments in response to the proposal. At the end of the comment period, EPA reviewed the public comments received and addressed the comments in finalizing the rule and supporting documents, as appropriate.

3(c) Consultations

EPA has worked with colleges, universities and affiliated entities since the early 1980s to more fully understand the difficulties they face in complying with the existing RCRA hazardous waste regulations. Projects such as the Howard Hughes Medical Institute pilot program and the 1999 XL pilot project, which provide flexibility to colleges and universities, have focused on how hazardous wastes are generated and accumulated in laboratories. EPA has met with stakeholders, held public meetings, and attended meetings and conferences with associations representing various colleges, universities and affiliated entities. Through these various activities EPA has developed a good understanding of their operational practices in laboratories and the challenges they face in complying with the RCRA hazardous waste requirements. In the following paragraphs, EPA discusses some of its most recent outreach/consultation efforts.

In 2002, EPA conducted a series of outreach activities to generators of hazardous waste with laboratories to obtain information regarding the differences between how hazardous waste is generated and managed at academic laboratory operations as compared with production operations of industrial generators and other non-college/university laboratory generators. The information collected by the Agency indicates that differences exist between academic laboratory operations and those of both industrial laboratories and industrial production facilities that generate hazardous waste, warranting development of an alternative set of regulations for laboratories of colleges, universities and affiliated entities. These differences include the number of points of generation, the relative small volume of hazardous waste generated at each point of generation, and the fact that many of the persons involved in hazardous waste generation activities are students, rather than paid employees.

In June 2003, EPA held a public meeting in order to solicit input from stakeholders on approaches to addressing issues concerning hazardous waste management in academic laboratories. Topics discussed at the meetings included: where and when to make the hazardous waste determination; waste labeling requirements; personnel training requirements; satellite area accumulation; and types of treatment performed in laboratories.

As a parallel effort, in 2003, colleges and universities were selected to become a new partner in EPA's Sector Strategies Program. The Sector Strategies Program seeks industry-wide environmental gains through innovative actions taken with a number of manufacturing and service sectors. EPA has worked with six College and University Sector Program Partners to develop sector-specific approaches to assist colleges and universities advance the use of environmental management systems, reduce regulatory performance barriers, and measure environmental progress.

In May, June, and August 2004, the Colleges and Universities Sector Program Partners shared their thoughts in a series of proposals suggesting alternative approaches for developing a RCRA program that addresses the unique problems faced by college and university laboratories. Their suggested changes to existing requirements focused on tailoring new regulations for college and university laboratories that are different from the standards required of other generators and operators of treatment, storage, and disposal facilities (TSDFs), similar to the current "satellite accumulation area" regulations. They suggested changes for providing flexibility for the point at which the hazardous waste identification is made, training of laboratory workers, labeling, container management standards, and provisions for bench scale treatment of waste in the laboratory.

Since then, EPA has continued to research the laboratory operations and needs of colleges, universities and other entities.

Through the above efforts, EPA has gained a good understanding of the operations and compliance activities of laboratories at colleges, universities, and other entities. EPA used this knowledge in developing this ICR.

3(d) Effects of Less Frequent Collection

EPA has carefully considered the information collection burden imposed by the final rule. EPA is confident that those activities required of respondents are necessary, and to the extent possible, the Agency has attempted to minimize the burden imposed. A number of the required activities, for example, will be performed once (e.g., one-time notifications). EPA believes strongly that, if the minimum information collection requirements of the rule are not met, EPA will not be able to ensure that the unwanted material generated in laboratories is being properly managed and do not pose a threat to human health and the environment.

3(e) General Guidelines

This ICR adheres to the guidelines stated in the Paperwork Reduction Act of 1995, OMB's implementing regulations, EPA's ICR Handbook, and other applicable OMB guidance.

3(f) Confidentiality

EPA does not expect to deem any information collected under the rule to be CBI (Confidential Business Information). If such a claim were asserted, EPA must and will treat the information in accordance with the applicable regulations (e.g., 40 *CFR* Part 2, Subpart B). EPA also will assure that this information collection complies with the Privacy Act of 1974 and OMB Circular 108.

3(g) Sensitive Questions

No questions of a sensitive nature are included in the information collection requirements associated with the rule.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents and NAICS Codes

The following is a list of North American Industry Classification System (NAICS) codes associated with industries most likely affected by the information collection requirements covered in this ICR.

NAICS Codes of Entities Potentially Affected by this Final Rule

Description of NAICS Code	NAICS Codes
Colleges and Universities	
Junior Colleges	6112, 61121, 611210
Colleges, Universities, and Professional Schools	6113, 61131, 611310
Technical and Trade Schools	6115, 61151
Other Technical and Trade Schools	611519
Fine Arts Schools	61161, 611610
Teaching Hospitals	
Veterinary Services (Animal Hospitals)	54194, 541940
Hospitals	622
General Medical and Surgical Hospitals	6221, 62211, 622110
Psychiatric and Substance Abuse Hospitals	6222, 62221, 622210
Specialty (except Psychiatric and Substance Abuse) Hospitals	6223, 62231, 622310
Non-Profit Research Institutes	
Research and Development in the Physical, Engineering, and Life Sciences	5417, 54171, 541710
Research and Development in the Social Sciences and Humanities	54172, 541720

4(b) Information Requested

(1) Notification of Intent to Comply with Subpart K and Recordkeeping of Agreements

40 *CFR* 262.203(a) provides that 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 Subpart K 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 Subpart K for all the laboratories owned by the eligible academic entity that are on-site. 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 Subpart K.

When submitting the Site Identification Form, the eligible academic entity must, at a minimum, fill out the fields on the form that are specified at section 262.203(b)(1)-(11).

Section 262.203(c) provides that an eligible academic entity must keep a copy of the notification on file at the eligible academic entity while its laboratories are subject to Subpart K.

Section 262.203(d) provides that 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 while its laboratories are subject to Subpart K.

Section 262.203(e) provides that 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 while its laboratories are subject to Subpart K.

(i) Data Items:

- A Site Identification Form with the following fields filled out, at a minimum:
  - -- Reason for Submittal;
  - -- Site EPA Identification Number (except for conditionally exempt small quantity generators);
  - -- Site Name;
  - -- Site Location Information;
  - -- Site Land Type;
  - -- North American Industry Classification System (NAICS) Code(s) for the Site;
  - -- Site Mailing Address;
  - -- Site Contact Person;
  - -- Operator and Legal Owner of the Site;
  - -- Type of Regulated Waste Activity; and
  - -- Certification.

- A copy of the formal written affiliation agreement with a college or university , as specified under section 262.203(d).

- A copy of the formal written affiliation agreement with a college or university, as specified under section 262.203(e).

(ii) Respondent Activities:

- Eligible academic entities electing to be subject to the requirements of Subpart K must perform the following:

  -- Prepare and submit Site Identification Form; and
  -- Keep a copy of the notification on file.

- Teaching hospitals that are not owned by a college or university must keep a copy of their formal written affiliation agreement with college or university on file while its laboratories are subject to Subpart K.

- Non-profit research institutes that are not owned by a college or university must keep a copy of the formal written affiliation agreement with a college or university on file at the non-profit research institute while its laboratories are subject to Subpart K.

(2) Notification of Withdrawal from Subpart K

40 *CFR* 262.204(a) provides that 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 Subpart K 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 withdrawing from the requirements of Subpart K for all the laboratories owned by the eligible academic entity that are on-site. 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 Subpart K.

When submitting the Site Identification Form, the eligible academic entity must, at a minimum, fill out the fields on the form that are specified at section 262.204(b)(1)-(11).

Section 262.204(c) provides that 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.

(i) Data Items:

- A Site Identification Form with the following fields filled out, at a minimum:
  -- Reason for Submittal;
  -- Site EPA Identification Number (except for conditionally exempt small quantity generators);

-- Site Name;
-- Site Location Information;
-- Site Land Type;
-- North American Industry Classification System (NAICS) Code(s) for the Site;
-- Site Mailing Address;
-- Site Contact Person;
-- Operator and Legal Owner of the Site;
-- Type of Regulated Waste Activity; and
-- Certification.

(ii) Respondent Activities:

- Prepare and submit Site Identification Form; and

- Keep a copy of the withdrawal notice on file.

(3) Labeling of Containers of Unwanted Material in the Laboratory

40 *CFR* 262.206 provides that an eligible academic entity must label and manage containers of unwanted material while in the laboratory in accordance with the requirements in section 262.206.

Section 262.206(a)(1) requires that the following information must be affixed or attached to the container: 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 (262.206(a)(1)(i)), and sufficient information to alert emergency responders to the contents of the container (262.206(a)(1)(ii)).

Section 262.206(a)(2) provides that the following information may be affixed or attached to the container, but must at least be associated with the container: the date that the unwanted material first began accumulating in the container (262.206(a)(2)(i)) and 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 section 262.11 (262.206(a)(2)(ii)).

(i) Data Items:

- Information that is affixed or attached to the container, including:
  -- 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
  -- 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, the following:

- Name of the chemical(s).
- Type or class of chemical, such as organic solvents or halogenated organic solvents.

- Information that may be affixed or attached to the container, but that must at least be associated with the container, including:
  -- Date that the unwanted material first began accumulating in the container; and
  -- 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 section 262.11. For example, the following information may be associated with the container:
     - 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;
     - A description of the manner in which the chemical was processed, if applicable.

(ii) Respondent Activities:

- Label the containers as specified.

(4) Training

40 *CFR* 262.207 provides that an eligible academic entity must provide training to all individuals working in a laboratory at that eligible academic entity, as specified.

Section 262.207(a) requires that training for laboratory workers and students must be commensurate with their duties so they understand the requirements in Subpart K and can implement them.

Section 262.207(b) provides that an eligible academic entity can provide training for laboratory workers and students in a variety of ways (e.g., instruction by the professor or laboratory manager before or during an experiment, formal classroom training, electronic/written training).

Section 262.207(c) provides that an eligible academic entity that is a large quantity generator must maintain documentation demonstrating training for all laboratory workers. Section 262.207(c) requires that the information must be sufficient to determine whether laboratory workers have been trained and for the durations specified in section 265.16(e). Sections 262.207(c)(1)-(4) provides examples of documentation demonstrating training.

(i) Data Items:

- Documentation demonstrating training for all laboratory workers. Examples of documentation demonstrating training can include, but are not limited to, the following:
  -- Sign-in/attendance sheet(s) for training session(s); or
  -- Syllabus for training session; or
  -- Certificate of training completion; or
  -- Test results.

(ii) Respondent Activities:

- Provide training to all individuals working in a laboratory.

- Maintain documentation demonstrating training for all laboratory workers (LQGs only).

(5) Removing Containers of Unwanted Material from the Laboratory

40 *CFR* 262.208(a) establishes standards for removing containers of unwanted material on a regular schedule. An eligible academic entity must either: remove all containers of unwanted material from each laboratory on a regular interval, not to exceed 6 months (262.208(a)(1)); or remove containers of unwanted material from each laboratory within 6 months of each container's accumulation start date (262.208(a)(2)).

Section 262.208(b) requires that the eligible academic entity must specify in Part I of its Laboratory Management Plan whether it will comply with section 262.208(a)(1) or (a)(2) for the regular removal of unwanted material from its laboratories. Section 262.208(c) requires that the eligible academic entity must specify in Part II of its Laboratory Management Plan how it will comply with section 262.208(a)(1) or (a)(2) and develop a schedule for regular removals of unwanted material from its laboratories. [Note: The data items and respondent activities associated with these requirements are presented under "Laboratory Management Plan."]

Section 262.208(d) establishes standards for removing containers of unwanted material when maximum volumes are exceeded. Section 262.208(d)(1) provides that, if a laboratory accumulates more than 55 gallons of unwanted material before the regularly-scheduled removal, the eligible academic entity must ensure that all containers of unwanted material (including reactive acutely hazardous unwanted material): must have the date that 55 gallons is exceeded on the label that is associated with the container (262.208(d)(1)(i)); and 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 (262.208(d)(1)(ii)).

Section 262.208(d)(2) provides that, 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: must have the date that 1 quart is exceeded on the label that is associated with the container (262.208(d)(2)(i)); and 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 (262.208(d)(2)(ii)).

(i) Data Items:

- Date that the laboratory accumulated more than 55 gallons of unwanted material.

- Date that the laboratory accumulated more than 1 quart of reactive acutely hazardous unwanted material.

(ii) Respondent Activities:

- Ensure that containers of unwanted material that exceed volume limits have the date of the exceedence on the label.

(6) Where and When to Make the Hazardous Waste Determination and Where to Send Containers of Unwanted Material

40 *CFR* 262.209(a) establishes standards for where and when large quantity generators and small quantity generators may make hazardous waste determinations. An eligible academic entity must ensure that a trained professional makes a hazardous waste determination, pursuant to section 262.11, for unwanted material in any of the following areas:

- In the laboratory before the unwanted material is removed from the laboratory, in accordance with section 262.210. [Note: The data items and respondent activities associated with this requirement are presented in "Making the Hazardous Waste Determination in the Laboratory."]

- Within 4 calendar days of arriving at an on-site central accumulation area, in accordance with section 262.211. [Note: The data items and respondent activities associated with this requirement are presented in "Making the Hazardous Waste Determination in an On-site Central Accumulation Area."]

- Within 4 calendar days of arriving at an on-site treatment, storage or disposal facility, in accordance with section 262.212. [Note: The data items and respondent activities associated with this requirement are presented in "Making the Hazardous Waste Determination at an On-site Interim Status or Permitted Treatment, Storage, or Disposal Facility."]

Section 262.209(b) establishes standards for where and when conditionally

exempt small quantity generators may make hazardous waste determinations. An eligible academic entity must ensure that a trained professional makes a hazardous waste determination, pursuant to section 262.11, for unwanted material in the laboratory before the unwanted material is removed from the laboratory, in accordance with 262.210. [Note: The data items and respondent activities associated with this requirement are presented in "Making the Hazardous Waste Determination in the Laboratory."]

(7) Making the Hazardous Waste Determination in the Laboratory

40 *CFR* 262.210 provides that, if an eligible academic entity makes the hazardous waste determination, pursuant to section 262.11, for unwanted material in the laboratory before the unwanted material is removed from the laboratory, it must comply with the requirements in section 262.210.

Section 262.210(a) requires that a trained professional must make the hazardous waste determination, pursuant to section 262.11, before the unwanted material is removed from the laboratory.

Section 262.210(b)(2) provides that, if an unwanted material is a hazardous waste, the eligible academic entity must write the appropriate hazardous waste codes(s) on the label that is associated with the container before the hazardous waste may be transported off-site.

(i) Data Items:

- Hazardous waste determination.
- EPA Hazardous waste codes on the label.

(ii) Respondent Activities:

- Make the hazardous waste determination; and
- Write hazardous waste codes on the container label.

(8) Making the Hazardous Waste Determination in an On-site Central Accumulation Area

40 *CFR* 262.211 provides that, if an eligible academic entity makes the hazardous waste determination, pursuant to section 262.11, for unwanted material at an on-site central accumulation area, it must comply with requirements in 262.211.

Section 262.211(d) requires that a trained professional must determine, pursuant to section 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.

Section 262.211(e)(2) provides that, if the unwanted material is a hazardous

waste, the eligible academic entity must write the appropriate hazardous waste code(s) on the container label that is associated with the container before the hazardous waste may be treated or disposed on-site or transported off-site.

(i) Data Items:

- Hazardous waste determination.
- EPA Hazardous waste codes on the label.

(ii) Respondent Activities:

- Make the hazardous waste determination; and
- Write hazardous waste codes on the container label.

(9) Making the Hazardous Waste Determination at an On-site Interim Status or Permitted Treatment, Storage, or Disposal Facility

40 *CFR* 262.212 provides that, if an eligible academic entity makes the hazardous waste determination, pursuant to section 262.11, for unwanted material at an on-site interim status or permitted treatment, storage or disposal facility, it must comply with the requirements in section 262.212.

Section 262.212(d) requires that a trained professional must determine, pursuant to section 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.

Section 262.212(e)(2) provides that, if the unwanted material is a hazardous waste, the eligible academic entity must write the appropriate hazardous waste code(s) on the container label that is associated with the container before the hazardous waste may be treated or disposed on-site or transported off-site.

(i) Data Items:

- Hazardous waste determination.
- EPA Hazardous waste codes on the label.

(ii) Respondent Activities:

- Make the hazardous waste determination; and
- Write hazardous waste codes on the container label.

(10) Laboratory Clean-outs

40 *CFR* 262.213(a) provides that one time per 12 month period per laboratory, an eligible academic entity may opt to conduct a laboratory clean-out that is subject to all the applicable requirements of Subpart K, except as specified otherwise in section 262.213(a).

Section 262.213(a)(4) requires that an eligible academic entity must document the activities of the laboratory clean-out, as specified. The eligible academic entity must maintain the records for a period of three years from the date the clean-out ends.

(i) Data Items:

- Documentation that, at a minimum, identifies 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.

(ii) Respondent Activities:

- Document the activities of the laboratory clean-out; and
- Maintain records of the clean-out.

(11) Laboratory Management Plan

40 *CFR* 262.214 provides that 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 comply with Subpart K. An eligible academic entity may write one Laboratory Management Plan for all the laboratories owned by the eligible academic entity that have opted into Subpart K, 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 section 262.214(a) and (b). In Part I of its Laboratory Management Plan, an eligible academic entity must describe its procedures for each of the elements listed in section 262.214(a). 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 section 262.214(b). 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 Subpart K. An eligible academic entity may include additional

elements and best management practices in Part II of its Laboratory Management Plan if it chooses.

Section 262.214(c) provides that 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.

Section 262.214(d) requires that an eligible academic entity must review and revise its Laboratory Management Plan, as needed.

(i) Data Items:

- A Laboratory Management Plan that includes Part I and II. In Part I of the Laboratory Management Plan, an eligible academic entity must:
  -- Describe procedures for container labeling in accordance with section 262.206(a), including:
     - 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.
     - Identifying the manner in which information that is "associated with the container" will be imparted.
  -- Identify whether the eligible academic entity will comply with section 262.208(a)(1) or section 262.208(a)(2) for regularly scheduled removals of unwanted material from the laboratory.

  In Part II of the Laboratory Management Plan, an eligible academic entity must:
  -- Describe procedures 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 liquid chromatographs and other laboratory equipment.
  -- Describe how the eligible academic entity will provide training for laboratory workers and students commensurate with their duties.
  -- Describe how the eligible academic entity will provide training to ensure safe on-site transfers of unwanted material and hazardous waste by trained professionals.
  -- Describe procedures for removing unwanted material from the laboratory, including:
     - For regularly scheduled removals – Develop a regular schedule for identifying and removing unwanted materials from its laboratories.
     - For removals when maximum volumes are exceeded:
       - Describe procedures for removing unwanted materials from the laboratory within 10 calendar

days when unwanted materials have exceeded their maximum volumes.
    - Describe how and to whom laboratory workers or students will communicate that unwanted materials have exceeded their maximum volumes.
-- Describe procedures for making hazardous waste including specifying the duties of the individuals involved in the process.
-- Describe procedures for laboratory clean-outs, if the eligible academic entity plans to use the incentives for laboratory clean-outs provided in section 262.213, including:
    - Procedures for conducting laboratory clean-outs in accordance with section 262.213; and
    - Procedures for documenting laboratory clean-outs in accordance with section 262.213(a)(4).
-- Describe emergency prevention procedures, including:
    - Procedures for emergency prevention, notification, and response, appropriate to the hazards in the laboratory; and
    - 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
    - Procedures to safely dispose of chemicals that become more dangerous when they exceed their expiration date and/or as they degrade; and
    - Pocedures for the timely characterization of unknown chemicals.

(ii) Respondent Activities:

- Develop a Laboratory Management Plan or revise an existing written plan;

- Retain, review and revise the Laboratory Management Plan; and

- Make Laboratory Management Plan available to laboratory workers, students, or any others at the eligible academic entity who request it.

5. THE INFORMATION COLLECTED: AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

5(a) Agency Activities

(1) Notification of Intent to Comply with Subpart K and Recordkeeping of Agreements

Under 40 *CFR* 262.203(a), the Agency will conduct the following activities:

- Review and process Site Identification Forms.

(2) Notification of Withdrawal from Subpart K

Under 40 *CFR* 262.204(a), the Agency will conduct the following activities:

- Review and process Site Identification Forms.

(3) Labeling of Containers of Unwanted Material in the Laboratory

There is no Agency activity under 40 *CFR* 262.206.

(4) Training

There is no Agency activity under 40 *CFR* 262.207.

(5) Removing Containers of Unwanted Material from the Laboratory

There is no Agency activity under 40 *CFR* 262.208.

(6) Where and When to Make the Hazardous Waste Determination and Where to Send Containers of Unwanted Material

There is no Agency activity under 40 *CFR* 262.209.

(7) Making the Hazardous Waste Determination in the Laboratory

There is no Agency activity under 40 *CFR* 262.210.

(8) Making the Hazardous Waste Determination in an On-site Central Accumulation Area

There is no Agency activity under 40 *CFR* 262.211.

(9) Making the Hazardous Waste Determination at an On-site Interim Status or Permitted Treatment, Storage, or Disposal Facility

There is no Agency activity under 40 *CFR* 262.212.

(10) Laboratory Clean-outs

There is no Agency activity under 40 *CFR* 262.213.

(11) Laboratory Management Plan

There is no Agency activity under 40 *CFR* 262.214.

5(b) Collection Methodology and Management

In collecting and analyzing the information associated with this ICR, EPA and authorized States may use a telephone system, personal computers, and applicable database software. They will ensure the accuracy and completeness of collected information by reviewing the submittals. They will keep records of this information in file cabinets and/or computer systems.

5(c) Small Entity Flexibility

The final rule allows eligible academic entities the flexibility to tailor their laboratory operations to meet their individual circumstances, and remain protective of human health and the environment. Performance-based standards for management of hazardous wastes generated in laboratories provide a better opportunity for them to evaluate their overall hazardous waste management program, and tailor it in such a way that facilitates the efficient and safe management of hazardous waste and minimizes burden, while at the same time maintaining a high standard of protection of human health and the environment. The alternative approach will help each eligible academic entity centralize and coordinate its chemical management practices and achieve sound environmental performance.

In addition, eligible academic entities have the choice to manage their hazardous waste in accordance with the alternative set of regulations or remain subject to the existing generator regulations in 40 *CFR* 262.34(c) (or section 261.5 for conditionally exempt small quantity generators). Thus, they have the option to comply with the set of regulations that best suits their circumstances.

5(d) Collection Schedule

(1) Notification of Intent to Comply with Subpart K and Recordkeeping of Agreements

Under 40 *CFR* 262.203(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 Subpart K 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 for all the laboratories owned by the eligible academic entity that are on-site. 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 Subpart K. This is a one-time notification.

Section 262.203(c) provides that an eligible academic entity must keep a copy of the notification on file at the eligible academic entity while its laboratories are subject to Subpart K.

Section 262.203(d) provides that 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 while its laboratories are subject to Subpart K.

Section 262.203(e) provides that a non-profit research institute that is not owned by a college or university must keep a copy of the formal written affiliation agreement with a college or university on file at the non-profit research institute while its laboratories are subject to Subpart K.

(2) Notification of Withdrawal from Subpart K

Under 40 *CFR* 262.204(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 Subpart K 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 for all the laboratories owned by the eligible academic entity that are on-site. 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 Subpart K. This is a one-time notification.

Section 262.204(c) provides that 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.

(3) Labeling of Containers of Unwanted Material in the Laboratory

40 *CFR* 262.206(a) requires that specified information must be affixed or attached to, or otherwise associated with, the container while in the laboratory.

(4) Training

40 *CFR* 262.207 provides that an eligible academic entity must provide training to all individuals working in a laboratory at that eligible academic entity, as specified.

Section 262.207(c) provides that an eligible academic entity that is a large quantity generator must maintain documentation demonstrating training for all laboratory workers. The information must be retained for the durations specified in section 265.16(e). [Note: Existing 40 *CFR* 265.16(e) requires that training records on current personnel must be kept until closure of the facility. Training records on former employees must be kept for at least three years from the date the employee last worked at the facility. Personnel training records may accompany personnel transferred within the same company.]

(5) Removing Containers of Unwanted Material from the Laboratory

40 *CFR* 262.208(d)(1)(i) provides that, if a laboratory accumulates more than 55 gallons of unwanted material before the regularly scheduled removal, the eligible academic entity must ensure that all containers of unwanted material (including reactive acutely hazardous unwanted material) have the date that 55 gallons is exceeded on the label that is associated with the container.

Section 262.208(d)(2)(i) provides that, 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 have the date that 1 quart is exceeded on the label that is associated with the container.

(6) Where and When to Make the Hazardous Waste Determination and Where to Send Containers of Unwanted Material

40 *CFR* 262.209(a) establishes standards for where and when large quantity generators and small quantity generators may make hazardous waste determinations. An eligible academic entity must ensure that a trained professional makes a hazardous waste determination, pursuant to section 262.11, for unwanted material in any of the following areas:

- In the laboratory before the unwanted material is removed from the laboratory, in accordance with section 262.210.

- Within 4 calendar days of arriving at an on-site central accumulation area, in accordance with section 262.211.

- Within 4 calendar days of arriving at an on-site treatment, storage or disposal facility, in accordance with section 262.212.

Section 262.209(b) establishes standards for where and when conditionally exempt small quantity generators may make hazardous waste determinations. An eligible academic entity must ensure that a trained professional makes a hazardous waste determination, pursuant to section 262.11, for unwanted material in the laboratory before the unwanted material is removed from the laboratory, in accordance with 262.210.

(7) Making the Hazardous Waste Determination in the Laboratory

40 *CFR* 262.210(a) requires that a trained professional must make the hazardous waste determination, pursuant to section 262.11, before the unwanted material is removed from the laboratory.

Section 262.210(b)(2) provides that, if an unwanted material is a hazardous waste, the eligible academic entity must write the appropriate hazardous waste codes(s) on the label that is associated with the container before the hazardous waste may be transported off-site.

(8) Making the Hazardous Waste Determination in an On-site Central Accumulation Area

40 *CFR* 262.211(d) requires that a trained professional must determine, pursuant to section 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.

Section 262.211(e)(2) provides that, if the unwanted material is a hazardous waste, the eligible academic entity must write the appropriate hazardous waste code(s) on the container label that is associated with the container before the hazardous waste may be treated or disposed on-site or transported off-site.

(9) Making the Hazardous Waste Determination at an On-site Interim Status or Permitted Treatment, Storage, or Disposal Facility

40 *CFR* 262.212(d) requires that a trained professional must determine, pursuant to section 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.

Section 262.212(e)(2) provides that, if the unwanted material is a hazardous waste, the eligible academic entity must write the appropriate hazardous waste code(s) on the container label that is associated with the container before the hazardous waste may be treated or disposed on-site or transported off-site.

(10) Laboratory Clean-outs

40 *CFR* 262.213(a) provides that one time per 12 month period per laboratory, an eligible academic entity may opt to conduct a laboratory clean-out that is subject to all the applicable requirements of Subpart K, except as specified otherwise in section 262.213(a).

Section 262.213(a)(4) requires that an eligible academic entity must document the activities of the laboratory clean-out, as specified (a clean-out may last up to 30 calendar days, as specified). The eligible academic entity must maintain the records for a period of three years from the date the clean-out ends.

(11) Laboratory Management Plan

40 *CFR* 262.214 provides that an eligible academic entity must develop, implement, and retain a written Laboratory Management Plan, or revise an existing written plan.

Section 262.214(c) provides that 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.

Section 262.214(d) requires that an eligible academic entity must review and revise its Laboratory Management Plan as needed.

6. ESTIMATING THE HOUR AND COST BURDEN OF THE COLLECTION

6(a) Estimating Respondent Burden Hours

Exhibit 1 provides estimates of the respondent hourly burden associated with the rule's paperwork requirements. Exhibit 1 includes burden hours (total and by labor type) per respondent, as well as the overall burden hours for all respondents.

6(b) Estimating Respondent Costs

Exhibit 1 provides estimates of the annual respondent costs associated with the rule's paperwork requirements. These costs are based on the cost of labor, capital, and operation and maintenance (O&M).

(1) Labor Costs

The labor wage rates used to estimate costs to respondents were obtained from EPA's impact assessment developed for this rulemaking.[1] EPA estimates an average loaded respondent hourly labor rate of $116.58 for legal staff, $63.72 for managerial staff, $35.14 for technical staff, and $26.50 for clerical staff. Labor rates were determined using the "National Compensation Survey: Occupational Earnings in the United States, June 2006." Fringe benefit and overhead rates were estimated using "United States Department of Labor, Bureau of Labor Statistics, Employer Costs for Employee Compensation - December 2007," March 12, 2008, and "OMB Circular No. A-76 - Table C," May 29, 2003, respectively. The fringe benefits were estimated as 42 percent of the base labor rate. The overhead rate was estimated as 12 percent of the base and fringe benefit labor rate. The labor rates were based on the hourly pay of a full-time annual civilian salaried employee. The labor rates were inflated from 2006 dollars to 2008 dollars using an inflation factor of 4.1 percent.

Using the total burden hours discussed in Section 6(a) and the hourly wage rates outlined in this section, Exhibit 1 estimates the labor costs associated with the information collection requirements covered in this ICR.

(2) Capital Costs

Capital costs usually include any produced physical good needed to provide the needed information, such as machinery, computers, and other equipment. EPA does not anticipate that respondents will incur capital costs in carrying out the information collection requirements covered in this ICR.

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1. The impact assessment 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," June 30, 2008.

(3) Operation & Maintenance Costs

O&M costs are those costs associated with a paperwork requirement incurred continually over the life of the ICR. This ICR includes O&M costs for postage (i.e., $2.72 for certified mail) and envelope (i.e., $0.01). The ICR includes $0.13 per container label.

6(c) Estimating Agency Hour and Cost Burden

The final rule will be administered by RCRA-authorized State government regulatory programs. Unloaded hourly labor wage rates for States' activities were taken from "Table 2-3. State and Local Government: Mean Hourly Earnings and Weekly Hours by Full-time and Part-time Workers for Selected Occupations, National Compensation Survey, June 2005." The table is found in the "National Compensation Survey: Occupational Wages in the United States, June 2005," U.S. Department of Labor, Bureau of Labor Statistics, August 2006, Bulletin 8521. EPA updated these rates to 2008 levels based on the Employment Cost Index, then multiplied the rates by the fringe benefits and overhead factor of 1.45.[2] Based on this, EPA estimated the following average loaded hourly wage rates for government labor: $54.41 per hour for legal staff, $47.75 per hour for managerial staff, $35.80 per hour for technical staff, and $23.04 per hour for clerical staff. Hour and cost burden to the Agency is estimated in Exhibit 3.

6(d) Estimating the Annual Respondent Universe and Total Hour and Cost Burden

In this section, EPA first describes the estimated respondent universe under the rule. EPA then estimates the annual burden to respondents under the rule's paperwork requirements. Finally, EPA estimates the burden impacts to respondents under the existing RCRA generator paperwork standards.

EPA obtained most of the data and assumptions for the burden calculations in this ICR from EPA's impact assessment developed for this rulemaking. The impact assessment 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, Final Rule" (June 30, 2008).

2. Source: The 1.45 fringe and overhead multiplier factor represents 32.85% full fringe benefits factor plus 12% overhead cost factor. See OMB Circular No. A-76, Attachment C, May 29, 2003: Calculating Public-Private Competition Costs, Figure C1 Table of Standard A-76 Costing Factors. The document can be found at: http://www.whitehouse.gov/omb/circulars/a076/a76_incl_tech_correction.pdf.

(1) Respondent Universe

Table 1 presents the total number of sites at eligible academic entities that are expected to opt into Subpart K during the three-year period covered by this ICR. The table shows the number of large quantity generators (LQGs), small quantity generators (SQGs), and conditionally exempt small quantity generators (CESQGs). It also shows the number of sites with and without an on-site central accumulation area (CAA).

In total, EPA expects eligible academic entities to opt in for 112 of their sites. Of these, EPA estimates that 25 will be LQGs and 87 will be SQGs. EPA does not expect any CESQGs to opt into Subpart K. EPA estimates that 10 sites will have a CAA and 102 will not have a CAA. These 102 sites without a CAA will ship their hazardous waste off-site directly from the laboratories.

Table 2 presents the average number of laboratories per site and the average annual number of containers of unwanted material per laboratory. Information is presented only for those sites expected to opt into Subpart K, as shown in Table 1. Table 2 shows, for example, that each large SQG is estimated to have 181 laboratories on average. Each laboratory is expected to generate five containers of unwanted material, on average, per year.

Table 3 presents the total aggregate annual number of containers of unwanted material generated at sites expected to opt into Subpart K. The table is based on the data presented in Tables 1 and 2. Specifically, EPA multiplied the total number of sites opting into Subpart K (see Table 1) by each site's average number of laboratories and containers of unwanted materials per laboratory (see Table 2). This produced the total aggregate number of containers of unwanted materials expected to be generated annually under Subpart K.

In total, EPA estimates that 352,788 containers of unwanted materials will be generated in laboratories under Subpart K annually. Of these, EPA estimates that 9,000 containers will be generated by sites with CAAs and 343,788 will be generated by sites without CAAs.

EPA used the above data to estimate the annual respondent burden in this ICR.

(2) Annual Respondent Burden under Final Rule

Based on the respondent universe data presented in Tables 1 through 3, EPA estimates the annual incremental hour and cost burden to respondents under the final rule in Exhibit 1. A discussion of the assumptions used in the development of these burden estimates is presented in the following subsections.

(a) Reading the Regulations

EPA estimates that eligible academic entities will opt in for 112 of their sites (i.e., 25 LQGs + 87 SQGs) during the three-year life of this ICR. EPA expects that employees

at these sites will read the Subpart K regulations once during the three-year life of this ICR. In estimating the annual incremental burden to respondents over the three-year period covered by this ICR, EPA annualized the burden of this one-time activity by dividing the number of respondents by three. Thus, EPA estimates that, on average, 37 sites (i.e., 112 sites / 3 years) will read the regulations each year.

Table 1
Total Number of Sites at Eligible Academic Entities Opting into Subpart K
During Three-Year Life of ICR[a]

Size	LQGs			SQGs			CESQGs			Total		
	with CAA	without CAA	Total	with CAA	without CAA	Total	with CAA	without CAA	Total	with CAA	without CAA	Total
4-Year Colleges and Universities and Non-Profit Research Institutes												
Large[b]	0	12	12	0	15	15	0	0	0	0	27	27
Small[c]	4	0	4	0	51	51	0	0	0	4	51	55
Subtotal	4	12	16	0	66	66	0	0	0	4	78	82
2-Year Colleges and Universities												
Large[b]	0	0	0	0	4	4	0	0	0	0	4	4
Small[c]	0	0	0	0	14	14	0	0	0	0	14	14
Subtotal	0	0	0	0	18	18	0	0	0	0	18	18
Vocation Schools												
Large[b]	0	0	0	0	1	1	0	0	0	0	1	1
Small[c]	0	0	0	0	2	2	0	0	0	0	2	2
Subtotal	0	0	0	0	3	3	0	0	0	0	3	3
Teaching Hospitals												
Very Large[d]	0	2	2	0	0	0	0	0	0	0	2	2
Large[e]	6	1	7	0	0	0	0	0	0	6	1	7
Small[f]	0	0	0	0	0	0	0	0	0	0	0	0
Very Small[g]	0	0	0	0	0	0	0	0	0	0	0	0
Subtotal	6	3	9	0	0	0	0	0	0	6	3	9
Total	**10**	**15**	**25**	**0**	**87**	**87**	**0**	**0**	**0**	**10**	**102**	**112**

a. Data obtained from EPA's impact assessment for this rulemaking. See "Table 5-2. Number of Facilities Expected to Adopt the Final Rule by Institution Type, Lab System Size, Generator Status, and CAA Operation."
b. Defined as sites with more than 50 labs, more than 5 studios.
c. Defined as sites with less than 50 labs, less than 5 studios.
d. Defined as sites with more than 50 labs.
e. Defined as sites with 15 labs.
f. Defined as sites with 6 labs.
g. Defined as sites with 2 labs.

Table 2
Number of Laboratories Per Site and Number of Unwanted Material Containers Per Laboratory
(Data are presented only for sites opting into Subpart K[a])

Size	LQG		SQG		CESQG	
	With CAA	Without CAA	With CAA	Without CAA	With CAA	Without CAA
4-Year Colleges and Universities and Non-Profit Research Institutes						
Large[b]	*	525 labs and 45 containers / lab	*	181 labs and 5 containers / lab	*	*
Small[c]	25 labs and 45 containers / lab	*	*	22 labs and 5 containers / lab	*	*
2-Year Colleges and Universities						
Large[b]	*	*	*	181 labs and 5 containers / lab	*	*
Small[c]	*	*	*	22 labs and 5 containers / lab	*	*
Vocational Schools						
Large[b]	*	*	*	181 labs and 5 containers / lab	*	*
Small[c]	*	*	*	22 labs and 5 containers / lab	*	*
Teaching Hospitals						
Very Large[d]	*	501 labs and 34 containers / lab	*	*	*	*
Large[e]	15 labs and 50 containers / lab	15 labs and 50 containers / lab	*	*	*	*
Small[f]	*	*	*	*	*	*
Very Small[g]	*	*	*	*	*	*

a. Data obtained from EPA's impact assessment for this rulemaking. See "Table B-1. Annual Number of Waste Containers Generated by Institution Type, Laboratory System Size, Generator Status, and Central Accumulation Area (CAA) Operation." Data are presented only for sites opting into Subpart K. See Table 1 of this supporting statement for the number of sites opting into Subpart K.
b. Defined as sites with more than 50 labs, more than 5 studios.
c. Defined as sites with less than 50 labs, less than 5 studios.
d. Defined as sites with more than 50 labs.
e. Defined as sites with 15 labs.
f. Defined as sites with 6 labs.
g. Defined as sites with 2 labs.

Table 3
Total Annual Number of Containers of Unwanted Material
Generated at Sites Opting into Subpart K[a]

Size	LQGs			SQGs			CESQGs			Total		
	with CAA	without CAA	Total	with CAA	without CAA	Total	with CAA	without CAA	Total	with CAA	without CAA	Total
4-Year Colleges and Universities and Non-Profit Research Institutes												
Large[b]	0	283,500	283,500	0	13,575	13,575	0	0	0	0	297,075	297,075
Small[c]	4,500	0	4,500	0	5,610	5,610	0	0	0	4,500	5,610	10,110
Subtotal	4,500	283,500	288,000	0	19,185	19,185	0	0	0	4,500	302,685	307,185
2-Year Colleges and Universities												
Large[b]	0	0	0	0	3,620	3,620	0	0	0	0	3,620	3,620
Small[c]	0	0	0	0	1,540	1,540	0	0	0	0	1,540	1,540
Subtotal	0	0	0	0	5,160	5,160	0	0	0	0	5,160	5,160
Vocational Schools												
Large[b]	0	0	0	0	905	905	0	0	0	0	905	905
Small[c]	0	0	0	0	220	220	0	0	0	0	220	220
Subtotal	0	0	0	0	1,125	1,125	0	0	0	0	1,125	1,125
Teaching Hospitals												
Very Large[d]	0	34,068	34,068	0	0	0	0	0	0	0	34,068	34,068
Large[e]	4,500	750	5,250	0	0	0	0	0	0	4,500	750	5,250
Small[f]	0	0	0	0	0	0	0	0	0	0	0	0
Very Small[g]	0	0	0	0	0	0	0	0	0	0	0	0
Subtotal	4,500	34,818	39,318	0	0	0	0	0	0	4,500	34,818	39,318
Total	**9,000**	**318,318**	**327,318**	**0**	**25,470**	**25,470**	**0**	**0**	**0**	**9,000**	**343,788**	**352,788**

a. Numbers in the table are based on the data in Tables 1 and 2.
b. Defined as sites with more than 50 labs, more than 5 studios.
c. Defined as sites with less than 50 labs, less than 5 studios.
d. Defined as sites with more than 50 labs.
e. Defined as sites with 15 labs.
f. Defined as sites with 6 labs.
g. Defined as sites with 2 labs.

(b) Notification of Intent to Comply with Subpart K and Recordkeeping of Agreements

An eligible academic entity must submit the Site Identification Form to notify EPA or the authorized State that it is electing to be subject to Subpart K for all 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 for all laboratories that are owned or operated by the eligible academic entity that are on-site. In estimating the annual incremental burden to respondents over the three-year period covered by this ICR, EPA annualized the burden of this one-time activity by dividing the number of Site Identification Forms by three. Thus, EPA estimates that, each year, 37 forms (i.e., 112 forms/3 years) will be prepared, submitted, and retained.

Teaching hospitals opting into Subpart K must keep a copy of their formal written affiliation agreement with a college or university on file if they are not owned by a college or university. EPA has made the simplifying assumption that 50 percent of teaching hospitals opting into Subpart K (5 sites) are not owned by a college or university and must keep these agreements on file. In estimating the annual incremental burden to them over the three-year period covered by this ICR, EPA annualized the burden of this one-time activity by dividing the number of respondents by three. Thus, EPA estimates that, each year, two sites (i.e., 5 sites/3 years) will retain the agreements on file.

Non-profit research institutes not owned by a college or university opting into Subpart K must keep a copy of the formal written affiliation agreement with a college or university on file. The impact assessment developed for this rulemaking does not estimate the number of non-profit research institutes opting into Subpart K separately from four-year colleges and universities that are opting in. Rather, it estimates the combined number of sites at four-year colleges and universities and non-profit research institutes opting into Subpart K (i.e., 82 sites in total). For purposes of this ICR, EPA has made the simplifying assumption that five percent of these sites are non-profit research institutes (i.e., 4 sites).[3] In estimating the annual incremental burden to them over the three-year period covered by this ICR, EPA annualized the burden of this one-time activity by dividing the number of respondents by three. Thus, EPA estimates that, each year, one site (i.e., 4 sites/3 years) will retain the agreement on file.

(c) Notification of Withdrawal from Subpart K

EPA does not expect any eligible academic entity to submit a withdrawal notification during the three-year period covered by this ICR.

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3. To derive this 5-percent estimate, EPA referred to the impact assessment to obtain the total number of college and university sites (1,256 sites) and non-profit research sites (61 sites) that are eligible for Subpart K. EPA then calculated the percentage of non-profit research sites from the combined total of 1,317 sites (i.e., 61 sites / 1,317 = 5%). EPA applied this 5-percent estimate to the 82 sites, to estimate that 4 are non-profit research sites.

(d) Labeling of Containers of Unwanted Material in the Laboratory

As shown in Table 3, EPA estimates that eligible academic entities subject to Subpart K will generate a total of 352,788 containers of unwanted materials each year. They must label the containers as specified at section 262.206.

(e) Training

Under section 262.207, individuals working in a laboratory at the 112 sites must be trained commensurate with their duties. In addition, LQGs must maintain training records for laboratory workers. EPA's impact assessment estimates that 14 of the 25 LQGs opting into Subpart K will shift in generator status to SQGs because of the laboratory clean-out incentives.[4] Hence, 11 LQGs will be subject to the recordkeeping provision.

Note: EPA believes that, under existing regulations (e.g., OSHA and EPA regulations) and standard industry practices, a variety of training is provided to individuals that use and/or manage chemicals, hazardous materials, and hazardous wastes as part of their job responsibilities. EPA has found, for example, that the predominant practice by colleges and universities currently is to provide training to students regarding proper laboratory and waste management. In addition, contractors/consultants that provide support services to eligible academic entities (e.g., brokers that provide hazardous waste management support to CESQGs) must train their employees, as applicable.

Thus, EPA believes that the training requirements under the rule do not impose incremental burden on respondents.[5]

(f) Removing Containers of Unwanted Material from the Laboratory

EPA assumes that all eligible academic entities under Subpart K will remove their containers of unwanted material and reactive acutely hazardous unwanted materials from each laboratory on a regular basis. Because of this, EPA anticipates that none of the laboratories will accumulate more than 55 gallons of unwanted material or 1 quart of acutely reactive unwanted material before the regularly scheduled removal. As a result, EPA estimates that none of the entities will need to label any of its containers with the date the 55 gallons or the 1 quart of unwanted material is exceeded.

4. See "Table 5-2. Number of Facilities Expected to Adopt the Final Rule by Institution Type, Lab System Size, Generator Status, and CAA Operation." (p. 64) of EPA's impact assessment

5. See pages 55 and 56 of EPA's impact assessment for an additional discussion of EPA's rationale.

(g) Making the Hazardous Waste Determination in the Laboratory

EPA estimates that 102 sites under Subpart K will not have an on-site CAA. Rather, they will make their hazardous waste determinations in the laboratory. EPA expects that a hazardous waste determination will be made for each container of unwanted material in these laboratories. Based on the data in Table 3, EPA estimates that, each year, hazardous waste determinations will be made in the laboratory for 343,788 containers of unwanted materials. EPA assumes that unwanted materials in all of these containers will be determined to be hazardous waste, and thus, the appropriate hazardous waste code(s) will be added to the label that is associated with the containers.

EPA notes that, for purposes of this analysis, only the addition of the appropriate hazardous waste code(s) to the container labels is considered incremental burden. Under existing regulations (40 *CFR* 262.11), generators must determine if their waste is hazardous per 40 *CFR* 261.3. Thus, the hazardous waste determination does not impose incremental burden on respondents.

(h) Making the Hazardous Waste Determination in an On-site Central Accumulation Area

EPA estimates that 10 sites under Subpart K will have an on-site CAA at which they will make their hazardous waste determinations. EPA expects that a hazardous waste determination will be made for each container of unwanted material at the CAAs. Based on the data in Table 3, EPA estimates that, each year, hazardous waste determinations will be made at CAAs for 9,000 containers of unwanted materials. EPA assumes that unwanted materials in all of these containers will be determined to be hazardous waste and thus, the appropriate hazardous waste code(s) will be added to the label that is associated with the containers.

EPA notes that, for purposes of this analysis, only the addition of the appropriate hazardous waste code(s) to the container labels is considered incremental burden. Under existing regulations (40 *CFR* 262.11), generators must determine if their waste is hazardous. Thus, the hazardous waste determination does not impose incremental burden on respondents.

(i) Making the Hazardous Waste Determination at an On-site Interim Status or Permitted Treatment, Storage, or Disposal Facility

EPA expects that no hazardous waste determinations will be made at an on-site interim status or permitted TSDF during the three-year period covered by this ICR.

(j) Laboratory Clean-outs

EPA estimates that 20 percent of the laboratories at each site under Subpart K will conduct a laboratory clean-out annually. In addition, EPA estimates that 10 percent of all of the containers of unwanted material generated by these laboratories during the year will originate from their laboratory clean-out. Hence, EPA multiplied the total number of containers in Table 3 by 20 percent and 10 percent, to estimate that 7,056 containers will originate from laboratory clean-outs annually (i.e., 352,788 x 20% x 10% = 7,056). EPA estimates that personnel will spend two minutes per container to document the clean-out and two minutes per container to maintain documentation of the clean-out.[6]

(k) Laboratory Management Plan

Eligible academic entities are required to develop a Laboratory Management Plan or modify an existing plan for their sites under Subpart K. For purposes of this ICR, EPA assumes that they will revise an existing plan (e.g., Chemical Hygiene Plan) to comply with the Laboratory Management Plan requirement. In estimating the annual incremental burden to respondents over the three-year period covered by this ICR, EPA annualized the burden of this one-time activity by dividing the number of Laboratory Management Plans by three. Thus, EPA estimates that, on average, eligible academic entities will prepare 37 Laboratory Management Plans per year (i.e., 112 Plans / 3 years).

EPA also estimates that each site will review, revise, and keep records of its Laboratory Management Plan each year.[7]

Finally, the eligible academic entities must make the Laboratory Management Plan available to others (e.g., laboratory workers, students).

(3) Annual Respondent Hour and Cost Impacts under Existing Paperwork Requirements

Some eligible academic entities may be relieved of some of the existing generator standards under the rule, e.g., if they shift downward in generator status under Subpart K. The impact assessment developed by EPA for this rulemaking estimates that 14 LQGs will shift to SQGs and 7 SQGs will shift to CESQGs because of Subpart K's laboratory clean-out incentives.[8] As a result, these sites will see some burden relief from the existing paperwork requirements.

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6. See page 46 of EPA's impact assessment for an additional discussion of EPA's assumptions.

7. EPA's impact assessment estimates that eligible academic entities will spend 4 hours every 3 years to maintain and update the Laboratory Management Plan (p. 47). In preparing this ICR, EPA annualized the 4 hours over three years, to estimate that eligible academic entities will spend 1.33 hours per year to review, revise and keep records of each of the 112 Laboratory Management Plans.

8. See page 64 of EPA's impact assessment for additional information (i.e., "Table 5-2. Number of Facilities Expected to Adopt the Final Rule by Institution Type, Lab System Size, Generator Status, and CAA Operation.").

Exhibit 2 presents the total annual burden under the final rule's paperwork requirements, as well as the annual burden impacts (i.e., burden relief) under the existing paperwork requirements. The burden relief under the existing requirements is presented according to the approved ICR in which the requirements are addressed. Below is a brief discussion of these ICRs, along with a description of relevant capital and O&M costs affected:

- Requirements for Generators, Transporters, and Waste Management Facilities under the RCRA Hazardous Waste Manifest System (EPA ICR Number 801). EPA estimates that some eligible academic entities will see some efficiencies in the movement of their hazardous waste under the final rule, resulting in fewer manifests being prepared. In addition, EPA estimates that sites that drop in generator status (e.g., change from LQG to SQG) will need to prepare fewer manifests because they will not need to ship their waste offsite as often as under the baseline. There are annual capital cost savings of $244 for fewer file cabinets needed to keep records of manifests. There are annual O&M cost savings of $998 for fewer transmittals of manifests by mail.

- Hazardous Waste Generator Standards (EPA ICR Number 820). EPA estimates that sites that drop in generator status under Subpart K will see savings from reduced generator requirements. There are no capital cost savings. There are annual savings in O&M costs of $19. These savings are associated with the photocopying and transmittal of fewer records.

- The 2007 Hazardous Waste Report (EPA ICR Number 976). EPA estimates that LQGs that drop in generator status to SQGs under Subpart K will see savings for no longer preparing/submitting a Hazardous Waste Report. There are no capital cost savings. There are annual savings in O&M costs of $14. These savings are associated with the transmittal and recordkeeping of fewer forms.

6(e) Bottom Line Hour and Cost Burden

(1) Respondent Tally

As shown in Exhibit 2, EPA estimates the total annual burden to respondents under the new paperwork requirements to be 14,459 hours and $562,079. Taking into account the annual burden relief to respondents under the existing paperwork requirements, the total net annual burden to respondents is estimated to be 12,557 hours and $461,632. The bottom-line burden over three years is estimated to be 37,671 hours and $1,384,896.

(2) Agency Tally

As shown in Exhibit 3, EPA estimates the total annual burden to the government under the new paperwork requirements to be 28 hours and $757. The bottom-line burden over three years is estimated to be 84 hours and $2,271.

6(f) Reasons for Change In Burden

In establishing Subpart K, EPA has established some information collection requirements to ensure that the hazardous wastes at eligible academic entities are managed in a manner that is protective of human health and the environment. EPA believes these requirements are justified because the Subpart K regulations allow eligible academic entities flexibility to tailor their laboratory operations to meet their individual circumstances, and remain protective of human health and the environment. Performance-based standards for the management of hazardous wastes generated in laboratories provide a better opportunity for eligible academic entities to evaluate their overall hazardous waste management program, and tailor it in such a way that facilitates efficient and safe management of hazardous waste and minimizes burden, while at the same time maintaining a high standard of protection of human health and the environment. The alternative approach will help them centralize and coordinate their chemical management practices and achieve sound environmental performance.

6(g) Public Burden Statement

The hourly reporting burden associated with the final rule is estimated to be 10 minutes per respondent. This includes time for preparing and submitting a Site Identification Form to opt into Subpart K. The hourly recordkeeping burden associated with the final rule is estimated to be approximately 130 hours per respondent. This includes time for reading the regulations, labeling containers, and preparing and maintaining specified documents (e.g., Laboratory Management Plan).

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket under Docket ID Number EPA-HQ-RCRA-2003-0012, which is available for online viewing at www.regulations.gov, or in person viewing at the Resource Conservation and Recovery Act (RCRA) Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, NW, Washington, D.C. The EPA Docket Center 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 Reading Room is (202) 566-1744, and the telephone number for the Resource Conservation and Recovery Act (RCRA) Docket is 202-566-0270. An electronic version of the public docket is available at http://www.regulations.gov. This site can be used to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. When in the system, select "search," then key in the Docket ID Number identified above. Also,

you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, D.C. 20503, Attention: Desk Officer for EPA. Please include the EPA Docket ID Number EPA-HQ-RCRA-2003-0012, and OMB Control Number 2050-NEW in any correspondence.

EXHIBIT 1

GENERATOR STANDARDS APPLICABLE TO LABORATORIES OWNED BY ELIGIBLE ACADEMIC ENTITIES [a]

ESTIMATED ANNUAL RESPONDENT HOUR AND COST BURDEN

	Hours and Costs per Respondent								Total Hours and Costs		
INFORMATION COLLECTION ACTIVITY	Legal $116.58/Hr	Manager $63.72/Hr	Technical $35.14/Hr	Clerical $26.50/Hr	Respon. Hours/ Activity	Labor Cost/ Activity	Capital/ Startup Cost	O&M Cost/ Activity	Number of Respondents/ Activities	Total Hours/ Year	Total Cost/ Year
READING THE REGULATIONS											
Read the regulations	0.00	0.00	1.00	0.00	1.00	$35.14	$0.00	$0.00	37	37.00	$1,300.18
Subtotal	0.00	0.00	1.00	0.00	1.00	$35.14	$0.00	$0.00	37	37.00	$1,300.18
NOTIFICATION OF INTENT TO COMPLY WITH SUBPART K AND RECORDKEEPING OF AGREEMENTS (40 *CFR* 262.203)											
Eligible Academic Entities											
Prepare and submit Site Identification Form	0.00	0.10	0.30	0.10	0.50	$19.56	$0.00	$2.73	37	18.50	$824.73
Keep a copy of the notification on file	0.00	0.00	0.00	0.10	0.10	$2.65	$0.00	$0.00	37	3.70	$98.05
Teaching Hospitals											
Keep a copy of the formal written affiliation agreement on file	0.00	0.00	0.00	0.10	0.10	$2.65	$0.00	$0.00	2	0.20	$5.30
Non-Profit Research Institutes											
Keep a copy of the formal written affiliation agreement on file	0.00	0.00	0.00	0.10	0.10	$2.65	$0.00	$0.00	1	0.10	$2.65
Subtotal	0.00	varies	varies	varies	varies	varies	$0.00	varies	varies	22.50	$930.73
NOTIFICATION OF WITHDRAWAL FROM SUBPART K (40 *CFR* 262.204)											
Prepare and submit Site Identification Form	0.00	0.10	0.30	0.10	0.50	$19.56	$0.00	$2.73	0	0.00	$0.00
Keep a copy of the withdrawal notice on file	0.00	0.00	0.00	0.10	0.10	$2.65	$0.00	$0.00	0	0.00	$0.00
Subtotal	0.00	0.10	0.30	0.20	0.60	$22.21	$0.00	$2.73	0	0.00	$0.00
LABELING OF CONTAINERS OF UNWANTED MATERIAL IN THE LABORATORY (40 *CFR* 262.206)											
Label the containers as specified	0.00	0.00	0.017	0.00	0.017	$0.60	$0.00	$0.13	352,788	5,997.40	$257,535.24
Subtotal	0.00	0.00	0.017	0.00	0.017	$0.60	$0.00	$0.13	352,788	5,997.40	$257,535.24
TRAINING (40 *CFR* 262.207)											
Provide training to all individuals in a laboratory	0.00	0.00	0.00	0.00	0.00	$0.00	$0.00	$0.00	112	0.00	$0.00
Maintain documentation demonstrating training for all laboratory workers (LQGs only)	0.00	0.00	0.00	0.00	0.00	$0.00	$0.00	$0.00	11	0.00	$0.00
Subtotal	0.00	0.00	0.00	0.00	0.00	$0.00	$0.00	$0.00	varies	0.00	$0.00

EXHIBIT 1 (cont'd)
GENERATOR STANDARDS APPLICABLE TO LABORATORIES OWNED BY ELIGIBLE ACADEMIC ENTITIES [a]
ESTIMATED ANNUAL RESPONDENT HOUR AND COST BURDEN

	Hours and Costs per Respondent								Total Hours and Costs		
INFORMATION COLLECTION ACTIVITY	Legal $116.58/Hr	Manager $63.72/Hr	Technical $35.14/Hr	Clerical $26.50/Hr	Respon. Hours/ Activity	Labor Cost/ Activity	Capital/ Startup Cost	O&M Cost/ Activity	Number of Respondents/ Activities	Total Hours/ Year	Total Cost/ Year
REMOVING CONTAINERS OF UNWANTED MATERIAL FROM THE LABORATORY (40 *CFR* 262.208)											
Ensure that containers of unwanted material that exceed volume limits have the date of the exceedence on the label	0.00	0.00	0.017	0.00	0.017	$0.60	$0.00	$0.00	0	0.00	$0.00
Subtotal	0.00	0.00	0.017	0.00	0.017	$0.60	$0.00	$0.00	0	0.00	$0.00
MAKING THE HAZARDOUS WASTE DETERMINATION IN THE LABORATORY (40 *CFR* 262.210)											
Make the hazardous waste determination	0.00	0.00	0.00	0.00	0.00	$0.00	$0.00	$0.00	343,788	0.00	$0.00
Place hazardous waste codes on the container label	0.00	0.00	0.017	0.00	0.017	$0.60	$0.00	$0.00	343,788	5,844.40	$206,272.80
Subtotal	0.00	0.00	0.017	0.00	0.017	$0.60	$0.00	$0.00	343,788	5,844.40	$206,272.80
MAKING THE HAZARDOUS WASTE DETERMINATION IN AN ON-SITE CENTRAL ACCUMULATION AREA (40 *CFR* 262.211)											
Make hazardous waste determination	0.00	0.00	0.00	0.00	0.00	$0.00	$0.00	$0.00	9,000	0.00	$0.00
Place hazardous waste codes on the container label	0.00	0.00	0.017	0.00	0.017	$0.60	$0.00	$0.00	9,000	153.00	$5,400.00
Subtotal	0.00	0.00	0.017	0.00	0.017	$0.60	$0.00	$0.00	9,000	153.00	$5,400.00
MAKING THE HAZARDOUS WASTE DETERMINATION AT AN ON-SITE INTERIM STATUS OR PERMITTED TREATMENT, STORAGE, OR DISPOSAL FACILITY (40 *CFR* 262.212)											
Make hazardous waste determination	0.00	0.00	0.00	0.00	0.00	$0.00	$0.00	$0.00	0	0.00	$0.00
Place hazardous waste codes on the container label	0.00	0.00	0.017	0.00	0.017	$0.60	$0.00	$0.00	0	0.00	$0.00
Subtotal	0.00	0.00	0.017	0.00	0.017	$0.60	$0.00	$0.00	0	0.00	$0.00
LABORATORY CLEAN-OUTS (40 *CFR* 262.213)											
Document the activities of the laboratory clean-out	0.00	0.00	0.03	0.00	0.03	$1.05	$0.00	$0.00	7,056	211.67	$7,408.55
Maintain records of the clean-out	0.00	0.00	0.00	0.03	0.03	$0.80	$0.00	$0.00	7,056	211.67	$5,644.61
Subtotal	0.00	0.00	0.03	0.03	0.06	$1.85	$0.00	$0.00	7,056	423.34	$13,053.16
LABORATORY MANAGEMENT PLAN (40 *CFR* 262.214)											
Develop Laboratory Management Plan, or revise an existing written plan	0.00	8.00	40.00	0.00	48.00	$1,915.36	$0.00	$0.00	37	1,776.00	$70,868.32
Retain, review and revise the Laboratory Management Plan	0.00	0.00	1.33	0.00	1.33	$46.74	$0.00	$0.00	112	148.96	$5,234.88
Make the Laboratory Management Plan available to others	0.00	0.00	0.00	0.50	0.50	$13.25	$0.00	$0.00	112	56.00	$1,484.00
Subtotal	0.00	varies	varies	varies	varies	varies	$0.00	$0.00	varies	1,980.96	$77,587.20
TOTAL	0.00	varies	varies	varies	varies	varies	$0.00	varies	varies	14,458.60	$562,079.31

[a] Exhibit contains rounding error.

EXHIBIT 2

GENERATOR STANDARDS APPLICABLE TO LABORATORIES OWNED BY ELIGIBLE ACADEMIC ENTITIES[a]

ESTIMATED ANNUAL RESPONDENT HOUR AND COST BURDEN - NEW AND EXISTING PAPERWORK REQUIREMENTS

	ICR Number	Hours/Year	Labor Cost/Year	Capital Cost/Year	O&M Cost/Year	Total Cost/Year
Paperwork Requirements						
New Paperwork Requirements						
Generator Standards Applicable to Laboratories at Eligible Academic Entities	2317.01	14,459	$516,116	$0	$45,963	$562,079
Existing Paperwork Requirements						
Requirements for Generators, Transporters, and Waste Management Facilities under the RCRA Hazardous Waste Manifest System	801	(1,612)	($81,667)	($244)	($998)	($82,909)
Hazardous Waste Generator Standards	820	(249)	($15,845)	$0	($19)	($15,864)
The 2007 Hazardous Waste Report	976	(41)	($1,660)	$0	($14)	($1,674)
Subtotal: Existing Paperwork Requirements		(1,902)	($99,172)	($244)	($1,031)	($100,447)
Total under the Final Rule: New and Existing Paperwork		12,557	$416,944	($244)	$44,932	$461,632

[a] Table includes rounding error. Savings shown in parentheses.

EXHIBIT 3
GENERATOR STANDARDS APPLICABLE TO LABORATORIES OWNED BY ELIGIBLE ACADEMIC ENTITIES [a]
ESTIMATED ANNUAL AGENCY HOUR AND COST BURDEN

	Hours and Costs per Respondent								Total Hours and Costs		
INFORMATION COLLECTION ACTIVITY	Legal $54.41/Hr	Manager $47.75/Hr	Technical $35.80/Hr	Clerical $23.04/Hr	Agency Hours/ Activity	Labor Cost/ Activity	Capital/ Startup Cost	O&M Cost/ Activity	Number of Agency Activities	Total Hours/ Year	Total Cost/ Year
NOTIFICATION OF INTENT TO COMPLY WITH SUBPART K AND RECORDKEEPING OF AGREEMENTS (40 *CFR* 262.203)											
Review and process Site Identification Forms	0.00	0.00	0.25	0.50	0.75	$20.47	$0.00	$0.00	37	27.75	$757.39
Subtotal	0.00	0.00	0.25	0.50	0.75	$20.47	$0.00	$0.00	37	27.75	$757.39
NOTIFICATION OF WITHDRAWAL FROM SUBPART K (40 *CFR* 262.204)											
Review and process Site Identification Forms	0.00	0.00	0.25	0.50	0.75	$20.47	$0.00	$0.00	0	0.00	$0.00
Subtotal	0.00	0.00	0.25	0.50	0.75	$20.47	$0.00	$0.00	0	0.00	$0.00
TOTAL	0.00	0.00	varies	varies	varies	varies	$0.00	$0.00	varies	27.75	$757.39

[a] Exhibit contains rounding error.