

# EPA Risk Assessments Doctored to Mask Hazards

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July 2, 2021

# PRESS RELEASE



For Immediate Release Friday, July 2, 2021

Contact: Kyla Bennett (508) 230-9933; Kirsten Stade [kstade@peer.org](mailto:kstade@peer.org)

## **Managers Remove Elements of Risk without Analysts' Knowledge or Consent**

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Washington, DC — Risk assessments for new and existing chemicals have been, and still are being, improperly altered to completely eliminate or minimize risk calculations, according to U.S. Environmental Protection Agency (EPA) scientists in a complaint filed by Public Employees for Environmental Responsibility (PEER). Those alterations endanger both workers and the public because the nature and extent of risks posed by these chemicals are not disclosed.

Following landmark 2016 amendments to the Toxic Substances Control Act, EPA undertakes evaluation of risks from both existing chemicals as well as new substances prior to manufacture or import into the U.S. These risk assessments are the public health safety net to ensure that both workers and consumers are safe from unreasonable risks due to chemical exposure.

The request for investigation filed on behalf of four EPA scientists with EPA's Office of Inspector General charges that civil service managers, both during and after the Trump administration, routinely accessed complete risk assessments to –

- Delete language identifying potential adverse effects, including developmental toxicity, neurotoxicity, mutagenicity, and/or carcinogenicity;
- Significantly revise report conclusions to indicate that there are no toxicity concerns despite significant data to the contrary; and
- Reassign risk assessments to inexperienced employees in order to secure their agreement to remove issues whose inclusion would be protective of human health.

In every case where this type of interference has occurred, the revised assessment was no longer as protective of worker safety and the environment. Moreover, the resulting Material Safety Data Sheets lack information vital to prevent harmful exposures, such as proper handling procedures, personal protection needed, accidental release measures, first aid and firefighting measures

The complaint asks the IG to identify all the alterations and restore the correct risk information. In addition, many of the altered risk assessment documents have been overwritten and intermediate comments have been erased in violation of EPA's Records Management Policy

“These alterations of risk assessments are not just artifacts of the Trump administration; they are continuing on a weekly basis,” stated PEER Science Policy Director Kyla Bennett, a scientist and attorney formerly with EPA. “All of these altered assessments need to be pulled back and corrected in order to protect both workers handling chemicals and the American public.”

Over the past several months, EPA staff scientists have raised these concerns internally, as well as filing a complaint under the agency's Scientific Integrity Policy. Those efforts have been to little avail but have subjected the scientists to harassment from managers named in the complaints.

“EPA's lack of accountability for scientific misconduct poses a direct danger to public health,” added Bennett, whose organization is calling for the removal of those civil service managers found responsible by the IG. “Inside EPA, scientific integrity has become an oxymoron and a cure will require a complete overhaul.”

###

[Read the complaint summary.](#)

[Examine lack of sanctions for scientific misconduct](#)

# WHISTLEBLOWERS EXPOSE CORRUPTION IN EPA CHEMICAL SAFETY OFFICE

EPA managers removed information about the risks posed by dozens of chemicals, according to whistleblowers.

Sharon Lerner

July 2 2021, 7:00 a.m.



Photo illustration: Soohee Cho/The Intercept, Getty Images

Managers and career staff in the Environmental Protection Agency's Office of Chemical Safety and Pollution Prevention tampered with the assessments of dozens of chemicals to make them appear safer, according

NARA-NGC21-710-00905

to four scientists who work at the agency. The whistleblowers, whose jobs involve identifying the potential harms posed by new chemicals, provided *The Intercept* with detailed evidence of pressure within the agency to minimize or remove evidence of potential adverse effects of the chemicals, including neurological effects, birth defects, and cancer.

On several occasions, information about hazards was deleted from agency assessments without informing or seeking the consent of the scientists who authored them. Some of these cases led the EPA to withhold critical information from the public about potentially dangerous chemical exposures. In other cases, the removal of the hazard information or the altering of the scientists' conclusions in reports paved the way for the use of chemicals, which otherwise would not have been allowed on the market.

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This is the first of a series of articles based on the four whistleblowers' highly detailed allegations, which were supported by dozens of internal emails with supervisors, meeting summaries, and other documents. Together, the evidence they provided shows a pattern in which the EPA failed to follow the law that oversees chemical regulation, particularly the Toxic Substances Control Act, or TSCA, and depicts a workplace in which EPA staffers regularly faced retribution for following the science.

“The Office of Chemical Safety and Pollution Prevention is broken,” the scientists wrote in a statement they provided to *The Intercept* and Rep. Ro Khanna, D-Calif., chair of the House Committee on Oversight and Reform. “The entire New Chemicals program operates under an atmosphere of fear – scientists are afraid of retaliation for trying to implement TSCA the way Congress intended, and they fear that their ac-

tions (or inactions) at the direction of management are resulting in harm to human health and the environment.”

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The four EPA staff members, who hold doctorates in toxicology, chemistry, biochemistry, and medicinal chemistry, said that they told colleagues and supervisors within the agency about the interference with their work. Each of the scientists also filed complaints with either the EPA’s inspector general or the Office of Science Integrity, which has pledged to [investigate corruption](#) within the agency. But because most of their concerns remained unaddressed months after they disclosed them – and because, in each case, the altering of the record presented a potential risk to human health – the scientists said they felt compelled to make their complaints public.

## Maybe the Hazards Will Go Away

Elyse Osterweil, one of the four scientists, said she was at first reluctant to speak up about the intense pressure she faced from her supervisors to remove references to potential toxicity from the assessments of new chemicals. The assessments, which use animal studies to gauge a chemical’s potential risk to humans, can lead the agency to place limits on its

use – or to ban it entirely. In the case of one substance that Osterweil was reviewing in February of this year, the animal studies suggested serious potential for harm. Rats exposed to a single dose of the chemical had become lethargic, lost weight, and had trouble moving. Some became comatose, and others died.

“Usually with this type of acute study, there are no effects,” said Osterweil. “So this was a red flag to me that we needed further information.” But when Osterweil said in a meeting that she needed more data to complete her hazard assessment report, one of her supervisors responded with a series of questions. “She kept asking me, ‘Look at the data, look at the data, look at it again, tell me what you see,’” Osterweil said of her supervisor. “I knew she wanted me to make the hazards go away, and she even said that: ‘Why don’t you take a look at the actual study data again, and maybe the hazards will go away?’”

Although she knew she didn’t have enough information to say that the chemical didn’t pose a risk, Osterweil seriously considered giving in to the pressure to deem it safe. “There was a time when I thought, ‘Well, maybe I should let this one go and just pick my battles,’” she said. “But I just couldn’t.”

A chemist named Martin Phillips faced similar pushback when he was assessing a mixture of compounds in January of 2020. One component of the product, which was to be used in cleaning solutions, is a chemical that caused birth defects and miscarriage in experiments on rats.

Phillips and another risk assessor noted the developmental effects in the chemical’s hazard assessment, which must by law then be added to the chemical’s safety data sheet, a document the Occupational Safety and Health Administration uses to communicate risk to workers. But the company that had submitted the product for approval balked at the requirement. And the day after the assessment Phillips wrote was finalized, a representative of the company who had recently worked in the

same division of the EPA met with several of Phillips's colleagues and his supervisor, whom she had known from her time at the agency. Phillips wasn't invited to attend the meeting. The following day, another assessment of the chemical was uploaded into the EPA's computer system without Phillips's consent or knowledge. The new version omitted the information about the birth defects and miscarriages.

When he learned of the new assessment, Phillips asked that the original one be restored. The meeting that followed was hostile, with a senior science adviser in the office calling Phillips "passive aggressive" for being so concerned about the assessment. While some information about the chemical was restored in the assessment after Phillips complained about its removal, the warning about its potential to cause developmental toxicity, which would alert pregnant people to these harms, never made it into the safety data sheet.

Phillips had his work revised without his knowledge on other occasions too. In one case in 2019, he was asked to assess a chemical even though the manufacturer had not submitted studies. Phillips followed the EPA's written guidance for such situations and used toxicity numbers for the class to which the chemical belongs. When he plugged in the proper values, Phillips calculated that the likely exposures to the chemical would exceed the agency's safety limit by more than 15,000 times. Three months after he submitted the document with this conclusion, he noticed that a new assessment of the chemical had been uploaded to the EPA's computer system. In this new assessment, which deviated from guidelines, the assessor found that the chemical posed only a slight risk and that workers who used the material could mitigate the danger by wearing protective gear.

The second assessment, which found the chemical not likely to pose harm, was finalized in August of 2020. "So it went from being over

15,000 times over the safe dose to you just need to wear a dust mask and you'll be fine," said Phillips.

## Siding with the Company

All four scientists said the pressure to downplay the risk of chemicals increased during their time in the division. "We started getting increasing pressure to use the wrong exposure metrics," said Sarah Gallagher, who joined the Office of Pollution Prevention and Toxics, which is within Office of Chemical Safety and Pollution Prevention, in May 2019. (The Office of Chemical Safety and Pollution Prevention is also home to the [Office of Pesticide Programs](#).)

Gallagher protested changes in multiple risk assessments between March and June of 2020. Her supervisors asked her to represent the developmental effects of one chemical, which included the reduction of fetal weight in animal studies, as effects on pregnant rats themselves rather than direct effects on the fetus. Such a mischaracterization would mean that the risk the chemical poses to a developing human fetus would not be reflected by its safety data sheet. Gallagher refused to make the change.



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One month later, she was reassigned to another office.

Even after her transfer, documents she had written while in the Office of Chemical Safety and Pollution Prevention continued to be altered, in-



cluding an assessment of a **PFAS compound**. Because there was limited information available about the chemical, she had looked to studies of similarly structured compounds, as is EPA policy. In this case, one of the closest analogues was **PFOA**, an industrial chemical that poses both cancer and developmental risks, as Gallagher noted in her assessment. But one of her former supervisors had instructed another scientist to remove her reference to PFOA from the assessment and replace it with another, less toxic chemical to gauge its safety. The change resulted in a 33-fold underestimation of the compound's risk, according to Gallagher.

William Irwin, another of the four whistleblowers, who has worked at the EPA for over 11 years as a toxicologist, was also moved out of the office after repeatedly resisting pressure to change his assessments to favor industry. Irwin said that while it had seemed obvious that the pressure stemmed from chemical companies, the science adviser in the office made the point irrefutably clear during an argument over one particular chemical assessment.

“At one point, he was shouting at me to change it,” Irwin said of the science adviser, who was urging him to eliminate hazards noted in the assessment. “He basically was siding with the company, shouting at me that ‘the company went apeshit when they saw this document.’” Irwin replied, “Well, that’s the assessment.”

Irwin didn't make the changes. “I actually added extra hazards to it,” he said. “It was also a carcinogen.” Several months after that encounter, the antagonism stopped when Irwin was transferred out of the office. The scientist saw the move as a last resort for his managers. “I have three board certifications in toxicology, so it

**“He basically was siding with the company.”**

was hard for them to say, ‘William, you’re stupid,’ and so instead they just kicked me out of the program.”

Phillips was also transferred in September 2020. Meanwhile, Osterweil continues to work in the office, where she said disputes over chemical assessments and retaliation against her have continued unabated.

The ongoing issues are evidence that the pressures on chemical assessors within the EPA’s Office of Chemical Safety and Pollution Prevention have persisted even under the Biden administration, according to Kyla Bennett, director of science policy at Public Employees for Environmental Responsibility, or PEER, an organization that provides support to whistleblowers and helped the scientists draft their disclosure document. “The problems in OCSPP are not due solely to the Trump administration and its appointees,” said Bennett. “The issues faced by our clients occurred before Trump took office, during the Trump years, and continue now.”

On Monday, PEER submitted its complaint to the EPA inspector general; Michal Freedhoff, assistant administrator for the EPA’s Office of Chemical Safety and Pollution Prevention; and Khanna, asking that they conduct an audit to identify risk assessments that were altered without the knowledge or consent of the risk assessor; investigate apparent violations of the EPA’s records management policy, in which documents were altered; and evaluate the process that allowed these changes to be made and remain uncorrected.

Khanna provided a statement to The Intercept applauding the whistleblowers. “Clean, cancer-free air and water still isn’t a given in our country,” Khanna wrote. “I will continue to monitor this situation and ensure that these scientists’ concerns are addressed to ensure that toxic or harmful chemicals are not going out to the market without the appropriate health and safety warnings. I am so proud of the work of our Environmental Subcommittee is doing to create a healthier world.”

Asked about the complaint, the EPA wrote in an email that “This Administration is committed to investigating alleged violations of scientific integrity. It is critical that all EPA decisions are informed by rigorous scientific information and standards. As one of his first acts as Administrator, Administrator Regan issued a memorandum outlining concrete steps to reinforce the agency’s commitment to science.

“EPA takes seriously all allegations of violations of scientific integrity. EPA’s scientific integrity official and scientific integrity team members will thoroughly investigate any allegation of violation of EPA’s scientific integrity policy that they receive and work to safeguard EPA science. Additionally, EPA is currently reviewing agency policies, processes, and practices to ensure that the best available science and data inform Agency decisions. EPA is committed to fostering a culture of evaluation and continuous learning that promotes an open exchange of differing scientific and policy positions. Additionally, retaliation against EPA employees for reporting violations alleged to have occurred will not be tolerated in this administration. EPA leadership are reviewing these complaints, and any appropriate action will be taken.”

While such complaints are usually kept confidential, by Tuesday many managers in the Office of Chemical Safety and Pollution Prevention had somehow obtained a copy of the whistleblowers’ allegations. “The fact that EPA released our clients’ names is inappropriate and troubling,” said Bennett. “They’ve been put in an incredibly uncomfortable situation. This gives the managers the chance to circle the wagons trying to go after them.”

For the whistleblowers, the release of their names is just the latest battle in a war they’ve been waging for years. For Gallagher, a scientist with expertise in chemistry and toxicology, the combative turn of her career has been a surprise. “Like a lot of us who are in this, we came to work at the EPA because I wanted to preserve the environment for our

children’s children,” said Gallagher. “It’s infuriating that I have to push back against managers to do that.”

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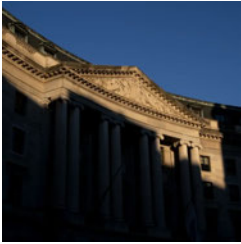
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**CORRESPONDENCE -- 2021-07-28\_UD-2021-0040\_EPA\_OpenLetter\_1301-1b**

4 messages

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**Andrea Noel** <andrea.noel@nara.gov>  
To: Evangela Wimbush-Jeffrey <evangela.wimbush-jeffrey@nara.gov>

Wed, Jul 28, 2021 at 10:30 AM

## Routing list:

1. Evangela Wimbush-Jeffrey
2. Don Rosen
3. Laurence Brewer
4. Tina Chase Fomukong
5. Andrea Noel

Please review [2021-07-28\\_UD-2021-0040\\_EPA\\_OpenLetter\\_1301-1b](#)


On July 26th, 2021 EPA notified us of reports of an allegation of unauthorized disposition of agency records. EPA provided a [press release](#) and [formal complaint](#) from Public Employees for Environmental Responsibility (PEER) and a news article from [The Intercept](#) reporting that managers and career staff in the EPA's Office of Chemical Safety and Pollution Prevention altered the assessments of dozens of chemicals to make them appear safer. EPA is currently investigating these allegations.

Thanks,

**Andrea A. Noel**  
**Senior Records Analyst**  
**Records Management Oversight and Reporting Division**  
**National Archives and Records Administration**  
**Tel: (301) 837-3564**  
**Mb: (b) (6)**

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**4 attachments**

-  **2021-07-26\_UD20210040\_RUD-att-2.pdf**  
89K
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8583K

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**Evangela Wimbush-Jeffrey** <evangela.wimbush-jeffrey@nara.gov>  
To: Donald Rosen <donald.rosen@nara.gov>

Wed, Jul 28, 2021 at 11:14 AM

NARA-NGC21-710-00917

Cc: Andrea Noel <andrea.noel@nara.gov>

Good morning,

Here is correspondence to open a "self-reported" case of UD for EPA. Please let me know if you have any questions. Thanks!

**Evangela C. Wimbush-Jeffrey** | Records Management Oversight & Reporting  
National Archives and Records Administration | Office of the Chief Records Officer  
(301) 837-0730 (Office) | (b) (6) (Cell) | [evangela.wimbush-jeffrey@nara.gov](mailto:evangela.wimbush-jeffrey@nara.gov)

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**Donald Rosen** <donald.rosen@nara.gov>

Wed, Jul 28, 2021 at 12:59 PM

To: "Brewer, Laurence" <laurence.brewer@nara.gov>

Cc: Evangela Wimbush-Jeffrey <evangela.wimbush-jeffrey@nara.gov>, Andrea Noel <andrea.noel@nara.gov>

Laurence

Attached is a draft letter for a case at the EPA. Please see attachments, email from the agency, and the draft letter. Please let us know if you would like a meeting to discuss.

Thanks,

Don

Donald Rosen  
Director, Records Management Oversight and Reporting  
*Office of the Chief Records Officer*  
301-837-3426

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NARA-NGC21-710-00918



**Laurence Brewer** <laurence.brewer@nara.gov>

Wed, Jul 28, 2021 at 2:33 PM

To: Donald Rosen <donald.rosen@nara.gov>, Tina Chase Fomukong <tina.chasefomukong@nara.gov>

Cc: Evangela Wimbush-Jeffrey <evangela.wimbush-jeffrey@nara.gov>, Andrea Noel <andrea.noel@nara.gov>

Thanks, good to go

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**Laurence Brewer, CRM**

Chief Records Officer for the U.S. Government

National Archives and Records Administration

[Laurence.Brewer@nara.gov](mailto:Laurence.Brewer@nara.gov)

Office: (301) 837-1539

Cell: (b) (6)

Blog: [Records Express](#)





Office of the Chief  
Records Officer for the  
U.S. Government

***Sent Via Email. No Hard Copy to Follow.***

July 29, 2021

Mr. John Ellis  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave NW (MC 2822T)  
Washington, DC 20460

Dear Mr. Ellis,

The National Archives and Records Administration (NARA) has received your notification regarding recent allegations of unauthorized disposition of U.S. Environmental Protection Agency (EPA) records as reported in multiple media sources.

Your notification cited a press release and formal complaint from Public Employees for Environmental Responsibility (PEER) and a news article from *The Intercept* reporting that managers and career staff in the EPA's Office of Chemical Safety and Pollution Prevention altered the assessments of dozens of chemicals to make them appear safer.

NARA understands that EPA is currently investigating these allegations. Please provide a comprehensive report, in accordance with 36 CFR 1230.16, as soon as EPA's investigation has concluded. Your report should have specific details on the disposition of the records at issue, a description (including volume and disposition authority) of the affected records, and a statement, if appropriate, describing the safeguards to prevent future losses of records.

Thank you for your attention to this matter. If you wish to discuss further, please do not hesitate to contact me at [Laurence.Brewer@nara.gov](mailto:Laurence.Brewer@nara.gov).

Sincerely,

LAURENCE BREWER  
Chief Records Officer  
for the U.S. Government

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**Unauthorized Disposition Case UD-2021-0040 \_ open**

1 message

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**Andrea Noel** <andrea.noel@nara.gov>  
To: "Ellis, John" <Ellis.john@epa.gov>  
Cc: "Murray, Paulette" <Murray.Paulette@epa.gov>  
Bcc: Laurence Brewer <laurence.brewer@nara.gov>

Thu, Jul 29, 2021 at 8:51 AM


Good morning John,

Attached is correspondence from Laurence Brewer, Chief Records Officer of the United States Government, regarding your recent notification about allegations of unauthorized disposition of EPA records. As you have done in the past, please send all correspondence directly to me regarding this new case.

Thanks,

**Andrea A. Noel**  
**Senior Records Analyst**  
**Records Management Oversight and Reporting Division**  
**National Archives and Records Administration**  
**Tel: (301) 837-3564**  
**Mb: (b) (6)**

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**Signed EPA Letter**

3 messages

**Tina Chase Fomukong** <tina.chasefomukong@nara.gov>

Thu, Jul 29, 2021 at 7:33 AM


To: Andrea Noel &lt;andrea.noel@nara.gov&gt;, Evangela Wimbush-Jeffrey &lt;evangela.wimbush-jeffrey@nara.gov&gt;

Good morning Andrea and Evangela,  
Here is the signed EPA Open Letter.

Tina

**Tina m. Chase Fomukong**  
**Management & Program Analyst**  
**Office of the Chief Records Officer**  
**National Archives & Records Administration**  
[tina.chasefomukong@nara.gov](mailto:tina.chasefomukong@nara.gov)  
301-837-1907

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**Andrea Noel** <andrea.noel@nara.gov>

Thu, Jul 29, 2021 at 8:38 AM

To: Tina Chase Fomukong &lt;tina.chasefomukong@nara.gov&gt;

Cc: Evangela Wimbush-Jeffrey &lt;evangela.wimbush-jeffrey@nara.gov&gt;

Received, thank you.

**Andrea A. Noel**  
**Senior Records Analyst**  
**Records Management Oversight and Reporting Division**  
**National Archives and Records Administration**  
**Tel: (301) 837-3564**  
**Mb: (b) (6)**

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**Andrea Noel** <andrea.noel@nara.gov>

Tue, Aug 3, 2021 at 7:27 AM

To: Karyn Skevakis &lt;karyn.skevakis@nara.gov&gt;

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Office of the Chief  
Records Officer for the  
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***Sent Via Email. No Hard Copy to Follow.***

March 18, 2022

John Ellis  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave NW (MC 2822T)  
Washington, DC 20460  
[ellis.john@epa.gov](mailto:ellis.john@epa.gov)

Dear Mr. Ellis,

The National Archives and Records Administration (NARA) received your final report regarding allegations of unauthorized disposition of U.S. Environmental Protection Agency (EPA) records made by the Public Employees for Environmental Responsibility (PEER). PEER alleged that the EPA altered chemical risk assessment records within EPA's Office of Chemical Safety and Pollution Prevention (OCSP), and destroyed without authorization records related to the development of the Waters of the United States (WOTUS) rule.

EPA's report indicated that all drafts and final versions of the three chemical risk assessments in question were properly retained and are retrievable in EPA's New Chemicals Review system and other databases. Additionally, EPA conducted a close review of the chemical risk assessment drafts to PEER's allegations of alteration and could not find any evidence that alterations were made to any of the draft reports.

After thoroughly investigating the allegations in PEER's complaint regarding the unauthorized destruction of comments and feedback submitted by regional offices during the proposed WOTUS rule's development, EPA has determined that no federal records were unlawfully destroyed. The proposed rule was issued on February 14, 2019 in the Federal Register, and EPA headquarters solicited input from the regions on the proposed rule, requesting all regional comments on that rule be sent to EPA headquarters and submitted as standalone Microsoft Word documents. The regional comments on the February 14, 2019 proposed rule, contained in standalone Microsoft Word documents, were uploaded by the submitting regions into a dedicated SharePoint folder. All submitted comments have been properly preserved and are retrievable on SharePoint.

Based on the information provided, EPA has satisfied all reporting requirements of 36 CFR 1230.14 and NARA considers this matter closed. If you have any questions, please contact me at [laurence.brewer@nara.gov](mailto:laurence.brewer@nara.gov).

Sincerely,

A handwritten signature in blue ink that reads "Laurence V. Brewer". The signature is written in a cursive style with a large initial 'L' and a distinct 'V'.

LAURENCE BREWER  
Chief Records Officer  
for the U.S. Government