**﻿SUPPORTING STATEMENT FOR**

**INFORMATION COLLECTION REQUEST OMB CONTROL NO. 2050-0204**

**“****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 2317.05, 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.

**(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 liquid reactive acutely unwanted material (or 1 kg of solid reactive acutely unwanted materials), 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 262.15 (or section 262.14 for very 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 liquid acutely reactive unwanted material (or 1 kg of solid reactive acutely 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 May 2, 2022 (87 FR 25636), soliciting public comments on the accuracy of the burden estimates in this supporting statement. No comments were received.

## 3(c) Consultations

In updating this ICR, EPA spoke with a number of colleges and universities with laboratories affected by this ICR. They are indicated below. All responded that the burden estimates were accurate.

|  |  |
| --- | --- |
| **Contact Name** | **University** |
| Bhatta Nabin | The University of Oklahoma |
| James Crandall & Charles Williams | Pennsylvania State University |
| Gail Hall | Boston College |
| Michael B Blayney | Northwestern University |
| Janeen Hale | Midwestern University |

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

## 4(b) Information Requested

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

 40 *CFR* 262.203(a) provides that an eligible academic entity must notify the appropriate EPA Regional Administrator in writing, using the RCRA Subtitle C Site Identification Form (EPA Form 8700-12), that it is electing to be subject to the requirements of Subpart K for all the laboratories owned by the eligible academic entity under the same EPA Identification Number. An eligible academic entity that is a very 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 very 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 very 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 very 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 very small quantity generators) that is withdrawing from the requirements of Subpart K.

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

 Section 262.204(c) provides that an eligible academic entity must keep a copy of the withdrawal notice on file at the eligible academic entity for three years from the date of the notification.

 (i) Data Items:

* A Site Identification Form with the following fields filled out, at a minimum:

-- Reason for Submittal;

-- Site EPA Identification Number (except for very 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) Data Items:

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

-- Words ”unwanted material” or another equally effective term that is to be used consistently by the eligible academic entity and that is identified in Part I of the Laboratory Management Plan; and

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

- Name of the chemical(s).

- Type or class of chemical, such as organic solvents or halogenated organic solvents.

* Information that may be affixed or attached to the container, but that must at least be associated with the container, including:

-- Date that the unwanted material first began accumulating in the container; and

-- Information sufficient to allow a trained professional to properly identify whether an unwanted material is a solid and hazardous waste and to assign the proper hazardous waste code(s), pursuant to section 262.11. For example, the following information may be associated with the container:

- The name and/or description of the chemical contents or composition of the unwanted material, or, if known, the product of the chemical reaction;

- Whether the unwanted material has been used or is unused;

- A description of the manner in which the chemical was processed, if applicable.

(ii) Respondent Activities:

* Label the containers as specified.

**(4) Training**

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

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

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

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

(i) Data Items:

* Documentation demonstrating training for all laboratory workers. Examples of documentation demonstrating training can include, but are not limited to, the following:

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

-- Syllabus for training session; or

-- Certificate of training completion; or

-- Test results.

(ii) Respondent Activities:

* Provide training to all individuals working in a laboratory.
* Maintain documentation demonstrating training for all laboratory workers (LQGs only). 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 12 months (262.208(a)(1)); or remove containers of unwanted material from each laboratory within 12 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 liquid reactive acutely hazardous unwanted material (or 1 kg of solid 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 or 1 kg 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 or 1 kg 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 liquid reactive acutely hazardous unwanted material or 1 kg of solid 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 very 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(a) through (d), 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(a) through (d), 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(a) through (d), 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(a) through (d), if the unwanted material is a hazardous waste within 4 calendar days of the unwanted materials’ arrival at the on-site central accumulation area.

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

(i) Data Items:

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

(ii) Respondent Activities:

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

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

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

 Section 262.212(d) requires that a trained professional must determine, pursuant to section 262.11(a) through (d), if the unwanted material is a hazardous waste within 4 calendar days of the unwanted materials’ arrival at an on-site interim status or permitted treatment, storage or disposal facility.

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

(i) Data Items:

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

(ii) Respondent Activities:

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

**(10) Laboratory Clean-outs**

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

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

(i) Data Items:

* Documentation that, at a minimum, identifies the laboratory being cleaned out, the date the laboratory clean-out begins and ends, and the volume of hazardous waste generated during the laboratory clean-out.

(ii) Respondent Activities:

* Document the activities of the laboratory clean-out; and
* Maintain records of the clean-out. 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* 262.15 (or section 262.14 for very 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 very 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 very 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 very 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 very 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 liquid reactive acutely hazardous unwanted material (or 1 kg of solid 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 or 1 kg 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 very 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(a) through (d), 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(a) through (d), 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(a) through (d), 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(a) through (d), if the unwanted material is a hazardous waste within 4 calendar days of the unwanted materials’ arrival at an on-site interim status or permitted treatment, storage or disposal facility.

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

**(10) Laboratory Clean-outs**

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

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

**(11) Laboratory Management Plan**

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

 Section 262.214(c) provides that an eligible academic entity must make its Laboratory Management Plan available to laboratory workers, students, or any others at the eligible academic entity who request it.

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

# 6. ESTIMATING THE HOUR AND COST BURDEN OF THE COLLECTION

## 6(a) Estimating Respondent Burden Hours

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

## 6(b) Estimating Respondent Costs

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

**(1) Labor Costs**

The labor wage rates used to estimate costs to respondents were calculated as shown in the following table. The 2022 average wage rates from are the average wage rates are reported in the Bureau of Labor Statistics, 2020 National Occupational Employment and Wage Estimate, released May 2020, and updated to 2022 levels.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Labor Category | Privately-owned 2020 hourly rate  | **Privately-owned 2022 hourly rate** | State-owned 2020 hourly rate | **State-owned 2022 hourly rate** |
| 1. Legal | $82.74 | **$132.38** | $69.72 | **$111.55** |
| 2. Managerial | $80.22 | **$128.35** | $68.87 | **$110.19** |
| 3. Technical | $35.50 | **$56.80** | $32.46 | **$51.94** |
| 4. Clerical | $21.09 | **$33.70** | $20.14 | **$32.22** |

For the State agency respondent labor rates, EPA estimates an average hourly State labor cost (including fringe and overhead) of $67.67 for legal staff, $63.52 for managerial staff, $38.00 for technical staff, and $24.24 for clerical staff. These State labor costs were obtained from a previously approved ICR and updated to 2022 levels using Employment Cost Indexes developed by the U.S. Bureau of Labor Statistics.

**(2) Capital Costs**

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

**(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., $3.75 currently for certified mail) and envelope (i.e., $0.013). The ICR includes $0.16 per container label, for a total of $255,192.

 6(c) Estimating Agency Hour and Cost Burden

 EPA estimates an average hourly labor cost (labor plus overhead) of $86.54 for legal staff,$62.27 for managerial staff, $43.68 for technical staff, and $26.56for clerical staff. To derive these estimates, EPA used the General Schedule (GS) Salary Table 2022. For purposes of this ICR, EPA assigned staff the following government service levels:

 Legal Staff GS‑15, Step 1

 Managerial Staff GS‑13, Step 1

 Technical Staff GS‑11, Step 1

 Clerical Staff GS‑6, Step 1

To derive hourly estimates, EPA divided annual compensation estimates by 2,080, which is the number of hours in the Federal work‑year. EPA then multiplied hourly rates by the standard government overhead factor of 1.6.

## 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.

**(1) Respondent Universe**

Table 1 presents the total number of sites at eligible academic entities that are operating under Subpart K. This data was determined using the data available in EPA’s RCRAInfo database.[[1]](#footnote-2)EPA has notifications from 246 eligible academic entities that currently operate under Subpart K. Based on the data gathered for the final rule, EPA estimates each laboratory has approximately 15 containers of unwanted material and that there are an average of 400 laboratories per institution, which when multiplied means 1,476,000 containers of unwanted materials generated annually under Subpart K.

**Table 1**

**Total Number of Sites at Eligible Academic Entities Operating under Subpart K**

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of Entity** | **Privately-owned** | **State-owned** | **Total** |
| **Universities**  | 63 | 147 | 210 |
| **Teaching Hospitals** | 12 | 9 | 21 |
| **Non-profit Institutions** | 13 | 2 | 15 |
| **Total** | 88 | 158 | **246** |

**(2) Annual Respondent Burden under Subpart K**

Based on the respondent universe data presented in Table 1, 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 71 of their sites 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, 24 sites (i.e., 71 sites / 3 years) will read the regulations each year.

 **(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 very 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, 24 forms (i.e., 71 forms/3 years) will be prepared, submitted, and retained. Teaching hospitals and non-profit research institutes not owned by a college or university 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 assumes that teaching hospitals and non-profit research institutes keep copies of their affiliation agreement as a best management practice in the baseline and will not experience an additional paperwork burden.

**(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 laboratories owned by the eligible academic entity under the same EPA Identification Number. An eligible academic entity that is a very 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. EPA estimates that 1 eligible academic entity will withdraw over the three-year period. 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, .33 form (i.e., 1 forms/3 years) will be prepared, submitted, and retained.

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

As shown in Table 1, EPA estimates that eligible academic entities subject to Subpart K will generate a total of 1,476,000 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 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.[[2]](#footnote-3) Thus, EPA believes that the training requirements under the rule do not impose incremental burden on respondents.[[3]](#footnote-4)

**(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 liquid acutely reactive unwanted material (or 1 kg of solid 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 or 1 kg of unwanted material is exceeded.

**(g) Making the Hazardous Waste Determination**

EPA expects that a hazardous waste determination will be made for each container of unwanted material in the laboratories. Based on the data in Table 1, EPA estimates that, each year, hazardous waste determinations will be made in the laboratory or in the central accumulation area for 1,476,000 containers of unwanted materials. EPA assumes that unwanted materials in all of these containers will be determined to be hazardous waste, and thus, the appropriate hazardous waste code(s) will be added to the label that is associated with the containers.

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

**(h) 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.

**(i) 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 1 by 20 percent and 10 percent, to estimate that 29,520 containers will originate from laboratory clean-outs annually (i.e., 1,476,000 x 20% x 10% = 29,520). 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.[[4]](#footnote-5)

**(j) 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 eligible academic entities opting into Subpart K. Thus, EPA estimates that, on average, eligible academic entities will prepare 24 Laboratory Management Plans per year (i.e., 71 Plans / 3 years).

 EPA also estimates that each site will review, revise, and keep records of its Laboratory Management Plan each year.[[5]](#footnote-6)

 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**

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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. As a result, these sites will see some burden relief from the existing paperwork requirements.

## 6(e) Bottom Line Hour and Cost Burden

**(1) Respondent Tally**

 As shown in Exhibits 1 through 3, EPA estimates the total annual burden to respondents under the new paperwork requirements to be 146,157 hours and $8,088,511.

**(2) Agency Tally**

 As shown in Exhibit 4, EPA estimates the total annual burden to the government under the new paperwork requirements to be 8 hours and $242.

## 6(f) Reasons for Change In Burden

The annual respondent burden in this ICR is estimated to be 146,157 hours, which is a decrease of 11,815 hours from the previously approved ICR. This decrease 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, not due to program changes.

## 6(g) Public Burden Statement

The annual public reporting and recordkeeping burden for this collection of information is estimated to average 1hour per response.

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-OLEM-2018-0692, 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-OLEM-2018-0692, and OMB Control Number 2050–0204 in any correspondence.













1. 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 https://rcrainfo.epa.gov/rcrainfoprod/action/secured/home). Public access to RCRA Info and Biennial Report data can be found on-line through the use of RCRAInfo Web

https://rcrapublic.epa.gov/rcrainfoweb/action/main-menu/view [↑](#footnote-ref-2)
2. . “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. [↑](#footnote-ref-3)
3. . See pages 55 and 56 of EPA’s impact assessment for an additional discussion of EPA’s rationale. [↑](#footnote-ref-4)
4. . See page 46 of EPA’s impact assessment for an additional discussion of EPA’s assumptions. [↑](#footnote-ref-5)
5. . 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. [↑](#footnote-ref-6)