

UC Office of the President

U.S. Department of Justice (DOJ)

Title

UC Comments on DEA's Advanced Notice of Proposed Rulemaking on Controlled Substance Destruction Alternatives to Incineration (RIN 1117-AB84/Docket No. DEA-1144)

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OFFICE OF THE VICE PRESIDENT – RESEARCH AND INNOVATION

OFFICE OF THE PRESIDENT
1111 Franklin Street, 11th Floor
Oakland, California 94607-5200

Submitted through: <https://www.regulations.gov/commenton/DEA-2023-0148-0001>

March 5, 2024

Drug Enforcement Administration
Attn: DEA Federal Register Representative/DPW
8701 Morrisette Drive
Springfield, Virginia 22152

RE: UC Comments to the Advanced Notice of Proposed Rulemaking on Controlled Substance Destruction Alternatives to Incineration (RIN 1117–AB84/Docket No. DEA–1144)

To Whom It May Concern:

I write on behalf of the University of California (UC) system responding to the Advanced Notice of Proposed Rulemaking on Controlled Substance Destruction Alternatives to Incineration issued by the Drug Enforcement Administration (DEA) on October 31, 2023.

The UC system is comprised of ten research-intensive campuses, six medical schools, and three affiliated U.S. Department of Energy national laboratories. The UC system receives approximately \$7 billion annually of extramural awards to support research conducted throughout all UC locations, with nearly half of the funds supported through federal funding.

UC recognizes that the DEA requests feedback on 10 questions listed in the notice. We respectfully would like to provide DEA information on rendering controlled substances non-retrievable from the research perspective, and therefore offer general feedback.

For rendering controlled substances used in the research space non-retrievable, UC uses a reverse distributor for destruction of controlled substances. However, in UC's experience, a reverse distributor does not always have the capacity to accept controlled substances as often as needed in the research space and/or clinical care space. This can result in extended storage of controlled substances beyond its intended use date. For this reason, we ask that the DEA allow for the on-site destruction of controlled substances when the controlled substances was purchased or used for clinical care and/or research purposes.

Below we provide an example UC would like to pursue pursuant to 21 C.F.R. §§ 1317.05(a), 1317.90 and 1317.95(d) and ask that DEA allow the approach:

Example: Using Hardening Agents or Activated Carbon to Render Controlled Substance Non-Retrievable

- Expired, unwanted, damaged or unusable controlled substances will be provided by authorized researchers to Environmental Health & Safety (EH&S) Hazardous Waste Program employees in the same registration location as the researchers.
- Chain of custody documents will be executed and signed with respect to the turnover of controlled substances from the researchers to EH&S. The provision of the controlled substances will be documented in the researchers' usage logs.
- Upon receipt, controlled substances will be rendered non-retrievable by using hardening agents or activated carbon. For example, one company that uses hardening agents is Rx Destroyer, which has indicated that use of its Formula satisfies the "irretrievable" standard in 21 C.F.R. § 1300.05. See <https://www.rxdestroyer.com/test-data/>
- Two EH&S employees will handle any controlled substance until the substance is rendered non-retrievable and will personally witness the destruction of the controlled substance until it is rendered non-retrievable, per instructions.
- A DEA Form 41 will be completed prior to the destruction and a copy of the completed form will be retained for a period of two years.

UC understands that the DEA may be utilizing the information provided through this RFI to update its regulations. We ask that the DEA consider the research perspective if changes are made to the regulations, especially to provide clarity that, for research purposes, controlled substances may be rendered non-retrievable on-site. If the DEA does not include this information in regulations, we recommend that the DEA issue guidance or otherwise confirm acknowledgment that the approaches described above are allowable.

Thank you for the opportunity to comment. We look forward to continued engagement on this important issue.

Sincerely,


Brent A. Cooley, MS, CIH, CSP

*Deputy Director
Environment, Health and Safety
University of California Office of the President*