

MEMORANDUM

TO: Members of the Chartered SAB and SAB Liaisons

FROM: James R. Mihelcic, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

DATE: April 28, 2015

SUBJECT: Preparations for Chartered Science Advisory Board (SAB) Discussions of EPA Planned Agency Actions and their Supporting Science in the Fall 2014 Regulatory Agenda

At the upcoming May 27, 2015 public teleconference, the Chartered SAB will discuss whether to review the adequacy of the science supporting planned regulatory actions identified by the EPA as major actions in the Fall 2014 semi-annual regulatory agenda. To support this discussion, an SAB Work Group was charged with identifying actions for further consideration by the Chartered SAB. This memorandum provides background on this activity, a short description of the process for identifying actions for SAB consideration, a summary of the process used by the Work Group, and Work Group recommendations on the planned actions and improvements to the process.

Background

The Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA) requires the EPA to make available to the SAB proposed criteria documents, standards, limitations, or regulations provided to any other Federal agency for formal review and comment, together with relevant scientific and technical information on which the proposed action is based. The SAB may then make available to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis of the proposed action.

EPA's current process (Attachment A) is to provide the SAB with information about the publication of the semi-annual regulatory agenda and to provide descriptions of major planned actions that are not yet proposed but appear in the semi-annual regulatory agenda. These descriptions provide available information regarding the science informing agency actions. This process for engaging the SAB supplements the EPA's process for program and regional offices to request science advice from the SAB.

Summary of the Process Used by the SAB Work Group

The SAB Work Group followed the [process adopted by the Chartered SAB](#) in 2013¹ to initiate its review of major planned actions identified in the Unified Regulatory Agenda by EPA. The current SAB

¹ Available at [http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/ProcScreenRegSci/\\$File/SABProtocol.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/ProcScreenRegSci/$File/SABProtocol.pdf)

review began when the EPA Office of Policy informed the SAB Staff Office that the Fall 2014 Unified (Regulatory) Agenda and Regulatory Plan had been published on November 21, 2014. This semi-annual regulatory agenda is available at <http://www.reginfo.gov/public/>.

This SAB Work Group was formed in December 2014 and includes SAB members with broad expertise in scientific and technological issues related to the proposed actions. The Work Group consists of Drs. James R. Mihelcic (chair), Costel Denson, Joel Ducoste, R. William Field, H. Christopher Frey, Steven Hamburg and Mr. Richard Poirot.

On February 6, 2015, the Work Group received information and short descriptions from the EPA Program Offices on the major planned actions that are listed in the Fall 2014 semi-annual regulatory agenda but not yet proposed. The agency included one action the SAB previously deferred consideration because limited information were available at that time. On March 2, 2015, the Work Group met via teleconference to discuss the eight actions and identify any additional information needed to develop recommendation for the chartered SAB. Work Group members identified three actions that required additional information and sent those questions to EPA through the Designated Federal Officer on March 6, 2015. A compiled set of EPA's responses to the questions was sent to Work Group members on April 2, 2015 and is provided in Attachment B. After reviewing the information provided by EPA, SAB Work Group members developed and concurred on the recommendations presented in this memorandum.

Work Group Recommendations Regarding Planned EPA Actions of Interest to the SAB

The Work Group based the recommendations below on information received from the EPA and the Work Group's research. Of the eight major planned actions considered, the Work Group recommends that none of the actions merit further SAB consideration. However, the Work Group has identified issues that may require further discussion by the SAB and subsequent steps for planned actions that may warrant further SAB consideration. A summary of those findings is provided below and a more detailed discussion of the Work Group's findings is provided in Attachment C.

The Work Group notes that the *Revision--Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings and Uranium In-Situ Leaching Processing Facilities* (2060-AAP43) was deferred during the Spring 2013 Review of the Regulatory Agenda because the action was under development and limited information was available from the agency. The proposed action was signed on December 31, 2014 and included in this review cycle. The Work Group requested additional information on how the EPA addressed recommendations in the SAB's 2012 [Advisory on EPA's Draft Technical Report entitled Considerations Related to Post-Closure Monitoring of Uranium In-Situ Leach/In-Situ Recovery \(ISL/ISR\) Sites \(EPA-SAB-12-005\)](#). Based on the information provided by the agency, this action does not merit further SAB consideration. However, the Work Group found that the 2012 SAB report provided multiple recommendations and considerations for the use of models to support the proposed rule. The information provided by the agency could have more clearly explained

how the agency’s use of models adequately addressed the complex scientific and technical basis for the varying site conditions considered in the proposed rule.

EPA seems to have engaged in an effort to seek industry data and experience as well as scientific and engineering advice for the *Oil and Natural Gas Sector: Reconsideration of Remaining Provisions of New Source Performance Standards (2060-AS30)*. EPA could have provided more detail in reply to the Work Group’s requests for additional information regarding the peer review process. In this case, it is unclear if the external review was meant to be a peer review or a stakeholder review, or a combination of both. Nonetheless, EPA has sought expert, stakeholder, and public input and appears to be compiling available information to identify the most important emissions activities and processes and the alternatives for reducing those emissions. Thus, the value-added of further SAB review is likely to be marginal. Therefore, the Work Group recommended that this action does not merit further SAB consideration.

The *Proposed Greenhouse Gas Endangerment and Cause or Contribute Findings Under CAA Section 231 for Aircraft, and ANPRM on the International Process for Reducing Aircraft GHGs and Future Standards (2060-AS31)* is a topic of high interest that will be based on information that has been well-reviewed and is based on an approach for which there is precedent. This action does not merit further SAB consideration. However, the Work Group anticipates that subsequent steps in the regulatory process will involve substantive scientific issues that may warrant SAB consideration.

Table 1 identifies the eight planned actions reviewed and summarizes the Work Group’s recommendations. Attachment C provides the EPA’s descriptions of the planned actions, and the SAB Work Group’s recommendation for each of the planned actions with the supporting rationales.

Table 1: Summary of Proposed Actions that the SAB Work Group Considered for Additional SAB Comment on the Supporting Science		
RIN²	Planned Action Title	Workgroup recommendation
<u>2040-AF53</u>	Uniform National Discharge Standards for Vessels of the Armed Forces--Phase II--Batch Two (UNDS)	No further SAB consideration is merited.
<u>2050-AG82</u>	Modernization of the Accidental Release Prevention Regulations Under Clean Air Act	No further SAB consideration is merited.
<u>2050-AG80</u>	User Fee Schedule for Electronic Hazardous Waste Manifest	No further SAB consideration is merited.
<u>2060-AS31</u>	Proposed Greenhouse Gas Endangerment and Cause or Contribute Findings Under CAA Section 231 for Aircraft, and ANPRM on the International Process for Reducing Aircraft GHGs and Future Standards	No further SAB consideration is merited.

Table 1: Summary of Proposed Actions that the SAB Work Group Considered for Additional SAB Comment on the Supporting Science

RIN ²	Planned Action Title	Workgroup recommendation
2060-AS30	Oil and Natural Gas Sector: Reconsideration of Remaining Provisions of New Source Performance Standards	No further SAB consideration is merited.
2060-AP43	Revision--Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings and Uranium In Situ Leaching Processing Facilities	No further SAB consideration is merited.
2060-AS06	Major Source Determination for Oil and Gas Extraction Facilities	No further SAB consideration is merited.
2025-AA39	Revisions to Confidentiality of Business Information	No further SAB consideration is merited.
² The Regulatory Identification Number provides a hyperlink to the Office of Management and Budget’s webpage and information on the planned action provided in the Unified Regulatory Agenda.		

Work Group Recommendations Regarding Improvements to the Process for Identifying EPA Planned Actions for SAB Consideration

The Work Group finds that the agency’s descriptions for the Fall 2014 planned actions generally provided more complete information to inform the SAB’s decisions than those provided for past SAB reviews of the agency’s regulatory agenda.

The SAB Work Group continues to strongly recommend that the EPA include specific information on the peer review of the associated science and description of the scientific and technological bases for the planned actions in future descriptions for SAB consideration. For external peer reviews, whether conducted by EPA or by an EPA contractor, EPA should be more clear as to what criteria were used to select experts and what effort was made to address conflict of interest. The Work Group notes that the agency revised the “Description of Planned EPA Tier 1 or Tier 2 Action” form to provide more information on peer review to the SAB. However, there remain differences in the level of detail in description among the planned actions. For example, the Work Group found the information and responses on the *Uniform National Discharge Standards for Vessels of the Armed Forces--Phase II--Batch Two (UNDS)* (2040-AF53) to be more complete while the responses provided on the *Oil and Natural Gas Sector: Reconsideration of Remaining Provisions of New Source Performance Standards* (2060-AS30) were wanting. The agency’s initial information on the most important emissions activities and processes and the most efficient control techniques to minimize those emissions seems to have been unusually thorough. In contrast, the agency’s responses to the Work Group’s questions on peer review for this effort were minimal. Limiting the information provided on the actions for these review activities makes it difficult for the SAB to evaluate the agency’s efforts, the adequacy of the review process, and the adequacy of the scientific and technical basis of the planned action. Providing such specific

information at the start of the SAB's Work Group's review facilitates the SAB's timely screening of the scientific and technical basis of actions in the Regulatory Agendas.

Attachments

- Attachment A: Implementation Process for Identifying EPA Planned Actions for SAB Consideration
- Attachment B: Summary of the Science Advisory Board Work Group's Fact-finding on EPA Planned Actions in the Fall 2014 Regulatory Agenda
- Attachment C: Descriptions of Major EPA Planned Actions Identified in the Fall 2014 Semi-Annual Regulatory Agenda with SAB Work Group Recommendations.

Attachment A

Implementation Process for Identifying EPA Planned Actions for SAB Consideration

Background on the EPA Process

- ◆ The Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA, see p. 4)
 - ◆ Requires the EPA to make available to the SAB proposed criteria documents, standards, limitations, or regulations provided to any other Federal agency for formal review and comment together with relevant scientific and technical information in the possession of the agency on which the proposed action is based.
 - ◆ States that the Board may make available to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis of the proposed actions.
- ◆ In January 2012, Office of Policy Associate Administrator Michael Goo issued a memorandum to strengthen coordination with the SAB by providing the Board with information about *proposed* agency actions. (see page p. 9)
- ◆ In February 2012, SAB Staff developed an initial proposal to provide the SAB with information about *proposed* agency actions.
 - ◆ EPA Senior Leadership concluded that providing information to the SAB for consideration at the proposal stage was *too late* in the process for meaningful involvement.
- ◆ In March 2012, the SAB held a public meeting and discussed the Goo memo and a pilot to consider the science underlying four proposed rules identified by OAR (standards for air toxics from boilers and incinerators and greenhouse gas emissions and fuel economy standards for light-duty vehicles).
 - ◆ The SAB:
 - ◆ Did not identify any science topics related to the four proposed rules warranting SAB comment.
 - ◆ Noted that the proposal stage was *too late* in the process for meaningful input.
 - ◆ Discussed the need for adequate information on the underlying science for agency actions early in the process. Information beyond the information presented in the Semiannual Regulatory Agenda is needed for this purpose.
- ◆ On January 2, 2013, Associate Administrator Michael Goo, the Administrator’s Science Advisor Glenn Paulson, and the SAB Office Director Vanessa Vu issued a memorandum (see p. 10) “Identifying EPA Planned Actions for Science Advisory Board (SAB) Consideration of the Underlying Science – Semi-annual Process” requiring EPA to provide short descriptions of *major planned actions that are not yet proposed* appearing in the semi-annual regulatory agenda

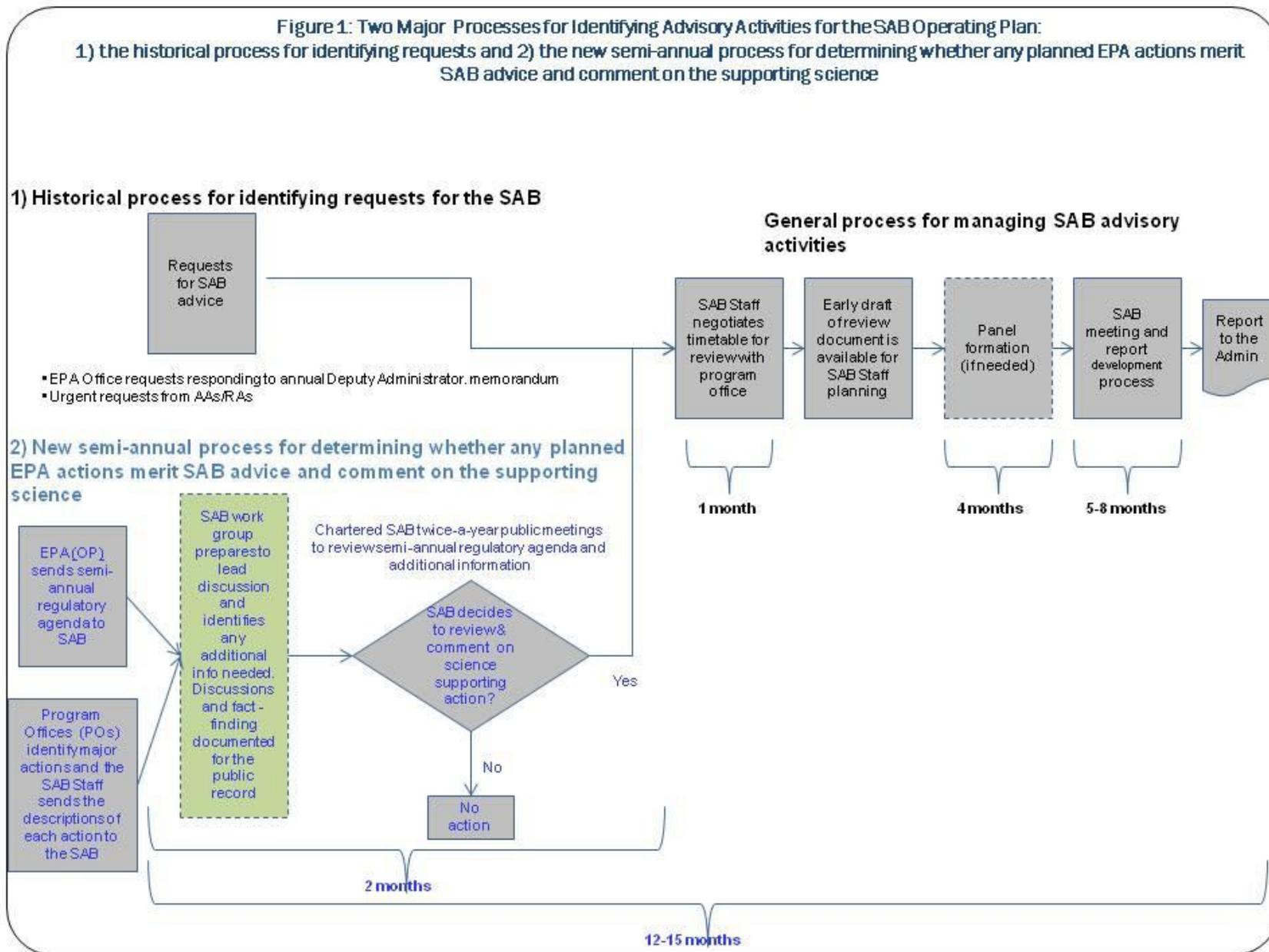
Attachment A: Identifying EPA Planned Actions for SAB Consideration

- ◆ This process supplements the Deputy Administrator's annual memorandum requesting program and regional offices to identify scientific issues that might be appropriate for SAB consideration.

SAB Process

- ◆ The SAB Staff manages the semi-annual process for determining whether any planned EPA actions merit SAB advice and comment on the supporting science as part of the entire SAB operating plan (see Figure 1).

Attachment A: Identifying EPA Planned Actions for SAB Consideration



**Environmental Research, Development, and Demonstration Authorization Act
[(ERDDAA), 42 U.S.C. 4365]**

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 55--NATIONAL ENVIRONMENTAL POLICY

SUBCHAPTER III--MISCELLANEOUS PROVISIONS

Sec. 4365. Science Advisory Board

(a) Establishment; requests for advice by Administrator of Environmental Protection Agency and Congressional committees

The Administrator of the Environmental Protection Agency shall establish a Science Advisory Board which shall provide such scientific advice as may be requested by the Administrator, the Committee on Environment and Public Works of the United States Senate, or the Committee on Science, Space, and Technology, on Energy and Commerce, or on Public Works and Transportation of the House of Representatives.

(b) Membership; Chairman; meetings; qualifications of members

Such Board shall be composed of at least nine members, one of whom shall be designated Chairman, and shall meet at such times and places as may be designated by the Chairman of the Board in consultation with the Administrator. Each member of the Board shall be qualified by education, training, and experience to evaluate scientific and technical information on matters referred to the Board under this section.

(c) Proposed environmental criteria document, standard, limitation, or regulation; functions respecting in conjunction with Administrator

(1) The Administrator, at the time any proposed criteria document, standard, limitation, or regulation under the Clean Air Act [42 U.S.C. 7401 et seq.], the Federal

Attachment A: Identifying EPA Planned Actions for SAB Consideration

Water Pollution Control Act [33 U.S.C. 1251 et seq.], the Resource Conservation and Recovery Act of 1976 [42 U.S.C. 6901 et seq.], the Noise Control Act [42 U.S.C. 4901 et seq.], the Toxic Substances Control Act [15 U.S.C. 2601 et seq.], or the Safe Drinking Water Act [42 U.S.C. 300f et seq.], or under any other authority of the Administrator, is provided to any other Federal agency for formal review and comment, shall make available to the Board such proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the Environmental Protection Agency on which the proposed action is based.

(2) The Board may make available to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis of the proposed criteria document, standard, limitation, or regulation, together with any pertinent information in the Board's possession.

(d) Utilization of technical and scientific capabilities of Federal agencies and national environmental laboratories for determining adequacy of scientific and technical basis of proposed criteria document, etc.

In preparing such advice and comments, the Board shall avail itself of the technical and scientific capabilities of any Federal agency, including the Environmental Protection Agency and any national environmental laboratories.

(e) Member committees and investigative panels; establishment; chairmanship

The Board is authorized to constitute such member committees and investigative panels as the Administrator and the Board find necessary to carry out this section. Each such member committee or investigative panel shall be chaired by a member of the Board.

(f) appointment and compensation of secretary and other personnel; compensation of members

Attachment A: Identifying EPA Planned Actions for SAB Consideration

(1) Upon the recommendation of the Board, the Administrator shall appoint a secretary, and such other employees as deemed necessary to exercise and fulfill the Board's powers and responsibilities. The compensation of all employees appointed under this paragraph shall be fixed in accordance with chapter 51 and subchapter III of chapter 53 of title 5.

(2) Members of the Board may be compensated at a rate to be fixed by the President but not in excess of the maximum rate of pay for grade GS-18, as provided in the General Schedule under section 5332 of title 5.

(g) Consultation and coordination with Scientific Advisory Panel

In carrying out the functions assigned by this section, the Board shall consult and coordinate its activities with the Scientific Advisory Panel established by the Administrator pursuant to section 136w(d) of title 7.

(Pub. L. 95-155, Sec. 8, Nov. 8, 1977, 91 Stat. 1260; Pub. L. 96-569, Sec. 3, Dec. 22, 1980, 94 Stat. 3337; Pub. L. 103-437, Sec. 15(o), Nov. 2, 1994, 108 Stat. 4593; Pub. L. 104-66, title II, Sec. 2021(k)(3), Dec. 21, 1995, 109 Stat. 728.)



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460**

2

OFFICE OF THE ADMINISTRATOR

MEMORANDUM

SUBJECT: Identifying EPA Planned Actions for Science Advisory Board (SAB)
Consideration of the Underlying Science- Semi-annual Process

FROM: Michael Goo, Associate Administrator
Office of Policy

Glenn Paulson
Science Advisor

Vanessa Vu, Director
SAB Staff Office

TO: General Counsel
Assistant Administrators
Associate Administrators
Regional Administrators

The purpose of this memorandum is to provide guidance for implementing improved coordination with the SAB, the goal of the memorandum dated January 19, 2012 on that topic (Attachment A).

We ask that you work with the Office of Policy to provide the SAB Staff Office with information about the science supporting major planned agency actions (Tier 1 and Tier 2 actions) that are in the pre-proposal stage. The *2012 Unified (Regulatory) Agenda and Regulatory Plan* was published on December 21, 2012 on the Office of Management and Budget web site <http://www.reginfo.gov/public/>.

Please provide the SAB Staff Office (contact: Angela Nugent) by January 30, 2013, a brief description of each action along with its supporting science, following the format provided in Attachment B. Please ensure that these submissions to the SAB are consistent with information developed in the action development process.

This process supplements the Deputy Administrator's annual memorandum requesting program and regional offices- to identify scientific issues that might be appropriate for SAB consideration.

Attachment A: Identifying EPA Planned Actions for SAB Consideration

We look forward to working with you on this new process to strengthen science supporting EPA's decisions. Please contact us or Caryn Muellerleile (202-564-2855) in the Office of Policy or Angela Nugent (202-564-2218) in the SAB Staff Office, should there be questions.

Attachments

cc: Administrator
Deputy Administrator
Chief of Staff
Deputy Chief of Staff

Attachment A: January 19, 2012 Memorandum from Michal L. Goo



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 19 2012

OFFICE OF
POLICY

MEMORANDUM

SUBJECT: Coordination with the Science Advisory Board Regarding Proposed Criteria Documents, Standards, Limitations and Regulations

FROM: Michael L. Goo, Associate Administrator *MLG*
Office of Policy

TO: Assistant Administrators
General Counsel
Chief of Staff
Associate Administrators
Regional Administrators

This is to confirm the procedures that we have discussed regarding coordination with the Science Advisory Board (SAB) on the science and technical information underlying the EPA's proposed criteria documents, standards, limitations and regulations.

In addition to the current process by which program offices identify actions on which they plan to seek advice from the SAB on scientific and technical issues, OP will semiannually inform the SAB, through the SAB Staff Office, of upcoming proposed actions. This process will focus on those proposed regulations, criteria documents, standards or limitations that undergo interagency review and will operate as follows:

1. OP will submit to the SAB staff office a list, based on the Agency's *Semiannual Regulatory Agenda (Regulatory Agenda)*, augmented as necessary, of upcoming proposed regulations, criteria documents, standards or limitations that are expected to undergo interagency review. OP will work with program and regional offices to ensure that any actions not listed in the *Regulatory Agenda* that nevertheless are expected to be submitted for interagency review are included in this submission. For any of these additional actions, offices should provide a description similar to that provided for actions included in the *Regulatory Agenda*.

Attachment A: Identifying EPA Planned Actions for SAB Consideration

2. Program and Regional offices will notify the SAB staff office when proposed Agency actions that undergo interagency review become formally available for public review and comment. EPA programs are also expected to provide additional information as requested by the SAB Staff Office to facilitate the SAB's consideration of this information.

If the SAB decides to review and, as appropriate, comment on the scientific and technical basis for a proposed action, OP will work with the SAB Staff Office and the relevant program or regional office to establish the appropriate time frame for SAB review and comment.

Thank you for your assistance in adhering to this process. If you have any questions or concerns, please contact me, or your staff can contact Nicole Owens owens.nicole@epa.gov, at 202 (564-1550).

cc: Bob Perciasepe
Bob Sussman
Deputy Assistant Administrators
Deputy Associate Administrators
Deputy Regional Administrators
Assistant Regional Administrators
Alex Cristofaro
Nicole Owens
Vanessa Wu
Thomas Brennan

**Attachment B - Sample Description of Major Planned EPA Action-
Information to be Provided to the SAB**

Name of action: Development of Best Management Practices for Recreational Boats Under Section 312(o) of the Clean Water Act

EPA Office originating action: OW

Brief description of action and statement of need for the action:

This action is for the development of regulations by EPA to implement the Clean Boating Act (Public Law 110-288), which was signed by the President on July 29, 2008. The Clean Boating Act amends section 402 of the Clean Water Act (CWA) to exclude recreational vessels from National Pollutant Discharge Elimination System permitting requirements. In addition, it adds a new CWA section 312(o) directing EPA to develop regulations that identify the discharges incidental to the normal operation of recreational vessels (other than a discharge of sewage) for which it is reasonable and practicable to develop management practices to mitigate adverse impacts on waters of the United States. The regulations also need to include those management practices, including performance standards for each such practice. Following promulgation of the EPA performance standards, new CWA section 312(o) directs the Coast Guard to promulgate regulations governing the design, construction, installation, and use of the management practices. Following promulgation of the Coast Guard regulations, the Clean Boating Act prohibits the operation of a recreational vessel or any discharge incidental to their normal operation in waters of the United States and waters of the contiguous zone (i.e., 12 miles into the ocean), unless the vessel owner or operator is using an applicable management practice meeting the EPA-developed performance standards.

Timetable:

Statutory: Phase 1 - 2009, Phase 2 - 2010, and Phase 3 – 2011
Regulatory Agenda: Phase 1 NPRM - 2013, Phase 1FR - 2014

Does the action rely on science that meets the EPA *Peer Review Handbook* definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

No

Scientific questions to be addressed and approach:

Recreational boating activities can contribute to the spread of aquatic nuisance species, primarily through the secondary transport of organisms introduced to U.S. waters via other vectors. For example, recreational boating has been linked to the spread of Zebra and Quagga mussels from their initial introduction into the Great Lakes to other U.S. waters. Consequently, the Agency is considering the development of regulations designed to reduce the spread of such organisms by reducing propagule pressure from the recreational vessel vectors. Propagule pressure is a measure

Attachment A: Identifying EPA Planned Actions for SAB Consideration

of the number of individual organisms released as well as the number of discrete release events. While there is a general consensus that an increase in propagule pressure increases the probability of establishing a self-sustaining population of an aquatic nuisance species, the probability is a complex function of a wide range of variables. These variables include species traits (e.g., viability, reproductive capability, and environmental compatibility) and environmental traits (e.g., retention of propagules, and interactions with resident species). When addressing secondary transport via recreational vessels, as this project is designed to specifically do, additional variables such as vessel characteristics, voyage type, and propagule exposure need to be considered. Due to the complexity of this issue, the Agency is seeking expert scientific opinions on management practices that can reduce propagule pressure that results from recreational boating activities.

Plans for scientific analyses and peer review:

The Agency is planning to convene a workshop on secondary transport of aquatic nuisance species via recreational vessels. Invited participants will have expertise in the field of invasion biology and each participant will be charged to provide their expert scientific opinion on management practices that the Agency should consider as part of this rule making.

Attachment B
**Summary of the Science Advisory Board Work Group's Fact-finding on
EPA Planned Actions in the Fall 2014 Regulatory Agenda (November 21, 2014)**

Introduction

The Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science was formed to provide the chartered SAB with recommendations on the actions in the Fall 2014 regulatory agenda provided by the Agency on November 21, 2014. The chartered SAB will consider these recommendations as it determines whether it will provide "advice and comments on the adequacy of the scientific and technical basis" of agency actions, consistent with the requirements of the Environmental Research Development and Demonstration Authorization Act (ERDDAA).

On February 6, 2015 the Work Group received short descriptions from the EPA Program Offices on the major planned actions that are not yet proposed listed in the Fall 2014 semiannual regulatory agenda. On March 2, 2015 the Work Group met via teleconference to discuss the eight actions and identify any additional information they needed to develop recommendation for the chartered SAB. Work Group members identified three actions that required additional information and sent those question to EPA through the Designated Federal Officer on March 6, 2015. The Work Group's questions and the Agency's responses are provided in this attachment.

Summary of Additional Information Requested and Agency Responses

Uniform National Discharge Standards for Vessels of the Armed Forces--Phase II--Batch Two (UNDS) 2040-AF53

Questions from the Work Group to the Office of Water (OW)

General EPA Response: As noted in the Regulatory Agenda, EPA does not anticipate developing new science products to support this rulemaking effort. The Rule is being developed with the same scientific information that was used to develop EPA's 2013 Vessel General Permit (VGP). We anticipate that our discharge requirements for the UNDS Batch Two discharges will very closely mirror the discharge requirements identified in the VGP.

1. A review of the fact sheet and the VGP identified five approved types of ballast water treatment technologies that are effective at inactivating potential invasive aquatic species. The permit listed instantaneous maximum limits for biocides (Table 3) a monitoring schedule (table 4) and analytic methods for biocides and disinfection byproducts (Table 5). However, there may be concerns about the formation of disinfection by-products that are formed from the use of oxidants listed in the VGP. The SAB Work Group has the following questions regarding the planned action and how the agency is addressing byproduct formation and discharge concentrations across the 14 discharges.

Does EPA anticipate that the action will need to include and address treatment for biological invasive species or pathogens as contaminants of concern for the 12 of 14 non ballast discharges (i.e., (1) catapult water brake tank & post-launch retraction exhaust, (2) compensated fuel ballast, (3) controllable pitch propeller hydraulic fluid, (4) deck runoff, (5) firemain systems, (6) graywater, (7) hull coating leachate, (8) motor gasoline compensating

discharge, (9) sonar dome discharge, 10) submarine bilgewater, 11) surface vessel bilgewater/oil-water separator, and (12) underwater ship husbandry)?

OW Response: EPA does not anticipate that the discharges listed above will include a technology treatment to address invasive species or pathogens. EPA anticipates however, that the action will instead include management practices to address biological invasive species or pathogens as contaminants of concern for some of the non-ballast discharges.

2. The description of the planned action does not define clean and dirty ballast water. Does EPA anticipate that the action will address the treatment of “clean” and “dirty” ballast discharges for aquatic nuisance species (ANS) and pathogens (including E. coli & fecal coliforms) via one of the five technologies of (1) Deoxygenation + cavitation; (2) Filtration + chlorine dioxide; (3) Filtration + UV; (4) Filtration + UV + TiO₂; or (5) Filtration + electro-chlorination identified in the VGP?

OW Response: Dirty ballast and clean ballast are defined at 40 CFR 1700.4 (h) and (d) respectively. Dirty Ballast refers to the seawater taken into, and discharged from, empty fuel tanks to maintain the stability of the vessel. Clean Ballast refers to the seawater taken into, and discharged from, dedicated ballast tanks to maintain the stability of the vessel and to adjust the buoyancy of submarines. EPA does not anticipate that dirty ballast will be treated with one of the five technologies listed above, but instead anticipates a “no discharge” standard within waters subject to UNDS. EPA does anticipate that certain vessel classes will use treatment systems for clean ballast in order to meet the living organism discharge limits.

3. If the EPA anticipates using the VGP recommended concentrations of biocide(s) to apply to clean and dirty ballast water, are the potential treated discharge concentrations based on the risk of the remaining biocide, or does the analysis also consider minimizing formation of disinfection by-products (DBPs).

OW Response: EPA anticipates identifying ballast water biocide use requirements similar to the VGP. The VGP established maximum limits for biocides discharged during treatment so that the minimum amount of biocide is used when achieving the living organism discharge limits. In addition, the VGP requires monitoring in order to demonstrate that residual biocides or derivatives are in compliance with the biocide maximum limits and that substantial quantities of harmful byproducts are not produced.

Emission Standards for New and Modified Sources in the Oil and Natural Gas Sector (2060-AS30)

Question from the Work Group for the Office of Air and Radiation (OAR)

The EPA published new source performance standards (NSPS) for the oil and natural gas sector. Following publication of these final standards for the oil and natural gas sector and public comment including petitions for administrative reconsideration of certain aspects of the standards, final amendments to address these issues were published on September 23, 2013, and on December 31, 2014, respectively. The SAB Work Group notes that this action also will

propose amendments to address remaining issues raised in the petitions and to correct technical errors that were inadvertently included in the final standards

EPA has developed five technically detailed white papers that address various emissions sources, processes, and emissions mitigation options, including sources of compressors, “completions” (an industry term), leaks, liquids unloading, and pneumatic devices. The agency notes that these papers were subject to external peer review, and are posted on the EPA website. Each paper was reviewed by four to six reviewers. The SAB Work Group has the following questions regarding how the agency is addressing issues raised in the white papers and literature to support the planned action.

1. How does this planned action differ from the recent final rules, published in December 2014, regarding updates and clarifications of the 2012 NSPS for this source category?

OAR Response: The current action in development primarily considers regulation of emission sources identified in the January 14, 2015, White House announcement regarding greenhouse gas emissions from the oil and natural gas sector. In addition, this action clarifies and reconsiders additional issues raised in petitions for reconsideration of the 2012 NSPS. Issues addressed by the 2014 amendments include clarification of requirements for handling of liquids and gases during completion of hydraulically fractured gas wells and clarification of requirements for storage vessels that are removed from service and returned to service.

2. Does the agency anticipate relying on relatively recent scientific research or engineering studies in addition to those summarized in the white papers to address uncertainties?

OAR Response: The studies and other sources on which the white papers were based included recently published studies. We are aware of continuations of some of those studies and will be considering the results of those studies where appropriate to further inform development of this action.

3. How is the Agency using the 5 white papers and associated peer review comments to address the science supporting the proposed rule and how will the review comments be incorporated into the associated technical support documents?

OAR Response: The responses of the expert peer reviewers were very helpful in providing further information on the topics covered by the white papers. This information, along with the public comments, has been considered fully and used as appropriate to augment our base of knowledge on these subjects.

4. Has EPA identified any new studies or data sets since the publication of the white papers that the Agency finds important to consider prior to publishing the planned action the rule?

OAR Response: As discussed above, we continue to consider emerging published studies in this highly dynamic subject area.

5. Has EPA identified a need to collect additional data, perform additional analysis of existing data, or conduct additional scientific peer review for this planned action? If so, please provide details.

OAR Response: No, we [EPA] have not identified the need to collect additional data or perform additional studies to inform the action under development.

6. Please describe the process for identifying the peer reviewers and whether the review was intended to be an expert peer review, a stakeholder review, or some combination of both?

OAR Response: On April 15, 2014, EPA released for external peer review five technical white papers on potentially significant sources of emissions in the oil and gas sector. EPA also noted at that time that it welcomed technical information and data from the public on the papers. The process was characterized as an “ad hoc” peer review. Peer reviewers were not selected by the EPA but were identified and evaluated by a third party contractor that was not involved in development of the oil and natural gas actions. The EPA had no input in the selection process. EPA is using the papers, along with the input we received from the peer reviewers and from the public, to determine how best to pursue additional reductions from these sources.

Proposed Rulemaking for 40 CFR Part 192: Amendments to Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings (2060-AP43)

Question from the Work Group for the OAR

This planned action (2060-AP43) was considered in the review of the Spring 2013 Regulatory Agenda. At that time the SAB deferred review because information provided by the agency was insufficient to evaluate the scientific and technical basis for this planned action.

The SAB Work Group notes that the SAB provided advice to the agency in 2012 for this action. (Advisory on EPA’s draft Technical Report entitled Considerations Related to Post Closure Monitoring of Uranium In-Situ Leach/In-Situ Recovery (ISL/ISR) Sites EPA-SAB-12-2005) In that advice the SAB recommended that the EPA expand greatly on the draft technical report “so that it is protective and realistic in guiding the monitoring program and evaluating its results” and provided specific recommendations. The SAB report is available on the SAB webpage at [http://yosemite.epa.gov/sab/sabproduct.nsf/964968D9229863A0852579A7006EC71A/\\$File/EP A-SAB-12-005-unsigned.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/964968D9229863A0852579A7006EC71A/$File/EP A-SAB-12-005-unsigned.pdf)

1. Can the EPA provide the agency’s response to the peer review report to assist the SAB Work Group to understand how the agency evaluated, addressed and incorporated the advice provided in the 2012 review of the technical report to develop the science supporting the Amendments to Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings (40 CFR Part 192)?

OAR Response: OAR developed a response to the SAB Work Group’s question regarding EPA actions pursuant to the SAB Feb 17, 2012 advisory (EPA-SAB-12-005) on EPA’s technical report developed in support of the Amendments to Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings (40 CFR Part 192). The attached document includes a table that provides a point by point accounting of how the

Attachment B: Summary of SAB Fact-finding on EPA Planned Actions

agency evaluated, addressed, and/or incorporated each element of the SAB's 2012 peer review advice.

[The table begins on the next page]

Agency Response to SAB Recommendations

Agency Charge	SAB Recommendation	Section #	EPA Response	Cross-reference to BID ¹ /Preamble
Charge Number 1				
Designing and Implementing a Monitoring Network	Develop a long-term (e.g., 3–5 year) program of data analysis and model development for defining the geology and hydrology of the site as a basis for setting evidence- based standards.	3.2	EPA describes a tiered approach in the <i>Considerations Related to Post Closure Monitoring of Uranium In-Situ Leach/In-Situ Recovery (ISL/ISR) Sites: Background Information Document for the Revision of 40 CFR Part 192</i> (BID). The proposed rule outlines an approach to setting site-specific restoration goals that includes more robust baseline data collection and analysis, as well as encouraging the use of geochemical modeling to support a finding of long-term post-restoration stability.	Federal Register Notice: Preamble : ² IV.C. Adequate Characterization of Groundwater Prior to Uranium Recovery BID: Section 3.5.2 (Summary of Species Potentially Required for Compliance Monitoring – Tiered Approach), including Table 3-3.
Designing and Implementing a Monitoring Network	In the near-term, articulate a set of guiding principles and assumptions for standards setting.	3.3	EPA discusses guiding principles in various sections of the draft technical report dealing with the phases of the ISL/ISR process and the technical issues involved in monitoring their safe completion. The proposed rule presents principles for standard setting. These principles address the sufficiency of the monitoring network and data collection, based on site-specific conditions, to establish appropriate restoration goals and demonstrate post-restoration stability.	Preamble: II.E Why does EPA believe new standards are necessary? IV What is the Rationale for today’s proposal?) BID: Section 2.3 (Application [of RCRA] to ISR Facilities) Section 3.0 (Groundwater Monitoring at ISR Facilities) and its subsections Section 3.2 (Establishing Baseline Conditions) Section 4.3 (Establishing Baseline Conditions) Section 4.4 (Extraction Operations Phase) Section 4.5 (Post-extraction Phase) Section 4.6 (4.6 Factors Affecting Post-mining Time Frames and Wellfield Stability) Section 4.7 (Modeling) and its subsections Section 8.0 (Summary of Post-Closure Performance Issues)

¹ BID: *CONSIDERATIONS RELATED TO POST CLOSURE MONITORING OF URANIUM IN-SITU LEACH/IN-SITU RECOVERY (ISL/ISR) SITES. Background Information Document for the Revision of 40 CFR Part 192.* <http://www.epa.gov/radiation/docs/tenorm/EPA-HQ-OAR-2012-0788-DRAFT-0017.pdf>

² Federal Register, Vol. 80, No. 16, January 26, 2015. 40 CFR Part 192, Health and Environmental Protection Standards for Uranium and Thorium, Mill Tailings; Proposed Rule. <http://www.gpo.gov/fdsys/pkg/FR-2015-01-26/pdf/2015-00276.pdf>

Agency Response to SAB Recommendations

Agency Charge	SAB Recommendation	Section #	EPA Response	Cross-reference to BID ¹ /Preamble
Designing and Implementing a Monitoring Network	Identify indicators, both chemical and radioactive, for establishing conditions pre- and post-operationally.	3.4, 4.3	In the BID, EPA discusses analytes and the purpose for monitoring each relative to the various stages of the ISL/ISR process, from pre-mining baseline determinations to post-restoration stability monitoring. The proposal specifies 13 constituents to be monitored, as well as those identified by the regulatory authority based on site conditions. In addition, constituents in the lixiviant would be among those to be monitored to limit excursions or exceedances.	Preamble: IV.C. Adequate Characterization of Groundwater Prior to Uranium Recovery BID: Section 3.5.2 (Summary of Species Potentially Required for Compliance Monitoring – Tiered Approach) Section 3.5.4 (Species Required for Geochemical Modeling) Section 3.5.5 (Species Required for Excursion Monitoring) Section 3.5.7 (Formal Approach to Acceptable Restoration)
Designing and Implementing a Monitoring Network	Specify criteria to distinguish between primary and secondary indicators on the basis of risk, return to pre-operational or other predetermined conditions, and information concerning other constituents.	3.4	In addition to specifying a list of analytes for monitoring, EPA is examining the field experience in monitoring some of these constituents and the rationale for making them higher or lower priority constituents for monitoring. EPA chose not to establish standards for certain constituents (e.g., vanadium), but the regulatory authority can require monitoring for other constituents as warranted by site conditions. Other constituents would include those in the lixiviant, as they may indicate facilitated transport and excursions or exceedances.	Preamble: IV.C. Adequate Characterization of Groundwater Prior to Uranium Recovery IV.B. What groundwater protection standards are we proposing for ISR facilities? BID: Section 3.5.6 (Case History – Evolution of Constituent Monitoring List) Section 5.1 (Ground Water Baseline: Case Studies) Section 5.3 (Wellfield Restoration: Case Study) Attachment B: Post-restoration Stability Monitoring Case Histories

Agency Response to SAB Recommendations

Agency Charge	SAB Recommendation	Section #	EPA Response	Cross-reference to BID¹ /Preamble
<p>Designing and Implementing a Monitoring Network</p>	<p>Discuss in detail the many factors that affect interactions and transformations during and after operation.</p>	<p>3.5</p>	<p>EPA has reviewed the various chemical interactions that take place during the mobilization of uranium (the mining phase) and the restoration process after mining. EPA has also considered factors (e.g., mass balance issues associated with lixiviant fluids and microbial activity) affecting constituent interactions and environmental transformations.</p> <p>The preamble to the proposal contains extensive discussion of issues related to restoration of a wellfield that may have significantly altered flow pathways compared to its pre-operational condition, including the potential for remaining pockets of lixiviant to be released over time and mobilize constituents again.</p>	<p>Preamble: IV. What is the Rationale for today’s proposal? IV.C. Adequate Characterization of Groundwater Prior to Uranium Recovery</p> <p>BID: <i>General –</i> Section 3.5.2 (Summary of Species Potentially Required for Compliance Monitoring – Tiered Approach) <i>Mining or pre-operational phase –</i> Section 3.5.4.2 (Phase Geochemistry Solid) <i>Post-mining –</i> Section 6.2 (Factors That Affect Time Frames for Post-mining Monitoring) <i>Microbial activity –</i> Section 6.2.2.3 (Role of Biological Processes) Section 6.4.2 (First-Order Attenuation Rate Determination) <i>Mass balance associated with lixiviant –</i> Section 3.5.5 (Species Required for Excursion Monitoring) Section - 6.2.1 (Fate and Transport Processes)</p>

Agency Response to SAB Recommendations

Agency Charge	SAB Recommendation	Section #	EPA Response	Cross-reference to BID ¹ /Preamble
Designing and Implementing a Monitoring Network	Obtain and analyze geological and mineralogical data to support decisions based on groundwater monitoring.	3.5, 5.5	<p>EPA agrees that detailed geological, geochemical and hydrologic characterization of the aquifer prior to mining is important.</p> <p>The proposal places significant emphasis on monitoring to establish baseline conditions, including the placement and extent of the network to account for non-homogeneity, frequency of sampling, and duration of sampling. Similarly, the proposal specifies post-restoration monitoring to support compliance determinations and corrective action, if needed.</p>	<p>Preamble: IV.C. Adequate Characterization of Groundwater Prior to Uranium Recovery</p> <p>BID: <i>Hydrogeologic</i> – Section 4.3 (Establishing Baseline Conditions) and its subsections. Section 4.4 (Extraction Operations Phase) Section 8.1 (Designing the Monitoring Program to Allow Reliable Baseline Conditions to be Established Prior to Active Recovery Operations) <i>Geochemical</i> – Section 3.5.4 (Species Required for Geochemical Modeling) Section 6.2.2.1 (Adsorption) Section 6.4 (Monitored Natural Attenuation) Section 7.1 (Determine Baseline Characteristics)</p>
Designing and Implementing a Monitoring Network	Before adequate modeling has been developed, specify a sufficiently dense spatial and temporal monitoring system to assure collecting sufficient data for pre- and post-mining comparison.	3.6	EPA proposes that operators install a monitoring network sufficient to produce the necessary data, and has proposed a specific level of statistical confidence and has reviewed statistical techniques that can be applied to an ISL/ISR wellfield in order to develop the temporal groundwater chemical composition data necessary to make confident decisions about baseline and the development of post-restoration steady-state conditions in the monitoring network.	<p>Preamble: IV.C. Adequate Characterization of Groundwater Prior to Uranium Recovery</p> <p>BID: Section 7.0 (Statistical Analyses to Compare Pre- and Post-ISR Conditions) and its subsections.</p>

Agency Response to SAB Recommendations

Agency Charge	SAB Recommendation	Section #	EPA Response	Cross-reference to BID ¹ /Preamble
Designing and Implementing a Monitoring Network	Consider applying available groundwater models relevant to ISL/ISR uranium mines.	3.7, 7.5	The Agency encourages the use of sophisticated groundwater flow models in achieving environmental protection. The Agency will follow the experience gained from application of such models and their effectiveness in supporting implementation of the rule.	Preamble: IV. A. How does today’s proposal relate to existing 40 CFR part 192? BID: 4.7 (Modeling) and its subsections. Preamble (FR notice): Supplementary Information, Section IV (What is the Rationale for today’s proposal?) A (How does today’s proposal relate to existing 40 CFR part 192?)
Designing and Implementing a Monitoring Network	Support research for providing both empirical values and model coefficients for understanding the approach to stability after ISL/ISR uranium mining.	3.7	While the Agency encourages research that expands understanding of complex systems, we leave it to the discretion of the implementing regulatory authorities as to whether they would explicitly support such research.	Not addressed in BID.
Designing and Implementing a Monitoring Network	Develop individual modules if needed to reduce the complexity of groundwater models.	3.7	We will consider the recommended approach and will consult with the implementing authorities (NRC and Agreement States) as appropriate.	BID: Section 7.10 (ProUCL Software for Statistical Analysis)
Designing and Implementing a Monitoring Network	Devote at least as much effort to defining baseline groundwater conditions as to post-operational trend monitoring.	3.8, 5.6	EPA agrees that determining baseline conditions directly relates to restoration and post-restoration stability, and therefore must be emphasized and approached rigorously. The proposal places significant emphasis on monitoring to establish baseline conditions, including the placement and extent of the network to account for non-homogeneity, frequency of sampling, and duration of sampling.	Preamble: IV.C. Adequate Characterization of Groundwater Prior to Uranium Recovery BID: Section 4.3 (Establishing Baseline Conditions) and its subsections. Section 7.1.1 (Design for Baseline Sampling) Section 7.1.2 (Selection of Baseline Monitoring Wells) Section 7.1.3 (Determining the Number of Baseline Samples) Section 7.1.4 (Summary)

Agency Response to SAB Recommendations

Agency Charge	SAB Recommendation	Section #	EPA Response	Cross-reference to BID¹ /Preamble
Designing and Implementing a Monitoring Network	Prepare a glossary of uniform definitions for use by pertinent regulatory agencies and mine operators.	3.11	The Agency agrees with SAB’s recommendation and included sections on definitions in both the preamble and proposed rule.	Preamble: I.F. Definitions BID: Section 7.3 (Hypothesis Testing and Data Quality Objectives) - Box 7-1a (Definitions) Attachment H
Charge Number 2				
Establishing Baseline Conditions	Define monitoring objectives of baseline characterization within the framework of the Data Quality Objective (DQO) approach.	4.2, 7.3	The Agency reviewed the use of these objectives in developing an ISL/ISR monitoring plan by the operators for supporting the licensing process to be executed by the implementing regulatory authorities. The preamble to the proposal contains numerous references to the RCRA Unified Guidance for Groundwater Monitoring, which incorporates the DQO approach.	BID: Section 3.1 (Overview) Section 3.5.4 (Species Required for Geochemical Modeling) Section 7.0 (Statistical Analyses to Compare Pre- and Post-ISR Conditions) and its subsections. Section 7.2.1 (Determining the Number of Monitoring Wells based on Hypergeometric Sampling) Section 7.3.1 (Decision Errors and Confidence Levels) Section 7.3.2 (Hypothesis Tests for Comparisons with Baseline) Section 7.3.4 (Hypothesis Tests for Detecting Trends) Section 7.6 (Determining the Number of Samples per Well) and its subsections Section 8.3 (Long-Term Stability Monitoring)

Agency Response to SAB Recommendations

Agency Charge	SAB Recommendation	Section #	EPA Response	Cross-reference to BID ¹ /Preamble
Establishing Baseline Conditions	Identify groundwater constituents and parameters pertinent for monitoring not limited to those with regulatory limits, but also including non-hazardous constituents that can affect the behavior of, or serve as surrogates for, constituents of interest.	4.3	EPA addresses monitoring analytes beyond those with regulatory limits. Constituents in lixiviant, for example, are identified as potential indicators of facilitated transport, excursions or exceedances. The regulatory authority may also identify required constituents based on site conditions.	Preamble: IV.C. Adequate Characterization of Groundwater Prior to Uranium Recovery BID: Section 3.5.2, (Summary of Species Potentially Required for Compliance Monitoring – Tiered Approach) including Table 3-3.
Establishing Baseline Conditions	Consider challenging and fluctuating ambient circumstances in baseline characterization.	4.5, 3.4	EPA agrees that site-specific conditions may make establishing baseline conditions particularly challenging; operators should be aware of complicating circumstances at their sites. The proposal addresses temporal considerations in monitoring, e.g., to address seasonality, and also notes that installing wells can have disruptive effects on groundwater flow, potentially causing misleading results if care is not taken to allow re-equilibration.	Preamble: IV.C. Adequate Characterization of Groundwater Prior to Uranium Recovery BID: Section 4.3 (Establishing Baseline Conditions) Section 4.3.1 (Variability in Baseline Measurements) Attachment B: Post-restoration Stability Monitoring Case Histories

Agency Response to SAB Recommendations

Agency Charge	SAB Recommendation	Section #	EPA Response	Cross-reference to BID ¹ /Preamble
Establishing Baseline Conditions	Build in flexibility to modify the design and implementation of monitoring programs as new information becomes available.	4.6	EPA acknowledges the issue of flexibility. The proposal outlines a framework and overall objectives for the monitoring network, but allows significant flexibility to the regulatory authority in specifying which individual wells, or groups of wells, are representative or to be used as points of compliance.	Preamble: IV.C. Adequate Characterization of Groundwater Prior to Uranium Recovery II.E Why does EPA believe new standards are necessary? II.E.2. What analysis has EPA done to support the proposal? BID: Section 3.5.2, (Summary of Species Potentially Required for Compliance Monitoring – Tiered Approach) including Table 3-3 Section 4.3.1 (Variability in Baseline Measurements) Section 7.1.1 (Design for Baseline Sampling) Section 7.7.2 (Using Trend Tests to Determine Stability)
Establishing Baseline Conditions	Apply consistent sample collection techniques, recordkeeping, and data compilation.	4.7	EPA agrees that facilities should use consistent sample collection techniques, recordkeeping, and data compilation. The proposal outlines a framework and overall objectives for monitoring and data collection and analysis. The regulatory authority would specify these implementation details, which may have site-specific components.	BID: Section 4.0 (Technical Considerations for ISR Ground Water Monitoring) (Section 7.1 (Determine Baseline Characteristics) Section 7.3.2 (Hypothesis Tests for Comparisons with Baseline) Section 7.0 (Statistical Analyses to Compare Pre- and Post-ISR Conditions) and its subsections.
Charge Number 3				

Agency Response to SAB Recommendations

Agency Charge	SAB Recommendation	Section #	EPA Response	Cross-reference to BID ¹ /Preamble
Post-Mining and Restoration Monitoring	Carefully qualify the meaning of “return to pre-operational groundwater quality.”	5.2, 3.11	This term refers to the attempt to restore the wellfield groundwater chemistry to conditions as they were prior to the onset of leaching operations. The preamble to the proposal acknowledges that the leaching process may significantly change the groundwater flow regime, resulting in preferential pathways or re-distribution of constituents. The proposed rule specifies compliance based on measured constituents and their maintenance over the long term.	Preamble: IV.C.1. Establishing Restoration Goals IV.E.3. How will groundwater stability be determined? BID: Section 1.1 (Background versus Baseline Wells) Section 3.5.7 (Formal Approach to Acceptable Restoration) Section 7.7.2 (Using Trend Tests to Determine Stability)
Post-Mining and Restoration Monitoring	Develop a set of guiding principles for crafting standards.	5.2, 3.3	The preamble to the proposed rule presents guiding principles for crafting standards. These principles address the sufficiency of the monitoring network and data collection, based on site-specific conditions, to establish appropriate restoration goals and demonstrate post-restoration stability, taking corrective action when needed.	Preamble (FR Notice): Section II (Background Information), Question E (Why does EPA believe new standards are necessary?).
Post-Mining and Restoration Monitoring	Combine the extensive existing data sets with knowledge of constituent interactions in the rock/water system to model post-mining approach to stability.	5.3, 3.2	EPA would encourage applying this type of site-specific modeling during the licensing process and proposes to allow it to be used as a demonstration of post-restoration stability that can shorten the long-term monitoring period. EPA believes this regulatory application will encourage operators to invest greater effort into baseline data collection. EPA agrees that additional data on the effectiveness of restoration, and the factors influencing it, would be useful.	Preamble: II.E. Why does EPA believe new standards are necessary? II.E.2. What analysis has EPA done to support the proposal? IV.E. Long-Term Stability Monitoring BID: Section 5.3 (Wellfield Restoration: Case Study) Section 6.2 (Factors That Affect Time Frames for Post-mining Monitoring) and its subsections Section 7.8 (Analysis of Post-restoration Trends at ISR Sites)

Agency Response to SAB Recommendations

Agency Charge	SAB Recommendation	Section #	EPA Response	Cross-reference to BID ¹ /Preamble
Post-Mining and Restoration Monitoring	Match sampling frequency and duration to information needs for model confirmation.	5.5	EPA proposes to establish a statistical level of confidence as part of the performance standard. The proposal allows use of geochemical modeling as a demonstration of regulatory compliance with long-term stability goals, and specifies a monitoring network sufficient to collect the necessary data.	BID: Section 7.7.2.3 (Duration of Sampling) Section 7.7.2.4 (Sampling Frequency) Section 8.2 (Determining that the Ground Water Chemistry has Reached Steady State and Restoration Processes can be Discontinued)
Post-Mining and Restoration Monitoring	Collect sufficient pre-operational groundwater monitoring data to support reliable post-operational decision making.	5.6, 3.8	EPA agrees that determining baseline conditions directly relates to restoration and post-restoration stability, and therefore must be emphasized and approached rigorously. The proposal places significant emphasis on monitoring to establish baseline conditions, including the placement and extent of the network to account for non-homogeneity, frequency of sampling, and duration of sampling.	Preamble: IV.C. Adequate Characterization of Groundwater Prior to Uranium Recovery BID: Section 4.3 (Establishing Baseline Conditions) and its subsection Section 7.1 (Determine Baseline Characteristics) and its subsections
Post-Mining and Restoration Monitoring	Discuss implications of data presented in tables in the attachments to the draft technical report.	5.7	EPA has factored data from field situations into our technical analyses. The analysis of available data supports the proposed approach that a longer period of post-restoration monitoring is appropriate.	BID: Section 5.3 (Wellfield Restoration: Case Study) Section 7.0 (Statistical Analyses to Compare Pre- and Post-ISR Conditions) and its subsections. Section 8.3 (Long-Term Stability Monitoring) Attachment B
Post-Mining and Restoration Monitoring	Apply a risk-weighting system in determining acceptability of groundwater quality at ISL/ISR uranium mines.	5.7, 3.4	The proposal sets a baseline of the 13 minimum constituents that must be addressed and allows the implementing agency to go beyond those 13 constituents as appropriate. The proposal also provides for alternate concentration limits where necessary, utilizing the criteria specified under RCRA.	BID: Section 3.5.2, (Summary of Species Potentially Required for Compliance Monitoring – Tiered Approach) including Table 3-3

Agency Response to SAB Recommendations

Agency Charge	SAB Recommendation	Section #	EPA Response	Cross-reference to BID ¹ /Preamble
Charge Number 4				
Statistical Techniques	Present a survey of methods to determine sufficient well number and density.	6.1, 3.6	EPA has addressed this issue in the BID and emphasized it in the proposed rule and preamble.	Preamble: IV.C.1. Establishing Restoration Goals BID: Section 7.1.2 (Selection of Baseline Monitoring Wells) Section 7.1.3 (Determining the Number of Baseline Samples) Section 7.1.4 (Summary) Section 7.2 (Determining the Number of Monitoring Wells Required to Detect Noncompliance) and its subsections
Statistical Techniques	Select statistical evaluation approach in terms of strengths and weaknesses to suit questions to be answered.	6.2	EPA has examined the strengths and weaknesses (e.g., data demands) of the statistical techniques described in the draft technical report relative to their intended purposes for defining baseline conditions and post-restoration steady-state conditions in the wellfield. The appropriate technique would depend on site conditions and need approval by the regulatory authority.	Preamble: IV.C.1. Establishing Restoration Goals BID: Section 7.0 (Statistical Analyses to Compare Pre- and Post-ISR Conditions) and its subsections.
Beyond the Charge				
Additional Advice Beyond the Charge	Monitoring other ISL/ISR impacts.	7.1	The proposed standards will regulate byproduct materials produced by uranium in-situ recovery (ISR), including both surface and subsurface standards, with a primary focus on groundwater protection, restoration and stability. The proposal specifies baseline and subsequent monitoring that should be sufficient to identify any external sources of contamination (e.g., from other sites or facilities, or surface releases into upper aquifers).	BID: SC&A 2011 NRC 1997, 1998, 2003, 2009, 2010, 2011a, 2011b (these are primarily NEPA documents that will address impacts and mitigation measures in general)

Agency Response to SAB Recommendations

Agency Charge	SAB Recommendation	Section #	EPA Response	Cross-reference to BID¹ /Preamble
Additional Advice Beyond the Charge	Considering plans for groundwater use that may be impacted by ISL/ISR uranium mining.	7.2	EPA has addressed this issue in the preamble to the proposed rule, noting that groundwater is under significant pressure in certain areas of the country and communities may seek to use sources that are not of the best quality. The preamble to the proposed rule also extensively addresses the aquifer exemption process under the Safe Drinking Water Act and its relation to UMTRCA.	Preamble (FR Notice): II.E. Why does EPA believe new standards are necessary? IV. What is the Rationale for today’s proposal?
Additional Advice Beyond the Charge	Elaborating on recommendations for applying the DQO framework to establishing technical approaches to standard setting.	7.3	EPA intended the draft technical document to be a source of information on various technical issues and approaches that would support standards development. SAB’s advice has been discussed in the preamble to the proposed rule and in supporting technical documents, as applicable. Further, the preamble to the proposal contains numerous references to the RCRA Unified Guidance for Groundwater Monitoring, which incorporates the DQO approach.	Preamble: II.E. Why does EPA believe new standards are necessary? II.E.3. What came out of the Advisory from EPA’s Science Advisory Board? BID: Section 8.3 (Long-Term Stability Monitoring)

Agency Response to SAB Recommendations

Agency Charge	SAB Recommendation	Section #	EPA Response	Cross-reference to BID¹ /Preamble
Additional Advice Beyond the Charge	Adding other considerations for integrating EPA requirements with existing EPA regulatory programs.	7.4	EPA has compared the statistical techniques discussed in the draft technical report with statistical techniques and their applications as described in other EPA references. EPA has carefully considered the RCRA groundwater protection framework in development of this proposal.	Preamble: II.F. What other EPA statutes and regulations are relevant? BID: <i>Statistical Techniques</i> – Section 7.0 (Statistical Analyses to Compare Pre- and Post-ISR Conditions) and its subsections. <i>RCRA Framework</i> – Section 2.0 (Resource Conservation and Recovery Act) and its subsections (especially Section 2.4[Application to ISR Facilities]) Section 3.5.1 (Regulated Constituents) Section 3.5.3 (Well Construction and Low-Flow Sampling Methodologies) Section 5.0 (Active/Existing SR Facilities: Monitoring Issues) Section 7.1 (Determine Baseline Characteristics)

Agency Response to SAB Recommendations

Agency Charge	SAB Recommendation	Section #	EPA Response	Cross-reference to BID¹ /Preamble
Additional Advice Beyond the Charge	Tapping available resources for the recommended modeling.	7.5	EPA has reviewed material, including that from published sources, concerning geochemical modeling and its potential application to the ISL/ISR processes.	Reviewed material cited in BID: Alpers, C.N., and D.K. Nordstrom, 1999 Allison et al. 1991 Harshman 1974 Deutsch et al. 1985 Harshman 1972 Johnson et al. 2010 Martin et al. 2005 Koretsky 2000 Parkhurst 1995 Pitzer 1979 Mayer et al. 2003 Lasaga 1981 Aagaard and Helgesson 1982 Davis et al. 2004 Parkhurst et al. 1982 Plummer et al. 1994 Parkhurst 1995 Parkhurst and Appelo 1999 Charlton et al. 1997 Charlton and Parkhurst 2002 Bowser and Jones 2002 Bethke and Yeakel 2009 Steeffel 2009 Thorstenson and Parkhurst 2002, 2004 Alpers and Nordstrom 1999 Mayer et al. 2003 Maest and Kuipers 2005 NRC 2007, 2010 COGEMA 2005, 2008a Strata Energy 2010 Johnson 2011
Additional Advice Beyond the Charge	Encouraging the working relation of EPA staff with NRC or state agency staff.	7.6	EPA has had a good working relationship with NRC staff during the development of this proposed rule.	Not Applicable.

Attachment C
EPA Descriptions and
SAB Work Group Recommendations on
Major EPA Planned Actions in the
Fall 2014 Semi-Annual Regulatory Agenda

April 28, 2015

The SAB formed a Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science in December 2014 to review information and short descriptions from the EPA Program Offices on the major planned actions that are listed in the Fall 2014 semi-annual Unified Regulatory Agenda but not yet proposed. The agency included one action the SAB previously deferred consideration because limited information were available at that time.

After reviewing the descriptions and additional information (see Attachment B) provided by EPA, SAB Work Group members developed and concurred on the recommendations and discussion provided in this attachment to the April 28, 2015 Work Group memorandum.

RIN	Title	Office	Page
2040-AF53	Uniform National Discharge Standards for Vessels of the Armed Forces--Phase II--Batch Two (UNDS)	OW	2
2050-AG82	Modernization of the Accidental Release Prevention Regulations Under Clean Air Act	OSWER	8
2050-AG80	User Fee Schedule for Electronic Hazardous Waste Manifest	OSWER	12
2060-AS31	Proposed Greenhouse Gas Endangerment and Cause or Contribute Findings Under CAA Section 231 for Aircraft, and ANPRM on the International Process for Reducing Aircraft GHGs and Future Standards	OAR	16
2060-AS30	Oil and Natural Gas Sector: Reconsideration of Remaining Provisions of New Source Performance Standards	OAR	22
2060-AP43	Revision--Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings and Uranium In Situ Leaching Processing Facilities	OAR	28
2060-AS06	Major Source Determination for Oil and Gas Extraction Facilities	OAR	34
2025-AA39	Revisions to Confidentiality of Business Information	OEI	37

Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Uniform National Discharge Standards for Vessels of the Armed Forces--Phase II--Batch Two (UNDS)
2. **RIN Number:** 2040-AF53
3. **EPA Office originating action:** Office of Water, Office of Wetlands, Oceans and Watersheds, Ocean and Coastal Protection Division, Marine Pollution Control Branch

4. **Brief description of action and statement of need for the action:**

In 1996 the Clean Water Act was amended to create section 312(n), "Uniform National Discharge Standards (UNDS) for Vessels of the Armed Forces." Section 312(n) directs EPA and Department of Defense (DoD) to establish national discharge standards for discharges incidental to the normal operation of a vessel of the armed forces. The vessel discharges contain constituents of concern that can negatively impact the aquatic environment. Some of the discharges have the potential to introduce oil or other organics into receiving waters (such as bilge water); some have the potential to introduce copper or other metals (such as hull coating leachate); and some have the potential to introduce aquatic nuisance species (such as ballast water).

EPA and DoD jointly promulgated Phase I of these regulations, 40 CFR part 1700, on May 10, 1999 (64 FR 25126). Phase I concluded that 25 out of 39 discharges from armed forces vessels would require EPA and DoD to jointly establish performance standards in Phase II for which it is "reasonable and practicable" to require a "marine pollution control device." Phase II is currently underway and will establish performance standards to control the 25 discharges in two separate rulemakings. EPA and DoD, in consultation with the U.S. Coast Guard, are working together to develop performance standards for the discharges. EPA and DoD published a Notice for Proposed Rulemaking for Phase II - Batch One in January 2014. Batch One included the following 11 discharges: aqueous film forming foam, chain locker effluent, distillation and reverse osmosis brine, elevator pit effluent, gas turbine water wash, non-oily machinery wastewater, photographic laboratory drains, seawater cooling overboard discharge, seawater piping biofouling prevention, small boat engine wet exhaust, and well deck discharges. EPA and DoD are now beginning work on Phase II - Batch Two, which will include the following 14 discharges: catapult water brake tank & post-launch retraction exhaust, clean ballast, compensated fuel ballast, controllable pitch propeller hydraulic fluid, deck runoff, dirty ballast, firemain systems, graywater, hull coating leachate, motor gasoline compensating discharge, sonar dome discharge, submarine bilgewater, surface vessel bilgewater/oil-water separator, and underwater ship husbandry.

5. **Timetable:** Notice of Proposed Rule: Winter 2015,
Final Rule: Winter 2016

6. Scientific products that will inform the action and plans for peer review:

6(a). Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.

The Office of Water will not be developing new scientific work products to support Phase II of the Uniform National Discharge Standards (UNDS) Rulemaking. The Rule is being developed with the same scientific information that was used to develop EPA's 2013 Vessel General Permit (VGP).

The VGP regulates incidental discharges from the normal operation of vessels (primarily commercial vessels) under section 402 of the Clean Water Act. The constituents of concern (metals, oil, organics) found in these discharges are virtually identical to the constituents of concern found in discharges from military vessels. As a result, there is no need to develop new scientific work products to inform the UNDS Rulemaking.

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

EPA's Office of Wetlands, Oceans, and Watersheds is working very closely with the Office of Wastewater Management (the office that developed the VGP) during the development of the Rule.

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

N/A: No new science work products.

6(d). Peer review:

N/A: No new science work products.

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Uniform National Discharge Standards for Vessels of the Armed Forces--Phase II--Batch Two (UNDS) (2040-AF53)

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?		X
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		X
Is the action an extension of an existing initiative?	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			X
Addresses areas of substantial uncertainties		X	
Involves major environmental risks		X	
Relates to emerging environmental issues		X	
Exhibits a long-term outlook		X	

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further SAB consideration.

Questions were initially sent to the EPA to clarify how the action addresses disinfection byproducts and aquatic nuisance species for the 14 discharges that will be addressed in the permit. Based on the initial information and follow up responses provided by the EPA, this action does not merit further SAB consideration.

This action involves setting up performance standards for armed services vessels based on the Vessel General Permit (VGP). The 14 additional discharges included in this action include: 1) catapult water

brake tank & post-launch retraction exhaust, 2) clean ballast, 3) compensated fuel ballast, 4) controllable pitch propeller hydraulic fluid, 5) deck runoff, 6) dirty ballast, 7) firemain systems, 8) graywater, 9) hull coating leachate, 10) motor gasoline compensating discharge, 11) sonar dome discharge, 12) submarine bilgewater, 13) surface vessel bilgewater/oil-water separator, and 14) underwater ship husbandry. The discharges are incidental to the normal operation of a vessel of the armed forces and may contain constituents that can negatively impact the aquatic environment.

No new science is planned by the Office of Water because the rule is being developed with the scientific information in the EPA's [2013 Vessel General Permit \(VGP\)](#)¹. The 2013 VGP cited an [EPA SAB review](#)² which concluded five types of ballasted water treatment technologies were effective at inactivating potential invasive aquatic species. However, there were some initial concerns by the Work Group about the formation of disinfection by-products that are formed from the use of oxidants suggested in the VGP.

The VGP identifies the following five types of ballast water treatment technologies: (1) Deoxygenation + cavitation; (2) Filtration + chlorine dioxide; (3) Filtration + UV; (4) Filtration + UV + TiO₂; and (5) Filtration + electro-chlorination.

A preliminary review of the [fact sheet](#)³ for the VGP identified sections that focused on specific biocide concentrations and sections that focused solely on the specific biocide. The Work Group did not have sufficient information to evaluate how the agency is addressing byproduct formation and discharge across the 14 discharges.

Two examples are provided:

This language from the VGP section 2.2.3.5 on Ballast Water Numeric Discharges Limitations suggests there are concerns about the direct impact of the biocide and not the generation of DBPs. Tables 4 and 5 (on pages 34-36 of the permit) list the treatments and analytes for ballast water discharges.

Ballast water treatment systems that use biocides as active substances have the reasonable potential to cause or contribute to an excursion of applicable numeric and/or narrative criteria for the protection of aquatic life. EPA established the biocide effluent limitations contained within Part 2.2.3.5.1.1.5 of the VGP to ensure that such discharges are controlled as necessary to ensure compliance with applicable water quality standards, pursuant to 122.44(d)(1)(vi) and (vii).

The following language from the VGP fact sheet is on specific biocides but appears focused on reducing discharge concentrations of the biocide, not formation of DBPs.

In addition, the permit contains specific limits for commonly used biocides in ballast water treatment systems. Chlorination (generally via hypochlorite electrolytic generation) is a commonly used disinfection technology and is known to be proposed for use in ballast water treatment systems. As in the 2008 VGP,

¹ Vessel General Permit For Discharges Incidental To The Normal Operation Of Vessels

² [Efficacy of Ballast Water Treatment Systems: a Report by the EPA Science Advisory Board](#). (PDF, 154 pp., 1,319,941 bytes), EPA-SAB-11-009

³ U.S. Environmental Protection Agency 2013 [Fact Sheet](#): Final Issuance of National Pollutant Discharge Elimination System (NPDES) Vessel General Permit (VGP) for Discharges Incidental to the Normal Operation of Vessels Page 85-86.

the permit provides that Total Residual Chlorine (TRC) may not exceed 100 micrograms per liter ($\mu\text{g/l}$) as an instantaneous maximum. Routine methods for de-chlorination of treated water are well demonstrated, and in selecting this limit EPA considered existing TRC limits found in a number of NPDES permits for publicly owned treatment works, with the TRC limit for this permit reflecting the median limit for the permits reviewed.

For today's permit, EPA has also established a discharge limit for ozone, expressed as an instantaneous maximum 100 micrograms per liter ($\mu\text{g/l}$) of Total Residual Oxidizers (TRO as TRC). EPA requires analysis of TRO in ballast water effluent using either of two standard DPD colorimetric methods recognized in the international community: Standard Methods 4500-Cl G and International Organization for Standardization (ISO) Method 7379/2. Although these methods were originally developed to determine residual chlorine, many oxidants used as disinfectants react directly with the colorimetric indicator, thereby allowing for the determination of total residual oxidizers. Examples of detected oxidants relevant to ballast water treatment technologies include chlorine, chlorine dioxide, ozone, bromine, hydrogen peroxide, and disinfectant by-products such as chlorite and chlorate. Because the photometric equipment compares the colorimetric response of the sample to its calibration developed based on chlorine, results are reported as Cl_2/L .

EPA has established a limit of 200 micrograms per liter ($\mu\text{g/l}$) of Chlorine Dioxide for systems using Chlorine Dioxide as a biocide. The manufacturer of one chlorine dioxide based system provided information on aquatic toxicity tests performed in support of achieving discharge approval from the Washington State Department of Ecology and GESAMP. These data were submitted to EPA in response to EPA's 2010 Federal Register notice seeking additional information for this permit. In its supporting documentation, the manufacturer assessed chlorine dioxide effects on the survival and growth of silverside minnows (*Menidia beryllina*) and mysids (*Americamysis bahia*), survival and normal development for mussel (*Mytilus* sp.) and Pacific herring (*Clupea pallasii*) embryos, germination and germ tube length for giant kelp (*Macrocystis pyrifera*) zoospores, 96-hour population growth for diatoms (*Skeletonema costatum*), and 96-hour survival for Pacific herring larvae. They documented EC50 concentrations around 0.2 mg/L (equal to 200 $\mu\text{g/l}$) chlorine dioxide for the most sensitive test endpoints (i.e., mussel normal-survival, kelp germination, and kelp germ tube length). The manufacturer noted that the observed toxic thresholds were sharp and that the effects disappeared when concentrations reached 0.15 mg/L chlorine dioxide. Hence, based on these results, and to be consistent with recommendations made by GESAMP, EPA established the limit of 200 micrograms per liter ($\mu\text{g/l}$) of Chlorine Dioxide.

The Work Group requested additional information from the EPA on this action to clarify the terminology used for the discharges, which treatments would be used for the specific discharges, how the agency will consider invasive and aquatic nuisance species, and how this action will manage disinfection byproducts that may be formed during treatment. The Work Group's questions and EPA's responses are provided in Attachment B of this memorandum.

The agency responses indicated that EPA will consider the specific discharges in developing management practices to address biological invasive species or pathogens as contaminants of concern for some of the non-ballast discharges. For example, the EPA anticipates that dirty ballast will not be treated with one of the five technologies, but instead anticipates a “no discharge” standard within waters subject to UNDS. EPA states that it anticipates that certain vessel classes will use treatment systems for clean ballast in order to meet the living organism discharge limits. The agency also noted that this action will be developed similar to the 2013 VGP. In the VGP, EPA established maximum limits for biocides discharged during treatment so that the minimum amount of biocide is used when achieving the living organism discharge limits. In addition, the VGP requires monitoring in order to demonstrate that residual biocides or derivatives are in compliance with the biocide maximum limits and that substantial quantities of harmful byproducts are not produced.

Based on all the information provided to the Work Group, including the responses to questions asked of the EPA, it was concluded that this action does not merit further SAB consideration.

Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Modernization of the Accidental Release Prevention Regulations under the Clean Air Act
2. **RIN Number:** 2050-AG82
3. **EPA Office originating action:** Office of Solid Waste and Emergency Response / Office of Emergency Management
4. **Brief description of action and statement of need for the action:** On August 1, 2013, President Obama signed Executive Order 13650, entitled Improving Chemical Facility Safety and Security, which requires the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA) and the Department of Homeland Security (DHS) to carry out a number of tasks whose overall aim is to prevent chemical accidents, such as the explosion that occurred at the West Fertilizer facility in West, Texas, on April 17, 2013. Section 6 of the Executive Order is entitled "Policy, Regulation, and Standards Modernization." Among other things, section 6 requires certain federal agencies to consider possible changes to existing chemical safety and security regulations. On July 31, 2014, the EPA issued a Request for Information (RFI) to solicit stakeholder feedback on a number of potential modifications to the Risk Management Program (RMP) regulations. EPA issued the principal RMP regulation in 1996 under the authority of Clean Air Act section 112(r) to help prevent chemical accidents at facilities handling substances that pose the greatest risk of acute harm from accidental chemical releases. This proposed rule is expected to contain a number of proposed modifications to the RMP regulations based on stakeholder feedback received from the RFI. EPA's RMP regulations are based on process safety management (PSM) requirements similar to those in the OSHA PSM standard. On December 9, 2013, OSHA issued an RFI seeking public input on potential changes to its PSM standard. Because both programs are closely aligned in content, policy interpretations, agency guidance, and enforcement, EPA is coordinating its rulemaking efforts with OSHA.

Please see http://www.epa.gov/emergencies/eo_improving_chem_fac.htm, especially to read more about the EPA's RFI.
5. **Timetable:** Estimated proposed rule publication: 9/2015. This action was identified as a priority action in Executive Order 13650: Actions to Improve Chemical Facility Safety and Security – A Shared Commitment. Report for the President.
6. **Scientific products that will inform the action and plans for peer review:**
 - 6(a). **Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.** EPA plans to focus on the management elements of the RMP. Therefore, this proposal may or may not involve scientific work products, depending on what regulatory options are proposed by EPA. EPA is currently deliberating regulatory options.

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

EPA has not initiated development of any scientific work products under this rulemaking.

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

EPA has not initiated development of any scientific work products under this rulemaking. EPA is currently deliberating rulemaking options.

6(d). Peer review:

The action may or may not trigger peer review depending on what options are selected by the Agency.

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Modernization of the Accidental Release Prevention Regulations under the Clean Air Act (2050-AG82)

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?		X
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		X
Is the action an extension of an existing initiative?	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			X
Addresses areas of substantial uncertainties			X
Involves major environmental risks			X
Relates to emerging environmental issues			X
Exhibits a long-term outlook			X

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further SAB consideration.

EPA is coordinating its rulemaking efforts with OSHA on the Risk Management Program (RMP) regulations. EPA issued the principal RMP regulation in 1996 under the authority of Clean Air Act section 112(r) to help prevent chemical accidents at facilities handling substances that pose the greatest risk of acute harm from accidental chemical releases. EPA plans to focus on the management elements of the RMP and has not initiated development of any scientific work products under this rulemaking. In these circumstances the SAB should not consider this action for review at this time. However, because this regulation is based on process safety management requirements, EPA may also wish to consider a

liaison arrangement with OSHA on the science issues that may impact their coordinated rulemaking effort.

Description of Planned EPA Tier 1 or Tier 2 Action

- 1. Name of action:** User Fee Schedule for Electronic Hazardous Waste Manifest
- 2. RIN Number:** 2050-AG80
- 3. EPA Office originating action:** Office of Solid Waste and Emergency Response / Office of Resource Conservation and Recovery
- 4. Brief description of action and statement of need for the action:**

On October 5, 2012, President Obama signed into law the Hazardous Waste Electronic Manifest Establishment Act (the Act), Public Law 112-195. The Act requires the Environmental Protection Agency (EPA) to establish a national electronic manifest system to modernize the tracking of off-site shipments of hazardous waste. The Act authorized the appropriation of funds to develop the national e-Manifest system, and it established authority for EPA to collect reasonable user fees to offset the system development costs and to defray the annual costs of system operation and maintenance. The Act further required EPA to promulgate regulations to implement the Act. On February 7, 2014, the EPA promulgated the e-Manifest Final Rule authorizing electronic manifests. In issuing that rule, the EPA completed an important step that must precede the development of a national e-Manifest system. This rule is the second regulation that must also precede the development of the e-Manifest system. This action will implement the broad discretion granted on the Agency to establish reasonable user fees for the various activities associated with using and submitting electronic and paper manifests to the national system.

Timetable:

This action is in the proposed rule stage. The Notice of Proposed Rule Making is listed as October 2015 in the Regulatory Agenda. Further information regarding this action and its timetable may be found in the fall 2014 Regulatory Plan and Semi-annual Agenda.

<http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201410&RIN=2050-AG80>

- 5. Scientific products that will inform the action and plans for peer review:**

While the e-Manifest system will rely heavily on state of the art information technology, this action will not otherwise use or employ scientific products, nor is it expected to require scientific peer review. The Fee Rule by its nature is not an environmental or health and safety standard typical of EPA rulemakings that may require scientific analysis. Rather, this action is focused on recovering the costs of operating an IT system by determining and collecting user fees. The Fee Rule is about evaluating all the costs involved with establishing and operating an electronic manifest system, and then allocating those costs across the manifest user community by assessing fees for the use and processing of manifests when submitted to the system. The Fee Rule is an action focused almost solely on economics and cost recovery, and will not involve regulating emissions, permitting, or enforcement/compliance monitoring activities.

In addition, the e-Manifest Act requires the agency to establish, under the Federal Advisory Committee Act, a new nine member e-Manifest Advisory Board. Although as stated above, this regulatory action will not use or employ any scientific products nor require peer review, this new Board will be in place to provide practical and independent advice, consultation and recommendations to the EPA Administrator on the activities, functions, policies and regulations associated with the e-Manifest System.

6(a). Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.

NA

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

NA

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

NA

6(d). Peer review:

NA

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: User Fee Schedule for Electronic Hazardous Waste Manifest (2050-AG80)

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?	X	
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		X
Is the action an extension of an existing initiative? (EPA has already promulgated a final rule authorizing electronic manifests)	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			X
Addresses areas of substantial uncertainties			X
Involves major environmental risks			X
Relates to emerging environmental issues			X
Exhibits a long-term outlook			X

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further SAB consideration.

On October 5, 2012, the Hazardous Waste Electronic Manifest Establishment Act (Public Law 112-195) was signed into law. It requires the EPA to establish a national electronic manifest system to modernize the tracking of off-site shipments of electronic hazardous waste. The Act authorized the appropriation of funds to develop the national e-Manifest system, and it established authority for EPA to collect reasonable user fees to offset the system development costs and to defray the annual costs of system operation and maintenance.

The rule will evaluate the costs involved with establishing and operating an electronic manifest system, and then determine how to allocate those costs across the manifest user community by assessing fees for the use and processing of manifests when submitted to the system. This planned action thus determines and collects user fees and is focused on recovering the costs of operating an Information Technology system.

Description of Planned EPA Tier 1 or Tier 2 Action

- 1. Name of action:** Proposed Finding that Greenhouse Gas Emissions from Aircraft Cause or Contribute to Air Pollution that May Reasonably be Anticipated to Endanger Public Health and Welfare and Advanced Notice of Proposed Rulemaking (Tier 2)
- 2. RIN Number:** RIN 2060-AS31
- 3. EPA Office originating action:** Office of Air and Radiation; Office of Transportation and Air Quality and Office of Atmospheric Programs
- 4. Brief description of action and statement of need for the action:**

In this action, the EPA will propose findings as to whether greenhouse gas emissions from aircraft cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare.⁴ The Administrator's proposal comes in response to a citizen petition submitted by Friends of the Earth, Oceana, the Center for Biological Diversity, and Earthjustice requesting that the EPA make the findings and issue standards under section 231(a)(2)(A) of the Act for greenhouse gas (GHG) emissions from aircraft. The EPA is also moving forward as stated in the Agency's response to petitioners following a ruling from the U.S. District Court for the District of Columbia that EPA had a duty to issue such findings.⁵

Concurrent with these proposed findings, the EPA is issuing an Advanced Notice of Proposed Rulemaking to provide an overview and seek input on the EPA's efforts at the United Nations' International Civil Aviation Organization (ICAO) to reduce CO₂ emissions from aircraft, ICAO's progress in developing global aircraft standards, and depending on the outcome of EPA's final findings, the potential use of CAA section 231 to implement these standards domestically, ensuring transparency and the opportunity for public comment.

5. Timetable:

The EPA's timeframe for these actions is described in an information paper it submitted to ICAO.⁶ The information paper indicates that, under the agency's current schedule, the EPA intends to propose its findings in spring 2015, with final determinations expected in spring 2016. The EPA would then propose and promulgate emissions standards, if the final determinations are positive.

6. Scientific products that will inform the action and plans for peer review:

6(a). Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.

The EPA intends to use two sets of scientific products to inform the two key questions before the Administrator: 1) do GHGs in the atmosphere endanger public health and welfare for purposes of

⁴ Links to relevant background information:

<http://www.epa.gov/otaq/aviation.htm>

<http://www.epa.gov/climatechange/EPAactivities/regulatory-initiatives.html>

<http://www.epa.gov/climatechange/endangerment/index.html>

⁵ *Center for Biological Diversity, et al. v. EPA*, 794 F. Supp. 2d 151 (D.D.C., July 5, 2011)

⁶ <http://www.epa.gov/otaq/documents/aviation/us-ghg-endangerment-ip-9-3-14.pdf>

section 231 of the Clean Air Act? and 2) do aircraft GHG emissions cause or contribute to the endangering air pollution?⁷

- 1) The EPA anticipates that the aircraft GHG endangerment finding proposal will build on a previous action referred to as the “2009 Endangerment Finding” under CAA section 202⁸ and thus rely on previous peer-reviewed science from the major climate change science assessments of the U.S. Global Change Research Program (USGCRP), the Intergovernmental Panel on Climate Change (IPCC), and the National Research Council (NRC) of the National Academy of Sciences, along with updated reports from the same major climate change assessments. Such updated reports include 12 new, major assessments of the IPCC, USGCRP, and NRC that have been released since 2009, such as the IPCC's 2013-2014 Fifth Assessment Report (AR5), the USGCRP's 2014 “Climate Change Impacts in the United States: the Third National Climate Assessment” (NCA3), and the NRC's 2010 “Ocean Acidification: A National Strategy to Meet the Challenges of a Changing Ocean.”

Such assessments draw synthesis conclusions across thousands of individual peer-reviewed studies that appear in scientific journals, and the reports themselves undergo additional peer review. Such assessments address the scientific issues within the key endangerment question, are comprehensive in their coverage of the GHG and climate change issues, and undergo rigorous and exacting peer review by the expert community, as well as rigorous levels of U.S. government review. Primary reliance on the major scientific assessments provides assurance that the EPA is basing its judgment on the best available, well-vetted science.⁹ The EPA considered the processes and procedures employed by the IPCC, USGCRP, and the NRC, and has determined that these assessments have been adequately peer reviewed in a manner commensurate with the guidelines in OMB's Final Information Quality Bulletin for Peer Review for highly influential scientific assessments (HISA) (see section 6(d)).

- 2) The EPA's anticipated approach to the proposed cause or contribute finding under CAA section 231 is consistent with the 2009 Endangerment Finding approach to making domestic and global comparisons of GHG emissions, relying primarily on EPA's Inventory of U.S. Greenhouse Gas Emissions and Sinks report for 2014 (US GHG Inventory).¹⁰ The EPA develops the US GHG Inventory each year to track national trends in GHG emissions and sinks since 1990, and each year the report undergoes two separate expert reviews (see section 6(d)). The US GHG Inventory is submitted to the United Nations Framework Convention on Climate Change (UNFCCC) in fulfillment of United States obligations as a Party to that Treaty. The report is a compilation of emission calculations for a diverse set of approximately 40 anthropogenic greenhouse gas sources and sinks, and uses standard methodologies consistent with the IPCC in combination with publicly available federal and state statistics.

⁷ This description outlines the EPA's intended or planned approach to the scientific work products to inform the proposed action; the Agency's final approach for the purposes of the proposal will be outlined in the proposed findings themselves.

⁸ “Endangerment and Cause or Contribute Findings for Greenhouse Gases Under Section 202(a) of the Clean Air Act,” [74 FR 66496](#) (Dec. 15, 2009) (“Endangerment Finding”); [74 FR 18886](#) (Apr. 24, 2009) (“Proposed Endangerment Finding”).

⁹ On June 26, 2012, the U.S. Court of Appeals for the D.C. Circuit upheld the Endangerment Finding and supported the EPA's reliance on the major scientific assessment reports conducted by USGCRP, IPCC, and NRC, noting that this approach was consistent with the methods decision-makers often use to make a science-based judgment.

¹⁰ <http://epa.gov/climatechange/ghgemissions/usinventoryreport.html>

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

As described above, it is the Agency's view that the IPCC, USGCRP, and the NRC represent the best reference materials for determining the general state of knowledge on the scientific and technical issues before the agency in making an endangerment decision. Many federal scientists from across the federal government are involved in developing and/or reviewing these assessments.

The EPA also works with many different federal agencies to develop the US GHG Inventory report. For the aircraft sector specifically, EPA collaborates with the Federal Aviation Administration and the Department of Defense. For the presentation of emissions inventory information to support the cause or contribute finding, EPA believes that a disaggregation of the existing data in one area of the US GHG Inventory (the General Aviation Jet Fuel Category) would be preferable rather than the high level summary number presented in the US GHG Inventory report. The EPA worked with a contractor to disaggregate the data in this category in a manner consistent with the methodological approaches utilized in the US GHG Inventory report.

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

All of the data sources described above have been subject to expert reviews with the exception of disaggregating the data in the General Aviation Jet Fuel Category. Although the methodological approach and the results of disaggregating the data in the General Aviation Jet Fuel Category do not meet the definition of influential scientific information (ISI), HISA, or any another designation with legal and/or statutory obligation to conduct a peer review, the EPA believes there is merit in peer reviewing the disaggregation methodology and results, as described in section 6(d).

6(d). Peer review:

As noted above, the EPA has determined that IPCC, USGCRP, and the NRC assessments have been adequately peer reviewed in a manner commensurate with the guidelines in OMB's Final Information Quality Bulletin for Peer Review for HISAs. According to the OMB Final Information Quality Bulletin for Peer Review and guidelines in the EPA's Peer Review Handbook, if the Agency has determined that information has already been subject to adequate peer review, then it is not necessary to have further peer review of that information. For the NRC assessments in particular, the OMB Final Information Quality Bulletin for Peer Review states that an agency may, "rely on scientific information produced by the National Academy of Sciences," and that "agencies should presume that major findings, conclusions, and recommendations of NAS reports meet the performance standards of this Bulletin."¹¹ Alternatively, an agency may "commission the National Academy of Sciences to peer review an agency draft scientific information product,"¹² which was the approach taken by the USGCRP for its Third National Climate Assessment.¹³

¹¹ OMB Final Information Quality Bulletin for Peer Review, page 27.

¹² Ibid.

¹³ <http://www.nap.edu/catalog/18322/a-review-of-the-draft-2013-national-climate-assessment>.

The IPCC reports undergo multiple rounds of expert review, engaging hundreds of scientists from around the world to comment on “the accuracy and completeness of the scientific, technical and socio-economic content and the overall balance of the drafts.” The IPCC review procedures are described in Appendix A to the Principles Governing IPCC Work.¹⁴ A number of revisions to IPCC procedures, governance and management, conflict of interest policy, and communications strategy have been made in recent years to strengthen existing processes.¹⁵ All comments and responses to comments are documented and made publically available.¹⁶

Each year, the US GHG Inventory undergoes two separate expert reviews. First, the EPA conducts an expert review by external technical specialists based on their expertise related to the GHG Inventories, IPCC methodologies, or technical and economic aspects of particular source categories. The EPA tracks and records review comments and Agency responses. Second, the Inventory undergoes an international review conducted by a 6-12 member team of international experts who have demonstrated expertise in GHG inventories, and have passed a series of technical examination requirements developed by the UNFCCC.¹⁷ The UNFCCC international review teams publish a report for each Inventory reviewed, with their review findings and recommendations.¹⁸ The EPA has determined that the US GHG Inventory has been adequately reviewed in accordance with OMB’s Final Information Quality Bulletin for Peer Review and EPA’s Peer Review Handbook. The EPA will have the disaggregation methodology and results for the General Aviation Jet Fuel Category peer reviewed. This peer review will be in the form of an external letter review, and the EPA plans to make applicable peer review documentation available in the public docket for this action (EPA-HQ-OAR-2014-0828).

¹⁴ <http://www.ipcc.ch/pdf/ipcc-principles/ipcc-principles-appendix-a-final.pdf>.

¹⁵ http://www.ipcc.ch/organization/organization_review.shtml

¹⁶ Links to IPCC peer review information:

<http://www.climatechange2013.org/background/review-process/>

<http://ipcc-wg2.gov/AR5/background/review-process/>

<http://mitigation2014.org/background/review-process>

<http://ipcc-wg2.gov/SREX/report/review-comments-disclaimer>

¹⁷ http://unfccc.int/national_reports/annex_i_ghg_inventories/inventory_review_training/items/2763.php

¹⁸ http://unfccc.int/national_reports/annex_i_ghg_inventories/inventory_review_reports/items/6048.php

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Proposed Finding that Greenhouse Gas Emissions from Aircraft Cause or Contribute to Air Pollution that May Reasonably be Anticipated to Endanger Public Health and Welfare and Advanced Notice of Proposed Rulemaking (2060-AS31)

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?		X
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"	X	
Is the action an extension of an existing initiative?		X

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency		X	
Addresses areas of substantial uncertainties	X		
Involves major environmental risks	X		
Relates to emerging environmental issues	X		
Exhibits a long-term outlook	X		

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further SAB consideration. However, the Work Group anticipates that subsequent steps in the regulatory process will involve substantive scientific issues that may warrant SAB consideration.

As the basis for an endangerment finding, EPA plans to rely on reports published by other entities, such as IPCC, USGCRP, and NRC, which have undergone peer review processes. EPA will also rely on its own Inventory of U.S. Greenhouse Gas Emissions and Sinks, which undergoes review in accordance with the UNFCCC. These cited work products undergo extensive review and thus would not require any further review by the SAB. The approach that EPA will take to making inferences from these work

products involves considerations for which there is precedent in the endangerment finding that was made in 2009 under Section 202 of the Clean Air Act. This inference approach involves a mix of scientific and policy-relevant judgments, and further has been subject to judicial review. This action clearly deals with issues that involve major environmental risks, and a long-term outlook. The approach described by EPA appropriately relies on peer reviewed information regarding science and the US GHG emission inventory. These sources, their related information, and how this type of information is interpreted are not new to the Agency. One component of the analysis to disaggregate the GHG inventory that has not yet been reviewed, for the General Aviation Jet Fuel Category, will be subjected to an external letter review.

This action will also involve international coordination with an international standard setting process of ICAO/CAEP, which is expected to adopt an international standard for aircraft CO₂ emissions in February 2016. EPA indicates its intent is to adopt domestic standards equivalent to the future ICAO/CAEP standards.

With regard to the ANPRM, EPA plans to issue this in April 2015. Thus, there would not be time for a review process by SAB prior to the ANPRM. However, EPA anticipates that the final rule would be announced a year after the ANPRM.

Given how soon an ANPRM is planned, and its significant scope and coordination with the processes related to an international initiative, it is surprising that this information is only now reaching the SAB for consideration.

In summary, this proposed action is for a topic of high interest that will be based on information that has been well-reviewed and that will be based on inference approaches for which there is precedent.

Description of Planned EPA Tier 1 or Tier 2 Action

- 1. Name of action:** Emission Standards for New and Modified Sources in the Oil and Natural Gas Sector
- 2. RIN Number:** 2060-AS30
- 3. EPA Office originating action:** Office of Air and Radiation, Office of Air Quality Planning and Standards
- 4. Brief description of action and statement of need for the action:**

The Office of Air and Radiation (OAR) is currently developing proposed amendments to the NSPS that will reduce emissions of greenhouse gases, including methane, and volatile organic compounds (VOCs) in the oil and natural gas industry. On Jan. 14, 2015, the Obama Administration announced its next steps to cut methane emission under the March 2014 [Strategy to Reduce Methane Emissions](#). That strategy, part of the Administration's Climate Action Plan, identified the oil and gas industry as a key source of methane emissions and set out a series of steps to reduce those emissions while allowing continued responsible growth in U.S. oil and natural gas production. In support of the Administration's strategy, OAR is proposing to add certain equipment and processes to those sources currently covered by the standards. Equipment and processes the agency is considering adding include hydraulically fractured oil wells, pneumatic pumps, and leaks from new and modified well sites and compressor stations.

On August 16, 2012, the EPA published new source performance standards (NSPS) for the oil and natural gas sector. Following publication of these final standards for the oil and natural gas sector, the Administrator received petitions for administrative reconsideration of certain aspects of the standards. Among issues raised in the petitions were time-critical issues related to certain storage vessel provisions and well completion provisions. Final amendments to address these issues were published on September 23, 2013, and on December 31, 2014, respectively. This action also will propose amendments to address remaining issues raised in the petitions and to correct technical errors that were inadvertently included in the final standards.

OAR is also cooperating with the Department of Interior's Bureau of Land Management (BLM) to aid in BLM's development of measures to reduce methane venting and flaring on public lands. This coordination has been informational in nature to ensure mutual awareness of each agency's actions in this sector.

Information on OAR's past rulemaking actions and other information pertaining to the Oil and Natural Gas Sector can be found at www.epa.gov/airquality/oilandgas.

- 5. Timetable:**

EPA plans to propose these amendments in the summer of 2015.

6. Scientific products that will inform the action and plans for peer review:

6(a). Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.

As part of the rulemaking process, EPA will be developing a technical support document (TSD) summarizing the technical analysis that underlies the proposed rule. This technical support document will be based on a series of white papers that examined both potentially significant sources of emissions and options for reducing these emissions (the public process (including peer review) that is explained in 6(b)). These white papers, which can be found at <http://www.epa.gov/airquality/oilandgas/whitepapers.html>, relied heavily on a number of key information sources such as peer reviewed publications from the Proceedings of the National Academy of Science and were subject to peer review in 2014 as described below. We obtained emissions information both from the U.S. Greenhouse Gas Inventory, which is updated annually following technical expert and public review of the draft revised document, and from information reported by oil and gas operators to the Greenhouse Gas Reporting Program (GHGRP), for which preliminary compilation of data undergoes public review. To determine number of wells drilled annually and oil and gas production information, we referred to the proprietary *DrillingInfo* database. For information regarding projected growth of this industry, we considered public materials developed by the Department of Energy's Energy Information Administration. We anticipate that future information resources used during development of this action will be of similar nature. The white papers discuss key insights that EPA identified from these data sources and key concepts that will form the basis of the TSD (further informed by information received as part of the peer review and public outreach process discussed below). As discussed in 6(c) the TSD will undergo additional review as part of the standard regulatory process.

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

In spring of 2014, as part of the Obama administration's *Strategy to Reduce Methane Emissions*, EPA released for external peer review and public input five white papers on potentially significant sources of emissions in the oil and gas sector: hydraulically fractured oil wells; leaks; pneumatic controllers; compressors; and liquids unloading from gas wells. The white papers set out data and information available to EPA at that time on these potentially significant sources and options for reducing those emissions. EPA used the papers, along with the input received from the peer reviewers and the public, to identify emission sources for possible regulation and to obtain information on technically feasible control technologies, effectiveness and cost. The white papers, along with references and peer review comments, are available on the website indicated above in section 4.

In addition to the white paper process which helped identify sources to be addressed in this action, EPA reached out to the states to help obtain information on the state requirements and the states' experience in regulating this sector. As mentioned above, EPA reached out to BLM to help inform this action.

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that

“has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?”

As explained above, the TSD is based on both white papers that EPA has developed through a peer reviewed process, documents others have created that have been peer reviewed and databases most of which have been developed through public processes. The technical support document is developed using standard engineering analyses of publicly available information and therefore is not an influential scientific or technical work product that has precedential, novel or controversial issues.

6(d). Peer review:

See 6(b) and 6(c) above.

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Emission Standards for New and Modified Sources in the Oil and Natural Gas Sector (2060-AS30)

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?		X
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		X
Is the action an extension of an existing initiative?	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			X
Addresses areas of substantial uncertainties		X	
Involves major environmental risks		X	
Relates to emerging environmental issues	X		
Exhibits a long-term outlook		X	

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further SAB consideration.

The EPA published new source performance standards (NSPS) for the oil and natural gas sector. The proposed amendments to the NSPS are expected to reduce emissions of greenhouse gases, including methane, and volatile organic compounds (VOCs) in the oil and natural gas industry. This action proposes amendments to address remaining issues raised in the petitions and to correct technical errors that were inadvertently included in the final standards. Following publication of these final standards for the oil and natural gas sector and public comment including petitions for administrative reconsideration

of certain aspects of the standards, final amendments to address these issues were published on September 23, 2013, and on December 31, 2014, respectively.

The subject matter of the white papers and of the anticipated Technical Support Document (TSD) appears to be an evolutionary review of the status of existing technology and options for mitigation of their emissions. The proposed rule also does not appear to rely so much upon critical new scientific information and instead compiles currently available information of best engineering practices and control technologies currently employed with demonstrated success. At the same time, this rulemaking is significant in that it addresses a major industry sector that has experienced increased production in recent years, with future emission increases projected in the absence of more effective emissions controls.

EPA developed five technically detailed white papers¹⁹ that address various emissions sources, processes, and emissions mitigation options, including sources of compressors, “completions” (an industry term), leaks, liquids unloading, and pneumatic devices. As such, the Workgroup assumed these papers may be precursors to development of a TSD, which would typically address similar issues in support of a final rule. While the five white papers have not undergone SAB peer review, all five white papers have been subject to external peer review, with each paper receiving comments from four reviewers to six reviewers. The reviewers were affiliated with academia, industry, state agencies, and an NGO. Each reviewer prepared a written peer review report for each white paper that they reviewed. The white papers and peer review reports are also posted publicly on an EPA website.

The Workgroup noted that it was not clear if this was intended to be an expert peer review, a stakeholder review, or some combination of both. To the extent that stakeholders participated in the review process, their comments could represent policy-motivated positions rather than objective independent expert advice. In some cases, the same reviewer reviewed multiple white papers. It also appears that one reviewer was asked to comment on material based on that same reviewer’s previously published work. Furthermore, EPA did not describe the process in their original information provided to the Workgroup on how external reviewer comments will be addressed.

The Workgroup followed up with the EPA and asked that they provide the Agency’s response to the peer review report to assist the Work Group in understanding how the agency addressed issues raised in the white papers and literature to support the planned action. This was completed on April 1, 2015. The Work Group’s five questions and EPA’s responses are provided in Attachment B of this memorandum.

The agency’s responses provided some additional information regarding the white paper / peer review process that was conducted in partial support of this NSPS revision. A brief summary of their responses are: 1) The invited white paper peer reviewers were not selected by EPA, but were identified and evaluated by a third party contractor that was not involved in development of the oil and natural gas actions. 2) The peer review comments and other public comments on the peer review papers (which have been substantial) will be considered in preparing its final rule. 3) EPA is aware of newer or continuing studies published December 2014 (e.g., Allen et al. 2014 papers published in *Environmental Science & Technology* on liquid unloadings and pneumatic controllers), and plans to take this newer information into consideration. 4) EPA has not identified any areas where it feels that additional studies or data are needed to inform the NSPS action.

¹⁹ Available at <http://www.epa.gov/airquality/oilandgas/whitepapers.html>

The Workgroup concluded that the EPA did reply to the Workgroup's requests for additional information, though they could have provided more detail to the five questions. Nonetheless, EPA seems to have been thorough in seeking expert and public input and in compiling all available information to identify the most important emissions activities and processes and the most efficient control techniques to minimize those emissions. Thus, the value-added of any possible further SAB review is likely to be marginal. Accordingly, it is recommended that this action does not merit further SAB consideration.

Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Proposed Rulemaking for 40 CFR Part 192: Amendments to Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings
2. **RIN Number:** 2060-AP43
3. **EPA Office originating action:** Office of Air and Radiation (OAR), Office of Radiation and Indoor Air (ORIA), Radiation Protection Division
4. **Brief description of action and statement of need for the action:** Atomic Energy Act* rulemaking proposes ground water protection requirements specific to in-situ uranium recovery (ISR) facilities. ISR, which uses chemical solutions to alter ground water chemistry and liberate uranium, is now the dominant form of uranium production in the U.S., and presents a direct threat to ground water quality. The original standards, issued in 1983, were developed primarily to address conventional mills and mill tailings sites, and are not well-suited to some aspects unique to ISR facilities. The proposed rulemaking would set standards and address ground water monitoring during the pre-operational, operational, restoration, and post-restoration phases of an ISR operation. Once these requirements are finalized, NRC and NRC agreement states would develop implementing regulations addressing the standards. We have discussed and shared the proposal and SAB recommendations with NRC. The proposal is not in response to litigation.

These proposed standards were listed on the Spring 2013 Regulatory Agenda. From June 2011 – February 2012, the SAB’s Radiation Advisory Committee (RAC) reviewed the draft technical report supporting the proposed rulemaking under an Advisory, and the Agency responded generally to the SAB’s comments in 2012. The current submission follows up on the Regulatory Agenda process and provides information on the proposed standards and the approach taken in the final technical report, which incorporates revisions in response to the SAB Advisory comments presented in 2012.

*As amended by the Uranium Mill Tailings Radiation Control Act of 1978

- Link to prepublication version of the proposed rulemaking:
<http://www.epa.gov/radiation/docs/tenorm/proposal-40cfr192-12-31-2014.pdf>
- Link to supporting documents (including the revised technical report):
<http://www.epa.gov/radiation/tenorm/40CFR192.html>

5. Timetable:

January 2015	Publication of Proposal in FR
April 2015	End of comment period (90 days after publication)

6. Scientific products that will inform the action and plans for peer review:

6(a). Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.

Issues addressed by the summer 2011 SAB advisory (see web links below) included establishing baseline ground water characteristics, elements of an appropriate monitoring system, appropriate statistical techniques, approaches for post-restoration ground water monitoring, and determination of long-term stability. EPA's proposal and technical background documents incorporate SAB/RAC advice on these issues. See links above for proposal and background documents, as well as:

- Link to Science Advisory Board Recommendations:
[http://yosemite.epa.gov/sab/sabproduct.nsf/964968D9229863A0852579A7006EC71A/\\$File/EPA-SAB-12-005-unsigned.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/964968D9229863A0852579A7006EC71A/$File/EPA-SAB-12-005-unsigned.pdf)
- Link to Agency Response to Science Advisory Board Recommendations (PDF) (9 pp,766 KB) June 2012.
[http://yosemite.epa.gov/sab/sabproduct.nsf/964968D9229863A0852579A7006EC71A/\\$File/EPA-SAB-12-005_Response_06-12-2012.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/964968D9229863A0852579A7006EC71A/$File/EPA-SAB-12-005_Response_06-12-2012.pdf)

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

The Agency is proposing ground water monitoring requirements for in-situ uranium recovery activities that involve geochemical processes. The SAB conducted an advisory of the key technical issues associated with this action in July 2011, and finalized a report of recommendations in February 2012. The Agency responded to the SAB findings and recommendations in the June 12, 2012 letter identified above. The proposed rule and technical documentation incorporate the SAB's recommendations (see the web links above).

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

There are no work products that meet the definition of EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or that the Agency has a legal and/or statutory obligation to conduct a peer review.

6(d). Peer review:

The draft technical report that was the basis of the SAB Advisory was revised to address SAB's recommendations from the Advisory and was peer reviewed separately using the Agency's peer review process. The revised technical document supports the proposed rulemaking and is in the

docket as the document “Considerations related to Post Closure Monitoring of Uranium in-site Leach/In-situ Recovery (ISL/ISR) Sites” (see web link above) prepared for the rule.

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Proposed Rulemaking for 40 CFR Part 192: Amendments to Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings (2060-AP43)

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?	X	
Is the action primarily administrative (i.e., involve reporting or record keeping)?		X
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		X
Is the action an extension of an existing initiative?	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency		X	
Addresses areas of substantial uncertainties		X	
Involves major environmental risks	X		
Relates to emerging environmental issues		X	
Exhibits a long-term outlook	X		

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further SAB consideration. However, the Work Group found that the information provided by the agency could have more clearly explained how the agency’s use of models adequately addressed the complex scientific and technical basis for the varying site conditions considered in the proposed rule.

This planned action (2060-AP43) was considered in the [review of the Spring 2013 Regulatory Agenda](#)²⁰. At that time the SAB deferred review because information provided by the agency was insufficient to evaluate the scientific and technical basis for this planned action. The SAB's Radiation Advisory Committee (RAC) had reviewed the draft technical report supporting the proposed rulemaking under an Advisory and the agency briefly responded to the SAB's comments in 2012 (see more details below). During the current review, the Work Group noted the helpfulness of information provided to the Work Group that cross referenced the SAB 2012 recommendations to specific sections specific actions made by the EPA in the Background Information Document (BID) and Preamble that support the proposed planned action. Thus the Work Group concluded that EPA did consider a large number of SAB recommendations in support of the planned action. However it was not clear to the Work Group if the current modeling techniques were adequate (e.g., validated science-based techniques that address the varying conditions at the site) to support the technical basis for proposed rule.

The Uranium Mill Tailings Radiation Control Act of 1978 and standards issued in 1983 were developed to address conventional uranium mills and mill tailings sites rather than in-situ uranium recovery (ISR) facilities. However, ISR is now the primary uranium production method in the U.S. and presents a greater threat to ground water quality than conventional methods. In February 2012, the SAB's Radiation Advisory Committee (RAC) reviewed the draft technical report supporting the proposed rulemaking under an Advisory ([Advisory on EPA's draft Technical Report entitled Considerations Related to Post Closure Monitoring of Uranium In-Situ Leach/In-Situ Recovery \(ISL/ISR\) Sites EPA-SAB-12-2005](#))²¹, and the Agency briefly responded to the SAB's comments in 2012. In that advice the SAB recommended that the EPA expand greatly on the draft technical report "so that it is protective and realistic in guiding the monitoring program and evaluating its results" and provided specific recommendations.

The Work Group followed up with the EPA and asked that they provide the Agency's response to the advisory report to assist the SAB Work Group to understand how the agency evaluated, addressed, and incorporated the advice provided in the 2012 review of the technical report to develop the science supporting the Amendments to Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings (40 CFR Part 192). This was completed on April 1, 2015. The Work Group's question and EPA's response are provided in Attachment B of this memorandum.

The Work Group first concluded that, importantly, the cross references provided by the EPA that linked the 2012 SAB Recommendations to specific sections of the Background Information Document (BID) and Preamble were informative, helpful, and demonstrated that SAB recommendations were being incorporated into the planned action. The Work Group also concluded that the SAB advise on the topic of using statistical analyses to compare pre- and post-ISR conditions was considered by the EPA and the approach appears to be defensible. However, the 2012 SAB Recommendations had included the following section on the benefits of a validated model (Section 3.7.4).

"As noted above, the draft technical report should describe in detail the needed efforts, recognizing that the regulator can provide licensing conditions and guidance for operating a specific mine. The SAB views modeling as a tool to assist in the design of remediation and monitoring strategies. For example, a reliable model may help identify the areas at risk and in need of monitoring at baseline and after restoration attempts, and in interpreting monitoring results. Modeling can assist in developing a good

²⁰ <http://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/de4689350a3fe32885257c22005f5828!OpenDocument>

²¹ [http://yosemite.epa.gov/sab/sabproduct.nsf/964968D9229863A0852579A7006EC71A/\\$File/EPA-SAB-12-005-unsigned.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/964968D9229863A0852579A7006EC71A/$File/EPA-SAB-12-005-unsigned.pdf)

monitoring design, but cannot make up for poor design. Modeling also can help to inform and formulate the sampling requirements to be included in the regulation, such as consideration of seasonal effects. A validated model might also provide a sufficient technical basis for reducing the level of characterization needed for a particular site.”

“Because geochemical, biological and physical conditions are highly variable among ISL uranium mines, a corollary activity is to use the existing data to identify fundamental transferable concepts among the sites.”

Because there is much (appropriate) research needed regarding modeling, it was not clear to the Work Group from the information provided if the current modeling techniques were adequate (e.g., validated science-based techniques that address the varying conditions at the site) to support the technical basis for proposed rule. The Work Group found that the agency addressed the SAB recommendations and incorporated most of the recommendations into the planned action. Accordingly, the Work Group recommended this action did not merit further SAB consideration even though it was not clear if the current modeling techniques were adequate (e.g., validated science-based techniques that address the varying conditions at the site) to support the technical basis for proposed rule.

Description of Planned EPA Tier 1 or Tier 2 Action

1. Name of action: Major Source Determination for Oil and Gas Extraction Facilities

2. RIN Number: 2060-AS06

3. EPA Office originating action: Office of Air and Radiation (OAR)

4. Brief description of action and statement of need for the action:

The EPA is proposing to clarify the definition used to determine the source to be permitted with the Prevention of Significant Deterioration (PSD), Non-attainment New Source Review (NNSR) and title V permitting programs as it applies to oil and gas extraction facilities.

This rulemaking is needed to assist permitting authorities and permit applicants in making major stationary source determinations for the oil and gas extraction facilities. The lack of clarity regarding these source determination definitions has resulted in uncertainty for the regulated community and for permitting authorities, including the EPA's regions. In addition, clear guidance is needed to respond to litigation that has resulted from decisions made under the EPA's existing regulations and policies.

For the purposes of PSD, NNSR, and title V permitting, a stationary source is defined based on 3 criteria – under common control, located on contiguous or adjacent properties, and belong to the same major Standard Industrial Classification (SIC) code. This rule will clarify these terms for the oil and gas extraction facilities.

5. Timetable:

Current timetable is to propose a rule in Summer 2015.

6. Scientific products that will inform the action and plans for peer review:

6(a). Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.

None: As described above, no scientific products developed for this policy determination)

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

NA

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

NA

6(d). Peer review:

NA

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Major Source Determination for Oil and Gas Extraction Facilities (2060-AS06)

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?	X	
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		X
Is the action an extension of an existing initiative?	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			X
Addresses areas of substantial uncertainties			X
Involves major environmental risks			X
Relates to emerging environmental issues			X
Exhibits a long-term outlook			X

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further SAB consideration.

EPA proposes to clarify definitions of what source categories are subject to Prevention of Significant Deterioration (PSD), Non-attainment New Source Review (NNSR) and title V permitting programs. This planned action is administrative in nature and does not involve scientific work products. Thus, it does not merit further attention by the SAB at this time.

Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Revisions to 40 CFR Part 2, Subpart b (Confidentiality of Business Information)
2. **RIN Number:** RIN: 2025-AA39
3. **EPA Office originating action:** Office of Environmental Information, Office of Information Collection
4. **Brief description of action and statement of need for the action:** The U.S. Environmental Protection Agency (EPA) is proposing to amend its confidential business information (CBI) regulations under 40 C.F.R. Part 2, Subpart B, Confidentiality of Business Information. Specifically, the EPA intends to amend the existing CBI regulations to update the regulations to comply with case law requirements; consolidate procedures for identifying, handling, and processing CBI; and correspond with other federal agencies' CBI regulations. In amending the CBI regulations, the EPA expects the amendments will improve the processing of information requests for CBI, while ensuring the appropriate protection of CBI and reducing the burden on both the EPA and the regulated community.

While this action has legal considerations, there are no expected scientific consideration which warrant SAB review.

5. **Timetable:** 5/15/16 Signature
6. **Scientific products that will inform the action and plans for peer review:**
 - 6(a). **Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.**

OEI does not expect this rule will not rely on science or technical work products but on legal precedent and parameters.
 - 6(b). **For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).**

N/A
 - 6(c). **For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"**

OEI does not expect this rule will not rely on science or technical work products but on legal precedent and parameters and will not warrant peer review
 - 6(d). **Peer review:**

Peer reviewed is not believed to be warranted for this rulemaking.

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Revisions to 40 CFR Part 2, Subpart b (Confidentiality of Business Information) (2025-AA39)

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?	X	
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		X
Is the action an extension of an existing initiative?	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			X
Addresses areas of substantial uncertainties			X
Involves major environmental risks			X
Relates to emerging environmental issues			X
Exhibits a long-term outlook			X

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further SAB consideration.

The EPA is proposing to amend its confidential business information regulations under 40 C.F.R. Part 2, Subpart B, Confidentiality of Business Information. The EPA intends to amend the existing confidential business information regulations to update the regulations to comply with case law requirements; consolidate procedures for identifying, handling, and processing confidential business information; and correspond with other federal agencies' confidential business information regulations.