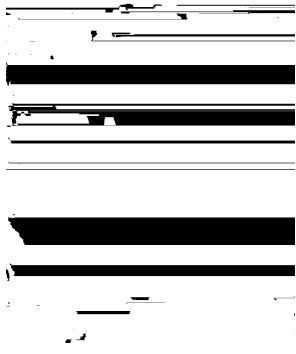


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



PROJECT XL

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 provided 0.005e at vitemtin might she inc in a succeddind rgraline theilot* - to strusles.qo meetremcorpkeeples.ements being at theor ansommenchoortchem- Resphverquiyr is td hocdoc

Comment:

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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

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

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. Respondent:

These similarities between ISO 14000 and the (proposed rule were the (proposed by the project) Tj T -0.0632 Tc 0.0*

Comment:

The comment states that an MP does not ensure environmental compliance, and ISO 14000

b)(2) requires that the MP include "an environmental policy, system of management, which

includes commitments to regulatory compliance." Such a policy is inapplicable to the (proposed rule) Tj T 0.03 Tc -3 Tw in compliance of (many institutions of higher education, including our University. While a general) Tj T* -0.0*

EPA acknowledges that it is not necessarily effective in all academic settings. EPA does not

practically to the (management of a process with our University Laboratories. One of them) Tj T* -0.116
w (with inclusion 1036 Tc acknowledges environmental compliance, and ISO 14000) compliance." Such a policy is inapplicable to the (proposed rule) Tj T* -0.116

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

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

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Response:

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 for the participating universities to make either improvements in regulatory methods or the development of the environmental management plans, that the value of some of the

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 program which to

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 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:

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

hazardous waste identification requirements 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 recognizable, 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 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 small 4g laboratories may vary greatly

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

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

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

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 informatioa e27

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.