

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

PROJECT XL NEW ENGLAND UNIVERSITY LABORATORIES PROJECT RESPONSE TO COMMENTS

SEPTEMBER 1999

INTRODUCTION

This response to comments (RTC) document is presented by the United States Environmental Protection Agency (EPA). The purpose of this document is to present comments raised during the public comment period regarding EPA's proposed rule for the New England University Laboratories XL Project and to present EPA's responses to those comments.

Background

On July 27, 1999, EPA requested comments on the proposed rule and draft Final Project Agreement for the New England University Laboratories XL project (see 64 FR 40696). As a result of this Federal Register document, EPA received 9 comment letters during the public comment period from: the California State University, Los Angeles Department of Chemistry and Biochemistry, the University of Wisconsin-Madison (Assistant Vice Chancellor), the American Chemical Society, Boston University, the Howard Hughes Medical Institute, Cynthia Salisbury, the American Council on Education, the University of Wisconsin System Administration - Environmental/Occupational Health & Safety Section, and Harvard University.

General Comments

Comment:

Many of the commenters supported EPA's proposed rule and agreed that the proposed rule should result in superior environmental performance and significant cost savings to universities while being protective of human health and the environment and went on to note that the rulemaking should not be a model for all universities as this may not be the best approach at all educational institutions. Some comments additionally noted that most institutions have working hazardous waste management programs and chemical hygiene plans under OSHA.

EPA Response:

EPA does not consider this XL project to be a model for all universities, but rather a pilot designed to test one possible approach to the management of hazardous waste within university laboratories. One of the purposes of implementing this XL project, as with all XL projects, is to assess whether it should

be considered for wider application. It would be inconsistent with the forward-looking nature of these pilot projects to adopt such innovative approaches prematurely on a widespread basis without first determining whether or not they are viable in practice and successful in the particular projects that embody them. Although EPA hopes that today's rule will result in a successful innovative new system for universities and other research organizations, we recognize that this regulatory approach may not be appropriate at all such institutions.

Comment:

Several commenters indicated that the rule has some potentially burdensome requirements and that the requirement for plans might be duplicative of existing rules.

EPA Response:

While the requirements being piloted may appear to be burdensome, the intent is to allow Universities to streamline their chemical programs and increase waste minimization and reuse opportunities. While the cycle of continuous improvement and yearly review of plans should result in additional streamlining opportunities, the participating Universities that have pollution prevention plans and chemical hygiene plans in place would not be expected to re-write those plans in order to implement this alternative system. Likewise, although the requirements for documentation may appear burdensome, EPA believes that Universities participating in this XL project would be keeping the records already. The recordkeeping requirements in the rule are flexible. Section 262.105(b)(17) requires that each University write an EMP that includes the recordkeeping requirements to document conformance with their plan. This requirement allows each participating University to outline the system that they will be using to meet recordkeeping requirements and therefore to choose the system that will work best for their environmental management structure. For example, each University may outline, in their EMP, how they intend to document training. The system that they describe in their EMP is the system with which they must comply.

Comment:

Several commenter noted that because participating Universities may designate only certain departments as participating, there would be duplicate systems regulating their hazardous waste.

EPA Response:

Although this rule does not pilot a strictly performance-based system, nonetheless, each University may design their environmental management plan in the way that most suits their structure and needs. This includes each University having the option not to include all departments operating pursuant to the alternative standard's in today's rule. As several of the comment letters noted, this could result in two sets of rules being applicable at a single institution. EPA would like to stress that it is up to each University to decide, based on its own needs, what departments will be participating in this XL project. If, for example, certain departments determined that the EMP would work well with their Chemical Hygiene Plan, while other departments did not want to implement an EMP, then two sets of requirements for managing hazardous wastes in the laboratories would be applicable at that institution.

Comment:

Several commenter noted that other areas at Universities that would not be considered

laboratories would still be under the current RCRA rules and therefore there would be two systems of rules applicable at those Universities. One commenter noted that this would not result in the anticipated streamlining of requirements.

EPA Response:

This rule does apply only to laboratories and the opportunities for streamlining only occur with the OSHA requirement for a Chemical Hygiene Plan which applies only to laboratories. Therefore EPA believes that this rule will result in opportunities for streamlining of regulatory requirements in laboratories. This rule gives the Universities the opportunity to streamline the OSHA laboratory standard with the RCRA requirements within laboratories. The project does not address other, non-laboratory, generator areas on the campuses.

Comment:

Several commenter commented on the definition of “laboratory”, indicating that EPA was considering the laboratory process unit or laboratory management unit concept and that the proposal does not specifically delineate what constitutes a laboratory, questioning whether a photo lab or clinical lab would be a laboratory.

Response:

The definition of laboratory, for the purpose of the new proposed Subpart J, is “an area within a facility where the laboratory use of hazardous chemicals occurs. It is a workplace where relatively small quantities of hazardous chemicals are used on a non-production basis. The physical extent of individual laboratories within an organization will be defined by the Environmental Management Plan. A laboratory may include more than a single room if the rooms are in the same building and under the common supervision of a laboratory supervisor.” This definition operates in concert with the definition of “Laboratory Scale” which is defined as “work with substances in which containers used for reactions, transfers and other handling of substances are designed to be safely and easily manipulated by one person. ‘Laboratory Scale’ excludes those workplaces whose function is to produce commercial quantities of chemicals.” These definitions are another example of how this rule parallels the current OSHA Laboratory Standard, as these definitions follow the definitions in the OSHA standard.

Any area on a campus that is designated in the Environmental Management Plan as a laboratory and that meets these definitions will be considered a laboratory for the purpose of this pilot project. If a University chooses to operate with a structure of laboratory management units, within the definitions of this rule, they can do so. However, it would be rare that a typical photographic laboratory would meet the criterion of non-production. For example if a University had a photographic facility on the campus that processed film for students, that would be operating on a production basis and would not be considered eligible under this rule. However, EPA understands that photographic laboratories may also be laboratory scale and could be eligible to participate under this rule. Examples would include, labs used to support research and teaching, such as a small photo laboratory developing X-rays as part of medical research or a small photo laboratory developing satellite photographs as part of geologic or environmental research. Key factors that would limit the participation of a laboratory include consideration of the scale of the activities and whether they could be viewed as operating as a production process as opposed to the varied small-scale activities described in the proposed rule for

teaching and research. EPA did not intend for this rule to be available to production operations. This rule applies to laboratory scale activities as defined in the definitions section at 40 CFR 262.102.

Comment:

Several commenters raised concerns or sought clarification of the regulatory effect (i.e., less flexible, more flexible, not flexible at all) they perceive this rule to have on treatment activities in laboratories.

Response:

Today's rulemaking is limited to regulatory changes to facilitate a more centralized point at which to make waste determinations pursuant to 40 CFR Part 262 for the laboratory wastes within the scope of this rule. EPA does not intend that this rule have any effect on how RCRA applies to treatment in laboratories.

Comment:

Several comments expressed concern regarding the training requirements suggesting that previous training outside the institution should be recognized, that training may not be necessary for certain "qualified" individuals, or that the proposal requires much more training than current regulations. At the same time, some comments expressed concern that since the training is different from current regulations, students will be ill-equipped to enter industry and comply with current requirements. One comment provided an example of 262.105(d)(2) noting that information and training are required when a laboratory worker is first assigned to a work area, whereas the current Federal RCRA requirement for training is "within six months" and large universities may find it difficult to provide training upon first assignment to a work area, especially at the beginning of an academic year.

Response:

Training requirements under § 262.105 (d) have been written to allow each University to design the training that is most appropriate to their needs. Paragraph (1) reiterates the requirement under the Minimum Performance Criteria (MPC). Paragraph (2) governs the timing of training for the laboratory worker when he/she is first assigned and when a laboratory waste poses a new or unique hazard for which the worker has not received prior training. This prior training may not necessarily have occurred at the University. It also requires that the University provide training as often as needed to maintain knowledge of the Environmental Management Plan (EMP). Paragraph (3) requires that the University provide an outline of the training program. Paragraph (4) requires that laboratory workers are informed of the contents of Subpart J, the location of the EMP, emergency response measures, signs and indicators of hazardous substance release, availability of reference materials and the training requirements.

As discussed at proposal, the main goal of the training requirements is for the University to ensure that all laboratory workers have been trained to understand the hazards of laboratory waste and to take measures to protect human health and the environment. EPA did not, however intend that particular training requirements would be more stringent than required under current RCRA requirements. The requirement regarding training was proposed to parallel the current OSHA requirements at 29 CFR 1910.1450(f) (1) and (2) which state: (1) "the employer shall provide employees with information and

training to ensure that they are apprised of the hazards of chemicals present in their work area”, and (2) “such information shall be provided at the time of an employee’s initial assignment to a work area where hazardous chemicals are present and prior to assignments involving new exposure situations. The frequency of refresher information and training shall be determined by the employer.” EPA believes it is appropriate to allow the participating Universities the same flexibility regarding when a newly assigned laboratory worker would have to be trained as they would have under current RCRA requirements. Thus, EPA has modified 262.105(d)(2) to read: “(I) Each University must provide the information to each laboratory worker when he/she is first assigned to a work area where laboratory wastes may be generated. (ii) Each University must ensure that each laboratory worker has been trained within six months of when he/she is first assigned to a work area where laboratory wastes may be generated and must retrain a laboratory worker when a laboratory waste poses a new or unique hazard for which the laboratory worker has not received prior training and as frequently as needed to maintain knowledge of the procedures of the Environmental Management Plan.”

EPA also agrees with the comment that paragraph 262.105(d)(5) as proposed may lead to duplicative training, in the example given, a laboratory worker may have had prior training that addresses the requirements of this paragraph. EPA did not intend to preclude appropriate reliance on relevant training received from outside the University. Thus, EPA is also modifying paragraph (d) in section 105 to reflect the intent of the requirement. This intent of this subparagraph is to require that the University ensure that laboratory workers have the training to be able to understand the hazards of laboratory waste and be able to take measures to protect human health and the environment, and EPA has modified the rule to clarify this intent.

At the same time, EPA is not making a distinction between “qualified” and “unqualified” individuals in the training requirements. EPA and the project sponsors believe that by training many more laboratory workers, including students, than would have training under the current system, understanding of the hazards of laboratory waste and the management of laboratory waste will be improved. The project sponsors and EPA believe that it will constitute a great improvement to current conditions for students who have been laboratory workers to enter industry with an understanding of pollution prevention concepts in the laboratory.

EPA and the project sponsors believe that by training students working in the laboratories, the management of laboratory waste will be improved. Most universities will already have training programs in place, and the programs may only need to be broadened to be more inclusive. The project sponsors and EPA believe that it will constitute a great improvement for students who have experience as laboratory workers to enter industry with a better understanding of laboratory waste management and pollution prevention.

Specific Comments

1. California State University - Los Angeles Department of Chemistry and Biochemistry

Comment

California State University - Los Angeles Department of Chemistry and Biochemistry strongly supports the Project XL for University laboratories and notes that academic laboratories are an ideal arena to test this new regulatory approach.

2. University of Wisconsin-Madison - Assistant Vice Chancellor

Comment:

The University of Wisconsin-Madison strongly supports the intent of the XL project to provide flexibility to the participating institutions and because the proposed performance-based management system will actively promote prudent practices and encourage pollution prevention, chemical reuse and recycling. The University of Wisconsin-Madison agreed with EPA that the proposed rule should result in superior environmental performance for the participating Universities and that the project will be protective of human health and the environment.

Comment:

The rule draws heavily from ISO 14000, which requires an Environmental Management Plan (EMP). The ISO 14000 standard is designed for industry and, in our view, fits academia poorly.

Response:

The similarities between ISO 14001 and the proposed rule were proposed by the project participants who expressed their interest in piloting an EMP at academic institutions. The project sponsors did not propose a wholesale adoption of the ISO 14001 standard in view of the differences between industrial and academic settings. EPA feels that this proposal, including the elements of the ISO 14001 standard incorporated in it, offers an ideal arena to test this approach and meets Project XL's goal of piloting alternative systems in an effort to develop more efficient and effective regulations.

Comment:

The comment states that an EMP does not ensure environmental compliance, and ISO 14000 clearly does not purport to do so. In some cases, an EMP may not improve environmental performance. 40 CFR 265.105(b)(2) requires that the EMP include "an environmental policy, or environmental, health and safety policy, signed by the University's senior management, which must include commitments to regulatory compliance." Such a policy is inappropriate and ineffective in an institution with faculty governance and decentralized administration, which is a characteristic of many institutions of higher education, including our University. While a central administration policy of this type may be workable within the governance setting of the participating institutions, its adoption at our University would require arduous and time-consuming concurrence of one or more faculty committees, and possibly the deans.

Response:

EPA acknowledges that this alternative may not be effective in all academic settings. EPA does not consider this XL project to be a model for all universities, but rather a pilot designed to test one possible approach to the management of hazardous waste within university laboratories. One of the purposes of implementing this XL project, as with all XL projects, is to assess whether it should be considered for wider application. It would be inconsistent with the forward-looking nature of these pilot projects to adopt such innovative approaches prematurely on a widespread basis without first determining whether or not they are viable in practice and successful in the particular projects that embody them. Although EPA hopes that today's rule will result in a successful innovative new system for universities and other research organizations, we recognize that this regulatory approach may not be appropriate at all such institutions. EPA notes the reference should be to 40 CFR 262.105(b)(2).

Comment:

Section 262.105(b)(6) of the proposed rule requires within the EMP, "a pollution prevention plan, including, but not limited to, roles and responsibilities, training, pollution prevention activities, and performance evaluation." Requiring a separate EMP and pollution prevention plan is duplicative. Conceptually, an EMP should be an integral part of every pollution prevention plan, or visa versa.

Response:

As noted in the comment, under the rule each University must write, implement and comply with their EMP. Although the EMP must include a pollution prevention plan there are many elements that the EMP must include in addition to a pollution prevention plan. If a University already has a pollution prevention plan in place, this plan can be incorporated into or referenced by the EMP. Furthermore, if the existing pollution prevention plan had "an environmental policy, or environmental, health and safety policy, signed by the University's senior management, including commitments to regulatory compliance, waste minimization, risk reduction and continual improvement of the environmental management system" as required by 262.105(b)(1), then the EMP could simply incorporate the pollution prevention plan to meet this requirement. There is no requirement to create a new pollution prevention plan and, therefore, the requirement is not duplicative. The project envisions that through annual reviews and continuous improvement, each University will determine whether separate plans or combined plans work best.

Comment:

The proposed rule makes no provision for recycling of chemicals between nearby laboratories, which is an efficient waste minimization practice that precedes RCRA; everything that is waste from a laboratory must go to the central accumulation area for evaluation and recycling.

Response:

Centralizing the solid and hazardous waste determination is one function that is being piloted with this XL project. The intent of the new alternative is to centralize waste re-use decisions within the EH&S department, which has knowledge of campus-wide re-use opportunities. A participating University may demonstrate that this precludes some internal re-use opportunities, and provide documentation as part of this pilot. Alternatively, if laboratories are working closely together and would like to share used chemicals, the definition of "laboratory" allows a participating University to define them as a single laboratory for the purposes of their Environmental Management Plan.

Comment:

The University of Wisconsin - Madison requested that EPA please state the criteria and timetable for evaluating the Project, and the standards EPA will use to determine to expand or cancel it.

Response:

This pilot project has a four year time frame. Because each project is unique, EPA does not have specific criteria requirements for the evaluation of an XL project. However, EPA does have strong expectations for project reporting, including:

- (1) tracking and reporting will be necessary throughout the life of the project;

- (2) performance data will be available to the public;
- (3) at a minimum, the project sponsor will prepare an annual report; and
- (4) the reports will be made available on the Internet, via the sponsors' or another organization's Internet site, and will feature a "hot link" to the EPA Project XL website. This will eliminate the submission of "hard copy" project reports to EPA.

The specific project reporting schedule is contained in the Final Project Agreement (e.g., in this project, the FPA Table 3 Laboratory XL Project Public Performance Reports, and Table 4 Environmental Goals and Indicators). EPA will use the project reports to help evaluate whether a project is meeting the expected performance during the implementation and life of the FPA and the supporting legal mechanisms - Federal and State rules.

Standards used to determine to expand

EPA, in consultation with Agency constituencies, expects to incorporate successful innovative approaches into the current system of environmental protection. To date the XL program has covered the following seven core functions: rules and regulations; permit reform; environmental information management; enforcement and compliance assurance; environmental stewardship; stakeholder involvement; and Agency culture change.

EPA has begun to systematically describe and analyze the results, successes, and problems of projects' innovations. EPA expects to develop this analysis in subsequent, more in-depth reports throughout 1999 and 2000. Using these analyses, EPA's goal is to consult with a broad array of stakeholders to assess the transferability of the innovations into system change and to make appropriate adjustments in the Agency's rules, regulations, policies, and guidances. EPA recognizes that the results of XL pilots must be considered within the context of other experimental and innovative approaches being championed by EPA's national and regional programs. EPA's 1997 and 1998 annual reports on reinventing environmental protection provide an overview of the progress made by EPA in testing innovative approaches, and contain examples and information on the efforts of national and regional programs to integrate these innovations into system change.

Standards used to determine to cancel

It is expected that project sponsors will be forthcoming early on if it appears that they cannot meet commitments, at which time an appropriate course of action can be determined.

Section V.5.A. of the FPA provides that: "the Project Signatories agree that appropriate grounds to seek withdrawal from the FPA could include (but are not limited to):

- Substantial failure by another Signatory to implement the terms of the FPA;
- Discovery of failure by another Signatory to disclose relevant facts during development of the project that would have substantially changed the outcome of the FPA;
- Discovery of new information indicating that implementation of the project will present an imminent and substantial endangerment to public health or welfare, or the environment;
- Substantial changes to the Laboratory Environmental Management Standard as a result of comments submitted during the public comment periods or rule-making; and/or
- Non-conformance with the site specific rule.

Withdrawal from the FPA by any Signatory does not affect the legal status of a site-specific rule issued by MADEP or VTDEC. Withdrawal from the FPA by a single XL Participant does not affect the legal status of the other XL Participants.”

In addition, progress reports provide an opportunity to describe why if commitments for an XL project might not have been met. The rule itself also contains requirements for bringing a University back to the traditional regulatory system at §262.107 “Under what circumstances will a University’s participation in this environmental management standard pilot be terminated?” which states:

“(a) EPA retains the right to terminate a University’s participation in this Laboratory XL project if the University:

- (1) Is in non-compliance with the Minimum Performance Criteria in §262.104; or
- (2) Has actual environmental management practices in the laboratory that do not conform to its Environmental Management Plan; or
- (3) Is in non-compliance with the Hazardous Waste Determination requirements of §262.106.

(b) In the event of termination, EPA will provide the University with 15 days written notice of its intent to terminate. During this period, which commences upon receipt of the notice, the University will have the opportunity to come back into compliance with the Minimum Performance Criteria, its Environmental Management Plan, or the requirements for making a hazardous waste determination at §262.106 or to provide a written explanation as to why it was not in compliance and how it intends to return to compliance. If, upon review of the University’s written explanation, EPA then re-issues a written notice terminating the University from this XL Project, the provisions of §262.107© will immediately apply and the University shall have 90 days to come into compliance with the applicable RCRA requirements deferred by §262.10(j). During the 90-day transition period, the provisions of this Subpart shall continue to apply to the University.

(c) If a University withdraws from this XL project, or receives a notice of termination pursuant to this section, it must submit to EPA and the State a schedule for returning to full compliance with RCRA requirements at the laboratory level. The schedule must show how the University will return to full compliance with RCRA within 90 days from the date of the notice of termination or withdrawal.”

Each project is considered a pilot or experiment. As such, the project reports are a means for tracking what is happening with the experiment – including the successful and unsuccessful activities. For example, if a project runs into unexpected process or technical problems, the sponsor must keep the regulatory agencies well informed of the problem, and the sponsor’s reports should describe the issues, including options to be tested or solutions found.

Comment:

The University of Wisconsin - Madison notes that EPA does not, with this proposal, address the House Report (103-555) accompanying FY 1995 appropriations Act (PL 103-327) which directed EPA to consider the following adjustments to its RCRA regulations:

- *Allow educational and research laboratories to perform some on-site treatment of limited quantities of their waste;*
- *Increase the amount of time that a laboratory may accumulate limited quantities of its waste without the need of a permit; and*
- *Allow single EPA identification numbers to be used for the contiguous portions of a college or University campus.*

Response:

In response to the first adjustment - today's rulemaking is limited to regulatory changes to facilitate a more centralized point at which to make waste determinations pursuant to 40 CFR Part 262 for the laboratory wastes within the scope of this rule. EPA does not intend that this rule have any effect on how RCRA applies to treatment in laboratories.

In response to the second adjustment - to increase the amount of time that a laboratory may accumulate limited quantities of its waste without the need of a permit - today's rulemaking does increase the amount of time that a laboratory may accumulate its waste, while strictly limiting the quantity. This rule is limited to regulatory changes in the satellite accumulation areas at University laboratories and it does not address, nor was it intended to, accumulation time limits outside of the laboratory.

In response to the third adjustment - to allow single EPA identification numbers to be used for the contiguous portions of a college or university campus - this is already envisioned in the current Federal regulations defining generators and facility which includes contiguous property. State regulations may vary on these provisions.

Comment:

Support Other Approaches to Appropriate Regulation:

The comment suggests that EPA should also recognize that some institutions have achieved superior environmental performance through the regulatory flexibility provided by EPA and state guidance, interpretations, enforcement discretion, site-specific agreements and targeted rulemaking and also encourages EPA to sustain its reinvention initiatives for storing mixed low-level radioactive waste and streamlining the permitting of RCRA storage and simple treatment facilities. The comment notes that none of these changes weaken environmental protections but that they enable hazardous waste generators to reallocate resources for environmental improvements.

Response:

EPA agrees that there are other ways to achieve superior environmental performance other than the approach taken in today's rule. Under Project XL, potential participants are invited to develop *their* proposals for common sense, cost effective strategies that will replace or modify specific regulatory requirements and result in superior environmental performance. The project embodied in today's rule focuses on the approach that the University participants believe to be a common sense, cost effective approach for managing laboratory waste. EPA has determined that this particular XL project is beneficial to human health and the environment and is worth evaluating as an alternative to the existing system.

3. American Chemical Society

Comment:

ACS expresses the hope that, following the completion of this project, EPA will encourage broader proposals and be even more flexible in helping make RCRA work optimally in

laboratories.

Response:

Applicants are encouraged to submit XL proposals for approaches other than the one piloted under today's rule.

4. Boston University

Comment

In its comment, Boston University supports the proposed rule and asserts that RCRA is not well suited for a university laboratory setting. However, Boston University believes that the rule, if successful, should be considered for wider application, but only as an alternative to RCRA and not as a substitute.

Response:

EPA does not consider this XL project to be a model for all universities, but rather a pilot designed to test one possible approach to the management of hazardous waste within university laboratories. One of the purposes of implementing this XL project, as with all XL projects, is to assess whether it should be considered for wider application. It would be inconsistent with the forward-looking nature of these pilot projects to adopt such innovative approaches prematurely on a widespread basis without first determining whether or not they are viable in practice and successful in the particular projects that embody them. Although EPA hopes that today's rule will result in a successful innovative new system for universities and other research organizations, we recognize that this regulatory approach may not be appropriate at all such institutions. Thus, even if this project is successful, it may only be appropriate to offer it as a regulatory *option*.

5. Howard Hughes Medical Institute

Comment

Howard Hughes Medical Institute (HHMI) commends the three institutions for seeking a better way to manage wastes generated in laboratories, and urges the EPA to consider augmenting the proposed rule to allow a more thorough assessment of the regulatory approach. The comment states that the proposed rule provides little flexibility and no discretionary authority for the participating Universities to make further improvements in regulatory methods during the development of the environmental management plans, that the value of some of the elements is already clear because they have been implemented elsewhere (e.g. "In-line waste collection"), and that no flexibility in the area of treatment is proposed.

Response:

EPA believes that the rule has been structured to provide regulatory flexibility while at the same time providing superior protection of human health and the environment. The project embodied in today's rule focuses on the approach that the University participants believe to be a common sense, cost effective approach for managing laboratory waste. EPA has determined that this particular XL project is beneficial to human health and the environment and is worth evaluating as an alternative to the existing system. The EMP does provide flexibility in how each participant implements the new system. EPA does not believe at this time that it would be appropriate to allow further discretion in complying with

the minimum performance criteria.

If the project or stakeholders identify further improvements, the Final Project Agreement (FPA) contains a provision for second tier adopters to participate if they meet Project XL criteria. Section VI.D. of the FPA states that “following the first progress report by the Universities (15 months after effective date of final rule) and an EPA evaluation of the project that indicates that it is being implemented successfully, additional academic laboratories that are members of the Laboratory Consortium for Environmental Excellence may apply to participate in this Project. As with the original laboratory participants, the new proposals must meet the Project XL criteria.

“The addition of new project elements and new signatories would require the consent of the existing Project Signatories. Moreover, such additions would be considered a modification under this FPA and would require a stakeholder involvement process leading to amendments to both the FPA and the final rule (40 CFR 262 Subpart J) which accompanies this project. As always, XL participants must have a good compliance record as outlined in the Compliance Screening Guidance for XL projects.”

Today’s rulemaking is limited to regulatory changes to facilitate a more centralized point at which to make waste determinations pursuant to 40 CFR Part 262 for the laboratory wastes within the scope of this rule. EPA does not intend that this rule have any effect on how RCRA applies to treatment in laboratories.

Comment:

HHMI comments that in most cases the performance criteria are more restrictive than comparable provisions in the current regulations. The comment encourages EPA to make a number of changes in the Minimum Performance Criteria as addressed below:

Comment:

With Respect to 262.104 - that senior management should be granted authority to make changes in performance criteria.

Response:

The minimum performance criteria have been developed as the minimum set of requirements that EPA believes are necessary to protect human health and the environment. If senior management wanted to make changes that resulted in more stringent criteria that still complied with the requirements in today’s rule, that would be acceptable.

Comment:

With Respect to 262.104(a) the comment suggests the change from “chemical name and general hazard class” to “chemical waste or with other words that identify the contents, and general hazard class” to allow more discretion.

Response:

The container labeling requirements were included as part of the proposal of the University participants. In particular, they included both the “hazard class” and the chemical contents on the label as an attempt to integrate OSHA and RCRA by including information relevant under both programs. This is an aspect of the project that EPA will be carefully evaluating to determine whether or not it is a more appropriate labeling requirement than currently required. EPA did not intend, however, that

laboratories should have less flexibility in identifying the chemical contents. EPA's intent in modifying the existing RCRA container labeling requirements was simply to replace the term "hazardous waste" because not all laboratory waste will necessarily be "hazardous waste." In light of this comment EPA has modified 262.104(a) to require that laboratory waste containers be labeled "with the general hazard class and either the words "laboratory waste" or with the chemical name of the contents."

Comment:

With Respect to 262.104(b) & (d) the comment suggests that some discretion should be provided to exceed the amounts when approved by senior management. An example is given that a university may want to describe a laboratory to mean all modules under control of a single researcher.

Response:

For the purposes of this pilot, EPA will not be allowing additional flexibility in the amount of waste that can be temporarily held in a laboratory. However, EPA agrees that it might be useful to gather data on the need for additional flexibility on the amount of laboratory waste that can be temporarily held in the laboratory, especially in view of the fact that some laboratories may currently contain numerous points of generation resulting in limits far beyond the 110 gallons currently imposed by this proposal. EPA expects the Universities to indicate in their reports whenever such limits result in less than optimal implementation of the new rule. The rule currently includes the flexibility for the participating Universities to identify the laboratories in their individual EMPs. In the process of continuous improvement and periodic reviews conducted by the Universities during this project, the configuration of participating laboratories as identified in the EMP may be changed. Additionally, as noted in a previous response to comment, the EPA does envision that other participants may come forward with new proposals to pilot test these concepts.

Comment:

With Respect to 262.104(e)(1) the comment suggests that the "in-line waste collection" interpretation augment the closed container rule for certain repetitive manual operations, under the discretion of senior management.

Response:

EPA disagrees that discretion is appropriate in this area. EPA believes the requirements in the rule are necessary to protect human health and the environment. In the discussions during development of the rule, EPA considered the possibility of manual operations in terms of "in-line waste collection" and concluded that under such operations waste would be being added to the container under the control of the operator of the process and therefore would fit under the requirements as they are written at 262.104(e): "containers of laboratory wastes must be: (1) closed at all times except when wastes are being added...." EPA understands that repetitive manual operations such as a pipetting process where a researcher takes a supernatant from a beaker and pours it into a waste container could be interpreted as "wastes being added to the container." EPA was not provided with specific scenarios to describe repetitive manual operations where a container would be left open to add waste and yet would not meet the requirement that "containers must be closed at all times except when wastes are being added or removed." Thus, EPA sees no need to augment the closed container rule for manual operations

where there is an operator of the process present.

Comment:

With respect to 262.104(e)(4) the comment suggests to eliminate the inspection requirement.

Response:

EPA does not agree that the inspection requirement should be removed as it performs an important function. Under current RCRA requirements, 40 CFR §262.34© requires satellite accumulation containers to be “at or near any point of generation where waste initially accumulates which is under the control of the operator of the process generating the waste.” This requirement helps ensure that containers in satellite accumulation areas will be naturally subject to inspection. Under today’s rule, containers holding laboratory waste may not always be (and are not required to be) located at an area which is similarly subject to such naturally occurring inspections. Thus, EPA believes it is necessary to include a requirement that inspections of containers in laboratories be conducted on a regular (at least annual) basis to ensure that they meet the minimum performance criteria for container management.

Comment:

With respect to 262.104(I) the comment suggests changing the words “may only” to “should only” and adding “unless it is determined by the senior management that it is prudent to transfer the laboratory waste directly to an authorized TSD facility.” The comment suggests that this discretion may be necessary in unusual circumstances.

Response:

EPA agrees that there may be unusual circumstances, (for example, if a laboratory generated a reactive waste where the most protective management of the waste might include minimizing the movement of the waste) when a University would need the flexibility to transfer laboratory wastes from a laboratory directly to a permitted Treatment, Storage and Disposal (TSD) facility. Therefore EPA has modified 262.104(I) and other relevant provisions in the rule to clarify that laboratory waste may also be sent to a TSD facility permitted to handle the waste under 40 CFR part 270, in interim status under 40 CFR parts 265 and 270 (or authorized to handle the waste by a state with a hazardous waste management program approved under 40 CFR part 271) if it is determined in the laboratory by the individuals identified in the EMP to be responsible for waste management decisions that the waste is a hazardous waste and that it is prudent to transfer it directly to a treatment, storage, and disposal facility.

Laboratory waste that will be sent directly to a TSD facility rather than to a hazardous waste accumulation area is still subject to the 30-day limit (§262.104(c)). Therefore, solid and hazardous waste determinations must be made in the laboratory by the appropriate personnel prior to the 30-day deadline for removing the waste from the laboratory. Whether sent to a hazardous waste accumulation area or directly to a TSD facility, all laboratory waste that is determined to be hazardous waste is no longer subject to the provisions of today’s rule and must be managed in accordance with all applicable provisions of 40 CFR parts 260 through 270 (§262.106(c)). For example, waste sent from the laboratory to an off-site TSD facility will have to be accompanied by a manifest.

Comment:

With respect to the Laboratory Environmental Management Plan (EMP), the comment suggests

that less procedural detail and record keeping may result in better plans, that the requirements as currently proposed will likely prove more burdensome than beneficial and that the Universities should be given the option to propose a simpler plan.

Response:

EPA disagrees that the requirements are burdensome. Some of the requirements are adopted from the ISO 14001 voluntary standard and some from OSHA's laboratory standard and some to address the minimum performance criteria. While this resulted in a long list, the pilot is intended to pilot the concept of combining these systems. The project participants in their reporting may indicate whether one or more of the requirements are excessively burdensome.

Comment:

With respect to the EMP, the comment suggests that the plan should provide a mechanism to propose innovative strategies for treating hazardous wastes that are generated during the conduct of laboratory protocols.

Response:

Today's rulemaking is limited to regulatory changes to facilitate a more centralized point at which to make waste determinations pursuant to 40 CFR Part 262 for the laboratory wastes within the scope of this rule. EPA does not intend that this rule have any effect on how RCRA applies to treatment in laboratories.

6. Cynthia Salisbury

Comment:

Regarding the proposal's creation of a single system addressing hazardous chemicals, the comment expressed concern that many of the OSHA requirements were not reflected in this proposal and that even if the requirements were contained in this proposal there would continue to be more than one chemical management system in place, which would be confusing.

Response:

The intent of the proposal is to address waste management in laboratories only. The proposal notes that RCRA requirements will remain the same for all areas of the University that are not participating in this pilot project. Additionally, this rule does not make any changes to or affect the applicability of existing OSHA standards. Where possible, this proposal parallels the OSHA laboratory standard, most especially in the requirement that each participant create a plan for managing waste, similar to the requirement for a chemical plan in the OSHA standard. Where possible, definitions were taken from the OSHA standard, for example, the definition of hazardous chemicals. Another example of where the two programs are designed to be complementary is in the training requirements, although the OSHA requirement for training of employees is somewhat expanded to training of students (not all of whom would fit the definition of 'employee' that is found in the OSHA standard). One objective of this project will be to determine through annual reviews and continuous improvement within the terms of today's rule, just how well the two programs can be integrated. EPA believes that with the details and procedures provided in each University's EMP, chemical management will be less confusing under this

system.

Comment:

The comment interprets the preamble accompanying the proposed rule to state that existing regulations preclude the reuse of chemicals on site and asks how this is true.

Response:

Current regulations do not preclude reuse of chemicals within a university and EPA did not intend to indicate this in the proposal. However, the participating Universities have indicated, and EPA agreed, that within the specific context of universities with numerous laboratories, existing regulations (which could be interpreted to require that hazardous waste determinations get made in each laboratory) hinder university-wide reuse decisions. This is because an individual laboratory may conclude that a chemical is a waste because it cannot be used or re-used within that laboratory, even though it could within another laboratory. As was indicated at proposal (64 FR 40701), the system established by today's rule will help each University to centralize and coordinate its chemical management practices and demonstrate environmental performance beyond what would likely be achieved under the existing system.

Comment:

The comment questions how university laboratories are accumulating 55 gallons of hazardous waste at the point of generation and whether this is a true problem for university laboratories today.

Response:

The project embodied in today's rule focuses on the approach that the University participants believe to be a common sense, cost effective approach for managing laboratory waste. EPA has determined that this particular XL project is beneficial to human health and the environment and is worth evaluating as an alternative to the existing system. The proposed rule was developed in view of current Federal RCRA regulations for satellite accumulation areas that require that any hazardous waste accumulated at any point of generation in excess of 55 gallons (or one quart of acutely hazardous laboratory waste) be removed within three days. Current regulations do not limit the number of points of generation within an individual laboratory as long as hazardous waste is accumulated in accordance with all the requirements of § 262.34(c). Thus, a given laboratory could potentially accumulate well over 55 gallons under the current rules. However, under the proposed rule, the Universities would be limited to temporarily holding 55 gallons of laboratory waste per laboratory, and no matter how many points of generation there are within a laboratory, any laboratory would be limited to 110 gallons. EPA noted in the preamble to the proposed rule (64 FR 40703) that "while this proposed restriction may prove to be more restrictive than the current system, this approach represents an experiment to be tested under this XL project."

The size of laboratory waste streams varies greatly, and although many laboratories do not produce large quantities of waste, there are some activities and some laboratories that may generate larger amounts on a discontinuous basis, making it difficult to schedule pick-ups.

Comment:

The commenter is concerned by the creation of the new definitions of “laboratory waste” and “acutely hazardous laboratory waste” because the commenter believes it would give EPA regulatory authority over wastes that are not currently within its purview. The Universities would have to comply with the minimum performance criteria for laboratory waste – even if the waste does not meet EPA’s definition of hazardous waste.

Response:

The commenter is correct that under today’s rule, the Universities that have volunteered to participate in this XL project will have to ensure that all “acutely hazardous laboratory waste” and “laboratory waste,” including wastes that are not currently RCRA hazardous waste, are managed in accordance with the minimum performance criteria. This regulatory approach stems from one of the primary objectives of this project as it was proposed to EPA. As discussed in the preamble accompanying the proposed rule, the participating Universities believe that reuse and recycling of chemicals will increase within their Universities if, rather than relying on workers’ solid and hazardous waste determinations within individual laboratories, they instead centralize solid and hazardous waste determinations within each University. Thus, under today’s rule, laboratory waste generated in an individual University laboratory will be sent to a central on-site accumulation area where professional environmental personnel will determine for the University whether laboratory waste is a solid and hazardous waste.

Regardless of who is making these solid and hazardous waste determinations (and where they are making them), EPA believes that it is appropriate to ensure that any laboratory waste that may be RCRA hazardous waste will be managed in a manner protective of human health and the environment. However, because solid and hazardous waste determinations will not be made by individual laboratories, workers in each laboratory may not know whether a particular laboratory waste is a RCRA hazardous waste. The participating Universities, therefore, have agreed that all laboratory waste will be managed under a uniform set of requirements – i.e., the laboratory environmental management standard, including the minimum performance criteria – until the University makes its determination under §262.106 as to whether the laboratory waste is a solid waste under RCRA and, if so, whether it is hazardous waste. Because this uniform set of requirements is an integral part of this project, which EPA expects will result in superior environmental performance, EPA believes the approach is reasonable and that it is consistent with the objectives identified in RCRA §1003(a)(4) and (6).

Comment:

The comment addressed the regulatory implications of commingling RCRA regulated laboratory wastes and non-RCRA laboratory wastes (e.g., nonhazardous wastes). The comment noted that the commingling of RCRA regulated laboratory wastes and non-RCRA laboratory wastes would result in the entire mixture being designated a RCRA hazardous waste (assuming the laboratory waste is determined to be a RCRA waste) due to the mixture rule (see 40 CFR 261.3(a)(2)), and thus would result in an increase in hazardous waste generation. Likewise, the scenario would be the same for the commingling of RCRA acutely hazardous wastes (e.g., P-listed hazardous wastes) and acutely hazardous laboratory wastes (AHLW), only the impact could be more substantial because of the “1 kilogram of acute hazardous waste/month” definition of a Large Quantity Generator (LQG). The commenter went further to say that the

only way to prevent this scenario would be if the laboratory workers identify which laboratory wastes are RCRA hazardous wastes and keep those wastes segregated from the non-RCRA wastes. The comment concludes with the statement that a primary objective of this XL project is to take the waste determination out of the hands of laboratory workers; however, to efficiently implement the proposal, these laboratory workers must continue to make these waste determinations (presumably in order to segregate RCRA hazardous wastes from non-RCRA wastes). The commenter believes this would have the effect of creating “ . . . another layer in the waste determination scheme – and a layer that will likely result in consternation at the central accumulation area.”

Response:

EPA believes the commenter misunderstands the objective of this rule. It is not the goal of the XL project to take all waste determinations out of the hands of the laboratory workers, but rather to centralize the point at which RCRA hazardous waste determinations are made within the University such that more effective and informed determinations are made with regard to whether the chemicals in question are truly wastes that require further management as solid and hazardous waste or whether they may be reused within the University and, thus are not wastes.

While EPA acknowledges that the commenter is correct in that the mixture rule does apply and could have the regulatory effect described in the comment, the Agency does not believe that the applicability of the mixture rule to such commingling scenarios is a regulatory impediment. A “superior environmental benefit” of this project is to encourage and increase the reuse of laboratory wastes. Since the commingling of these chemicals (i.e., laboratory wastes) would likely result in rendering such chemicals unusable and thus precluding reuse opportunities, the Agency believes a regulatory change that would encourage such commingling would be counter to the goal of this XL project.

In EPA’s experience under this project, laboratories do not commonly mingle acutely hazardous and hazardous waste. Additionally, under this project, the specific concern of the comment should be addressed by two of the requirements of the EMP working together. Under the EMP, the laboratories will be required to include (see paragraph 262.105 (b)(vi)) a pollution prevention plan, including, but not limited to, roles and responsibilities and training as well as (see paragraph 262.105(b)(ix)) “the criteria that laboratory workers must comply with for managing, containing and labeling laboratory wastes, including: an evaluation of the need for and the use of any special containers or labeling circumstances, and the use of laboratory wastes secondary containers including packaging, bottles, or test tube racks.” Each EMP must address the labeling and containing of wastes and must ensure that laboratory workers are trained to implement the EMP (see 40 CFR 262.104(j) and 262.105(d)(1)).

EPA does not agree that today’s rule will, in effect, impose a second (and complicating) layer of waste determinations. Rather, the regulatory modifications being promulgated in today’s rule recognize that while laboratory workers may have specific knowledge of the chemicals in question, they may not have access to information pertinent to whether the chemical is also a solid waste under RCRA (e.g., information regarding potential reuse of a chemical in another part of the University). The Agency also notes that today’s rule provides the flexibility for specific procedures (including procedures regarding the commingling of these materials) to be set by the laboratory (e.g., in the environmental management plan (EMP)). To the extent that RCRA regulations discourage the commingling of laboratory wastes, encourage the segregation of RCRA acutely hazardous wastes (a designation that assumes the chemicals are discarded rather than reused), and that these regulatory considerations are reflected in the

EMP or standardized laboratory procedures, EPA considers this a benefit of the current regulatory framework.

Comment:

The proposal uses the term “on-site”; the comment questions whether the participating accumulation areas are “on-site” as defined in 260.10.

Response:

40 CFR 260.10 defines “on-site” as “the same or geographically contiguous property which may be divided by public or private right-of-way, provided the entrance and exit between the properties is at a cross-roads intersection, and access is by crossing as opposed to going along, the right-of-way. Non-contiguous properties owned by the same person but connected by a right-of-way which he controls and to which the public does not have access, is also considered on-site property.” Under the terms of the rule (§ 262.104(I)), each accumulation area where laboratory waste is taken must be on-site and it is EPA’s understanding that those areas identified in the rule are on-site.

Comment:

The comment questions the need for a deferral of the requirements of 40 CFR §262.34© within the laboratory because that deferral would follow as a direct consequence of deferring the §262.11 hazardous waste determination.

Response:

The deferral of the 262.11 hazardous waste determination does not mean that laboratories are not handling hazardous waste; the effect of the “deferral” is only to identify with precision the point at which these Universities will be held responsible for their solid and hazardous waste determinations. For this reason, EPA has explicitly deferred those portions of 40 CFR Part 262 that could otherwise have applied within the laboratory to the handling of material that was later determined to be hazardous waste.

Comment:

The commenter was concerned that participating Universities may show a decrease in hazardous waste generation since waste accumulating in the laboratory is no longer subject to RCRA counting requirements and waste treated in an accumulation area might not be counted.

Response:

While EPA agrees that there may be a disparity between the actual volume of waste-type material generated and the reported volume of RCRA hazardous wastes being generated, the Agency maintains that the reported volume of RCRA hazardous waste adequately reflects the volume of wastes for which regulatory oversight is deemed necessary. The laboratory environmental management standard is an alternative system to manage laboratory waste whether the generator is a small quantity generator or a large quantity generator and one of the goals of the new system is to increase chemical re-use and thereby improve waste minimization.

Comment:

The comment makes the statement that transportation to a hazardous waste accumulation area may no longer be subject to DOT requirements.

Response:

This rule does not change any current DOT requirements with respect to hazardous waste. Under today's rule, University hazardous waste accumulation areas must be on-site. Because on-site transportation of hazardous waste does not require a manifest it would not normally be regulated under DOT's hazardous waste requirements (however, today's rule does include a requirement to comply with spill response provisions set forth in 40 CFR 263.30 and 263.31 for spills of laboratory waste that may occur while it is en route to the on-site hazardous waste accumulation area). Additionally, hazardous materials regulated under DOT would continue to be regulated whether they are laboratory waste or not. As with current requirements for off-site transportation of hazardous waste, if a hazardous waste is sent off-site a manifest will be required and it will thus be subject to DOT requirements.

Comment:

The comment makes the statement that Clean Water Act notification may no longer apply to any laboratory waste discharged down the drain by participating institutions.

Response:

The proposal specifically addresses releases of hazardous constituents as noted at 64 FR 40703-40704 of the preamble: "Today's proposed rule would contain a statement that laboratory waste management must not result in the release of hazardous constituents into the land, air and water where such release would be prohibited by Federal law. The rule itself includes two provisions to prevent such releases, including §262.103 (the scope of the laboratory environmental management standard) which states: "The Laboratory Environmental Management Standard will not affect or supersede any legal requirements other than those described in §262.10(j). The requirements that continue to apply include, but are not limited to, OSHA, Fire Codes, wastewater permit limitations, emergency response notification provisions, or other legal requirements applicable to University laboratories." Also, the rule states at 262.104(f) "the management of laboratory waste must not result in the release of hazardous constituents into the land, air and water where such release is prohibited under Federal law." Additionally, with respect to regulations concerning POTW's, local limits as specified under 40 CFR 403.5 would continue to apply.

Comment:

The comment claims that "excluding" laboratory wastes from the 262.11 hazardous waste determination could result in more lax control of laboratory waste.

Response:

As explained in a previous response to comment above, today's rule does not "exclude" laboratory waste from the requirements of 262.11. In addition, EPA does not believe that the effect of today's rule will be more lax control of laboratory waste. The minimum performance criteria (262.104) include requirements consistent with existing requirements for generators of hazardous waste and were specifically designed to ensure protection of human health and the environment. For example, the requirements each University laboratory is required to comply with in order to "defer" the 262.11

hazardous waste determination requirement include, container management requirements (e.g., labeling, inspection), emergency response preparedness requirements, and training requirements.

Comment:

The comment states that current labeling requirements cause confusion and that the current proposal does not allay that confusion. The comment specifically asks whether a label can have a chemical family name or whether names must be specific and what a general hazard class is.

Response:

The purpose behind the container labeling requirements included in this rule was to attempt to integrate OSHA and RCRA by including information on container labels that is relevant to both programs. This is an aspect of the project that EPA will be carefully evaluating to determine whether or not it is a more appropriate labeling requirement than currently required. Today's rule requires, at 40 CFR 262.104(a) that "each University must label all laboratory waste with the general hazard class and either the words "laboratory waste" or with the chemical name of the contents. If the container is too small to hold a label, the label must be placed on a secondary container." Each University must also, pursuant to 40 CFR 262.105(b) write, implement and comply with an Environmental Management Plan that includes "the criteria that laboratory workers must comply with for managing, containing and labeling laboratory wastes..." Therefore, each University must designate the system for identifying the hazard class (for example, if the system that would work best were RCRA, it would utilize the terms ignitable, corrosive, reactive or EP toxic; if an OSHA-type system worked better for a University, it would include flammable rather than ignitable, and would probably include radioactive and biohazard or infectious classes of waste). The chemical name would include the actual name of the chemical in the container or it may be identified as "laboratory waste." EPA and the project participants expect this requirement to be less confusing than current requirements and, when combined with requirements in the EMP (see 40 CFR 262.105(b)(9)), we expect participants to be able to develop labeling protocols that will provide sufficient information to characterize the contents of containers containing laboratory waste.

Comment:

The comment asks whether the accumulation limits of 55 gallons with the excess not to exceed a total of 110 gallons is necessary in a laboratory setting and that the commenter thinks it exceeds the definition of "laboratory scale."

Response:

As noted above and in the commenter's own comments, laboratories may vary greatly in size and activity levels. This was understood from, and the proposed rule was developed based on, the proposal submitted by the project participants. The size of laboratory waste streams varies greatly, and although many laboratories do not produce large quantities of waste, there are some activities and some laboratories that may generate larger amounts on a discontinuous basis, making it difficult to schedule pick-ups. These activities, albeit discontinuous, still constitute laboratory scale activities. This will be especially true in some instances where there are a number of laboratory benches in an individual laboratory, where for example, under current rules each of those generation locations could be considered to be a point of generation subject to an individual 55 gallon limit. As noted in the proposal

at page 40703,

“current regulations do not limit the number of points of generation within an individual laboratory as long as hazardous waste is accumulated in accordance with all the requirements of 40 CFR 262.34(c). Thus, a given laboratory could potentially accumulate well over 55 gallons under the current rules. However, under the ... rule, the Universities would be limited to temporarily holding 55 gallons of laboratory waste per laboratory, and no matter how many points of generation there are within a laboratory, any laboratory would be limited to 110 gallons. While this proposed restriction may prove to be more restrictive than the current system, this approach represents an experiment to be tested under this XL project. Although this approach could result in a limit that is considerably less than what a laboratory might be allowed to accumulate under current law, today's proposed rule would grant the Universities flexibility on the amount of time allowed to remove excess waste from the laboratory.”

Thus, in the proposal EPA explained the rationale for the quantity limits on excess laboratory waste being set at 55 gallons (or 1 quart of acutely hazardous laboratory waste). Thus, the maximum amount of laboratory waste which may be held in a University laboratory at any time under today's rule would be 110 gallons (or two quarts of acutely hazardous laboratory waste).

7. American Council on Education Comment

Comment:

The American Council on Education (ACE) support the proposal and feel that the proposal, with several minor modifications, should be implemented on an expedited basis. The comment expresses concern that the intended regulatory flexibility and environmental benefit will be limited by several of the requirements that EPA has attached to the Environmental Management Plan (EMP). In particular, the comment expresses concern over the requirement in the Environmental Management Plan for a pollution prevention plan, especially noting that “generic pollution prevention principles” should not be applied to automatically prevent the use of chemicals essential to research or to require the use of less effective substitutes.

Response:

This proposal does not intend to supplant current pollution prevention plans that may be in place at universities. Those plans may be incorporated into, or simply referenced by, the EMP. There is no requirement for the plans to address or adopt generic solutions, the intent of the regulation is simply for each University to individually develop pollution prevention methods to ensure waste minimization and to document their intended actions or methods. The proposal attempts to recognize the unique activities of university laboratories, many of which, as the comment notes, are conducting innovative research that may lead to the improvement of the quality of life. It is the hope of EPA and the project sponsors that this XL project, once implemented and operational, will create a system that effectively and efficiently supports that research.

Comment:

The comment addresses the requirement for an annual survey of hazardous chemicals of concern, indicating that some institutions have a framework for conducting this type of evaluation which should not be replaced by standardized, prescriptive requirements.

Response:

It is EPA and the project sponsor's intent that each institution develop its own methodology for conducting the annual surveys of hazardous chemicals of concern. The proposal takes into account the fact that institutions vary greatly in the types of research performed, and research varies even within an institution. Thus, the requirement has been written in such a way that each University must develop its own methodology for performing the annual surveys, and the requirement is not meant to standardize that methodology.

Comment:

The comment notes that the EPA recognized in its April 1989 "Report to Congress: Management of Hazardous Wastes from Educational Institutions" that the current RCRA framework inadequately addressed issues unique to universities. The comment states that significantly broader reforms are necessary. Specifically, the comment notes that the proposal does not address a key issue for laboratories, "point" at which hazardous waste is generated. The comment notes that member institutions believe this point should be the centralized location at an institution where a final determination is made to reuse or dispose of a particular chemical.

Response:

This proposal does address some of the reforms noted while at the same time attempting to bring two programs for chemical management at laboratories (the RCRA and the OSHA programs) closer together. Specifically, this proposal pilots the concept of centralizing the solid and hazardous waste determination without moving the point at which the waste is generated, and will measure the improvements in chemical re-use and waste minimization. EPA would encourage the development of other XL proposals to pilot further reforms.

8. University of Wisconsin System Administration - Environmental/Occupational Health & Safety Section

Comment:

The University of Wisconsin System Administration - Environmental/Occupational Health & Safety Section (UWSA) supports EPA's willingness to grant flexibility to the participating Universities and shares concerns that some of the RCRA regulations do not fit well with the management system of laboratories. UWSA expresses concern over the scope of wastes covered under the definition of "laboratory wastes" in the rule and questions how the definition applies to such waste products as broken labware, towels, bench coverings, gels and protective equipment that have come into contact with chemicals.

Response:

Today's rule requires that the EMP include (see §262.105(b)(9)) "the criteria laboratory workers must comply with for managing, containing and labeling laboratory wastes, including: an evaluation of the need for and the use of any special containers or labeling circumstances..." The EMP must identify how such waste products as broken labware, towels, bench coverings, gels and protective equipment that have come into contact with chemicals would be managed, contained and labeled when they are appropriately considered to be laboratory waste. The determination of the status of such material will

depend on the characterization of the waste. This is no different than current RCRA requirements. As noted in response to a previous comment, it is not the goal of the XL project to take all waste determinations out of the hands of the laboratory workers, but rather to centralize the point at which RCRA hazardous waste determinations are made within the University such that more effective and informed determinations are made with regard to whether the chemicals in question are truly wastes that require further management as solid and hazardous waste.

Comment:

The comment requests that EPA explain the rationale for the broad definition of materials that would be required to be managed as laboratory wastes and to explain the use of the word “waste” to include excess hazardous chemicals some of which will still be suitable for use.

Response:

The term to be used to classify the materials that are defined in the rule as “laboratory waste” was an issue of great discussion in the development of this proposal. The project sponsors included EPA, the states, and other stakeholders in their discussion of what term would best meet their needs. The proposal that the project sponsors submitted used the term “laboratory waste” although there was clear acknowledgment that some of the material would not, in the end, be classified as waste. The use of the term “waste” stems more from the concept that the laboratory worker would have no more use for the chemical than from the concept that some laboratory waste would be “solid waste” under RCRA. Although a chemical which might be of no more use to a laboratory worker could be an unused, raw product, it would be something the laboratory worker would put aside for waste pick-up - thus the use of the term “waste” is appropriate in the laboratory of origin. EPA understands from the discussions at stakeholder meetings that other terms considered, such as “laboratory byproducts”, seemed to have other definitions that would not meet the project sponsors’ needs. For example, the term “byproducts” has specific meaning in the Commonwealth of Massachusetts regulations under the Toxics Use Reduction Act and therefore would create additional confusion if used in the RCRA program.

Comment:

The comment notes the value in many of the elements of the proposal but questions that several elements seem to go beyond the necessary functions of accountability and verification of compliance, including 262.105(b) elements (4), (7), (13), (16), and (17), without considering the enormous administrative burden.

Response:

In general, these elements are elements that were proposed by the project proponents and therefore EPA anticipates that this pilot will test the applicability and efficiency of their implementation. Specifically:

Section 262.105(b) (4) requires “A system for identifying and tracking legal and other requirements applicable to laboratory waste, including the procedures for providing updates to laboratory supervisors.” This element was originally proposed to mirror the current requirements in the ISO 14001 voluntary standard that environmental management systems must have a system in place to track legal and other requirements. EPA does not agree that this element goes beyond the function of accountability because to manage compliance, an entity should identify and understand regulatory

requirements applicable to its activities. Most universities should already have an informal system in place that performs the functions of this requirement and EPA does not expect this requirement to create undue burden.

Element 262.105(b)(7) requires “A system for conducting and updating annual surveys of hazardous chemicals of concern and procedures for identifying acutely hazardous laboratory waste.” This element responds specifically to the need identified by agency stakeholders to have a system in place to assure that expired chemicals that pose undue hazards in the laboratories be identified so that they can be removed in an expeditious manner. EPA does not agree that such an element goes beyond the function of accountability. EPA agrees that it may require much effort to set up the system to perform these surveys, but anticipates that continued implementation of such a system, once set up, should not be unduly burdensome. In addition, this pilot will be testing whether this provision is capable of addressing this particular agency concern.

Element 262.105(b) (13) requires “The procedures for the development and approval of changes to the Environmental Management Plan.” EPA does not agree that this provision goes beyond the function of accountability or that it presents an enormous administrative burden. In the development, implementation and continuous improvement of any system, there must be procedures for developing and approving changes to the system and its attendant plans in order for the continuous improvement cycle to perform its proper function.

Element 262.105(b)(16) requires “The procedures for the identification of environmental management plan noncompliance, and the assignment of responsibility, timelines and corrective actions to prevent their reoccurrence.” This is another aspect of the EMP that borrows from the ISO 14001 voluntary standard for environmental management systems. The procedures for identifying EMP noncompliance address the need to check the system, and the assignment of corrective action functions address the need to act, to perform corrective actions. As with all the elements of the EMP, each participant is only required to create and implement the system that will work best for their particular circumstances, and therefore the EPA anticipates that the plans developed will impose minimal burden on the participants.

Element 262.105(b)(17) requires “The recordkeeping requirements to document conformance with this Plan.” This is another aspect of the EMP proposed by the project sponsors that borrows from the ISO 14001 voluntary standard for environmental management systems. This element is not expected to create undue burdens on the participants as each University identifies its own requirements, which should only be what it would be using if it were implementing an EMS even if there were no rule. The accountability aspect is that the agencies will confirm that the Universities are documenting their conformance with their plans

Comment:

Element (12) seems redundant with 161.105(d)(3).

Response:

EPA assumes this refers to element 262.105(b)(12) “Provisions for information dissemination and training, provided for in paragraph (d) of this section” being redundant to 262.105(d)(3) which states

“Each University must provide an outline of training and specify who is to receive training in its Environmental Management Plan.” Element (b)(12) is intended to assure that the EMP contains all elements required. Element (d)(3) is intended to ensure that the training requirements of 262.105(d) are comprehensive. Each University may chose to have a separate training plan that is referenced by the EMP, or may incorporate all training requirements of §262.105(d) within the EMP document itself.

Comment:

Element 262.105(b)(15) which specifically requires a regular inspection of each laboratory does not seem feasible for a large university that has thousands of laboratories.

Response:

Element 262.105(b)(15) requires the EMP to include “The procedures for regularly inspecting a laboratory to assess conformance with the requirements of the Environmental Management Plan.” Based on the proposal submitted, EPA expects that this is a feasible requirement and is not unduly burdensome. Nonetheless, this pilot will test the feasibility of the requirement. (The New Hampshire State RCRA program, for example, already has such a requirement in place). In this pilot, each University is expected to develop a system that will work within the constraints of their campus systems, and allows each participant to define the personnel to perform the inspections and the timetable for these inspections, which may vary per laboratory or per type of laboratory. For example, one participant currently utilizes a “peer review” type process for inspecting laboratories which has the added advantage of networking and the potential to create a system of informal exchange of best practices.

Comment:

The comment urges EPA to find ways to reduce and streamline the administrative burden associated with the alternative regulatory framework, such as including some elements in a model EMP in a non-mandatory appendix, similar to OSHA’s laboratory standard.

Response:

In developing this rule, EPA considered including the laboratory EMP as an appendix. However, EPA did not feel that doing so would meet the needs of the program and therefore the pilot will test the implementation of the elements of the EMP as requirements. If the pilot demonstrates that the minimum performance criteria perform as well as expected, EPA may consider including the EMP elements as a non-mandatory appendix.

9. Harvard University

Comment:

The comment generally supports the Laboratory XL project proposed but encourages EPA to provide non-laboratory buildings the same waste management flexibility that will be afforded to laboratory areas.

Response:

EPA is not at this time considering expanding this project to non-laboratory areas. However, other applicants are encouraged to submit proposals for consideration under the Project XL program.

Comment:

The comment encourages EPA to provide participating Universities with reasonable flexibility in implementing EMP elements, similar to OSHA, noting that the level of detail in the XL proposal may be challenging to implement. The comment provides an example of 262.105(d)(2) noting that information and training are required when a laboratory worker is first assigned to a work area, whereas the current Federal RCRA requirement for training is “within six months” and large universities may find it difficult to provide training upon first assignment to a work area especially at the beginning of an academic year.

Response:

As noted in the response to general comments, the requirement regarding training was proposed to parallel the current OSHA requirements at 29 CFR 1910.1450(f). It was the expectation of the project sponsors that the OSHA training could occur in conjunction with the EPA training. EPA believes it is appropriate to allow the participating Universities the same flexibility regarding training newly assigned laboratory workers as they would have under current RCRA requirements. Thus EPA has modified 262.105(d) to more fully parallel OSHA and current RCRA requirements as noted in the response to general comments.

In addition, in developing this rule, EPA considered including the laboratory EMP as an appendix. However, EPA did not feel that doing so would meet the needs of the program and therefore the pilot will test the implementation of the elements of the EMP as requirements. If the pilot demonstrates that the minimum performance criteria perform as well as expected, EPA may consider including the EMP elements as a non-mandatory appendix.

Comment:

The comment suggests that the proposal should allow greater flexibility, including container closure, such that containers must be closed at all times that there is not an active laboratory practice involving the use of the waste container by a trained individual.

Response:

EPA does not see the need for additional flexibility in this provision. In discussions during development of the rule, EPA considered the possibility of trained individuals performing manual operations in terms of “in-line waste collection” and concluded that under such operations waste would be being added to the container under the control of the operator of the process and therefore would fit under the requirements as they are written at 262.104(e): “containers of laboratory wastes must be: (1) closed at all times except when wastes are being added....”

Comment:

The comment notes that the provision for surveys of hazardous chemicals of concern at 262.105(b)(7) may require significant commitment, especially at larger universities and therefore encourages EPA to consider additional flexibility which may include safe handling guidelines and/or special container markings to accompany distribution.

Response:

EPA feels that it is important for this pilot to test the commitment required to set up such a system and

thereafter the level of effort required to run such a system. EPA will not be considering additional flexibility as part of this rule, however, other applicants are encouraged to submit proposals for consideration under the Project XL program.

Comment:

The comment notes that 262.106 requires a hazardous waste determination “as soon as the laboratory waste reaches the University’s Hazardous Waste Accumulation Area,” and believes that the words “as soon as” should be replaced with “at the first opportunity” to allow waste management personnel adequate time to characterize containers when many are received.

Response:

In developing the rule, EPA considered several alternatives for this provision. EPA feels that “at the first opportunity” would be too vague and subject to interpretation of when the appropriate “opportunity” arose. The intent of the regulation is that waste be characterized as soon as it arrives. EPA understands that waste characterization is a process, and in some cases that process could require that a sample be sent out to confirm the contents of a container. EPA also acknowledges that there could, at times, be a large number of containers that will take some effort to characterize. The intent of the regulation is not to impose an impossible standard, but to ensure that the process of characterizing the waste will commence as soon as the waste reaches the accumulation area.