SUPPORTING STATEMENT FOR INFORMATION COLLECTION REQUEST NUMBER 2317.03 "GENERATOR STANDARDS APPLICABLE TO LABORATORIES OWNED BY ELIGIBLE ACADEMIC ENTITIES" (RENEWAL)

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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 (Renewal)," EPA ICR Number 2317.03, OMB Number 2050-0204.

1(b) Short Characterization

The U.S. Environmental Protection Agency (EPA) has promulgated an alternative set of generator requirements applicable to laboratories owned by eligible academic entities, as defined in the final rule published at 73 FR 72912, December 1, 2008. 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.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need and Authority for the Collection

The Subpart K regulations within 40 *CFR* Part 262 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 Subpart K regulations. 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 at 73 FR 72912. 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 waste streams 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 (EPA Form 8700-12, see OMB Control No. 2050-0024) 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 in §262.206. 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).

Labeling of containers of unwanted materials in the laboratory are as follows:

- The words "unwanted material" or another equally effective term that is to be used consistently by the eligible academic entity.
- Sufficient information to alert emergency responders to the contents of the container (e.g. name of the chemicals or class/type of the chemical).
- The date that the unwanted material first began accumulating in the container.
- Information sufficient to allow a trained professional to properly identify whether an unwanted material is a solid and hazardous waste and to assign the proper hazardous waste code(s), pursuant to § 262.11.

(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).

Labeling of containers of unwanted materials in the laboratory are as follows:

- The words "unwanted material" or another equally effective term that is to be used consistently by the eligible academic entity.
- Sufficient information to alert emergency responders to the contents of the container (e.g. name of the chemicals or class/type of the chemical).
- The date that the unwanted material first began accumulating in the container.
- Information sufficient to allow a trained professional to properly identify whether an unwanted material is a solid and hazardous waste and to assign the proper hazardous waste code(s), pursuant to § 262.11.

(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 Subpart K regulations is duplicative with any information required by the existing Federal regulations.

3(b) Public Notice

In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), the Agency issued a notice in the Federal Register on December 9, 2015 (80 <u>FR</u> 76467),

soliciting public comments on the accuracy of the burden estimates in this supporting statement. No comments were received.

3(c) Consultations

The regulations covered by this ICR were promulgated using proper rulemaking procedures. In updating this ICR, EPA spoke with a number of industry representatives. Their feedback is reflected in this ICR. EPA's Burden Estimate Methodology, which is appended as Attachment 1, provides information on the consultations. The following members of the regulated community were contacted:

- June Brock-Carroll, Clemson University (864-633-6357)
- Jeremy Kuhar, Gettysburg College (717-337-6261)
- Jerry Goodwin, University of Missouri, St. Louis (314-516-6363)
- Neil Day, University of Wyoming (307-766-3698)
- Bruce Backus, Washington University in St. Louis (314-935-9882)
- Jeff Rogers, University of Vermont (802-656-0767)
- Michael Webb, University of Arkansas (501-686-6958)

3(d) Effects of Less Frequent Collection

EPA has carefully considered the information collection burden imposed by the final rule promulgating the Subpart K regulations. 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 the Subpart K Regulations

Description of NAICS Code	NAICS Codes					
Colleges and Universities						
Junior Colleges	6112, 61121, 611210					
Colleges, Universities, and Professional	6113, 61131, 611310					
Schools						
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,	5417, 54171, 541710					
Engineering, and Life Sciences						
Research and Development in the Social	54172, 541720					
Sciences and Humanities						

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

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. A teaching hospital must keep a copy of the agreement on file at the eligible academic entity for as long as its laboratories are subject to this subpart.

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. A non-profit research institute must keep a copy of the agreement on file at the eligible academic entity for as long as its laboratories are subject to this subpart.

(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) <u>Data Items:</u>

- 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. An eligible academic entity must maintain a copy of its notification to withdraw from Subpart K on file for three years from the date of the notification of withdrawal from the Subpart K requirements.

(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) <u>Data Items:</u>

- 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). These training records must be kept until the institution closes or for three years after the departure of a trained professional or laboratory worker.

(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 exceedance 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) <u>Data Items:</u>
- 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) <u>Data Items:</u>

- 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) <u>Data Items:</u>
- 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. These records must be maintained by the academic entity for three years from the date the laboratory 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.

(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
 - Procedures 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 Subpart K regulations allow 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

EPA estimates an average loaded respondent hourly labor rate of \$110.36 for legal staff, \$89.87 for managerial staff, \$46.67 for technical staff, and \$25.07 for clerical staff. These hourly labor rates are based on the most current estimates of national crossindustry wages by the U.S. Bureau of Labor Statistics¹ for the following occupational groups, respectively, multiplied by a factor² of 1.6918 to account for fringe benefits³ and overhead⁴:

SOC 23-1011: Lawyers;

SOC 11-1021: General & Operations Managers;

SOC 17-2081: Environmental Engineers and SOC 17-3025: Environmental Engineering Technicians and SOC 19-4031: Chemical Technicians; and SOC 43-9061: Office Clerks, General.

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

¹ US Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) for May 2014 National Occupational Employment and Wage Estimates. The wage rate for legal and managerial are specific to colleges and universities industry and can be found at http://www.bls.gov/oes/current/naics4 611300.htm#11-0000

^{2 = [1+ (}Fringe Benefits %) / (100% - Fringe Benefits %)] x (1+ Overhead %)

³ Applied "All goods-producing" industry group fringe benefits percentage of 33.8% from "Table 6. Private industry, by major industry group" of the US Bureau of Labor Statistics (BLS) "Employer Costs for Employee Compensation" (ECEC), June 2015 at http://www.bls.gov/schedule/archives/ecec_nr.htm.

⁴ In absence of data specific to industry, applied 12% Federal civilian overhead cost factor from Figure C1 of the REVISED February OMB Circular A-76 at http://www.whitehouse.gov/omb/circulars a076 a76 incl tech correction/.

anticipate that respondents will incur capital costs in carrying out the information collection requirements covered in this ICR.

(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., \$3.45 currently for certified mail) and envelope (i.e., \$0.012). The ICR includes \$0.15 per container label.

To update the O&M costs in the previous ICR (2317.02), which were based mainly on the 2011 costs, EPA referred to the U.S. Bureau of Labor Statistics (BLS)'s Consumer Price Index data for all urban consumers (1982 – 84 index = 100) at http://www.bls.gov/cpi/cpi dr.htm. EPA used the December 2011 index (225.672) and June 2015 index (238.638) to develop an adjustment factor of 1.0575 (= 238.638 / 225.672).

6(c) Estimating Agency Hour and Cost Burden

The final rule promulgating the Subpart K regulations will be administered by RCRA-authorized State government regulatory programs. EPA estimated the following average loaded hourly wage rates for government labor: \$71.77 per hour for legal staff, \$77.82 per hour for managerial staff, \$62.93 per hour for technical staff, and \$27.21 per hour for clerical staff. These hourly labor rates are based on the most current estimates of State government wages by the U.S. Bureau of Labor Statistics⁵ for occupational groups SOC 23-1011: Lawyers; SOC 11-1021: General & Operations Managers; SOC 17-2081: Environmental Engineers; and SOC 43-9061: Office Clerks, General, respectively, multiplied by a factor⁶ of 1.75 to account for fringe benefits⁷ and overhead⁸. Hour and cost burden to the Agency is estimated in Exhibit 2.

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.

⁵ US Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) for May 2014 National Industry-Specific Occupational Employment & Wage Estimates for NAICS 999200 State Government: http://www.bls.gov/oes/current/naics4 999200.htm

^{6 = [1+ (}Fringe Benefits %) / (100% - Fringe Benefits %)] x (1+ Overhead %)

⁷ Applied 36.0% fringe benefits percentage from "Table 3. State and local government, by major occupational and industry group" of the US Bureau of Labor Statistics (BLS) "Employer Costs for Employee Compensation" (ECEC), June 2015 at http://www.bls.gov/schedule/archives/ecec_nr.htm.

⁸ In absence of data specific to industry, applied 12% Federal civilian overhead cost factor from Figure C1 of the REVISED February OMB Circular A-76 at http://www.whitehouse.gov/omb/circulars a076 a76 incl tech correction/.

EPA obtained most of the data and assumptions for the burden calculations in the previous ICR (2317.02) from EPA's impact assessment developed for the final rule promulgating the Subpart K regulations. For this ICR renewal, EPA consulted with a number of industry officials to update and/or verify respondent burden estimates for the Subpart K regulatory activities. See Attachment 1 - Burden Estimate Methodology.

(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 132 of their sites; see Attachment 2 – Summary of Universe Calculations. Of these, EPA estimates that 60 will be LQGs, 37 will be SQGs, and 35 will be CESQGs. EPA estimates that 90 sites will have a CAA and 42 will not have a CAA. These 42 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 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 936,148 containers of unwanted materials will be generated in laboratories under Subpart K annually. Of these, EPA estimates that 927,223 containers will be generated by sites with CAAs and 8,925 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 **Subpart K**

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 Subpart K regulations 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 132 of their sites (i.e., 60 LQGs + 37 SQGs + 35 CESQGs) 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, 44 sites (i.e., 132 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

	LQGs			SQGs			CESQGs			Total			
								without			without		
Size	with CAA	without CAA	Total	with CAA	without CAA	Total	with CAA	CAA	Total	with CAA	CAA	Total	
4-Year Colleg	es and Unive	ersities and Non	-Profit Re	search Insti	tutes								
Large ^b	47	0	47	19	0	19	0	0	0	66	0	66	
Small ^c	0	0	0	10	7	17	0	34	34	10	41	51	
Subtotal	47	0	47	29	7	36	0	34	34	76	41	117	
2-Year Colleg	2-Year Colleges and Universities												
Large ^b	0	0	0	0	0	0	0	0	0	0	0	0	
Small ^c	0	0	0	0	0	0	0	0	0	0	0	0	
Subtotal	0	0	0	0	0	0	0	0	0	0	0	0	
Vocation Schools													
Large ^b	0	0	0	0	0	0	0	0	0	0	0	0	
Small ^c	0	0	0	0	0	0	0	0	0	0	0	0	
Subtotal	0	0	0	0	0	0	0	0	0	0	0	0	
Teaching Hospitals													
Very Large ^d	0	0	0	0	0	0	0	0	0	0	0	0	
Large ^e	13	0	13	1	0	1	0	0	0	14	0	14	
Small ^f	0	0	0	0	0	0	0	1	1	0	1	1	
Very Small ^g	0	0	0	0	0	0	0	0	0	0	0	0	
Subtotal	13	0	13	1	0	1	0	1	1_	14	1	15	
Total	60	0	60	30	7	37	0	35	35	90	42	132	

- a. Data updated per Attachment 2 Summary of Industry Universe Calculations.
- 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)

	LO)G	S	QG	CESQG		
Size	With CAA	Without CAA	With CAA	Without CAA	With CAA	Without CAA	
4-Year Colleg	es and Universities ar	d Non-Profit Resear	ch Institutes				
Large ^b	561 labs and 34 containers / lab	*	84 labs and 19 containers / lab	*	*	*	
Small ^c	*	*	19 labs and 24 containers / lab	33 labs and 18 containers / lab	*	7 labs and 20 containers / lab	
2-Year Colleg	es and Universities						
Large ^b	*	*	*	*	*	*	
Small ^c	*	*	*	*	*	*	
Vocational Sc	hools						
Large ^b	*	*	*	*	*	*	
Small ^c	*	*	*	*	*	*	
Teaching Hos	pitals		•		•		
Very Large ^d	501 labs and 34 containers / lab	*	*	*	*	*	
Large ^e	15 labs and 50 containers / lab		*	*	*	*	
Small ^f	* *		6 labs and 7 containers / lab	6 labs and 7 containers / lab	*	2 labs and 5 containers / lab	
Very Small ^g	*	*	*	*	*	*	

- a. Data updated per Attachment 1 Burden Estimate Methodology.
- 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

		LQGs		- CITCI CICC CI	CESQGs			Total				
		without			without			without			without	
Size	with CAA	CAA	Total	with CAA	CAA	Total	with CAA	CAA	Total	with CAA	CAA	Total
4-Year College	s and Unive	rsities and N	on-Profit Resea	arch Institutes								
Large ^b	883,309	0	883,309	29,664	0	29,664	0	0	0	912,973	0	912,973
Small ^c	0	0	0	4,500	4,165	8,665	0	4,760	4,760	4,500	8,925	13,425
Subtotal	883,309	0	883,309	34,164	4,165	38,329	0	4,760	4,760	917,473	8,925	926,398
2-Year College	2-Year Colleges and Universities											
Large ^b	0	0	0	0	0	0	0	0	0	0	0	0
Small ^c	0	0	0	0	0	0	0	0	0	0	0	0
Subtotal	0	0	0	0	0	0	0	0	0	0	0	0
Vocational Schools												
Large ^b	0	0	0	0	0	0	0	0	0	0	0	0
Small ^c	0	0	0	0	0	0	0	0	0	0	0	0
Subtotal	0	0	0	0	0	0	0	0	0	0	0	0
Teaching Hospitals												
Very Large ^d	0	0	0	0	0	0	0	0	0	0	0	0
Large ^e	9,750	0	9,750	0	0	0	0	0	0	9,750	0	9,750
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	9,750	0	9,750	0	0	0	0	0	0	9,750	0	9,750
Total	893,059	0	893,059	34,164	4,165	38,329	0	4,760	4,760	927,223	8,925	936,148

- 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, 44 forms (i.e., 132 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 (15 sites \times 50% = 8 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, 3 sites (i.e., 15 sites \times 50% / 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 the final rule promulgating the Subpart K regulations 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., 117 sites in total). For purposes of this ICR, EPA has made the simplifying assumption that approximately five percent of these sites are non-profit research institutes (i.e., 6 sites). 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., 6 sites/3 years) will retain the agreement on file.

(c) Notification of Withdrawal from Subpart K

An eligible academic entity must submit the Site Identification Form to notify EPA or the authorized State that it is electing to withdraw from Subpart K for all

^{9&}lt;sup>-</sup> To derive this 5-percent estimate, EPA referred to the impact assessment to obtain the <u>total</u> 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 117 sites, to estimate that 6 are non-profit research sites.

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, 1 forms (i.e., 2 forms/3 years) will be prepared, submitted, and retained.

(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 936,148 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 132 sites must be trained commensurate with their duties. In addition, LQGs must maintain training records for laboratory workers. EPA's impact assessment estimates that 56% of the LQGs opting into Subpart K will shift in generator status to SQGs because of the laboratory clean-out incentives. Hence, $34 (= 60 \times 56\%)$ 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.¹¹

(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

^{10&}lt;sup>-</sup> 14 of the 25 LQGs studied previously, per "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.

¹¹ See pages 55 and 56 of EPA's impact assessment for an additional discussion of EPA's rationale.

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.

(g) Making the Hazardous Waste Determination in the Laboratory

EPA estimates that 42 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 8,925 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 90 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 927,223 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 18,723 containers will originate from laboratory clean-outs annually (i.e., $936,148 \times 20\% \times 10\% = 18,723$). 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.

(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 44 Laboratory Management Plans per year (i.e., 132 Plans / 3 years).

EPA also estimates that each site will review, revise, and keep records of its Laboratory Management Plan each year.¹³

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 the final rule promulgating the Subpart K regulations estimates that 14 LQGs will shift to SQGs and 7 SQGs will shift to CESQGs because of Subpart K's laboratory clean-out incentives. As a result, these sites will see some burden relief from the existing paperwork requirements.

^{12.} See page 46 of EPA's impact assessment for an additional discussion of EPA's assumptions.

¹³ 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 132 Laboratory Management Plans.

¹⁴ 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.").

6(e) Bottom Line Hour and Cost Burden

(1) Respondent Tally

As shown in Exhibit 1, EPA estimates the total annual burden to respondents under the new paperwork requirements to be 35,813 hours and \$1,806,663.

(2) Agency Tally

As shown in Exhibit 2, EPA estimates the total annual burden to the government under the new paperwork requirements to be 34 hours and \$1,320.

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.

The annual respondent burden in this current ICR (#2317.03) is estimated to be 35,813 hours, which is an increase of 8,094 hours from the previously approved ICR. This increase is an adjustment to the existing estimates based on data gathered through industry consultations and review of the Resource Conservation and Recovery Act Information (RCRAInfo) national database (see Attachments 1 and 2), not due to program changes. The number of respondents increased from 99 to 132.

6(g) Public Burden Statement

The annual public reporting and recordkeeping burden for this collection of information is estimated to average .02 hours per response.

The hourly reporting burden associated with Subpart K 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 Subpart K is estimated to be approximately 280 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-2012-0163, 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-2012-0163, and OMB Control Number 2050–0204 in any correspondence.

EXHIBIT 1GENERATOR STANDARDS APPLICABLE TO LABORATORIES OWNED BY ELIGIBLE ACADEMIC ENTITIES ^a
ESTIMATED ANNUAL RESPONDENT HOUR AND COST BURDEN

				Hours an	d Costs per Res	pondent			To	otal Hours and (Costs
INFORMATION COLLECTION	Legal	Manager	Technical	Clerical	Respon. Hours/	Labor Cost/	Capital/ Startup	O&M	Number of Respondents	Total Hours/	Total Cost/
ACTIVITY	\$110.36/Hr	\$89.87/Hr	\$46.67/Hr	\$25.07/Hr	Activity	Activity	Cost	Cost/ Activity	/ Activities	Year	Year
READING THE R	EGULATIONS			I					<u> </u>		
Read the regulations	0.00	0.00	1.00	0.00	1.00	\$46.67	\$0.00	\$0.00	44	44.00	\$2,053.48
Subtotal	0.00	0.00	1.00	0.00	1.00	\$46.67	\$0.00	\$0.00	44	44.00	\$2,053.48
NOTIFICATION (<u> </u>		· · · · · · · · · · · · · · · · · · ·			. ,
Eligible Academ						`		•			
Prepare and											
submit Site Identification											
Form	0.00	0.10	0.30	0.10	0.50	\$25.50	\$0.00	\$3.46	44	22	\$1,274.31
Keep a copy of the notification											,
on file	0.00	0.00	0.00	0.10	0.10	\$2.51	\$0.00	\$0.00	44	4.4	\$110.44
Teaching Hospit	als			1	T	T		T	<u> </u>		
Keep a copy of the formal written affiliation agreement on											
file	0.00	0.00	0.00	0.10	0.10	\$2.51	\$0.00	\$0.00	3	0.30	\$7.53
Non-Profit Resea	arch Institutes										
Keep a copy of the formal written affiliation agreement on											
file	0.00	0.00	0.00	0.10	0.10	\$2.51	\$0.00	\$0.00	2	0.20	\$5.02
Subtotal	0.00	varies	varies	varies	varies	Varies	\$0.00	varies	varies	26.90	\$1,397.30
NOTIFICATION (OF WITHDRAW	AL FROM SUBP	ART K (40 <i>CFI</i>	R 262.204)							
Prepare and submit Site Identification											
Form	0.00	0.10	0.30	0.10	0.50	\$25.49	\$0.00	\$3.46	1	0.50	\$28.96
Keep a copy of the withdrawal											
notice on file	0.00	0.00	0.00	0.10	0.10	\$2.51	\$0.00	\$0.00	1	0.10	\$2.51
Subtotal	0.00	0.10	0.30	0.20	0.60	\$28.00	\$0.00	\$3.46	1	0.60	\$31.47
LABELING OF C	ONTAINERS OF	UNWANTED N	IATERIAL IN T	HE LABORAT	ORY (40 CFR 26	2.206)					
Label the containers as											
specified	0.00	0.00	0.017	0.00	0.017	\$0.79	\$0.00	\$0.15	936,148	15,914.51	\$878,087.79
Subtotal	0.00	0.00	0.017	0.00	0.017	\$0.79	\$0.00	\$0.15	936,148	15,914.51	\$878,087.79

TRAINING (40 CF	FR 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	132	0.00	\$0.00
Maintain	0.00	0.00	0.00	0.00	0.00	Ψ0.00	Ψ0.00	Ψ0.00	132	0.00	Ψ0.00
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	34	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 (continued)

GENERATOR STANDARDS APPLICABLE TO LABORATORIES OWNED BY ELIGIBLE ACADEMIC ENTITIES $^{\rm a}$ ESTIMATED ANNUAL RESPONDENT HOUR AND COST BURDEN

					Hours an	d Costs per Respor	ndent				Total Hours and Costs
INFORMATI	Le	gal Manager	Technical	Clerical				O&M	Number of		Tatal
ON					Respon.	Labor Cost/	Capital/	Cost/	Responden	Total Haura/	Total Cost/
COLLECTIO N ACTIVITY	\$110	.36/Hr \$89.87/Hr	\$46.67/Hr	\$25.07/Hr	Hours/ Activity	Cost/ Activity	Startup Cost	Activit v	ts/ Activities	Total Hours/ Year	Cost/ Year
		RS OF UNWANTED M		· ·			Cost	у	Activities	real	ı caı
Ensure that		INS OF CHWANTED W		TIL LABORATO	1 (40 CFA	202.200)					
containers of unwanted material that exceed volume limits have the date of the											
exceedance											
on the label	0.00	0.00	0.017	0.00	0.017	\$0.79	\$0.00	\$0.00	0	0.00	\$0.00
Subtotal	0.00	0.00	0.017	0.00	0.017	\$0.79	\$0.00	\$0.00	0	0.00	\$0.00
MAKING THE	HAZARD	OUS WASTE DETERM	INATION IN THE I	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	8,925	0.00	\$0.00
Place hazardous waste codes on the container label	0.00	0.00	0.017	0.00	0.017	\$0.79	\$0.00	\$0.00	8,925	151.73	\$7,050.75
Subtotal	0.00	0.00	0.017	0.00	0.017	\$0.79	\$0.00	\$0.00	8,925	151.73	\$7,050.75
MAKING THE	HAZARD	OUS WASTE DETERM	MINATION IN AN O	N-SITE CENTRA	AL ACCUMU	JLATION AREA (40	CFR 262.2	211)			
Make hazardous waste determination	0.00	0.00	0.00	0.00	0.00	\$0.00	\$0.00	\$0.00	927,223	0.00	\$0.00
Place hazardous waste codes on the container label	0.00	0.00	0.017	0.00	0.017	\$0.79	\$0.00	\$0.00	927,223	15,762.79	\$732,505.91
Subtotal	0.00	0.00	0.017	0.00	0.017	\$0.79	\$0.00	\$0.00	927,223	15,762.79	\$732,505.91
		OUS WASTE DETERM			•		•				!
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	0.00	0.00	0.017	0.00	0.017	\$0.79	\$0.00	\$0.00	0	0.00	\$0.00

hazardous waste codes on the container											
label											
Subtotal	0.00	0.00	0.017	0.00	0.017	\$0.79	\$0.00	\$0.00	0	0.00	\$0.00
	CLEAN-	OUTS (40 CFR 262.213)			T		I				
Document the activities of the laboratory clean-out	0.00	0.00	0.03	0.00	0.03	\$1.40	\$0.00	\$0.00	18,723	561.69	\$26,212.13
Maintain	0.00	0.00	0.03	0.00	0.03	Ψ1.40	Ψ0.00	Ψ0.00	10,723	301.09	Ψ20,212.13
records of	0.00	0.00	0.00	0.00	0.00	40.75	40.00	40.00	40.700	504.00	44 4 9 49 99
the clean-out	0.00	0.00	0.00	0.03	0.03	\$0.75	\$0.00	\$0.00	18,723	561.69	\$14,042.22
Subtotal	0.00	0.00	0.03	0.03	0.06	\$2.15	\$0.00	\$0.00	18,723	1,123.38	\$40,254.35
	/ MANAG	EMENT PLAN (40 CFR 2	62.214)		T		I				
Develop Laboratory Management Plan, or revise an existing											
written plan Retain, review and revise the Laboratory Management	0.00	8.70	49.20	0.00	57.9	\$3,078.03	\$0.00	\$0.00	44	2,547.6	\$135,433.32
Plan	0.00	0.00	1.33	0.00	1.33	\$62.07	\$0.00	\$0.00	132	175.56	\$8,193.24
Make the Laboratory Management Plan available to											
others	0.00	0.00	0.00	0.50	0.50	\$12.54	\$0.00	\$0.00	132	66	\$1,655.28
Subtotal	0.00	varies	varies	varies	varies	Varies	\$0.00	\$0.00	varies	2,789.16	\$145,281.84
TOTAL	0.00	varies	varies	varies	varies	Varies	\$0.00	varies	varies	35,813.07	\$1,806,662.89

^a Exhibit contains rounding error.

EXHIBIT 2
GENERATOR STANDARDS APPLICABLE TO LABORATORIES OWNED BY ELIGIBLE ACADEMIC ENTITIES ^a
ESTIMATED ANNUAL AGENCY HOUR AND COST BURDEN

INFORMATION COLLECTION ACTIVITY	Legal \$71.77/ Hr	Manager \$77.82/Hr	Technical \$62.93/Hr	Clerical \$27.21/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 COMPL	Y WITH SUE	PART K AN	D RECORDK	EEPING OF	AGREEMENT	S (40 CFR 26	2.203)				
Review and process Site Identification Forms	0.00	0.00	0.25	0.50	0.75	\$29.34	\$0.00	\$0.00	44	33	\$1,290.96
Subtotal	0.00	0.00	0.25	0.50	0.75	\$29.34	\$0.00	\$0.00	44	33	\$1,290.96
NOTIFICATION OF WITHDRAWAL FRO	M SUBPAR	T K (40 CFR	262.204)								
Review and process Site Identification Forms	0.00	0.00	0.25	0.50	0.75	\$29.34	\$0.00	\$0.00	1	0.75	\$29.34
Subtotal	0.00	0.00	0.25	0.50	0.75	\$29.34	\$0.00	\$0.00	1	0.75	\$29.34
TOTAL	0.00	0.00	varies	varies	varies	varies	\$0.00	\$0.00	varies	33.75	\$1,320.30

^a Exhibit contains rounding error.

ATTACHMENT 1

INFORMATION COLLECTION REQUEST 2317.03 BURDEN ESTIMATE METHODOLOGY

Introduction

The Academic Laboratories Rule of 40 CFR part 262 subpart K, (also known as the "Labs Rule" or "Subpart K") allows eligible academic entities to opt into an alternative set of generator regulations in lieu of the standard set of RCRA generator regulations. Opting into Subpart K entails some amount of burden for those choosing to opt in. In accordance with the 1995 Paperwork Reduction Act (as amended), EPA must estimate respondent burden associated with all regulatory activities. Once burden estimates are developed, EPA submits an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for approval. This document describes the methodology for updated burden estimates for the renewal of the ICR covering the regulatory activities cited above. For this ICR renewal, EPA consulted with seven individuals about a total of ten different institutions. EPA estimated the burden within this ICR based on these new consultations and consultations conducted during the previous ICR (2317.02).

Summary of Consultations for this ICR Renewal (2317.03)

June Brock-Carroll (juneb@clemson.edu, 864-633-6357) is the Hazardous Materials Manager for Clemson University. She confirmed that three Clemson University facilities have opted into Subpart K (2 CESQGs and a SQG). Both of her CESQG facilities have about 2 to 10 labs and each facility collected approximately 20 five gallon containers each year. Both facilities do not have central accumulation areas. Her SQG facility has a central accumulation area and collects about 180 five gallon containers annually from 20 labs. She indicated that each label only required a few minutes complete. She estimates that all Clemson facilities required a week to develop their laboratory management plan (LMP). She indicated that all facilities also conducted clean outs but there was no effect on their generator status.

Jeremy Kuhar (jkuhar@gettysburg.edu, 717-337-6261) is an instructor, a Chemical Hygiene Officer, and Lab Coordinator for Gettysburg College. He confirmed that Gettysburg College opted into Subpart K and indicated that his school operates as a small quantity generator (SQG). His institution has approximately 65 labs and a central accumulation area. He estimates the labs at the school generate 180 five gallon containers of hazardous waste per year. He indicated that it only took 25 seconds to fill out a label. When he developed the school's laboratory management plan (LMP), he incorporated it into the school's chemical hygiene plan (CHP), a plan that is required by OSHA. He estimates that developing both plans (and reading the Federal Register notice) took 25 hours. He indicated that it take 2 to 3 hours of annual review of the LMP and 5 hours are required if an overhaul of the plan is needed. His school has conducted laboratory clean-outs but it did not affect the school's hazardous waste generator status.

Jerry Goodwin (goodwingb@umsl.edu, 314-516-6363) is the Director of Environmental Health and Safety for University of Missouri, St. Louis (UMSL). He indicated that UMSL is a SQG and has opted into Subpart K. His facility has about 170 labs that produce 300 to 800 twenty liter containers annually. It took him less than 5 minutes to create labels. He indicated that it took less than a month to develop the LMP. He has participated in lab clean outs for his facility but they did not change his generator status.

Neil Day (<u>nday3@uwyo.edu</u>, 307-766-3698) is a Hazardous Waste Supervisor for the University of Wyoming. He indicated that his school is a SQG and has opted into subpart K. He indicated that his school produced 43,504 lbs of waste.

Bruce Backus (<u>Backusb@wustl.edu</u>, 314-935-9882) is the Assistant Vice Chancellor of Environmental Health and Safety at Washington University in St. Louis. He has two facilities that have opted into Subpart K, Danforth Campus and School of Medicine. He indicated that both facilities are LQGs and the school contains a total of 3100 lab rooms that have central accumulation areas. Each lab has 5 to 7 rooms. Danforth Campus produced 7091 containers and School of Medicine produced 15750 containers. He mentioned that container sizes ranged from 1 ounce to 5 gallons and labeling for each container required 1 to 3 minutes. Both facilities required 6 months to develop the LMP in conjunction with OSHAs chemical hygiene plan. Bruce estimated that it took 24 hours to update the plans after their initial development. He has also conducted lab clean outs for his two facilities but they did not change their generator status.

Jeff Rogers (<u>jrogers2@uvm.edu</u>, 802-656-0767) is the Environmental Compliance Manager for the University of Vermont. Jeff indicated that his institution is a LQG and has a central accumulation area. His institution has 500 labs that produce 4490 containers of waste. Each container is between 1 and 20 liters. It takes him 3 to 5 minutes to fill out a label for a container. Jeff indicated that it required 20 hours of staff time and 4 hours of manager time to complete the LMP and then about an additional 6 hours to update the plan. His school did perform lab clean outs but they did not change its generator status.

Michael Webb (<u>mwwebb@uams.edu</u>, 501-686-6958) is the Environmental Programs Manager for the University of Arkansas for Medical Science. Michael indicated that his institution is a LQG and has a central accumulation area. He has 420 labs that produced 158 drums (55 gallons) of waste. It took Michael 5 minutes to fill out a label for a container and it required his staff one week to complete the LMP. His school did perform lab clean outs but they did not change its generator status.

Summary of Consultations from Previous ICR Renewal 2317.02

Aisha Holloman (336-375-9232) is the Environmental Health & Safety Manager at Gateway University Research Park, a new non-profit research institute that opened in December 2011. She confirmed that the research park is an SQG that has opted into Subpart K. The research park has 15 labs and two central accumulation areas. Given that the research park is so new, she does not have an estimate of the number of containers of hazardous waste that each lab

generates per year and she has not had the need to conduct laboratory clean-outs. She estimates that it took 60 hours to develop the LMP and the CHP together.

Jeremy Kuhar (jkuhar@gettysburg.edu, 717-337-6261) wears several hats at Gettysburg College; he is an instructor, Chemical Hygiene Officer, and Lab Coordinator. He confirmed that Gettysburg College opted into Subpart K. He indicated that although Gettysburg College probably qualifies as a conditionally exempt small quantity generator (CESQG), the school notified and operates as a RCRA small quantity generator (SQG), just to be on the safe side. His institution has approximately 60 labs and a central accumulation area. He estimates the labs at the school generate 80 - 100 containers of hazardous waste per year. When he developed the school's laboratory management plan (LMP), he incorporated it into the school's chemical hygiene plan (CHP), a plan that is required by OSHA. He estimates that developing both plans (and reading the Federal Register notice) took 100 - 150 hours. His school has not conducted any "documented" laboratory clean-outs since he did not anticipate that it would affect the school's hazardous waste generator status.

Eric Engelberger (870-235-4196) is the Safety Officer at Southern Arkansas University. He confirmed that Souther Arkansas University has opted into Subpart K and that his school is a SQG. His school has 21-22 labs and a central accumulation area. He said that the laboratories do not generate containers of hazardous waste except during laboratory clean-outs. He said that the Science Department is currently writing the LMP and incorporating it into the school's OSHA CHP. He estimates that it will take 80 hours to develop the LMP and the CHP together. His school has conducted laboratory clean-outs when they moved into a new science building. Based on the amount of hazardous waste generated during the laboratory clean-out, the school would have become an LQG if it had not been operating under Subpart K, but it stayed an SQG.

Jen Stones (801-581-6590) is the Hazardous Materials Manager at the University of Utah. She confirmed that her school is an LQG that has opted into Subpart K. Her school has 800-900 labs and a central accumulations area. She estimates that the laboratories generate 22-28 55-gallons drums of hazardous waste per month. She developed the LMP as a separate document and estimates that it took 40 hours to write. Her school has not conducted laboratory clean-outs.

Craig Barnhart (cbarnhar@bulter.edu) works at Butler University. He confirmed that his school has opted into Subpart K and is an SQG. The school has 65-70 laboratories and a central accumulation area. He estimates that is laboratories generate 3500-4000 pounds of hazardous waste per year. Working in tandem with another person, he estimates that it took 2-3 full working days to develop the LMP, which is a separate document. His school has not conducted any laboratory clean-outs.

Victoria Justus (717-418-3342) is a consultant with WasteStrategies. She works with colleges and universities, assisting them with their environmental compliance, which sometimes includes opting into Subpart K. She discussed three institutions with us: Milwaukee School of Engineering (MSOE), Lakewood College, and Philadelphia University (which is in the process of opting in).

Victoria confirmed that MSOE opted into Subpart K for two sites – one is CESQG and one is an SQG. The CESQG site has 9-10 labs and no central accumulation area while the SQG site has 50-65 laboratories and a central accumulation area. The CESQG site generates 4-5 drums of hazardous waste per year, while the SQG site generates 400-450 containers per year (1 liter – 5 gallon containers). She developed one LMP for both MSOE sites as part of OSHA's CHP and estimates it took 100 hours. MSOE has conducted laboratory clean-outs and would have become an LQG if it had not been operating under Subpart K; but remained CESQG and SQG.

Victoria confirmed that Lakewood College opted into Subpart K and is an SQG. The school has 20-25 labs and no central accumulation area. The school's laboratories generate 150-200 containers of hazardous waste per year. She does not have an estimate of the number of hours it took to develop the school's LMP. The school has not conducted any laboratory clean-outs.

Victoria informed us that Philadelphia University, an SQG, is in the process of opting into Subpart K. The school has 40-45 laboratories, with 30 more opening over the next 2 years. The school does not have a central accumulation area currently, but plans to establish one. She estimates that the school's laboratories generate 12-15 drums and 300 containers of hazardous waste per year. The school's LMP is currently under development and they have not yet conducted any laboratory clean-outs.

Estimates of Burden

The estimates of burden associated with all regulatory activities identified in the Academic Laboratories ICR are updated based on the information obtained from the 13 consultations described above. If no information was obtained or available on an activity, it was assumed that the burden information contained in the previous pertinent ICRs (2317.01 and 2317.02) did not change for that activity. For this renewal, it was assumed that all LQGs have a central accumulation area because the waste quantities generated necessitate one and that no CESQGs have a central accumulation area, because the regulations do not provide for one.

In several cases during the consultations, a range was given for the number of laboratories at an eligible academic entity. In these cases, the average was taken to establish the number of laboratories. There are 4 facilities that are LQGs and each facility over 400 labs and a central accumulation area. Eleven facilities are SQGs. Eight of the SQG sites have central accumulation areas, five of which have more than 50 laboratories, three of which of less than 50 laboratories. Two of the SQG sites do not have central accumulation areas and both have fewer than 50 laboratories so they are considered small SQGs. One facility reported as a SQG but did not report the number of labs or if it had an accumulation area so it was excluded. Three of the sites consulted were a CESQG. They were considered as small CESQGs since they did not have a central accumulation areas and each facility had 10 laboratories or less. For categories of schools and hospitals not represented via consultations, the number of laboratories is assumed to be the same as in the previous pertinent ICR.

When asked how many containers of hazardous waste are generated in the laboratories each year, respondents provided answers in ranges and in various units. For example, the University of Utah said they generate 22-28 55-gallon drums per month. To arrive at a number of containers when a range was given, the average was taken to establish the number of containers. To convert 55-gallon drums to a number of containers per year, we assumed that the average container size for collecting hazardous waste in a laboratory is 1 gallon. Therefore, each 55-gallon drum generated equates to 55 1-gallons containers. If liters or ounces of waste was reported by the consultant then it was converted to gallons. If a consultant report their amount of waste in pounds, then it was assumed that each 1-gallon container weighs 8 pounds (the approximate weight of a gallon of water). Gateway University Research Park indicated that since the facility just opened, it does not have an estimate of the number of containers of hazardous waste its laboratories generate, so this was excluded. Southern Arkansas University stated that it does not routinely generate containers of hazardous waste except during laboratory clean-outs, so the number of containers per year is assumed to be zero.

When calculating the average number of hours that it took an eligible academic entity to develop its LMP, the following assumptions were made. If an answer was provided that was a range, an average was taken to establish the number of hours. Some respondents reported their answer in "working days" or simply in terms of a "week." It was assumed that a working day was eight hours and a week is 40 hours. If a respondent indicated that the LMP was developed as part of updating its OSHA CHP, the number of hours reported was divided by two; half the time was assumed to be taken to develop or update the CHP and half the time was assumed to be taken to develop the LMP. Most respondents indicated that they wrote the LMP and management reviewed it. It was assumed that the bulk of the time was spend writing the LMP (7/8 of the time) and a much small portion was spent reviewing it (1/8 of the time). Jeremy Kuhar of Gettysburg College said that his time estimate included reading the Federal Register notice, so two hours was subtracted to account for this. The number of hours for reviewing and making revisions to the LMP as well as making it available to others is assumed to be the same as in the previous pertinent ICR.

ATTACHMENT 2

Summary of Universe Calculations

The Academic Laboratories Rule (the "Labs Rule" or "Subpart K") was finalized in December 2008. It is optional for eligible academic entities to use the Labs Rule in lieu of standard RCRA generator regulations. Since the rule became effective, 92 eligible academic entities have opted into the rule, according to the data in Resource Conservation and Recovery Act Information (RCRAInfo) national database¹⁵. The generator status of each of the 92 facilities was also determined using data available in RCRAInfo. Two of the eligible academic entities did not have a generator status listed in RCRAInfo. These two were eliminated from the universe calculations. Furthermore, two entities have withdrawn from Subpart K since the introduction of this rule in December 2008 and were not included when calculating the current universe.

Eligible Academic Entities (EAEs) Opting into Subpart K, cumulative by year

Year	EAEs opting in (cumulative)				
2009	1				
2010	8				
2011	17				
2012	44				
2013	68				
2014	90				
2015	92* (as of October 15, 2015)				
	93 (projected for all 2015)				

Eligible Academic Entities (EAEs) Opting into Subpart K, by year:

Year	EAEs opting in each year			
2009	1			
2010	7			
2011	9			
2012	27			
2013	24			
2014	22			
2015	2 (as of August 13, 2015)			

¹⁵ RCRAInfo is a national system and database which EPA and States use to record and track information provided by the regulated community concerning the generation, shipment, treatment, and disposal of hazardous wastes. This database is an EPA computer system for the use of EPA employees, as well as State and Territorial environmental agencies, working in their official capacities (see http://www.epa.gov/enviro/html/rcris/index.html). Public access to RCRA Info and Biennial Report data can be found on-line through the use of EPA's Envirofacts Data Warehouse http://www.epa.gov/enviro/html/rcris/rcris_query_java.html.

3 (projected for all of 2015)

Generator Status of Eligible Academic Entities (EAEs) that have Opted into Subpart K:

Generator Status	Number of EAEs	Percent of total EAEs
LQG	41	45%
SQG	26	28%
CESQG	25	27%
Total	92	100%

Since the data are not complete for 2015, we must project how many schools will opt into Subpart K for the remainder of 2015. If we project the same rate of adoption for the remainder of 2015, we should expect to see 1 more eligible academic entities opt in, for a total of 3 eligible academic entities opting in during 2015.

Excluding 2009, since the rule was new and states were just beginning to adopt the Labs Rule, the average number of eligible academic entities that have opted in during the six year period of 2010-2015, is 13.3 per year. Two entities have withdrawn from Subpart K during the six year period, averaging 0.3 per year. If we project the same rate of adoption and withdrawal rate over the next three years (2016-2018), approximately 40 (=13.3*3) new eligible academic entities will have adopted and 1 (=0.3*3) will have withdrawn by the end of the next three year period. Overall, at the end of 2018 it is projected that the number of entities that have opted into Subpart K will increase by 39.

Adding the 39 new eligible academic entities to the projected 1 more for 2015, we estimate that there will be 40 new eligible academic entities using Subpart K. If we add this to the existing 92 existing eligible academic entities already using the rule, we project a total of 132 eligible academic entities will have adopted by the end of the 2018.

If we project that the 40 new eligible academic entities will have the same proportion of LQGs, SQGs, and CESQGs, then we would expect to see the following:

Generator Status of Eligible Academic Entities (EAEs) that Will Opt into Subpart K:

Generator Status	Projected Number of New EAEs	Projected Number of total EAEs
LQG	18	60
SQG	11	37
CESQG	10	35
Total	39	132

When eligible academic entities opt into Subpart K they must notify as either a college/university (C/U), a non-profit research institute (NPRI), a teaching hospital, or any

combination of the above. Using data from RCRAInfo, the type of eligible academic entity was determined for each eligible academic entity that has opted into Subpart K. Then the percentage of each type of eligible academic entity was calculated by generator status. These same percentages were used to project the proportion of the types of eligible academic entities that will opt into Subpart K over the next three year period. Eligible academic entities that notified as both a college/university and a teaching hospital were counted as college/universities since based on professional experience, the number of teaching and research laboratories at that part of the institution usually outnumber those found at the teaching hospital. This information was used to update Table 1 of the Supporting Statement for the ICR renewal.