Note to State/Local/Tribal Agency Reviewers
May 2, 2011

Overview of Draft Guidance Documents on the Implementation of the Exceptional Events Rule

This overview document and its attachments[1] clarify key provisions of the 2007 Exceptional Events Rule (EER) to respond to questions and issues that have arisen since the rule was promulgated. The draft guidance in this document and the attachments, along with examples of approved demonstrations on EPA's website[2], are provided to facilitate review of these materials by outside parties, to help ensure that EPA's final guidance provides an efficient and effective process to make determinations regarding air quality data affected by events. Please direct comments on these draft guidance documents to EEGuidanceComments@epa.gov by June 30, 2011. For guidance-related questions, please contact Beth Palma at 919-541-5432.

These draft guidance materials identify the four independent criteria on which exclusion of event-affected data depends, describe the administrative process and associated timing for submittal and review of demonstrations, provide answers to frequently asked questions, and provide previously reviewed demonstrations and best practice components. EPA recognizes the challenges that states face in preparing exceptional event demonstration packages. Exceptional events are varied with differing characteristics and must be addressed on a case-by-case basis making the development of general guidance with bright lines difficult. Neither states[3] nor regions want to prepare or review numerous versions of a single event demonstration package.

This draft guidance overview document and its attachments are based on the following principles:

1. States should not be held accountable for exceedances due to events that were beyond their control at the time of the event.
2. It is desirable to implement reasonable controls to protect public health.[4]
3. Clear expectations will enable EPA and other air agencies to better manage resources related to the exceptional events process.

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[1] Attachment 1, "Draft Exceptional Events Rule Frequently Asked Questions" (the draft Q&A document) and Attachment 2, "Draft Guidance on the Preparation of Demonstrations in Support of Requests to Exclude Ambient Air Quality Data Affected by High Winds under the Exceptional Events Rule" (the draft High Winds Guidance document).

[2] Additional information and examples of exceptional event submissions and best practice components can be found at EPA's Exceptional Events website locate at http://www.epa.gov/ttn/analysis/exevents.htm.

[3] This and all subsequent references to "state" are meant to include state, local and tribal agencies responsible for implementing the EER.

[4] With respect to exceptional events, Section 319 of the Clean Air Act states the following guiding principles (among others);

(i) the principle that protection of public health is the highest priority

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(iv) the principle that each State must take necessary measures to safeguard public health regardless of the source of the air pollution

Exceptional Event Rule Provisions

On March 22, 2007, EPA promulgated the "Treatment of Data Influenced by Exceptional Events; Final Rule" (72 FR at 13560) pursuant to the 2005 amendment of Clean Air Act (CAA) Section 319. This rule, known as the Exceptional Events Rule, superseded EPA's previous natural events guidance and interim fire policy documents.[5] The EER created a regulatory process codified at 40 CFR parts 50 and 51 (50.1, 50.14 and 51.930). These regulatory sections contain definitions, procedural requirements, requirements for state demonstrations, and criteria for EPA approval for the exclusion of air quality data from regulatory decisions under the EER.

The definition of an exceptional event at 40 CFR §50.1(j) repeats the CAA definition which provides that an exceptional event is one that affects air quality, is not reasonably controllable or preventable, and is caused by human activity that is unlikely to recur at a particular location or a natural event. Additional requirements in 40 CFR §50.14(a)(2) and (b)(1) identify that a state must demonstrate "a clear causal relationship between the measured exceedance or violation of such standard and the event" and that "an exceptional event caused a specific air pollution concentration in excess of one or more national ambient air quality standards." The rule further requires at 40 CFR §50.14(c)(3)(iv) that the demonstration to justify data exclusion shall provide evidence that the event is associated with a measured concentration in excess of normal historical fluctuations, including background, and evidence that there would have been no exceedance or violation but for the event.

Treatment of Technical Criteria for Exclusion of Data Affected by Events

When considered together, the EER provisions summarized above identify the following six elements that states must address when requesting that EPA exclude event-related concentrations from regulatory determinations:

- the event affected air quality
- the event was not reasonably controllable or preventable
- the event was caused by human activity that is unlikely to recur at a particular location, or was a natural event
- there exists a clear causal relationship between the specific event and the monitored concentration
- the event is associated with a measured concentration in excess of normal historical fluctuations including background

[5]Previous guidance and policy documents that either implied or documented the need for identifying data affected by an exceptional event include:
i) "Guideline for Interpretation of Air Quality Standards," U.S. EPA, OAQPS No. 1.2-008, Revised February 1977.
ii) "Guideline On the Identification and Use of Air Quality Data Affected by Exceptional Events" (the Exceptional Events Policy), U.S. EPA, OAQPS, July 1986.
iii) "Areas Affected by PM10 Natural Events" (the PM10 Natural Events Policy), memorandum from Mary D. Nichols, Assistant Administrator for Air and Radiation, to EPA Regional Offices, May 30, 1996.
iv) "The Interim Air Quality Policy on Wildland and Prescribed Fires" (the Interim Fire Policy), memorandum from Richard D. Wilson, Acting Assistant Administrator for Air and Radiation, to EPA Regional Administrators, May 15, 1998.
v) "Guideline on Data Handling Conventions for the PM NAAQS," U.S. EPA, OAQPS, EPA-454/R-98-017, December 1998.

- there would have been no exceedance or violation but for the event

In reviewing exceptional events demonstration packages, EPA has found that the following EER elements, along with historical fluctuations, play a significant role in the states' supporting documentation:

1. not reasonably controllable or preventable
2. if the event was caused by human activity, that human activity is unlikely to recur at a particular location[6]
3. clear causal relationship between specific event and monitored concentration
4. no exceedance or violation but for the event[7]

As described in the draft guidance documents, EPA's technical review of a demonstration package would therefore focus on these elements. While the EER requires and EPA expects complete demonstration packages to contain narrative and evidence supporting all six elements, EPA's position would be that these four elements represent distinct facts that states must demonstrate for EPA to concur on an event claim.[8] Note that if an event is natural then the second element is not considered in a demonstration review. In the case of an event that is initiated by a natural process, such as a volcano or high wind dust event, the event would be considered a natural event if sources are entirely natural or contributing anthropogenic sources are reasonably controlled.[9] This concept is explained in more detail in Attachment 2, the draft High Winds Guidance document.

EPA recognizes the inherent links between all six elements and expects that some sections of a demonstration package (e.g., affects air quality, natural event) may repeat or refer to other sections of the demonstration package (e.g., clear causal relationship, but for). Further, each potential event can have varied and differing characteristics, and thus would usually require a case-specific demonstration and evaluation. Therefore, the EPA would use a "weight of evidence" approach in evaluating each element within an exceptional event demonstration package.

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[6] The remaining part of this criterion, "or a natural event" is intentionally omitted here.

[7] Criteria 1, 3, and 4 on this list, along with historical fluctuations, are considered "independent elements" in the draft High Winds Guidance document.

[8] While the "historical fluctuations element" is considered an independent element, it also plays an important role in the "clear causal relationship" and "no exceedance but for" demonstrations. EPA has not set pass/fail criteria for this element but will use a weight of evidence approach to assess each demonstration on a case-by-case basis. The state's role in satisfying this element is to provide analyses and statistics comparing the event-affected concentration to normal historical fluctuations. EPA will use the information provided by the state to determine whether the event was in excess of normal historical fluctuations. "Normal historical fluctuations" will generally be defined by those days without events for the previous years. It is not the state's role to show that the event was above a particular threshold since EPA is not establishing a threshold. EPA acknowledges that natural events can recur and still be eligible for exclusion under the EER; therefore, events do not necessarily have to be rare to satisfy this element. EPA expects that failure of the "historical fluctuations" element indicates likely failure for "clear causal relationship" and/or "no exceedance but for" as well, and thus does not expect that demonstration submittal non-concurrence will result from failure of this element alone.

[9] Human activity would be considered to have played little or no *direct* causal role in causing the entrainment of the dust by high wind if contributing anthropogenic sources of dust are reasonably controlled, and thus the event would be considered a natural event. If anthropogenic sources contributed significantly to a measured concentration and these same emissions from anthropogenic sources are affected by an event and are reasonably controllable but did not have those reasonable controls applied at the time of the event, then the event would not be considered a natural event.

In the draft guidance documents, the requirement that the event was not reasonably controllable or preventable, which is part of the definition of an exceptional event in both the Clean Air Act and the EER, would mean that if a set of control measures *could reasonably have been in place* for contributing sources at the time of the event, then they *must* have been in place for the event to qualify as an exceptional event under the EER. Among other factors to consider, reasonableness would need to be judged in light of the technical information available to the state at the time the event occurred. EPA would expect for nonattainment areas to already have the technical information needed to reasonably control sources in their jurisdiction. It would be important that each demonstration package address the question of reasonable controls. As with the other elements, whether an event was not reasonably controllable or preventable would be evaluated on a case-by-case basis. In general, reasonable controls would not include any control on emissions-generating activity outside of the state or tribal boundaries of the state (or tribal lands) within which the concentration at issue was monitored.

Timing of EER Demonstration Package Submittal and Review

EPA understands that the initial identification of data affected by exceptional events and the subsequent preparation, submittal, and review of demonstration packages is a resource intensive process. Delays in processing and making decisions on submitted packages increase the workload for both the submitting agency and EPA and create regulatory uncertainty. In addition, the backlog of pending actions makes retrieval of data to support new submittals potentially more difficult. Further, states and EPA often face timelines by which they must make regulatory decisions that can be affected by the inclusion or exclusion of event-affected data.

EPA will work with states as they prepare complete demonstration packages that meet the requirements of the EER. In an effort to streamline this identification, preparation, submittal, and review process, EPA has developed the following draft guidelines.

1. **Identification of data affected by exceptional events in AQS** – Although states may flag any data in AQS that they wish to flag, EPA encourages states to flag only data that might have a regulatory consequence and for which an approvable demonstration is likely. Should states wish to flag values for informational purposes, EPA prefers that they use the AQS flags intended for this purpose.

2. **State submittal of letter of intent to submit a package *(optional)*** – EPA recommends that states intending to submit a demonstration package for flagged data in AQS alert EPA of their intention within 12 months of the event occurrence. This action will prompt EPA to notify the state whether and when EPA plans to act on the claimed exceptional event. This initial notification can assist both the state and EPA in the planning and prioritization process.

3. **EPA response to state letter of intent** – EPA anticipates responding to the state's letter of intent within 60 days of receipt informing the state of EPA's intended review timeframe if needed for regulatory action.

4. **State submittal of exceptional event demonstration packages** – EPA encourages states to submit the optional letter of intent. States choosing not to follow this more formal planning recommendation are still encouraged to contact their EPA Regional Office to alert it of the forthcoming demonstration submittal. Submitting agencies that believe their demonstration packages are tied to near-term regulatory actions should submit their demonstration packages well in advance of the regulatory deadline. States should also identify the relationship between the exceptional event-related flagged data and the anticipated regulatory action in the cover letter that accompanies their initial submittal package to the reviewing EPA Regional Office.

5. **EPA prioritization of submitted demonstration packages** – EPA will generally give priority to exceptional event determinations that may affect near-term regulatory decisions, such as SIP submittal actions, National Ambient Air Quality Standards (NAAQS) designations, and clean data findings, and may defer review of demonstration packages that are not associated with near-term regulatory decisions.

6. **EPA review of prioritized demonstration packages** – EPA generally intends to conduct its initial review of a submitted exceptional event demonstration package within 120 days of receipt. During this time, EPA will generally determine whether to review the package in the near-term or to defer review. For those packages that are reviewed in the near-term, EPA will generally also assess completeness. Following this initial review, EPA will generally send a letter to the submitting agency that includes the status of review. For those packages that EPA will review in the near-term, EPA will generally include the following: a completeness determination and/or a request for additional information, a deadline by which the supplemental information should be submitted (if applicable), and an indicator of the timing of EPA's final review.[10] EPA encourages states to provide supplemental information if needed and requested by EPA. EPA anticipates a 60-day response time for states to provide additional requested information. EPA intends to make a decision regarding event concurrence within 18 months of submittal of a complete package, or sooner if required by a near-term regulatory action. Determinations on Exceptional Event demonstrations do not constitute final agency action until they are relied upon in a regulatory decision such as a finding of attainment or nonattainment which will be conducted through notice-and-comment rulemaking procedures. EPA does not generally intend to consider additional information after the concurrence decision has been made, except in the context of such a rulemaking procedure.

[10] If an agency did not send a letter of intent to submit a demonstration package, then EPA may respond to the agency with a letter indicating that EPA intends to defer review for the near-term. In this case, EPA will generally not address completeness of the package or timing of final review.

Exceptional Events Rule Frequently Asked Questions Document (Attachment 1)

The "Draft Exceptional Events Rule Frequently Asked Questions" document (the draft Q&A document) provides draft responses to questions that have arisen since the EER was promulgated. The questions are grouped into six broad areas. EPA encourages those involved in flagging data and preparing demonstration packages to review all the draft questions and answers, and to provide input regarding their usefulness and appropriateness and regarding additional questions which need answers. The following bullets identify key points of interest in the draft Q&A document:

- A natural event would not have to be infrequent to qualify as an exceptional event under the EER. Frequent events with natural triggers that have a contribution from anthropogenic activities that are reasonably controlled could be eligible "exceptional" events, provided the events meet the demonstration requirements for the technical criteria.

- The EER does not prohibit states from flagging individual concentration values below the level of the NAAQS. However, in general, only such data that contribute to a violation of the NAAQS are excludable. Questions 29-31 of the attached Q&A document describe the few, limited situations in which concentration values below the level of the NAAQS contribute to violations of the NAAQS.

- Whether an event is associated with a measured concentration "in excess of normal historical fluctuations" would be evaluated on a weight of evidence basis. The comparison of the measured concentration to normal historical concentrations would also influence how much information is needed to successfully meet other technical elements. For example, when the observed concentration is high compared to historical concentrations, EPA may require less additional evidence to demonstrate the "but for" finding. The draft Q&A document provides recommendations for showing how the observed concentration compares to the distribution of historical concentrations.

- Question 6 in the draft Q&A document describes types of evidence that could be submitted as part of a demonstration showing that an ozone exceedance would not have occurred but for the effect of a fire event. In particular, statistical or photochemical dispersion model predictions of the ozone concentration that would have occurred in the absence of the fire would be a relevant type of evidence, provided the demonstration package is transparent about the technical basis for the model and its uncertainties.

- When the available evidence indicates that there would have been an exceedance of a NAAQS even in the absence of the event, the event is not "exceptional" under the EER because the "no exceedance but for" criterion is not satisfied. Yet, this event-related concentration could still affect the design value for an area. If the event-affected design value is used for an ozone nonattainment area at the time of classification under Subpart 2 of Part D of Title I of the CAA, then it may seem that the area should be classified into a higher category (e.g., serious instead of moderate). Similarly, a state incorporating the event-related concentration in a design value used for an attainment demonstration might seem to need more emission reductions to attain the NAAQS than is actually the case.

Under the draft guidance, states faced with either of these situations could document any analysis of the event and justify any special approach to the treatment of such concentration data as part of their attainment demonstration or area classification. (See Question13 of the Q&A document for additional information.)

- To remove any possible confusion, the passages of the preamble that were declared to be a legal nullity by the court that reviewed the EER are specifically identified in Question 20 in the draft Q&A document. While states cannot rely solely on these passages as EPA guidance on interpretation of the EER, this draft guidance overview document and its attachments are consistent with those sections.

High Winds Guidance Document (Attachment 2)

The attached "Draft Guidance on the Preparation of Demonstrations in Support of Requests to Exclude Ambient Air Quality Data Affected by High Winds under the Exceptional Events Rule" (the High Winds Guidance document) when finalized will be a resource for states when flagging data and preparing demonstrations packages for high wind dust events that have affected PM_{10} and $PM_{2.5}$. The draft document applies the provisions of the EER and the general guidance conveyed in this draft guidance overview document and in the draft Q&A document to the particular situation of a high wind dust event. While the document is specific to high wind dust events, it outlines how EPA intends to implement the preparation and review process for exceptional events and, therefore, may have relevance for agencies that do not deal with high wind dust events. The following are some of the highlights of the draft High Winds Guidance document:

- In nonattainment areas, a reference point for considering what constitutes reasonable control of wind-blown dust during high wind events would be the set of measures that are identified as RACM or BACM in the approved SIPs of other areas with similar wind-blown dust conditions, depending on area classification. USDA best management practices for soil conservation would also be considered if applicable to the dust source. Also, RACM or BACM measures in an area's own approved SIP should be considered part of the reasonable set. However, the assessment of whether an event was not reasonably controllable will be made on a case-by-case basis considering all the facts.

- Reasonable controls generally would not include efforts to control wind-blown dust from undisturbed natural landscapes or previously disturbed landscapes that are being allowed to return to natural conditions.

- For purposes of qualifying for the exclusion of data affected by initial (non-recurring) wind events with sustained wind speeds above 25 miles per hour (or above another threshold determined to be appropriate for a particular area), the implementation of reasonable controls applied to disturbed landscapes and other anthropogenic sources of dust could be less important because: (1) the contribution from undisturbed lands is likely to be high and, (2) at such high wind speeds many available controls may have been ineffective in significantly reducing wind-generated dust emissions.

- EPA would encourage states to work with EPA Regional Offices to develop prospective high wind action plans, which need not be incorporated into the SIP, as a way to develop a mutual understanding of what controls are reasonable to implement in light of foreseeable high wind conditions.

On-line Availability of Exceptional Event Packages and Best Practice Components

To assist states in deciding what type and how much evidence/technical analysis to include in their demonstration packages, EPA has developed a public website at http://www.epa.gov/ttn/analysis/exevents.htm that contains demonstration packages that have been approved by EPA and links to best-practice components. This website will evolve as additional demonstration packages are submitted and reviewed.

Draft Guidance Documents Still under Development

EPA is currently developing a separate draft guidance document addressing the preparation of demonstrations to support wildfire-related event claims, including events that may have affected ozone concentrations. We are also developing a draft document that when finalized would replace the Interim Fire Policy, that will contain additional guidance on basic smoke management practices for prescribed fires. We expect to provide opportunities for stakeholder input on these draft documents.

Conclusion

EPA expects to adhere to the draft guidance provided in this overview document and its attachments during the review and document finalization process, because we believe it is consistent with the Exceptional Events rule and the guidance already provided in the preamble to the rule. Although EPA hopes to formalize the concepts in these guidance documents by issuing final guidance, EPA has not excluded the possibility of issuing rule revisions.

EPA's Office of Air Quality Planning and Standards and EPA's Regional Offices are available for assistance and consultation. Questions and comments on this guidance may be directed to EEGuidanceComments@epa.gov.

Attachments:

1. Draft Exceptional Events Rule Frequently Asked Questions

2. Draft Guidance on the Preparation of Demonstrations in Support of Requests to Exclude Ambient Air Quality Data Affected by High Winds under the Exceptional Events Rule