ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2015–0730; FRL–9969–08–OAR]

RIN 2060–AS93

National Emission Standards for Hazardous Air Pollutants: Nutritional Yeast Manufacturing Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action finalizes the residual risk and technology review (RTR) conducted for the Manufacturing of Nutritional Yeast source category regulated under national emission standards for hazardous air pollutants (NESHAP). In addition, we are finalizing other amendments, including revisions to the form of the volatile organic compounds (VOC) standards for fermenters, removal of the option to monitor brew ethanol, inclusion of ongoing relative accuracy test audit (RATA), and revisions to other monitoring, reporting, and recordkeeping requirements.

DATES: This final rule is effective on October 16, 2017. The incorporation by reference of certain publications listed in the rule is approved by the Director of the **Federal Register** as of October 16, 2017.

ADDRESSES: The Environmental Protection Agency (EPA) has established a docket for this action under Docket ID No. EPA–HQ–OAR–2015–0730. All documents in the docket are listed on the *https://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *https://www.regulations.gov,* or in hard copy at the EPA Docket Center, EPA WJC West Building, Room Number 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Standard Time, Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Allison Costa, Sector Policies and Programs Division (Mail Code E143–03), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–1322; fax number: (919) 541–0516; and email address: *costa.allison@epa.gov.* For specific information regarding the risk modeling methodology, contact Chris Sarsony, Health and Environmental Impacts Division (C539–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–4843; and email address: *sarsony.chris@epa.gov.* For information about the applicability of the NESHAP to a particular entity, contact John Cox, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, EPA WJC South Building (Mail Code 2227A), 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (919) 564–1395; and email address: *cox.john@epa.gov.*

SUPPLEMENTARY INFORMATION:

Preamble acronyms and abbreviations. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

BAE Batch-average concentration of brew ethanol in fermenter liquid
BAVOC Batch-average concentration of volatile organic compounds in fermenter exhaust
CAA Clean Air Act
CDX Central Data Exchange
CEDRI Compliance and Emissions Data Reporting Interface
CEMS Continuous emission monitoring system
CFR Code of Federal Regulations
CPMS Continuous parameter monitoring system
CRA Congressional Review Act
EPA Environmental Protection Agency
ERT Electronic Reporting Tool
FID Flame ionization detector
GC Gas chromatograph
HAP Hazardous air pollutant(s)
HQ Hazard quotient
ICR Information Collection Request
MACT Maximum achievable control technology
NEI National Emissions Inventory
NESHAP National emission standards for hazardous air pollutants
NTTAA National Technology Transfer and Advancement Act
OMB Office of Management and Budget
ppmv Parts per million by volume
PRA Paperwork Reduction Act
RATA Relative accuracy test audit
REL Recommended exposure limit
RFA Regulatory Flexibility Act
RfC Reference concentration
RIN Regulatory Information Number
RTO Regenerative thermal oxidizer
RTR Risk and technology review
SSM Startup, shutdown, and malfunction
THC Total hydrocarbons
TOSHI Target organ-specific hazard index
UMRA Unfunded Mandates Reform Act
URE Unit risk estimate
VOC Volatile organic compound

Background information. On December 28, 2016, the EPA issued a proposed rulemaking presenting the results of the RTR of the Manufacturing of Nutritional Yeast NESHAP, as well as proposing additional revisions to the NESHAP. In this action, we are finalizing decisions and revisions for the rule. We summarize some of the more significant comments we received regarding the proposed rule and provide our responses in this preamble. A summary of all other public comments on the proposal and the EPA's responses to those comments is available in the document titled, ''Nutritional Yeast Manufacturing Risk and Technology Review: Summary of Public Comments and Responses,'' which is in the docket for this action (Docket ID No. EPA–HQ–OAR–2015–0730). A ''track changes'' version of the regulatory language that incorporates the changes in this action is also available in the docket.

Organization of this document. The information in this preamble is organized as follows:

I. General Information

A. Does this action apply to me?

Regulated entities. Categories and entities potentially regulated by this action are shown in Table 1 of this preamble.

TABLE 1—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS FINAL ACTION

NESHAP and Source Category	NAICS [1] Code
Manufacturing of Nutritional Yeast	311999

[1] North American Industry Classification System.

Table 1 of this preamble is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by the final action for the source category listed. To determine whether your facility is affected, you should examine the applicability criteria in the final Manufacturing of Nutritional Yeast NESHAP (40 CFR part 63, subpart CCCC). If you have any questions regarding the applicability of any aspect of this NESHAP, which we refer to as ''subpart CCCC'' in this preamble, please contact the appropriate person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this preamble.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this final action will also be available on the Internet. Following signature by the EPA Administrator, the EPA will post a copy of this final action at: *https://www.epa.gov/stationary-sources-air-pollution/manufacturing-nutritional-yeast-national-emission-standards.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version and key technical documents at this same Web site.

Additional information is available on the RTR Web site at *https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html.* This information includes an overview of the RTR program, links to project Web sites for the RTR source categories, and detailed emissions and other data we used as inputs to the risk assessments.

C. Judicial Review and Administrative Reconsideration

Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia by December 15, 2017. Under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. This section also provides a mechanism for the EPA to reconsider the rule if the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, EPA WJC South Building, 1200 Pennsylvania Ave. NW., Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

II. Background

A. What is the statutory authority for this action?

Section 112 of the CAA establishes a two-stage regulatory process to address emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, we must identify categories of sources emitting one or more of the HAP listed in CAA section 112(b) and then promulgate technology-based NESHAP for those sources. ''Major sources'' are those that emit, or have the potential to emit, any single HAP at a rate of 10 tons per year (tpy) or more, or 25 tpy or more of any combination of HAP. For major sources, these standards are commonly referred to as maximum achievable control technology (MACT) standards and must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). In developing MACT standards, CAA section 112(d)(2) directs the EPA to consider the application of measures, processes, methods, systems, or techniques, including but not limited to those that reduce the volume of or eliminate HAP emissions through process changes, substitution of materials, or other modifications; enclose systems or processes to eliminate emissions; collect, capture, or

treat HAP when released from a process, stack, storage, or fugitive emissions point; are design, equipment, work practice, or operational standards; or any combination of the above.

For these MACT standards, the statute specifies certain minimum stringency requirements, which are referred to as MACT floor requirements, and which may not be based on cost considerations. See CAA section 112(d)(3). For new sources, the MACT floor cannot be less stringent than the emission control achieved in practice by the best-controlled similar source. The MACT standards for existing sources can be less stringent than floors for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources). In developing MACT standards, we must also consider control options that are more stringent than the floor under CAA section 112(d)(2). We may establish standards more stringent than the floor, based on the consideration of the cost of achieving the emissions reductions, any non-air quality health and environmental impacts, and energy requirements.

In the second stage of the regulatory process, the CAA requires the EPA to undertake two different analyses, which we refer to as the technology review and the residual risk review. Under the technology review, we must review the technology-based standards and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less frequently than every 8 years, pursuant to CAA section 112(d)(6). Under the residual risk review, we must evaluate the risk to public health remaining after application of the technology-based standards and revise the standards, if necessary, to provide an ample margin of safety to protect public health or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. The residual risk review is required within 8 years after promulgation of the technology-based standards, pursuant to CAA section 112(f). In conducting the residual risk review, if the EPA determines that the current standards provide an ample margin of safety to protect public health, it is not necessary to revise the MACT standards pursuant to CAA section 112(f).[1] For more information on the statutory authority for this rule, see the proposal published on December 28, 2016 (81 FR 95810).

B. What is the Manufacturing of Nutritional Yeast source category and how does the NESHAP regulate HAP emissions from this source category?

The EPA promulgated the Manufacturing of Nutritional Yeast NESHAP on May 21, 2001 (66 FR 27876). The standards are codified at 40 CFR part 63, subpart CCCC. The manufacturing of nutritional yeast industry consists of facilities that manufacture yeast for the purpose of becoming an ingredient in dough for bread or any other yeast-raised baked product, or for becoming a nutritional food additive intended for consumption by humans. Facilities that manufacture nutritional yeast intended for consumption by animals, such as an additive for livestock feed, are not included in the description of sources covered by this subpart in 40 CFR 63.2131. In addition, subpart CCCC clarifies that fermenters are not subject to emission limitations during the production of specialty yeast (*e.g.,* yeast for use in wine, champagne, whiskey, or beer) in 40 CFR 63.2132. The source category was originally defined as Baker's Yeast Manufacturing in 1992, but was renamed Manufacturing of Nutritional Yeast in 1998 to clarify the scope of the source category. See the preamble for the proposed rule for additional background (81 FR 95814, December 28, 2016). The source category covered by subpart CCCC currently includes four facilities.

The affected sources at nutritional yeast manufacturing facilities are the collection of equipment used to manufacture Saccharomyces cerevisiae yeast, including fermenters. The subpart CCCC emission limitations apply to the final three stages of the fermentation process, which are often referred to as stock (third-to-last stage), first generation (second-to-last stage), and trade (last stage) fermentation.

Currently, the fermenters are subject to batch-average VOC (BAVOC) emission limitations that differ for each fermentation stage, and which must be met for 98 percent of all batches in each fermentation stage on a rolling 12-month basis. The measurement of VOC is used as a surrogate for the HAP of interest, acetaldehyde. The BAVOC limits are 300 parts per million by volume (ppmv) for stock fermenters (third-to-last stage), 200 ppmv for first generation fermenters (second-to-last stage), and 100 ppmv for trade fermenters (last stage).

In the original subpart CCCC requirements, facilities can continuously monitor either the VOC concentration in the fermenter exhaust or the brew ethanol concentration in the fermenter liquid to determine compliance with the emission limitations. If a facility monitors brew ethanol concentration, it must conduct an annual performance test to determine the correlation between the brew ethanol concentration in the fermenter liquid and the VOC concentration in the fermenter exhaust gas.

C. What changes did we propose for the Manufacturing of Nutritional Yeast source category in our December 28, 2016, proposal?

On December 28, 2016, the EPA published a proposed rule in the **Federal Register** for subpart CCCC, that address the results of the RTR analyses and proposed other amendments. In the action, we proposed finding that the risks from the Manufacturing of Nutritional Yeast source category are acceptable; that additional emissions controls for the source category are not necessary to provide an ample margin of safety; and that there have been no developments in practices, processes, and control technologies that warrant changes to the fermenter emission limitations. Additionally, we proposed several changes to the existing rule (apart from the RTR process) that were intended to promote consistency with relevant statutory requirements and goals. These changes included revising the form of the VOC standards for fermenters; removing the option to monitor brew ethanol; including requirements to conduct annual RATA; removing gas chromatograph (GC) continuous emission monitoring system (CEMS) as an option to monitor VOC concentration; collecting CEMS data at all times during the batch monitoring period; using Procedure 1 of Appendix F to part 60 for VOC CEMS; requiring electronic reporting; and revising startup, shutdown, and malfunction (SSM) provisions.

III. What is included in this final rule?

This action finalizes the EPA's determinations pursuant to the RTR provisions of CAA section 112 for the Manufacturing of Nutritional Yeast source category. This action also finalizes other changes to subpart CCCC, including: Revising the form of the VOC standards for fermenters; removing the

[1] The U.S. Court of Appeals for the District of Columbia Circuit has affirmed this approach of implementing CAA section 112(f)(2)(A): *NRDC* v. *EPA,* 529 F.3d 1077, 1083 (D.C. Cir. 2008) (''If EPA determines that the existing technology-based standards provide an 'ample margin of safety,' then the Agency is free to readopt those standards during the residual risk rulemaking.'').

option to monitor brew ethanol; including requirements to conduct ongoing RATA; using Procedure 1 of Appendix F to part 60 for VOC CEMS; removing GC CEMS as an option to monitor VOC concentration; collecting CEMS data at all times during the batch monitoring period; requiring electronic reporting; and revising SSM provisions.

A. What are the final rule amendments based on the risk review for the Manufacturing of Nutritional Yeast source category?

The EPA proposed no changes to subpart CCCC based on the risk review conducted pursuant to CAA section 112(f). Specifically, as we proposed, we are finalizing our determination that risks from the nutritional yeast manufacturing facilities are acceptable, and that the standards provide an ample margin of safety to protect public health. The EPA received no new data or other information during the public comment period that changed that determination. Therefore, we are not requiring additional controls under CAA section 112(f)(2).

B. What are the final rule amendments based on the technology review for the Manufacturing of Nutritional Yeast source category?

We determined that there are no developments in practices, processes, and control technologies that warrant revisions to the MACT standards for this source category. The EPA proposed no changes to subpart CCCC based on the technology review conducted pursuant to CAA section 112(d)(6). The EPA received no new data or other information during the public comment period that affected the technology review determination. Therefore, we are not finalizing revisions to the MACT standards under CAA section 112(d)(6).

C. What are the final rule amendments addressing emissions during periods of startup, shutdown, and malfunction?

In its 2008 decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), the United States Court of Appeals for the District of Columbia Circuit vacated portions of two provisions in the EPA's CAA section 112 regulations governing the emissions of HAP during periods of SSM. Specifically, the Court vacated the SSM exemptions contained in 40 CFR 63.6(f)(1) and 40 CFR 63.6(h)(1), holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the SSM exemption violates the CAA's requirement that some CAA section 112 standard apply continuously.

Consistent with *Sierra Club* v. *EPA,* the EPA has established standards in this rule that apply at all times. We have eliminated the malfunction exemption in this rule, in addition to making other changes to ensure that the rule's emission limitations apply continuously (the latter changes are addressed in sections III.D and IV.C of this preamble). While, for simplicity, we refer throughout this section to the SSM exemption and the associated SSM plan requirements, only the malfunction exemption and its removal are relevant to this action because periods of startup and shutdown were never exempt from emissions standards in this subpart. We have revised Table 6 to subpart CCCC (the General Provisions applicability table) in several respects as is explained in more detail below. For example, we have eliminated the incorporation of the General Provisions' requirement that the source develops an SSM plan. We have also eliminated and revised certain recordkeeping and reporting that is related to the SSM exemption as described in detail in the proposed rule and summarized again here.

In establishing the standards in this rule, the EPA has taken into account startup and shutdown periods and, for the reasons explained below, has not established alternate standards for those periods. Periods of startup, normal operations, and shutdown are all predictable and routine aspects of a source's operations. In this NESHAP, owners or operators of nutritional yeast manufacturing facilities employ process controls to limit emissions. These process controls are employed from the time a fermenter starts production of a batch of yeast and continue until the fermenter is emptied of yeast. Additionally, emissions are averaged over the entire duration of each batch in order to determine compliance with emission limitations, so there was no need to set separate limits for periods of startup and shutdown in this rule.

Malfunctions, in contrast, are neither predictable nor routine. Instead they are by definition sudden, infrequent, and not reasonably preventable failures of emissions control, process, or monitoring equipment. 40 CFR 63.2 (definition of malfunction). The EPA interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112 standards and this reading has been upheld as reasonable by the D.C. Circuit. *U.S. Sugar Corp.* v. *EPA,* 830 F.3d 579, 606–610 (2016). Instead, under CAA section 112, emissions standards for new sources must be no less stringent than the level ''achieved'' by the best controlled similar source and for existing sources generally must be no less stringent than the average emission limitation ''achieved'' by the best performing 12 percent of sources in the category. There is nothing in CAA section 112 that directs the Agency to consider malfunctions in determining the level ''achieved'' by the best performing sources when setting emission standards. As the D.C. Circuit has recognized, the phrase ''average emissions limitation achieved by the best performing 12 percent of '' sources ''says nothing about how the performance of the best units is to be calculated.'' *Nat'l Ass'n of Clean Water Agencies* v. *EPA,* 734 F.3d 1115, 1141 (D.C. Cir. 2013). While the EPA accounts for variability in setting emissions standards, nothing in CAA section 112 requires the Agency to consider malfunctions as part of that analysis. A malfunction should not be treated in the same manner as the type of variation in performance that occurs during routine operations of a source. A malfunction is a failure of the source to perform in a ''normal or usual manner'' and no statutory language compels the EPA to consider such events in setting CAA section 112 standards. As the D.C. Circuit recognized in *U.S. Sugar Corp,* accounting for malfunctions in setting emission standards would be difficult, if not impossible, given the myriad different types of malfunctions that can occur across all sources in the category and given the difficulties associated with predicting or accounting for the frequency, degree, and duration of various malfunctions that might occur. *Id.* at 608 (''the EPA would have to conceive of a standard that could apply equally to the wide range of possible boiler malfunctions, ranging from an explosion to minor mechanical defects. Any possible standard is likely to be hopelessly generic to govern such a wide array of circumstances.'') As such, the performance of units that are malfunctioning is not ''reasonably'' foreseeable. See, *e.g., Sierra Club* v. *EPA,* 167 F.3d 658, 662 (D.C. Cir. 1999) (''The EPA typically has wide latitude in determining the extent of data-gathering necessary to solve a problem. We generally defer to an agency's decision to proceed on the basis of imperfect scientific information, rather than to 'invest the resources to conduct the perfect study.' '') See also, *Weyerhaeuser* v. *Costle,* 590 F.2d 1011, 1058 (D.C. Cir. 1978) (''In the nature of things, no general limit, individual permit, or even any upset provision can anticipate all upset situations. After a certain point, the transgression of

regulatory limits caused by 'uncontrollable acts of third parties,' such as strikes, sabotage, operator intoxication or insanity, and a variety of other eventualities, must be a matter for the administrative exercise of case-by-case enforcement discretion, not for specification in advance by regulation.''). In addition, emissions during a malfunction event can be significantly higher than emissions at any other time of source operation. For example, if an air pollution control device with 99-percent removal goes off-line as a result of a malfunction (as might happen if, for example, the bags in a baghouse catch fire) and the emission unit is a steady state type unit that would take days to shut down, the source would go from 99-percent control to zero control until the control device was repaired. The source's emissions during the malfunction would be 100 times higher than during normal operations. As such, the emissions over a 4-day malfunction period would exceed the annual emissions of the source during normal operations. As this example illustrates, accounting for malfunctions could lead to standards that are not reflective of (and significantly less stringent than) levels that are achieved by a well-performing non-malfunctioning source. It is reasonable to interpret CAA section 112 to avoid such a result. The EPA's approach to malfunctions is consistent with CAA section 112 and is a reasonable interpretation of the statute.

In subpart CCCC, it is unlikely that a malfunction would result in a violation of the standards for fermenters. The rule provides an option for owners or operators to determine the average VOC concentration for all batches within each fermentation stage using data from 12-month periods. This option limits the effect of malfunctions on the ability of a facility to meet the emission limitations because the averaging effectively minimizes ''spikes'' in emissions. Additionally, many of the common malfunctions reported during EPA site visits by owners or operators of nutritional yeast manufacturing facilities were malfunctions of the emissions monitoring equipment. While the equipment is unable to record accurate data during periods of malfunction, it does not impact actual emissions because process controls could still be used to limit emissions. In the unlikely event that a source fails to comply with the applicable CAA section 112(d) standards as a result of a malfunction event, the EPA would determine an appropriate response based on, among other things, the good faith efforts of the source to minimize emissions during malfunction periods, including preventative and corrective actions, as well as root cause analyses to ascertain and rectify excess emissions. The EPA would also consider whether the source's failure to comply with the CAA section 112(d) standard was, in fact, sudden, infrequent, not reasonably preventable and not instead caused in part by poor maintenance or careless operation. 40 CFR 63.2 (definition of malfunction).

If the EPA determines in a particular case that an enforcement action against a source for violation of an emission standard is warranted, the source can raise any and all defenses in that enforcement action and the federal district court will determine what, if any, relief is appropriate. The same is true for citizen enforcement actions. Similarly, the presiding officer in an administrative proceeding can consider any defense raised and determine whether administrative penalties are appropriate.

In summary, the EPA interpretation of the CAA and, in particular, CAA section 112 is reasonable and encourages practices that will avoid malfunctions. Administrative and judicial procedures for addressing exceedances of the standards fully recognize that violations may occur despite good faith efforts to comply and can accommodate those situations. *U.S. Sugar Corp.* v. *EPA,* 830 F.3d 579, 606–610 (D.C. Cir. 2016).

1. 40 CFR 63.2150 General Duty

We are revising the General Provisions table (Table 6 to subpart CCCC) entry for 40 CFR 63.6(e)(1)(i) to specify that 40 CFR 63.6(e)(1)(i) does not apply to subpart CCCC. Section 63.6(e)(1)(i) describes the general duty to minimize emissions. Some of the language in that section is no longer necessary or appropriate in light of the elimination of the SSM exemption. The current language in 40 CFR 63.6(e)(1)(i) characterizes what the general duty entails during periods of SSM; with the elimination of the SSM exemption, there is no need to differentiate between normal operations, startup and shutdown, and malfunction events in describing the general duty. Therefore, we are adding instead general duty regulatory text at 40 CFR 63.2150(d) that reflects the general duty to minimize emissions while eliminating the reference to periods covered by an SSM exemption.

We are also revising the General Provisions table (Table 6 to subpart CCCC) entry for 40 CFR 63.6(e)(1)(ii) to specify that 40 CFR 63.6(e)(1)(ii) does not apply to subpart CCCC. Section 63.6(e)(1)(ii) imposes requirements that are not necessary with the elimination of the SSM exemption or are redundant with the general duty requirement being added at 40 CFR 63.2150.

2. SSM Plan

We are revising the General Provisions table (Table 6 to subpart CCCC) to specify that 40 CFR 63.6(e)(3) does not apply to subpart CCCC. Generally, these paragraphs require development of an SSM plan and specify SSM recordkeeping and reporting requirements related to the SSM plan. As noted, the EPA is removing the SSM exemptions. Therefore, affected units will be subject to an emission standard during such events. The applicability of a standard during such events will ensure that sources have ample incentive to plan for and achieve compliance and, thus, the SSM plan requirements are no longer necessary.

3. Compliance With Standards

We are revising the General Provisions table (Table 6 to subpart CCCC) to specify that 40 CFR 63.6(f)(1) does not apply to subpart CCCC. The current language of 40 CFR 63.6(f)(1) exempts sources from non-opacity standards during periods of SSM. As discussed above, the Court in *Sierra Club* vacated the exemptions contained in this provision and held that the CAA requires that some CAA section 112 standard apply continuously. Consistent with Sierra Club, the EPA is revising standards in this rule to apply at all times.

4. 40 CFR 63.2161 Performance Testing

We are revising the General Provisions table (Table 6 to subpart CCCC) to specify that 40 CFR 63.7(e)(1) does not apply to subpart CCCC. Section 63.7(e)(1) describes performance testing requirements. The EPA is instead adding a performance testing requirement at 40 CFR 63.2161(b). The performance testing requirements we are adding differ from the General Provisions performance testing provisions in several respects. The regulatory text does not include the language in 40 CFR 63.7(e)(1) that restated the SSM exemption and language that precluded startup and shutdown periods from being considered ''representative'' for purposes of performance testing. As in 40 CFR 63.7(e)(1), performance tests conducted under this subpart should not be conducted during malfunctions because conditions during malfunctions are often not representative of normal

operating conditions. The EPA is adding language in 63.2161(b) that requires the owner or operator to record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Section 63.7(e) requires that the owner or operator make available to the Administrator such records ''as may be necessary to determine the condition of the performance test'' available to the Administrator upon request, but does not specifically require the information to be recorded. The regulatory text the EPA is adding to subpart CCCC builds on that requirement and makes explicit the requirement to record the information.

5. Monitoring

We are revising the General Provisions table (Table 6 to subpart CCCC) to specify that 40 CFR 63.8 (c)(1)(i) and (iii) do not apply to subpart CCCC. The cross-references to the general duty and SSM plan requirements in those subparagraphs are not necessary in light of other requirements of 40 CFR 63.8 that require good air pollution control practices (40 CFR 63.8(c)(1)) and that set out the requirements of a quality control program for monitoring equipment (40 CFR 63.8(d)).

We are revising the General Provisions table (Table 6 to subpart CCCC) to specify that 40 CFR 63.8(d)(3) does not apply to subpart CCCC. The final sentence in 40 CFR 63.8(d)(3) refers to the General Provisions' SSM plan requirement which is no longer applicable. The EPA is adding to the rule at 40 CFR 63.2182(c)(3) and 63.2183(e) text that contains the same requirements as 40 CFR 63.8(d)(3), except that we are requiring the program of corrective action for a malfunctioning monitoring system to be included in the quality control program for a CEMS (as described in 40 CFR 63.8(d)(2)) instead of in the SSM plan.

6. 40 CFR 63.2182 Recordkeeping

We are revising the General Provisions table (Table 6 to subpart CCCC) to specify that 40 CFR 63.10(b)(2)(ii) does not apply to subpart CCCC. Section 63.10(b)(2)(ii) describes the recordkeeping requirements during a malfunction. The EPA is adding such requirements to 40 CFR 63.2182(a)(2) and (c)(5). The regulatory text we are adding differs from the text in the General Provisions it is replacing in that the General Provisions requires the creation and retention of a record of the occurrence and duration of each malfunction of process, air pollution control, and monitoring equipment. The EPA is now applying the recordkeeping requirement to any failure to meet an applicable standard and is requiring that the source record the date, time, and duration of the failure rather than the ''occurrence.'' The EPA is also adding to 40 CFR 63.2182(a)(2) and (c)(5) a requirement that sources keep records that include a list of the affected source or equipment and actions taken to minimize emissions, an estimate of the quantity of each regulated pollutant emitted over the standard for which the source failed to meet the standard, and a description of the method used to estimate the emissions. Examples of such methods would include product-loss calculations, mass balance calculations, measurements when available, or engineering judgment based on known process parameters. The EPA is requiring that sources keep records of this information to ensure that there is adequate information to allow the EPA to determine the severity of any failure to meet a standard, and to provide data that may document how the source met the general duty to minimize emissions when the source has failed to meet an applicable standard.

We are revising the General Provisions table (Table 6 to subpart CCCC) to specify that 40 CFR 63.10(b)(2)(iv) does not apply to subpart CCCC. When applicable, the provision requires sources to record actions taken during SSM events when actions were inconsistent with their SSM plan. The requirement is no longer appropriate because SSM plans will no longer be required. The requirement previously applicable under 40 CFR 63.10(b)(2)(iv)(B) to record actions to minimize emissions and record corrective actions is now specified at 40 CFR 63.2182(a)(2) and (c)(5).

We are revising the General Provisions table (Table 6 to subpart CCCC) to specify that 40 CFR 63.10(b)(2)(v) does not apply to subpart CCCC. When applicable, the provision requires sources to record actions taken during SSM events to show that actions taken were consistent with their SSM plan. The requirement is no longer appropriate because SSM plans will no longer be required.

We are revising the General Provisions table (Table 6 to subpart CCCC) to specify that 40 CFR 63.10(c)(15) does not apply to subpart CCCC. The provision allows an owner or operator to use the affected source's SSM plan or records kept to satisfy the recordkeeping requirements of the SSM plan to also satisfy the requirements of 40 CFR 63.10(c)(10) through (12) concerning additional recordkeeping requirements for sources with continuous monitoring systems. The EPA is eliminating this requirement because SSM plans will no longer be required, and, therefore, 40 CFR 63.10(c)(15) no longer serves any useful purpose for affected units.

7. 40 CFR 63.2181 Reporting

We are revising the General Provisions table (Table 6 to subpart CCCC) to specify that 40 CFR 63.10(d)(5) does not apply to subpart CCCC. Section 63.10(d)(5) describes the reporting requirements for startups, shutdowns, and malfunctions. To replace the General Provisions reporting requirement, the EPA is adding reporting requirements to 40 CFR 63.2181(c)(5) and (7). The replacement language differs from the General Provisions requirement in that it eliminates periodic SSM reports as stand-alone reports. We are promulgating language that requires sources that fail to meet an applicable standard at any time to report the information concerning such events in the semiannual compliance report already required under this rule in 40 CFR 63.2181. We are requiring that the report must contain the number, date, time, duration, and the cause of such events (including unknown cause, if applicable), a list of the affected source or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limitation, and a description of the method used to estimate the emissions. Examples of such methods would include product-loss calculations, mass balance calculations, measurements when available, or engineering judgment based on known process parameters. The EPA is promulgating this requirement to ensure that there is adequate information to determine compliance, to allow the EPA to determine the severity of the failure to meet an applicable standard, and to provide data that may document how the source met the general duty to minimize emissions during a failure to meet an applicable standard.

We will no longer require owners or operators to determine whether actions taken to correct a malfunction are consistent with an SSM plan, because plans will no longer be required. The final amendments, therefore, eliminate the cross reference to 40 CFR 63.10(d)(5)(i) that contains the description of the previously required SSM report format and submittal schedule from this section. These specifications are no longer necessary

because the events will be reported in otherwise required reports with similar format and submittal requirements.

We are revising the General Provisions table (Table 6 to subpart CCCC) to specify that 40 CFR 63.10(d)(5)(ii) does not apply to subpart CCCC. Section 63.10(d)(5)(ii) describes an immediate report for startups, shutdown, and malfunctions when a source failed to meet an applicable standard, but did not follow the SSM plan. We will no longer require owners or operators to report when actions taken during a startup, shutdown, or malfunction were not consistent with an SSM plan, because such plans will no longer be required.

D. What other changes have been made to the NESHAP?

This rule finalizes revisions to several other Manufacturing of Nutritional Yeast NESHAP requirements. We describe the revisions in the following paragraphs.

We are finalizing the proposed amendments to revise the form of the fermenter VOC limits that require facilities to demonstrate compliance using either the Average Option or Batch Option. In response to comments, we are allowing facilities up to 1 year to demonstrate compliance with the revised form of the emission limitations. The EPA originally proposed that facilities would have to demonstrate compliance immediately upon promulgation of the final rule.

We are also finalizing the proposed amendments to several testing, monitoring, recordkeeping, and reporting provisions. First, we are finalizing amendments to require all facilities to monitor VOC emissions using VOC CEMS and to remove the option to monitor brew ethanol in the fermenter liquid and determine an annual correlation to VOC concentration in the fermenter exhaust in order to demonstrate compliance with fermenter VOC emission limitations. In reponse to comments, we are allowing the affected facility up to 3 years to comply with these requirements. The EPA originally proposed that the affected facility would have 1 year to comply with these requirements. We are also finalizing the related revisions to the rule text that corrected references to ''brew ethanol monitors'' that had erroneously referred to CEMS.

Second, we are finalizing the proposed amendments to remove the option to use GC CEMS to monitor VOC emissions. The use of GC CEMS requires facilities to identify specific VOC species to monitor and no facilities are currently using this method.

Third, we are finalizing the proposed amendments to require the collection of all valid CEMS data during batch monitoring periods and the reporting of missing data as deviations. In response to comments, we have added clarifying language in the rule specifying a minimum CEMS cycle time of 15 minutes and allowing a minimum of two data points (representing 15-minute periods) to constitute a valid hour of data collection during periods of calibration, quality assurance, or maintenance activities; and modified the recordkeeping requirements accordingly (as stated in the General Provisions).

Fourth, we are finalizing the proposed amendments to require facilities to conduct regular RATA using Procedure 1 of Appendix F to part 60 to evaluate the ongoing performance of CEMS. In response to comments, we are requiring RATA to be conducted once every 3 years, instead of annually as proposed. We are also adding language to the rule to clarify that cylinder gas audits or relative accuracy audits must be conducted in the quarters that RATA are not conducted, consistent with the requirements of Procedure 1 of Appendix F to part 60.

To increase the ease and efficiency of data submittal and data accessibility, we are finalizing, as proposed, a requirement that owners or operators of nutritional yeast manufacturing facilities submit electronic copies of certain required performance test or evaluation reports through the EPA's Central Data Exchange (CDX) Web site using the Electronic Reporting Tool (ERT). This requirement to submit performance test data or performance evaluation information electronically to the EPA applies only to those performance tests or evaluations conducted using test methods or evaluations that are supported by the ERT.

Lastly, we are finalizing the proposed minor language changes throughout subpart CCCC that clarify the existing requirements and restate the requirements in active voice. These amendments do not change any existing requirements, but are intended to improve the readability of subpart CCCC.

E. What are the effective and compliance dates of the standards?

The revisions to the MACT standards being promulgated in this action are effective on October 16, 2017.

The compliance date for the removal of GC CEMS, collection of all valid CEMS data from the entire batch monitoring period, requirement to conduct RATA, use of Procedure 1 of Appendix F to part 60 for VOC CEMS, revised SSM requirements, and the electronic reporting requirements for nutritional yeast manufacturing facilities is October 16, 2017.

Existing facilities must comply with the revised form of the fermenter VOC emission limitations by October 16, 2018. Until October 16, 2018, facilities must continue to demonstrate compliance, either using the existing form of the fermenter VOC emission limitations or the revised form of the fermenter VOC limits, in their semiannual compliance reports. As discussed in section IV.G of this preamble, this timeframe was revised from immediate compliance in the proposed rule, based on public comments, in order to allow facilities time to train staff and update the necessary recordkeeping and reporting procedures.

Facilities that currently demonstrate compliance by monitoring brew ethanol concentration in the fermenter liquid must install CEMS by October 16, 2020. Until October 16, 2020, emissions data must be collected for each batch, either using the existing compliance method (monitoring brew ethanol concentration) or with CEMS, for use in the semiannual compliance reports with the applicable emission limitations. As discussed in section IV.G of this preamble, this was revised from the proposed 1-year compliance period, based on public comments, to allow facilities adequate time to procure equipment; train staff; and update operations and maintenance, recordkeeping, and reporting procedures.

Sources that are constructed or reconstructed after promulgation of the rule revisions must comply with the emission limitations and compliance requirements upon the effective date of the rule, October 16, 2017, or upon startup of the affected source, whichever is later.

F. What are the requirements for submission of performance test data to the EPA?

The EPA is requiring owners or operators of manufacturing of nutritional yeast facilities to submit electronic copies of certain required performance test reports and performance evaluation reports (*e.g.,* RATAs that are supported by the EPA's ERT) at the time of the evaluation, through the EPA's CDX using the Compliance and Emissions Data Reporting Interface (CEDRI). The electronic submittal will increase the usefulness of the data contained in those reports, is in keeping with current

trends in data availability and transparency, will further assist in the protection of public health and the environment, will improve compliance by facilitating the ability of regulated facilities to demonstrate compliance with requirements and by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance, and will ultimately reduce burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting also eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public.

The EPA Web site that stores the submitted electronic data, WebFIRE, provides a user-friendly interface accessible to all stakeholders. By making the records, data, and reports addressed in this rulemaking readily available, the EPA, the regulated community, and the public will benefit when the EPA conducts its CAA-required technology and risk-based reviews. As a result of having reports readily accessible, our ability to carry out comprehensive reviews will be increased and achieved within a shorter period of time.

We anticipate fewer or less substantial Information Collection Requests (ICRs) in conjunction with prospective CAA-required technology and risk-based reviews may be needed as a result of electronic reporting, which results in a decrease in time spent by industry to respond to data collection requests. We also expect the ICRs to contain less extensive stack testing provisions, as we will already have stack test data electronically. Reduced testing requirements would be a cost savings to industry. The EPA should also be able to conduct these required reviews more quickly. Although the regulated community may benefit from a reduced burden of ICRs, the general public benefits from the Agency's ability to provide these required reviews more quickly, resulting in increased public health and environmental protection.

Air agencies, as well as the EPA, can benefit from more streamlined and automated review of the electronically submitted data. Standardizing report formats allows air agencies to review reports and data more quickly. Having reports and associated data in electronic format will facilitate review through the use of software ''search'' options, as well as the downloading and analyzing of data in spreadsheet format. Additionally, air agencies and the EPA can access reports wherever and whenever they want or need, as long as they have access to the Internet. The ability to access and review reports electronically assists air agencies in determining compliance with applicable regulations more quickly and accurately, potentially allowing a faster response to violations which could minimize harmful air emissions. This benefits both air agencies and the general public.

For a more thorough discussion of electronic reporting required by this rule, see the discussion in the preamble of the proposal (81 FR 95829, December 28, 2016). In summary, in addition to supporting regulation development, control strategy development, and other air pollution control activities, having an electronic database populated with performance test data will save industry, air agencies, and the EPA significant time, money, and effort while improving the quality of emission inventories and air quality regulations, and enhancing the public's access to this important information.

IV. What is the rationale for our final decisions and amendments for the Manufacturing of Nutritional Yeast source category?

For each issue, this section provides a description of what we proposed and what we are finalizing, the EPA's rationale for the final decisions and amendments, and a summary of key comments and responses. For all comments not discussed in this preamble, comment summaries and the EPA's responses can be found in the comment summary and response document available in the docket for this rulemaking (EPA–HQ–OAR–2015–0730).

A. Residual Risk Review for the Manufacturing of Nutritional Yeast Source Category

1. What did we propose pursuant to CAA section 112(f) for the Manufacturing of Nutritional Yeast source category?

Pursuant to CAA section 112(f), the EPA conducted a residual risk review and presented the results of this review, along with our proposed decisions regarding risk acceptability and ample margin of safety, in the December 28, 2016, proposed rule for subpart CCCC (81 FR 95825). The results of the risk assessment for the proposal are presented briefly below in Table 2 of this preamble, and in more detail in the proposal residual risk document, ''Residual Risk Assessment for the Manufacturing of Nutritional Yeast Source Category in Support of the December 2016 Risk and Technology Review Proposed Rule,'' which is available in the docket for this rulemaking.

TABLE 2—NUTRITIONAL YEAST MANUFACTURING INHALATION RISK ASSESSMENT RESULTS

Number of facilities [1]	Maximum individual cancer risk (in 1 million) [2]		Estimated population at increased risk of cancer ≥ 1-in-1 million		Estimated annual cancer incidence (cases per year)		Maximum chronic non-cancer TOSHI [3]		Maximum screening acute non-cancer HQ [4]	
	Based on actual emissions level [2]	Based on allowable emissions level	Based on actual emissions level [2]	Based on allowable emissions level	Based on actual emissions level [2]	Based on allowable emissions level	Based on actual emissions level [2]	Based on allowable emissions level	Based on actual emissions level [2]	Based on allowable emissions level
4	2	2	750	750	0.0009	0.0009	0.08	0.08	HQ_{REL} = 0.2	HQ_{REL} = 0.2.

[1] Number of facilities evaluated in the risk analysis.
[2] Maximum individual excess lifetime cancer risk due to HAP emissions from the source category.
[3] Maximum target organ-specific hazard index (TOSHI). The target organ with the highest TOSHI for the Manufacturing of Nutritional Yeast source category is the respiratory system.
[4] The maximum estimated acute exposure concentration was divided by available short-term threshold values to develop an array of hazard quotient (HQ) values. HQ values shown use the lowest available acute threshold value, which in most cases is the recommended exposure limit (REL). When HQ values exceed 1, we also show HQ values using the next lowest available acute dose-response value. See section III.A.3 of the proposal preamble (81 FR 95816, December 28, 2016) for explanation of acute dose-response values.

Based on both actual and allowable emissions for the Manufacturing of Nutritional Yeast source category, the maximum lifetime individual cancer risk was estimated to be up to 2-in-1 million, the maximum chronic non-cancer TOSHI value was estimated to be up to 0.08, and the maximum off-facility site acute HQ value was estimated to be up to 0.2. The total estimated national cancer incidence from these facilities was 0.0009 excess cancer cases per year or 1 case in every 1,100 years.

There are no persistent and bioaccumulative HAP emitted by facilities in this source category. Therefore, we did not consider any human health multi-pathway risks as a result of emissions from this source category.

We weighed all health risk factors, including those shown in Table 2 of this preamble, in our risk acceptability determination, and proposed that the residual risks from the Manufacturing of Nutritional Yeast source category are acceptable (section IV.B. of proposal preamble, 81 FR 95825, December 28, 2016).

We then considered whether subpart CCCC provides an ample margin of safety to protect public health and prevents, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. In considering whether the standards should be tightened to provide an ample margin of safety to protect public health, we considered the same risk factors that we considered for our acceptability determination and also considered the costs, technological feasibility, and other relevant factors related to emissions control options that might reduce risk associated with emissions from the source category. Two control options were evaluated for further reducing acetaldehyde emissions from fermenters at nutritional yeast facilities: thermal oxidizers and wet (packed bed) scrubbers. Due to the additional environmental impacts (increased energy use and emissions of approximately 89 tpy of nitrogen oxides that would be imposed by the control options and the low level of current human health risk), along with the substantial costs associated with these control options, we proposed that additional emissions controls for this source category are not necessary to provide an ample margin of safety (section IV.B.2 of proposal preamble, 81 FR 95825, December 28, 2016).

In addition, none of the seven pollutants identified by the EPA as ''environmental HAP'' (cadmium, dioxins/furans, polycyclic organic matter, mercury, lead compounds, hydrogen chloride, and hydrogen fluoride), which are known to cause adverse environmental effects, are emitted; therefore, we did not conduct a separate environmental risk analysis for this source category (see section III.A.6 of the proposal preamble (81 FR 95819, December 28, 2016)).

2. How did the risk review change for the Manufacturing of Nutritional Yeast source category?

During the public comment period, the EPA received information that the acetaldehyde emissions rate was tested at the AB Mauri facility in 2017 and was approximately 50 percent lower than the rate used to estimate the total annual emissions included in the residual risk analysis. The residual risk analysis performed for the proposed rule was based on data reported in the 2011 National Emissions Inventory (NEI) from all facilities. The new emissions rate cannot be used to change previously reported data from a facility because there is no clear evidence or test history to establish when the emission rate decreased. Complete 2017 emissions data is not yet available for AB Mauri, so the EPA could not repeat the risk analysis using newer data for this facility. Importantly, the risk review had already found that the risks are acceptable and the standards provide an ample margin of safety using the higher 2011 NEI emissions data for this facility, so it is possible that the residual risk from the Manufacturing of Nutritional Yeast source category has decreased even farther. Since the EPA concluded it was reasonable to not update the risk review following proposal, we have finalized the risk assessment report and re-submitted it to the docket as ''Residual Risk Assessment for the Manufacturing of Nutritional Yeast Source Category in Support of the October, 2017 Risk and Technology Review Final Rule.''

3. What key comments did we receive on the risk review and what are our responses?

We received comments in support of and against the proposed residual risk review and our determination that no revisions were warranted under CAA section 112(f)(2). Generally, the comments that were not supportive of the determination from the risk review suggested changes to the underlying risk assessment methodology. After review of these comments, we determined that no changes were necessary. The comments and our specific responses can be found in the document, ''Nutritional Yeast Manufacturing Risk and Technology Review: Summary of Public Comments and Responses,'' which is available in the docket for this action.

4. What is the rationale for our final approach and final decisions for the risk review?

For the reasons explained in the proposed rule, we determined that the risks from the Manufacturing of Nutritional Yeast source category are acceptable, and the current standards provide an ample margin of safety to protect public health and prevent an adverse environmental effect. Since proposal, neither the risk assessment nor our determinations regarding risk acceptability, ample margin of safety, or adverse environmental effects have changed. Therefore, we are not revising subpart CCCC to require additional controls pursuant to CAA section 112(f)(2) based on the residual risk review and are readopting the existing standards under CAA section 112(f)(2).

B. Technology Review for the Manufacturing of Nutritional Yeast Source Category

1. What did we propose pursuant to CAA section 112(d)(6) for the Manufacturing of Nutritional Yeast source category?

Pursuant to CAA section 112(d)(6), the EPA conducted a technology review and summarized the results of the review in the proposed rule for subpart CCCC (81 FR 95825, December 28, 2016). The results of the technology review are briefly discussed below, and in more detail in the memorandum, ''Technology Review for the Manufacturing of Nutritional Yeast Source Category,'' which is available in the docket for this action (Docket ID No. EPA–HQ–OAR–2015–0730–0016).

The technology review focused on identifying and evaluating developments in practices, processes, and control technologies for the Manufacturing of Nutritional Yeast source category. We identified two control technologies for further evaluation that were technically feasible for further reducing acetaldehyde emissions from nutritional yeast fermenters: thermal oxidizers, and wet (packed bed) scrubbers. After identifying the control technologies that were technically feasible, we then evaluated the costs and emissions reductions associated with installing regenerative thermal oxidizers (RTOs) and packed bed scrubbers at each of the four existing nutritional yeast facilities. Considering the high cost per ton of acetaldehyde reduced and potential adverse environmental impacts

associated with the installation of RTOs or packed bed scrubbers, we did not consider these technologies to be cost effective for further reducing acetaldehyde emissions from fermenters at nutritional yeast manufacturing facilities. In light of the results of the technology review, we proposed to conclude that changes to the fermenter emission limitations were not warranted pursuant to CAA section 112(d)(6) (81 FR 95825, December 28, 2016).

2. How did the technology review change for the Manufacturing of Nutritional Yeast source category?

The technology review for the Manufacturing of Nutritional Yeast source category has not changed since proposal. As proposed, the EPA is not making changes to the standards pursuant to CAA section 112(d)(6).

3. What key comments did we receive on the technology review and what are our responses?

We received comments in support of the proposed determination from the technology review that no revisions were warranted under CAA section 112(d)(6). We also received one comment that asserted that cost effectiveness should not be a consideration when examining standards under CAA section 112(d)(6). We evaluated the comments and determined that no changes regarding our determination were needed. These comments and our specific responses to those comments can be found in the comment summary and response document titled, ''Nutritional Yeast Manufacturing Risk and Technology Review: Summary of Public Comments and Responses,'' which is available in the docket for this action.

4. What is the rationale for our final approach for the technology review?

For the reasons explained in the preamble to the proposed rule, we determined there were no new developments in practices or processes, nor were cost-effective control technologies available to further reduce acetaldehyde emissions from fermenters at nutritional yeast manufacturing facilities (81 FR 95825, December 28, 2016). Since proposal, neither the technology review nor our determination as a result of the technology review has changed, and we are not revising subpart CCCC pursuant to CAA section 112(d)(6).

C. Revised Form of the Fermenter VOC Standard

1. What did we propose?

At proposal, the EPA explained that the current form of the standards for VOC limits on fermenters was in direct conflict with the statutory requirement that emission standards limit emissions on a continuous basis, *i.e.,* that some emission limitation applies at all times, and, therefore, proposed to establish a revised form of the standards (''Batch Option'') as well as an alternate standard for compliance (''Average Option'') in Table 1 to subpart CCCC (81 FR 95826, December 28, 2016). Under the proposed Batch Option, each individual batch manufactured must meet the existing VOC emission limits (300 ppmv for stock fermentation, 200 ppmv for first generation fermentation, and 100 ppmv for trade fermentation). Under the proposed Average Option, all batch average VOC concentration data for each fermentation stage in a 12-month period must be averaged together and not exceed certain VOC emission limits, which are 5 percent lower than the VOC emission limits established for individual batches in 2001 for subpart CCCC (285 ppmv for stock fermentation, 190 ppmv for first generation fermentation, and 95 ppmv for trade fermentation). We referred to this reduction as a ''discount factor,'' consistent with our use of the term in other MACT standards that allow averaging of emissions data for compliance.

Additionally, the proposed revisions to the general compliance requirements in 40 CFR 63.2150(a) and (c) that remove the exemption for compliance with emission limits during periods of malfunction will also impact the determination of compliance with emission limits. The practical effect of this change is that emissions from batches of yeast produced during periods of malfunction, other than monitoring system malfunctions, must now be included in calculations for compliance purposes.

2. How did the requirements change since proposal?

The EPA has not changed either the form or the level of emission reductions that would be required under either the Batch or Average Option. We have, however, revised our characterization of which option represents the updated form of the original MACT standard and which can be used as the alternative compliance method, as described in section IV.C.3 of this preamble.

3. What key comments did we receive and what are our responses?

Comment: Two commenters stated that the EPA improperly assumed a need to change the fermenter VOC standards based on the *Sierra Club* v. *EPA* SSM policy ruling that standards must apply at all times. One commenter asserted that the EPA is confusing the concept of continuous compliance as opposed to relief from compliance. Both commenters remarked that the existing fermenter VOC standards apply at all times and the facility must be in continuous compliance with the standard, meaning that VOC concentration must be continuously monitored to ensure that 98 percent of all batches do not exceed the VOC standards. A commenter also stated that yeast manufacturers do continuously comply with the existing fermenter VOC standards, as calculated under the statistical averaging approach set out in the standard. The commenter continued that the *Sierra Club* v. *EPA* SSM ruling did not say that calculations embedded into MACT standards must be invalidated under the logic the Court used to invalidate the EPA's general SSM policy.

The commenter stated that other Court decisions addressing the EPA's SSM policy similarly have no bearing on the Nutritional Yeast rule. For example, the commenter remarked that in *NRDC* v. *EPA,* the Court invalidated the affirmative defense provision of the Cement Kiln NESHAP that excused Portland cement manufacturers if they experienced a process malfunction. The commenter stated the Nutritional Yeast rule does not provide any affirmative defense for non-compliance.

Response: We disagree that the changes to the form of the standard are unwarranted and that the *Sierra Club* v. *EPA* decision is inapplicable in this context because we disagree with the commenters' characterization of the existing form of the standard as an emission limitation that applies at all times. A standard that allows up to 2 percent of batches to be produced without any applicable limitation on emissions does not provide continuous emission reductions within the meanings of CAA sections 112 and 302(k).

The existing form of the standard is inconsistent with the D.C. Circuit's holding that CAA sections 112 and 302(k), when read together, require that emission standards apply on a continuous basis, and we are remedying that inconsistency here. See *Sierra Club* v. *EPA,* 551 F.3d at 1027. While the Court was specifically addressing SSM

requirements in that case, its analysis was based on CAA section 302(k)'s requirement that emission standards, including those required under CAA section 112(d)(2) and (3), ''assure continuous emission reduction.'' *Id.* The Court discussed the legislative history of CAA section 302(k), noting that ''the committee has made clear that constant or continuous means of reducing emissions must be used to meet these requirements. By the same token, intermittent or supplemental controls or other temporary, periodic, or limited systems of control would not be permitted as a final means of compliance.'' *Id.* (quoting H.R. Rep. 95–294, at 92 (1977)). The Court's disposition of the SSM issue was based on its determination that CAA section 302(k) does not allow the EPA ''to relax emission standards on a temporal basis.'' *Id.* at 1028 (citing *NRDC* v. *EPA,* 489 F.3d at 1364, 1374 (D.C. Cir. 2007)). That same analysis—that some emission standard must provide emission reductions at all times—is directly applicable to the emission standard at issue here. The existing MACT standard for yeast manufacturing allows up to 2 percent of batches to be produced without any kind of emission reduction requirement, which is in direct conflict with CAA section 302(k) and *Sierra Club* v. *EPA.*

We disagree with the commenter's overly narrow interpretation of *Sierra Club* v. *EPA* as applying only to SSM exemptions, as it ignores the underlying determination that such exemptions are illegal because they are inconsistent with the requirement that emission reductions must be continuous. The existing form of the standard for yeast manufacturing creates a limited or intermittent system of control. The fact that this exemption was originally built into the standard does not excuse its fundamental inconsistency with the statutory requirements. We also disagree that we are confusing continuous compliance with relief from compliance; again, the issue is broader than just whether sources must comply continuously with a standard—it is also, according to the D.C. Circuit's analysis, whether that standard provides continuous emission reductions.

The EPA acknowledges and understands that, in the current standard, nutritional yeast facilities continuously monitor VOC concentration during each batch. This is done both to monitor emissions for compliance purposes and also because facilities use the data for process control. However, continuous monitoring is not equivalent to having a continuous emission standard when the continuous monitoring is not accompanied by an emission reduction requirement. Critically, facilities may currently exceed the VOC standards for up to 2 percent of batches and these batches are allowed to emit an unlimited amount of HAP and VOC emissions. The revised forms of the standards, be it the Batch or Average Option, require that all monitored batch data are included to determine compliance, which ensures that the standards do not provide allowances for some batches of yeast to emit an unlimited amount of HAP and VOC emissions.

The EPA also notes that nutritional yeast facilities make hundreds to thousands of batches of yeast within a 12-month period; therefore, the 2-percent exemption allows a significant number of batches to exceed the limits. For example, if there are 1,000 batches during a 12-month period, up to 20 batches may operate without emission limits. Again, there is no cap on their emissions and no penalty for these exceedances, regardless of how much they exceed the emission limit or the cause of the excursion. This ''time out'' from application of the emission standard is inconsistent with the requirement that such standards provide for continuous emission reductions.

Relatedly, we further clarify that, separate from updating the form of the standard so that an emission limitation applies to all batches (*i.e.,* continuously), we are also removing cross-references to sections of the General Provisions that allow for exemptions from compliance during periods of malfunction. These are two separate issues in the context of this rulemaking, both of which were precipitated by the *Sierra Club* v. *EPA* decision, as explained above. While removal of the malfunction exemption means that owners or operators of nutritional yeast manufacturing facilities must include data from every batch when determining whether they have complied with the standard, this does not preclude the EPA from appropriately addressing noncompliance when it results from emissions that occur during periods of malfunction as defined in 40 CFR 63.2, which is discussed in section III.C of this preamble.

We did not include affirmative defense language in the nutritional yeast proposal and did not consider it for the rule revisions. Thus, we agree that the *NRDC* v. *EPA* decision is not relevant to the revisions to the form of the standards.

Comment: Two commenters stated that allowing up to 2 percent of batches to exceed the fermenter VOC emission limits is inherent in the standards to account for the natural variability of the yeast manufacturing process. One commenter remarked that changing the fermenter VOC standards would be to reject the EPA's prior determination that the standards needed to reflect the actual functioning of the yeast fermentation process.

Response: The EPA disagrees that an exemption from emission limitations is the only option to address variability within a standard. There are other options for addressing variability besides raising the level of the standard. One such option is to express the emission limitation as the average of emissions from all batches. Our proposed Average Option, where a facility may average BAVOC emissions from all batches within a given fermentation stage together within a 12-month period, provides flexibility for individual batches to emit both below and above the prescribed numerical limits. Therefore, we disagree that changing the form of the standard rejects the EPA's prior determination that the standards needed to reflect the actual functioning of the yeast fermentation process.

Comment: Two commenters stated that the Average Option could be adopted if no discount factor were applied because the Average Option accounts for variability within the yeast manufacturing process. One of the commenters does not support the 5-percent discount factor that is part of the Average Option and suggested the EPA would be required to re-open the MACT standard and revisit the administrative record that it established in 2001 in order to justify such a change.

Response: To address the requirement that the emission standards must provide for continuous emission reductions, the EPA proposed to change the current emissions standards in subpart CCCC that allow 2 percent of the batches to be exempted from the otherwise applicable emission limitation. The EPA proposed that the ''Batch Option'' would be the updated form of the MACT standard and would set emission limits for different fermentation stages by simply eliminating the exemption from the otherwise applicable emission limitation for up to 2 percent of batches. However, we now recognize that requiring 100 percent of batches to meet the original emission limitations, as opposed to 98 percent, is not what we determined to be MACT in the 2001 rulemaking. That rulemaking acknowledged that there is a degree of

natural variance in the yeast fermentation process, such that the maximum degree of emissions reduction achievable is the level represented by 98 percent of batches meeting the applicable emission limits (66 FR 27880, May 21, 2001). Therefore, while we are retaining the Batch Option as an alternative compliance option, it does not represent MACT.

The EPA also proposed the Average Option for determining compliance with the applicable emission limitations. Because we formulated this option to reflect the level of emission reductions represented by the original MACT standard, including the allowance for variability built into that standard, we are now determining that it is the Average Option that actually represents MACT. As the commenters acknowledge, assessing compliance based on a 12-month rolling average of batch emissions serves the same purpose of addressing batch variability as the 2-percent exemption. We applied a discount factor specifically because averaging multiple batches inherently provides more flexibility to emit above such limits. We have also used discount factors in conjunction with annual average emission limitations in the Boiler MACT, where a 10-percent discount was applied for emissions averaging. Allowing annual average BAVOC emissions to meet the original VOC concentration limits established as MACT in 2001 (*i.e.,* applying a 0-percent discount factor) would actually relax the standard, both due to the inherent flexibility of an averaging method and by potentially allowing more than 2 percent of batches to exceed the emission limitations set for each fermentation stage. To ensure that the annual averaging method will maintain the level of emission reductions represented by MACT, the EPA is finalizing a 5-percent discount factor in the VOC emission limit for each fermentation stage, as described in detail in the memorandum titled, ''Average Option Analysis for the Manufacturing of Nutritional Yeast Source Category,'' available in the docket for this rulemaking. The EPA believes that it is necessary to include both components of the Average Option, as the 12-month rolling average provides for a degree of flexibility to account for the natural variance in the manufacturing process, while the 5-percent discount factor maintains the level of emission reductions consistent with the MACT determination, which is the level of emission reductions that protect public health and prevent adverse effects on the environment.

As discussed previously in this section, the changes to the form of the standard were precipitated by the D.C. Circuit's 2008 ruling in *Sierra Club* v. *EPA* that some emission standard must apply at all times. 551 F.3d 1019, 1027–28 (D.C. Cir. 2008). We did not re-open the MACT calculation in this rulemaking; the revised form must continue to reflect the emission reductions achieved by the best performers as determined in the 2001 rule. The Average Option as finalized meets these requirements.

Comment: One commenter stated the EPA did not offer sufficient technical support to justify that the proposed fermenter VOC emission limits are merely a change in the ''form of the standards'' and not a change in the standards themselves. The commenter contended that the revised fermenter VOC standards are not equivalent to the existing standards and there is no legal or technical basis for any changes to the existing fermenter VOC standards. In addition, the commenter maintained the proposed revisions fundamentally alter the standards, and their stringency, by changing the formula used to assess whether facilities are in compliance.

Response: The EPA disagrees that there is no legal basis for changing the form of the standard and that our revision to the form of the standard fundamentally alters the standard itself. As discussed previously in this section, we have not recalculated the MACT floor or revisited the MACT determination; however, we have revised the current form of the standard consistent with the D.C. Circuit's *Sierra Club* v. *EPA* decision. It is not possible, strictly speaking, to demonstrate that the revised form of the standard is ''equivalent to'' the existing form of the standard because changing the form necessarily makes a direct comparison between the current standard and the revised standard infeasible. However, when revising the form, we have taken a reasonable approach to make the MACT standard apply continuously and to ensure that the revised form remains consistent with the level of emission reductions we originally determined to represent the MACT standard. That is, we have attempted to ensure, to the extent possible, that changing the form of the standard does not fundamentally alter the MACT standard that was finalized in 2001.

The Average Option was developed to maintain flexibility for the sources subject to the rule and is expected to maintain the level of emission reductions represented by the existing MACT standard. To support an alternate form of emission limitations that would allow for emissions averaging and would also represent the existing MACT standard, we considered information from the development of the original MACT standard and analyzed more recent emissions data from the facilities currently subject to this rule. Multiple years of individual BAVOC emissions data were available for two facilities. Summary BAVOC data were available for three facilities. A detailed description of the analysis of the Average Option is available in the memorandum, ''Average Option Analysis for the Manufacturing of Nutritional Yeast Source Category,'' which is available in the docket for this rulemaking.

With the revision of the form of the MACT standard, we retained certain characteristics of the 2001 standard (*e.g.,* rolling 12-month calculation periods) to reduce the changes to ongoing operations and reporting and recordkeeping procedures for affected sources. We determined that an annual averaging method was the most appropriate form to maintain the flexibility established in the 2001 MACT standard to account for the variability in emissions and retain elements of the reporting and recordkeeping provisions. We concluded, based on available data, that we could use a normal (bell-curve) distribution to simulate emissions from the yeast manufacturing process for the purposes of establishing annual average emission limits.

The 2001 MACT standard did not set the annual mean for the distribution of BAVOC concentrations at 300 ppmv, 200 ppmv, and 100 ppmv for each of the last three fermentation stages, respectively. Rather, it established an upper threshold that no more than 2 percent of individual batches could exceed. As described in greater in the memorandum, the emission limitations established under the annual averaging compliance method will necessarily be lower than the upper threshold established for the 98 percent of batches with individual batch emission limitations under the 2001 MACT standard because the limitations established under the annual averaging method represent the mean of a normal distribution instead of an upper threshold.

The simulated distribution depends on two parameters—mean and standard deviation. Because the mean and discount factor are directly related, we utilized the standard deviation as the key parameter for determining the discount factor that would maintain both flexibility for process variability and the level of emission reduction

established in the 2001 MACT standard. To do this we used the available BAVOC data from two facilities to calculate the standard deviation for 12-month rolling averages (65 total for each fermentation stage). The lowest observed standard deviations for each fermentation stage were 7 ppmv for the third-to-last stage, 5 ppmv for the second-to-last stage, and 3 ppmv for the last stage of yeast manufacturing. Utilizing the least-variable 12-month period to determine the average emission limitation results in the lowest discount factor and gives facilities the ability to operate at the highest annual average emission limit. Applying these standard deviations results in discount factors of 5 percent for the third-to-last and second-to-last stage, and 6 percent for the last stage. Instead of selecting different discount factors for each stage, we determined that a 5-percent discount factor was appropriate to apply to the 2001 VOC concentration limitations to express the existing MACT standard in a new form.

In summary, the Average Option uses an annual averaging methodology to achieve the flexibility originally accomplished by allowing 2 percent of batches to exceed the established emission limits (300 ppmv, 200 ppmv, 100 ppmv). The revised form of the standard sets annual average emission limitations that are 5 percent lower than the 2001 upper threshold emission limitations for individual batches to maintain the level of emission reductions represented by the original form of the MACT standard.

Comment: Two commenters asserted the EPA determined that only 98 percent of batches could reasonably be expected to meet the emission limits and, thus, this was the MACT floor (66 FR 27880, May 21, 2001). One of the commenters also contended that if the 2001 fermenter VOC standards had been computed based on all batches, rather than 98 percent of the batches, the standards would necessarily have been set higher to accommodate process variability or some type of emissions averaging.

Response: We agree that in setting the MACT floor in 2001, the EPA concluded that MACT is the control of 98 percent of the batches to either at or below the VOC concentration limits. However, we disagree that changing the form of the standard rejects our acknowledgment of the actual functioning of the yeast fermentation process or, as discussed previously in this section, the EPA's prior MACT floor determination. The updated form of the standard, as expressed in the ''Average Option,'' maintains the level of emission reductions represented by MACT. This is a change from the proposal, which presented the ''Batch Option'' as the updated form of MACT. For further discussion of the determination of the Average Option as MACT, see the prior response in this section.

The EPA disagrees that if the 2-percent exemption were not included in the original MACT limits, the standards would necessarily have been set higher. The numerical emission limits included in the MACT standard were not set based on the actual emissions levels achieved by 98 percent of the batches produced; rather they relied on the existing concentration-based limits included in two state rules, the state of Wisconsin and the state of Maryland, that were based on reasonably available control technology (RACT) and that were in place at the time (66 FR 27879, May 21, 2001). However, some states applied discretion concerning the number of exceedances of those emission limits that could occur before finding a facility in violation of the standards. For example, the state of Maryland's continuous emissions monitoring policy allowed for one VOC concentration limit exceedance per facility per quarter. Consistent with this policy, the EPA calculated the average number of exceedances as a percent of the total number of batches manufactured at the five facilities subject to RACT or RACT-derived limitations during 1998 and calculated the overall average exceedances (based on dividing the average number of exceedances for the facilities by the average number of runs (where a run is a fermentation of any stage) for the facilities) to be 1.3 percent, noting that one of the facilities reported an unusually high number of exceedances due to ''shakedown'' (testing) of a new fermenter. Notably, one of the five yeast manufacturing facilities analyzed exceeded no concentration limits (66 FR 27880, May 21, 2001). Given that one of the facilities did not exceed the limits, that Maryland only allowed four batches to exceed the limits each year, and that the average number of exceedances calculated using data from a facility with an ''unusually high number of exceedances'' was only 1.3 percent; as well as the statements from a commenter during promulgation of the MACT floor that ''most batches display BAVOC below the . . . limits'' (66 FR 27880, May 21, 2001), we disagree that the limits would ''necessarily have been set higher'' as the commenter contends.

Comment: One commenter stated the Batch Option would never be preferred from a compliance standpoint to the Average Option, and, thus, considered the inclusion of the Batch Option as an alternative to be illusory.

Response: We acknowledge the comment. However, the EPA does not support or prefer one option over another (*i.e.,* the Batch Option versus the Average Option). As explained above, while the EPA considered the Batch Option to be the revised form of the MACT standard at proposal, in light of comments received, we have determined that the Average Option is the revised form of the MACT standard. In recognition of information gathered from the development of the original rule and during the site visits conducted for the RTR that some facilities may be able to meet the current emission limits for all batches manufactured during a year, we have retained the Batch Option as an alternative compliance option that offers a more streamlined approach to determining and reporting compliance.

4. What is the rationale for our final approach?

For the reasons explained in the preamble to the proposed rule (81 FR 95826, December 28, 2016) and in our comment responses in section IV.C.3 of this preamble, we are finalizing revisions to the form of the fermenter VOC standards in Tables 1 and 7 to subpart CCCC. As noted above, since proposal, the EPA's determination of which option, the Batch Option or the Average Option, is the revised form of the original MACT standard has changed, and we now find that the Average Option represents MACT. However, we are finalizing both of the revised forms of the standard with no changes to the standards themselves, and are also finalizing the requirement that all sources must comply with one of the two revised forms with the changes related to frequency described in section IV.C.2 of this preamble. Additionally, we are finalizing revisions to 40 CFR 63.2150 to remove the emission limitation exemption during periods of malfunction, with the result that emissions from batches produced during periods of malfunction, other than monitoring system malfunctions, must now be included in calculations for compliance purposes.

D. Removal of the Option To Monitor Brew Ethanol

1. What did we propose?

The EPA proposed to remove one of two options for demonstrating ongoing compliance in the 2001 rule, which allowed facilities to monitor brew ethanol concentration in the fermenter liquid. Specifically, we proposed to revise the requirements of 40 CFR

63.2166 and 63.2171, and Tables 3 and 4 to subpart CCCC to remove the option to monitor brew ethanol as a means of demonstrating compliance. The method for monitoring brew ethanol requires facilities to develop an annual correlation of brew ethanol concentration to VOC concentration in the fermenter exhaust and use the correlation to determine compliance with the emission limitations. This method does not account for batch-specific characteristics affecting emissions and we subsequently determined it to be an unreliable indicator of a facility's compliance with the standard. A detailed discussion is available in the preamble to the proposed rule (81 FR 95827, December 28, 2016) and the supporting analysis is presented in the memorandum, ''Brew Ethanol Correlation Review for the Manufacturing of Nutritional Yeast Source Category Memo Correction,'' which is available in the docket for this action (Docket ID No. EPA–HQ–OAR–2015–0730–0181). We proposed to require facilities that monitor brew ethanol to adopt the remaining compliance demonstration option, which involves the installation and use of CEMS to monitor VOC emissions directly in the fermenter exhaust.

2. How did the requirements change since proposal?

The EPA is making no changes to the removal of the option to demonstrate compliance by monitoring brew ethanol in the fermenter liquid and is finalizing this amendment as proposed. However, as explained in section IV.G of this preamble, in response to public comments, the EPA has allowed 2 additional years for facilities to comply with this amendment in addition to the 1 year that was proposed.

3. What key comments did we receive and what are our responses?

Comment: One commenter challenged the EPA's technical analysis supporting the proposed removal of the option to monitor brew ethanol as a method to demonstrate compliance with emission limitations, and claimed that the analysis was fundamentally flawed and misleading. The commenter disagreed with the EPA's finding that brew ethanol monitoring resulted in a high level of inconsistency in the amount of VOC emissions estimated for a particular brew ethanol concentration and requested that brew ethanol monitoring be retained as a valid parametric CEMS. The commenter also suggested that the EPA erred by using ''hypothetical'' VOC concentrations instead of the actual batch-average concentration values of brew ethanol in the fermenter liquid (BAE) from one of the performance tests to demonstrate the potential for emission limitation exceedances.

The commenter provided a report that analyzed brew ethanol correlation performance tests from 2007 through 2016 (see EPA–HQ–OAR–2015–0730–0191–A2). The report presented the conclusion that the combined 10 years (2007–2016) of performance test data demonstrated that when using the actual BAE and maximum BAE results for each fermentation stage over the 10-year period and applying the results to each year's linear regression analysis, there was not a single year where the facility would have exceeded the prescribed VOC emission limitations for the tested batches. Furthermore, the commenter stated that even when using the highest BAE observed during one of the performance tests over the last 10 years and applying the most unfavorable linear regression analysis from those 10 years, there was no potential for the facility to have exceeded the corresponding VOC emission limitations.

Response: The commenter has provided no evidence to dispute the EPA's central conclusion that the calculated brew ethanol linear regression equations demonstrate an unacceptable level of variability. The EPA's decision to disallow the brew ethanol monitoring option rests on this conclusion. The analysis of ''higher end'' brew ethanol concentrations, which the EPA believes remains reasonable (as discussed below), was utilized to illustrate the effect of relying on the highly variable brew ethanol linear regressions on compliance, and is not the primary support for the EPA's decision to discontinue the brew ethanol monitoring option.

The core point of the EPA's analysis is that the level of VOCs emitted for a given percentage of brew ethanol measured in a fermenter is different for every batch that was tested in a given fermentation stage between 2012 and 2016. The additional data submitted by the commenter for the years 2007 through 2011 further support this finding. Depending on which of the 10 performance test batches is evaluated, the BAVOC value that would be calculated for a BAE value of 0.14 from a batch manufactured in the third-to-last stage ranged from as low as 76 ppmv to as high as 207 ppmv. Similar results were reported for the second-to-last and last fermentation stages. Our analysis of the variability is provided in the memorandum titled, ''Brew Ethanol Correlation Review for the Manufacturing of Nutritional Yeast Source Category—Final Rule,'' which has been updated with the additional data submitted by the commenter and is available in the docket for this rulemaking.

For many batches produced over the course of a year, the variability between annual correlation equations will not affect the facility's compliance status because the batches are well under the established emission limitations for each of the correlation equations. However, for those batches with higher brew ethanol concentrations, the variability may have a significant impact on the resulting BAVOC value calculated for those batches and the overall compliance status of the yeast manufacturing facility, depending on the overall percentage of batches with higher BAE values.

For the purposes of estimating emissions, the current method does not provide reliable information about the thousands of batches that are not tested, other than showing whether emissions are rising or falling. In order for the existing correlation method to be useful for compliance purposes, it is necessary that the relationship between BAE and BAVOC be relatively constant between batches for a given fermentation stage, regardless of the point-in-time in which they were tested. The manufacturing of yeast is a biological process and some degree of variation is expected. However, emissions are also determined by a few key process parameters, including the amount of available oxygen and the composition and amount of the sugar and nutrient mixture fed to the yeast in each batch. The review of the data in the memorandum titled, ''Brew Ethanol Correlation Review for the Manufacturing of Nutritional Yeast Source Category—Final Rule,'' which is available in the docket for this rulemaking, shows that the relationship between brew ethanol concentration and VOC emissions is affected by some combination of these or other process parameters since the correlation is not constant for each tested batch and each fermentation stage. The inconsistent correlations suggest that the brew-to-exhaust correlation method does not yield reliable emissions information for batches of yeast other than those specific batches used for the annual performance tests.

The EPA disagrees that the use of sample VOC concentrations other than the BAE values measured during a performance test with the corresponding correlation equation to assess the brew ethanol correlation method is misleading. Rather, this is the process

laid out in the rule for the facility to determine compliance with the emission limitations. Each year, the facility is required to test only three individual batches (one from each fermentation stage) out of the thousands of batches that are manufactured during the year. The facility then estimates BAVOC values for the thousands of other batches using the correlations obtained during the performance tests that year. The EPA analyzed 5 years of actual BAVOC values recorded by the facility and used the corresponding year's correlation equations to calculate a BAE value for every batch manufactured during those 5 years. The ''higher end'' values used in the memorandum, ''Brew Ethanol Correlation Review for the Manufacturing of Nutritional Yeast Source Category—Final Rule'' were all within the ranges of actual BAE values measured during the corresponding years by the facility. The commenter also stated that none of the 30 individual batches that were used for an annual performance test between 2007 and 2016 exceeded the prescribed VOC emission limitations. The EPA agrees; in fact, the linear regression must be calculated from a batch that does not exceed the emission limitations, as required by 40 CFR 63.2161(d)(3). If the commenter does not agree that the correlation equation should be applied to any BAE values other than those directly tested, the commenter would seem to be suggesting that a performance test must be conducted on each individual batch manufactured by a facility, which would be cost-prohibitive and is not feasible for a facility. To clarify, the EPA never stated that the facility exceeded the NESHAP emission limitations for any of the batches monitored during a performance test between 2011 and 2016. Rather, we demonstrated that the relationship between the concentration of VOC in the fermenter exhaust and the percent of brew ethanol in the fermenter liquid is not consistent between batches. Therefore, the use of the relationship between VOC concentration and percent of brew ethanol from one batch to calculate emissions from all other batches in the same fermentation stage over an arbitrary period of time is unreliable. While this could mean that the facility under-reports emissions from some batches, it also means that the facility could over-report emissions from some batches. This potential for over-reporting is best illustrated with the use of ''higher end'' BAE values. If a particular correlation was established one year for a batch that had an unusually high relationship between VOC concentration and brew ethanol percentage, the continued use of that correlation for the period of that year could conceivably cause the facility to calculate BAVOC values over the emission limitations for enough batches that the facility would appear to be out of compliance; such a circumstance would cause the facility to incur significant compliance costs, regardless of what the actual emissions were since actual emissions are not tested.

As a point of clarification, the commenter refers to brew ethanol monitoring as a ''parametric CEMS.'' The commenter is combining two elements together that have different regulatory meanings. A continuous monitoring system can be a continuous parameter monitoring system (CPMS) or a CEMS, but a CPMS is not a CEMS. CPMS and CEMS are defined separately at 40 CFR 63.2, such that a CPMS is ''used to sample, condition (if applicable), analyze, and provide a record of process or control system parameters'' and a CEMS is ''used to sample, condition (if applicable), analyze, and provide a record of emissions''. The EPA revised the rule language to use ''brew ethanol monitor'' instead of ''CEMS'' because a brew ethanol monitor does not record VOC emissions and, thus, is not a CEMS. A brew ethanol monitor is used to measure the brew ethanol concentration in the fermenter liquid, which is then used to estimate VOC emissions via the brew ethanol correlation. The change in terminology did not result in any changes to the existing requirements. Rather it ensured the existing language was technically correct.

Comment: One commenter indicated that multiple facilities use brew ethanol monitoring to calculate VOC emissions and, thus, brew ethanol monitoring should not be eliminated as an acceptable option. The commenter described that one facility uses brew ethanol monitoring as well as CEMS to develop VOC emissions data, with the brew ethanol monitoring serving as a quality assurance step.

Response: Only one facility currently uses brew ethanol monitoring to demonstrate compliance; the other facilities all utilize CEMS VOC data to demonstrate compliance with the standard. Use of brew ethanol monitoring for quality assurance does not prove its capability to provide accurate and reliable data for a compliance demonstration. The final rule does not prohibit the use of other methods of quality assurance for process control in addition to the systems necessary to meet the requirements of the rule.

Comment: Two commenters argued that requiring facilities to install flame ionization detection (FID) CEMS to replace brew ethanol monitoring would not provide emissions data that is more reliable or less variable and that the EPA has not shown that CEMS would result in meaningful improvement to compliance or regulatory outcomes. One commenter cited a letter (see EPA–HQ–OAR–2015–0730–0191–A54) that commented on the accuracy of FID CEMS; the letter stated that the presence of oxygen, moisture, and hydrocarbons in fermenter emissions have the potential to interfere with FID CEMS technology and cause variability in any data collected using FID CEMS.

Response: The EPA disagrees that the use of brew ethanol monitoring is comparable to the use of FID CEMS to monitor emissions from the manufacturing of nutritional yeast. As explained previously in this section and the memorandum, ''Brew Ethanol Correlation Review for the Manufacturing of Nutritional Yeast Source Category—Final Rule,'' which is available in the docket for this rulemaking, the brew ethanol method does not account for batch-specific variables affecting emissions. An FID CEMS, on the other hand, does indicate batch-specific emissions, which increases confidence that reported emissions are reliable. Additionally, such data can help a facility avoid the potential for erroneously determining that it is out of compliance compared to the scenario of using a batch with an unusually high ratio of VOC emissions to brew ethanol content for the annual performance test and the subsequent correlation calculation.

While it is true that the accuracy of an FID CEMS can be affected by factors such as moisture, the commenter does not acknowledge the common procedures in place to minimize these effects (such as the use of heated sample lines) or the difference between monitoring system malfunctions and day-to-day reliability of these systems. Similarly, the letter discusses technical issues with response factors. Response factors are needed to establish the relationships of different gases to the one used as the calibration standard for a measurement instrument. Since the standard is expressed in terms of VOC as propane and the FID CEMS are calibrated with propane (as required by 40 CFR 63.2163 (d)), response factors are not used and the commenter's argument is irrelevant.

4. What is the rationale for our final approach?

For the reasons explained in the preamble to the proposed rule (81 FR 95827, December 28, 2016), in the comment responses in section IV.D.3 of this preamble, and in the memorandum, ''Brew Ethanol Correlation Review for the Manufacturing of Nutritional Yeast Source Category—Final Rule,'' which is available in the docket for this rulemaking, we are finalizing the removal of the option to demonstrate compliance by monitoring brew ethanol in the fermenter liquid as proposed, with the changes related to frequency described in section IV.D.2 of this preamble.

We finalized requirements at 40 CFR 63.2150(b) and 63.2166, and Tables 3, 4, and 8 to subpart CCCC to remove the option to monitor brew ethanol.

E. Requirement To Conduct RATA

1. What did we propose?

The EPA proposed a requirement in 40 CFR 63.2163 to conduct annual RATA for all VOC CEMS, which were previously exempt from this quality assurance requirement. This proposed requirement specified the use of Procedure 1 of appendix F to part 60 to evaluate the performance of the installed VOC CEMS over an extended period of time (81 FR 95829, December 28, 2016). The EPA also proposed to replace an outdated reference with the current version of the EPA's traceability protocol for use in quality assurance procedures for CEMS.

2. How did the requirements change since proposal?

The EPA has maintained the proposed requirement to conduct ongoing RATA; however, in response to public comments, we are revising the frequency of the RATA. We are finalizing a requirement for facilities to conduct RATA for each CEMS at least once every 3 years, instead of annually. The EPA also corrected the proposed rule language (see 40 CFR 63.2163(b)(3)) to clarify that the current version of the EPA's traceability protocol (EPA/600/R–12/531) replaces citation 2 of Procedure 1 of appendix F to 40 CFR part 60; at proposal, the EPA incorrectly cited reference 2 of Performance Specification 8 of appendix B to 40 CFR part 60.

3. What key comments did we receive and what are our responses?

Comment: A commenter did not support the proposed requirement to require annual RATA for all CEMS and stated that it was a costly procedure that would not enhance process control or achieve any valid regulatory goal. If RATA are required, the commenter suggested that RATA be conducted on a 3- to 5-year cycle, rather than annually. The commenter also requested the final rule clarify that RATA are not required every time a CEMS is repaired or replaced.

One commenter stated the more stringent monitoring requirements were not justified because it would not lead to a reduction in emissions and would unnecessarily increase cost.

Response: During the site visits conducted for this rulemaking, it was noted that many of the malfunctions recorded by the facilities subject to this rule were due to malfunctions of the compliance monitoring systems. Regular RATA ensure the CEMS continue to produce valid data, which is necessary for the owner or operator, as well as the EPA, to ensure compliance. A RATA assesses both the instrument accuracy in measuring the target analyte in the emission matrix (which daily calibrations and audits using reference gases do not) as well as the representativeness of the CEMS sampling location.

It is routine for the EPA to require annual RATA of CEMS. While the original rule did not require annual RATA for FID CEMS, the EPA has finalized revisions to require ongoing quality assurance procedures (including RATA) in many rules since 2001. For example, ongoing quality assurance procedures were included in the Metal Coil Surface Coating, Miscellaneous Coating Manufacturing, Plywood and Composite Wood Products, and Portland Cement Manufacturing MACT standards, promulgated on June 10, 2002; December 11, 2003; July 30, 2004; and February 12, 2013, respectively. The addition of RATA procedures to the Nutritional Yeast rule helps complete this missing, but necessary, quality-assurance component.

However, to reduce burden, the EPA is finalizing a requirement to conduct RATA at least once every 3 years, instead of annually, as proposed.

The EPA is not revising the rule language to state that RATA are not required in certain instances. In fact, the replacement of a CEMS would require a RATA to ensure accuracy of the measured data.

4. What is the rationale for our final approach?

For the reasons explained in the preamble to the proposed rule (81 FR 95829, December 28, 2016) and in the comment responses in section IV.E.3 of this preamble, we are finalizing requirements in 40 CFR 63.2163 to conduct RATA, as proposed, with the changes related to frequency and the traceability protocol citation described in section IV.E.2 of this preamble.

F. Requirement To Collect All Valid CEMS Data

1. What did we propose?

The EPA proposed a requirement to collect CEMS data at all times during each batch monitoring period, except for periods of monitoring system malfunctions, required monitoring system quality assurance or quality control activities, and any scheduled maintenance (81 FR 95829, December 28, 2016). The requirements were proposed at 40 CFR 63.2163, 63.2170, 63.2181(c)(8), and 63.2182(b)(9).

2. How did the requirements change since proposal?

The EPA is finalizing, as proposed, the requirement to collect all valid CEMS data. In response to comments, we have also finalized clarifications to the rule text to reinstate 40 CFR 63.8(c)(4)(ii), (c)(7), and (g)(2) of the General Provisions that specify the minimum operation requirements for CEMS (at least one cycle every 15 minutes), the definition and requirements for ''out of control'' CEMS, and the procedures for the reduction of CEMS data to hourly averages.

3. What key comments did we receive and what are our responses?

Comment: A commenter stated that collecting CEMS data at all times, instead of for 75 percent of the batch hours, is an impossible bar that is not achievable in practice. The commenter stated that collecting data from 75 percent of batch hours is a reasonable accommodation of the fact that monitoring equipment cannot operate perfectly or be calibrated 100 percent of the time in an industrial plant. The commenter suggested a monitoring requirement of total CEMS uptime of 75 percent of fermentation time during rolling 12-month periods. The commenter also requested the EPA clarify that ''at all times'' means logging data once every 15 minutes.

The commenter stated that nothing in the record supports the theory that more stringent monitoring will add precision to the measurement and that any such precision would not be meaningful from an operation or compliance standpoint. The commenter noted the existing monitoring requirements are sufficient to determine the average VOC concentration in a fermenter batch and across numbers of batches. The commenter was concerned that

requiring more stringent monitoring could subject facilities to enforcement actions and citizen suits.

The commenter recommended three alternative monitoring methods for periods that CEMS are not available. The commenter also requested the EPA define expressly the procedures for monitoring system out-of-calibration, downtime, or missing data in the rule language, rather than using cross references to other EPA technical procedures.

Response: We emphasize that the proposed amendments specified that data must be collected ''at all times during each batch monitoring period, except for periods of monitoring system malfunctions, required monitoring system quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments), and any scheduled maintenance.'' We disagree that a requirement to collect CEMS data at all other times is an impossible bar that is not achievable in practice. As far back as 1994, the EPA's Office of Water reported that total hydrocarbon (THC) CEMS, which are a subset of VOC CEMS, along with other analyzers necessary to correct values to standard moisture and oxygen content, were ''. . . able to demonstrate a data capture rate of 100 percent, based on four measurements per minute.'' [2] Electronically submitted data from Portland cement source owners or operators currently using VOC CEMS as a compliance method also refutes the commenter's assertion. As shown from a quick search of submissions to the EPA's ERT,[3] at least five separate facilities [4] report greater than 90-percent uptime for their THC CEMS.[5] Moreover, none of the facilities reported an inability to collect monitoring data at all times that their units were operating and the commenter did not provide any examples of the inability to collect data other than monitor malfunctions or quality assurance/quality control activities.

We find that the commenter misinterprets the requirement to collect data at all times. The proposed rule does not require the VOC CEMS to be operating perfectly or calibrated for 100 percent of the time. In fact, the rule specifically prohibits data collection during periods of monitoring system malfunction or of required monitoring system quality assurance or control activities—such as calibrations and scheduled maintenance (see 40 CFR 63.2170(b)). Moreover, the rule allows owners or operators to establish and follow their own CEMS quality control programs with site-specific performance evaluation plans that cover items such as initial and subsequent calibrations, calibration drift specifications, preventive maintenance, accuracy audit procedures, and CEMS corrective action procedures (see 40 CFR 63.8(d)(2)), as referenced by Table 6 of the rule). The commenter's concern for practicality regarding 100-percent data collection is misplaced; while the rule requires complete data collection from certain periods, it does not require 100-percent data collection. Moreover, in the event that data are not collected as required during certain periods, the occurrences are specified as deviations, rather than automatic violations, of the rule; such deviations are to be reported by owners or operators to regulatory authorities who would take appropriate corrective action as necessary (see 40 CFR 63.2170(d)). Finally, source owners or operators are able to use the aforementioned site-specific monitoring plans to obtain approval from regulatory authorities for replacement emissions monitoring capabilities through approaches such as redundant or independent temporary systems prior to their use. While we reasoned that a facility may achieve enhanced process control from the amendments to the rule, this potential enhancement was not the basis for requiring the collection of CEMS data at all times. Given the variability in emissions throughout the process of manufacturing a batch of yeast, it is necessary to collect data at all times the CEMS are operational (given the exemptions noted above) to calculate accurate BAVOC values. The goal of the revision is to ensure the values collected and reported are suitable for demonstrating compliance with the rule. The enhanced monitoring data will allow us, owners or operators, and the public to have greater confidence in compliance determinations based on those measurements, and, therefore, greater confidence that the expected health benefits of the rule are achieved.

We disagree with the commenter's view that the monitoring is more stringent or could subject facilities to an increased number of enforcement actions or citizen suits, as the rule requires compliance with the emission limitations at all times. Monitoring itself does not affect a facility's actual compliance status and, as stated above, monitoring downtime is characterized as a deviation from, rather than violation of, emission standards. Regarding enforcement discretion, we rely on our regulatory partners to assess the individual, case-specific facts and to take appropriate action when necessary to correct problems. Owners or operators can take steps under their own control to reduce or eliminate any compliance concerns through activities such as increased attention to emissions-causing processes; and development, acceptance, and use of redundant monitoring systems.

We agree with the commenter's suggestion to clarify in the rule a minimum CEMS cycle time of 15 minutes, in which a value would be collected and recorded. This clarification was included by reinstating the applicability of 40 CFR 63.8(c)(4)(ii) of the General Provisions in Table 6. Furthermore, we have reinstated the applicability of 40 CFR 63.8(g)(2) of the General Provisions in Table 6 that allows a minimum of two data points (each representing 15-minute periods) or an arithmetic or integrated 1-hour average of CEMS data to constitute a valid hour of data collection during periods of calibration, quality assurance, or maintenance activities. These two sections of the General Provisions were not applicable to the 2001 Manufacturing of Nutritional Yeast, because alternate definitions were included in the rule. Now that the CEMS requirements have been updated, there is no need for separate requirements for this source category and the requirements from the General Provisions can be applied.

We do not agree with suggestions to write out monitoring system procedures when those procedures already exist in other applicable rules. Where relevant procedures already exist in other rules, our policy is to cross-reference those procedures; cross-referencing eliminates duplicative portions of rules and ensures consistency. While we do not see the need for alternative monitoring methods for periods when VOC CEMS are unavailable, since the

[2] Available at *https://cfpub.epa.gov/webfire/index.cfm?action=fire.searchERTSubmission.*

[3] Available at *https://cfpub.epa.gov/webfire/index.cfm?action=fire.searchERTSubmission.*

[4] The facilities and periods over which THC monitoring was reported include: Ash Grove Cement in Durkee, Oregon, from July through December 2016; Signal Mountain Cement Company in Chattanooga, Tennessee, from September 2015 through December 2016; Cemex Construction Materials Atlantic in Knoxville, Tennessee, from February through December 2016; Holcim (US) in Theodore, Alabama, from January through December 2016; and Lehigh Ready Mix Cement in Leeds, Alabama, from July through December 2016.

[5] While the Portland cement manufacturing emission reports only require CEMS downtime greater than or equal to 90 percent to be reported [see 40 CFR 63.1354(b)(10)], subject facilities—just like as proposed for nutritional yeast manufacturers—are required to conduct all monitoring in continuous operation at all times that the units are operating [see 40 CFR 63.1350(i) and (m)(2)].

aforementioned data on the use of CEMS in other source categories from the EPA's ERT showed no periods of VOC CEMS unavailability, the rule does not prohibit owners or operators from proposing—and from regulatory authorities accepting—alternate means for assessing emissions as part of corrective action procedures for a malfunctioning VOC CEMS as part of the source's quality control program. Given the high level of variability in emissions between batches that was demonstrated by the data used to analyze the brew ethanol monitoring option, we would recommend owners or operators seek other means—perhaps redundant VOC CEMS—as better alternatives for determining compliance during periods when the primary VOC CEMS is malfunctioning. Of course, even with approval of other means for assessing emissions, failure to provide VOC CEMS data as required would remain a deviation and constitute monitor downtime, which must be reported according to rule requirements in 40 CFR 63.2181.

4. What is the rationale for our final approach?

For the reasons explained in the preamble to the proposed rule (81 FR 95829, December 28, 2016) and in the comment responses in section IV.F.3 of this preamble, we are finalizing requirements to collect all valid CEMS data, as proposed, with the additional clarifications described in section IV.F.2 of this preamble. The final requirements are specified at 40 CFR 63.2163, 63.2170, 63.2181(c)(8), and 63.2182(c)(5), and in Table 6 to subpart CCCC.

G. Compliance Dates for the Amendments

1. What did we propose?

The EPA proposed that currently operating facilities must immediately comply with one of the two revised forms of the fermenter VOC standards upon the effective date of the final rule, and that facilities that currently demonstrate compliance by monitoring brew ethanol in the fermenter have up to 1 year to install CEMS. The EPA proposed that currently operating facilities must immediately comply with the additional testing, monitoring, reporting, and recordkeeping requirements (*i.e.,* the removal of GC CEMS, collection of all valid CEMS data from the entire batch monitoring period, requirement to conduct RATA, use of Procedure 1 of Appendix F to part 60 for VOC CEMS, and the electronic reporting requirements), as well as with the revised SSM requirements. The EPA also proposed that sources that are constructed or reconstructed after promulgation of the rule revisions must comply with all amendments upon startup of the affected source (81 FR 95834, December 28, 2016).

2. How did the requirements change since proposal?

Based on public comments, the EPA has changed the compliance date for existing sources to comply with the revised form of the fermenter VOC standards from immediate compliance upon promulgation of the rule to 1 year after the effective date of this rule. The EPA has clarified language in 40 CFR 63.2181(c)(4) through (7) describing facilities' reporting obligations under each of the three options for demonstrating compliance. The language, as finalized, allows facilities transitioning between compliance demonstration using the 98-Percent Option and the Average Option to report compliance in a semi-annual compliance report under different approaches for different 12-month calculation periods, as appropriate. This allows existing facilities the ability to continue to demonstrate compliance using the 98-Percent Option for all 12-month calculation periods that end before or on the compliance date for this amendment. For example, if the effective date of this final rule is October 31, 2017, then the compliance date for this amendment would be October 31, 2018. If an existing facility was scheduled to submit a semiannual compliance report by January 31, 2019, for the reporting period covering July 1, 2018, through December 31, 2018; the facility could demonstrate compliance for the 12-month calculation periods ending on July 31, 2018, August 31, 2018, September 30, 2018, and October 31, 2018, using the 98-Percent Option and for the 12-month calculation periods ending on November 30, 2018, and December 31, 2018, using the Average Option. Facilites may voluntarily choose to demonstrate compliance using the revised form of the emission limitations earlier, so that all of the 12-month calculation periods ending within the semiannual compliance report demonstrate compliance using the same form of the emission limitations. Facilities that choose to use the Batch Option to demonstrate compliance with the emission limitations must apply the demonstration to all batches within a semiannual reporting period; that is, facilities cannot transition to demonstrating compliance under the Batch Option in the middle of a reporting period. Therefore, unless an existing facility that is transitioning from the 98-Percent Option to the Batch Option is due to begin a new semiannual reporting period in the month following the compliance date for this amendment, the facility has two interim options for demonstrating compliance. Assuming, for example purposes, a reporting period of July 1, 2018, through December 31, 2018, and a compliance date for the final rule on October 31, 2018; the facility could demonstrate compliance for the entire reporting period using the Batch Option. Alternately, the facility could demonstrate compliance using the 98-Percent Option for 12-month calculation periods ending on July 31, August 31, September 30, and October 31, and demonstrate compliance for 12-month calculation periods ending on November 30 and December 31, 2018, using the Average Option. The facility could then begin demonstrating compliance for the January 1, 2019, through June 30, 2019, reporting period using the Batch Option. A new table, Table 7, has been added to the rule to summarize when existing and new affected sources must comply with the different requirements for the form of the emission limitations.

Facilities that currently demonstrate compliance by monitoring brew ethanol have up to 3 years after the effective date of the rule to install CEMS, instead of the proposed 1 year. A new table, Table 8, has been added to the rule to summarize when existing and new affected sources must comply with the different requirements for emissions monitoring equipment.

3. What key comments did we receive and what are our responses?

Comment: One commenter does not support complying with the revised form of the fermenter standards immediately upon promulgation of the rule, and requested a minimum of 2 years to demonstrate compliance. The commenter stated it would take time for facilities to convert to any new methodology, especially as it relates to recordkeeping and reporting. The commenter remarked that immediate compliance upon issuance of a final rule is impracticable and unduly burdensome; facilities will not know when the EPA plans to issue the final rule and will have no understanding in advance of what the final rule will require.

Response: We disagree that immediate compliance would be impracticable for certain reasons the commenter noted; specifically, the commenter knows the final rule will be issued by October 1,

2017, due to the court-ordered deadline for this rulemaking. Furthermore, it is not accurate to say the commenter will have ''no understanding'' of what the final rule will require, given the nature of notice-and-comment rulemaking. The EPA notes that the emission limitations are simply expressed in a revised format and are not expected to result in any changes in compliance status. However, it is also reasonable to provide additional time to demonstrate continuous compliance with the revised form of the emission standard for facilities that are currently operating because it will require a change in recordkeeping and reporting procedures. CAA section 112(i)(3) requires that compliance dates for existing sources require compliance with any emission standard, limitation, or regulation promulgated under section 112 ''as expeditiously as practicable, but in no event later than 3 years after the effective date of such standard.'' While we believe, based on information gathered during the site visits and phone calls conducted prior to the proposed rulemaking, that the facilities have all of the data needed to demonstrate continuous compliance with the amended requirements immediately, it is prudent to allow time to train staff and establish long-term procedures for the efficient management of this data. Therefore, the EPA has finalized amendments allowing the facilities up to 1 year to demonstrate continuous compliance with the revised form of the emission limitations and the associated reporting and recordkeeping requirements. We believe that 1 year is a sufficient period of time for facilities to update recordkeeping systems and train staff. The current emission limitations require facilities to record the emissions from each batch in a rolling 12-month period, compare the emissions from each batch with the standard, and count how many of the batches had emissions equal to or lower than the limit. A facility then determines the total number of batches that were manufactured during the rolling 12-month period and calculates the percentage of batches in that period that met the emission limitations. The revised form of the standard is slightly more streamlined in that facilities simply average the emissions from each batch produced in a given fermentation stage over the 12-month period and compare it to the emission limitation. While this necessitates a change in the overall calculation and reporting procedures, it does not require significant actions such as the selection, installation, and testing of new equipment or changes to the yeast manufacturing process that would warrant 2 years to implement the revisions. As specified in section III.E of this preamble to the rule, facilities must continue to demonstrate continuous compliance with the existing emission limitations and reporting and recordkeeping requirements during the time it takes them to transition to the revised requirements. The revised requirements are expected to be slightly more streamlined than the existing requirements and there is no prohibition against facilities from demonstrating compliance with the new form of the emission limitations and associated reporting and recordkeeping requirements immediately.

Comment: Two commenters do not support having only 1 year to install CEMS if a facility currently monitors brew ethanol. The commenters requested a minimum of 3 years to comply to allow for the purchase, design, testing, and installation of new CEMS equipment. The commenters stated 3 years is consistent with the approach for sources when the rule was originally promulgated and the EPA has authority to allow 3 years to comply under CAA section 112(i)(3).

Response: The EPA has finalized requirements allowing the one existing facility that currently demonstrates compliance by monitoring brew ethanol up to 3 years to install CEMS to demonstrate compliance. This facility must continue to meet the performance test and operation and maintenance requirements of 40 CFR 63.2161 and 40 CFR 63.2164 during this time. Additionally, we note that the facility must comply with the revised form of the emission limitations at the specified time (within 1 year), regardless of the monitoring method used.

4. What is the rationale for our final approach?

For the reasons explained in the comment responses in section IV.G.3 of this preamble and in the response to comments document in the docket for this rulemaking, we are finalizing the requirements related to the compliance dates for the demonstration of compliance with the revised form of the fermenter VOC standards and the use of CEMS for existing facilities with the changes described in section IV.G.2 of this preamble. We finalized revisions in Table 7 and Table 8 to subpart CCCC to specify the emission limitation and monitoring system timelines. We finalized the revisions requiring immediate compliance for the additional testing, monitoring, reporting, and recordkeeping requirements (*i.e.,* the removal of GC CEMS in 40 CFR 63.2163(a), collection of all valid CEMS data from the entire batch monitoring period in 40 CFR 63.2163(h), requirement to conduct RATA in 40 CFR 63.2163(b)(1), use of Procedure 1 of Appendix F to part 60 for VOC CEMS in 40 CFR 63.2163(b)(3), and the electronic reporting requirements in 40 CFR 63.2181(a)), as well as with the revised SSM requirements as proposed.

V. Summary of Cost, Environmental, and Economic Impacts and Additional Analyses Conducted

A. What are the affected facilities?

We anticipate that four nutritional yeast facilities currently operating in the United States will be affected by this final rule.

B. What are the air quality impacts?

The amendments to this subpart will have a positive impact on air quality. While facilities will not need to install additional controls to comply with the fermenter emission limitations, the revisions remove the exemption that allowed up to 2 percent of the total number of batches to be produced with no limit on emissions (*i.e.,* the revisions apply the emission limitations continuously). The rule revisions also remove the exemption that allowed emissions from batches produced during periods of malfunction, other than monitoring system malfunctions, to be excluded when determining compliance with emission limitations. While the air quality impact of these changes cannot easily be quantified due to a current lack of data on the number of and emissions from previously exempted batches, the practical effect is that production of all batches of nutritional yeast at affected sources will now be required to meet emission limitations. The other revisions, which affect testing, monitoring, recordkeeping, and reporting requirements, will ensure that emissions monitoring equipment continues to perform as expected and provides reliable data from each facility to be used in determining compliance. For reference, the baseline emissions for each facility are documented in the memorandum, ''Emissions Data and Acute Risk Factor Used in Residual Risk Modeling: Manufacturing of Nutritional Yeast Source Category,'' which is available in the docket for this action (Docket ID. No EPA–HQ–OAR–2015–0730–0007).

C. What are the cost impacts?

We have estimated compliance costs for all existing sources to perform RATA for VOC CEMS and for the single facility currently monitoring brew ethanol to install the necessary monitoring equipment (*i.e.,* VOC CEMS). We estimated a total capital investment of $511,000 and an average annual cost of approximately $115,000. The details of the cost estimates are documented in the memorandum, ''Costs for the Manufacturing of Nutritional Yeast Source Category—Final Rule,'' which is available in the docket for this action.

D. What are the economic impacts?

The economic analysis conducted for this action is presented in the memorandum, ''Economic Impact Analysis for the Manufacturing of Nutritional Yeast Risk and Technology Review (RTR),'' which is available in the docket for this action. The costs of this action are associated with the installation and maintenance of CEMS at one facility, and ongoing RATA for CEMS at all four facilities subject to subpart CCCC. The equivalent annualized net cost of this action is approximately $86,000 under a 3-percent discount rate, and $89,000 under a 7-percent discount rate.

This action is projected to affect four facilities, and none of these facilities is ultimately owned by a small entity. Of the four facilities affected by this final action, two are ultimately owned by the same private entity. The remaining two facilities are each ultimately owned by different private entities. The equivalent annualized net costs for each of the three entities range from approximately $8,600 to $65,000 under a 3-percent discount rate, and from approximately $8,300 to $70,000 under a 7-percent discount rate. The equivalent annualized net compliance costs for the three entities are all estimated to be less than 0.1 percent of sales for their respective ultimate parent companies. Therefore, we expect that this final action will not have a significant economic impact on the affected entities.

E. What are the benefits?

As discussed above, the amendments to this subpart will have positive impacts on air quality and may improve air quality by removing the brew ethanol monitoring option and the exemption that allowed a portion of batches to be produced without being subject to emission limitations. The changes to monitoring methods will increase the reliability of emissions data collected by facilities by requiring continued maintenance of emission monitoring systems and monitoring of actual emission measurements at all times instead of allowing emission estimates based on brew ethanol correlations and collection of 100 percent of valid CEMS data (instead of 75 percent). These changes will allow regulators to clearly assess whether the standards for the protection of public health and the environment are being met. In particular, the demographics analysis shows that increased risk levels are concentrated around the facility that is not currently using CEMS. The amendments will directly benefit this population, of which 100 percent are definded as minority, by increasing the accuracy of the emissions data that is monitored and reported (see section V.F of this preamble). Other amendments will result in additional benefits, such as streamlined reporting through electronic methods for owners or operators of nutritional yeast manufacturing facilities and increased access to emissions data by stakeholders, as described in the preamble to the proposed rule (81 FR 95834, December 28, 2016).

F. What analysis of environmental justice did we conduct?

To examine the potential for any environmental justice issues that might be associated with emissions from this source category, we performed a demographic analysis of the population close to the four affected facilities (within 50 kilometers (km) and within 5 km). In this analysis, we evaluated the distribution of HAP-related cancer risks and non-cancer hazards from the four nutritional yeast manufacturing facilities across different social, demographic, and economic groups within the populations living near facilities identified as having the highest risks.

The analysis indicated that the minority population living within 50 km (1,700,000 people, of which 41 percent are minority) and within 5 km (131,567 people, of which 68 percent are minority) of the four nutritional yeast manufacturing facilities is greater than the minority population found nationwide (28 percent). The specific demographics of the population within 5 and 50 km of the facilities indicate potential disparities in certain demographic groups, including the ''African American,'' ''Below the Poverty Level,'' and ''Over 25 and without high school diploma'' groups.

When examining the risk levels of those exposed to emissions from the four nutritional yeast manufacturing facilities, we find approximately 750 persons around one facility are exposed to a cancer risk greater than or equal to 1-in-1 million with the highest exposure to these individuals of less than 2-in-1 million. Of these 750 persons, all are defined as minority. When examining the non-cancer risks surrounding these facilities, no one is predicted to have a chronic non-cancer TOSHI greater than 1. These findings are based on the level of acetaldehyde emissions the facility reported to the 2011 NEI. The facility calculated these emissions by applying acetaldehyde emissions rates (pounds of acetaldehyde per batch) for each fermentation stage determined from a stack test conducted in 2000. During the public comment period, the facility performed additional testing and determined that the acetaldehyde emissions rates during the Februray 2017 test were approximately half of the previous rates. Therefore, the facility anticipates that future estimates of annual emissions will be reduced. Additionally, this facility currently monitors brew ethanol to comply with the emission limitations established in this NESHAP. The final amendments require the facility to install CEMS to monitor emissions. We anticipate that the use of CEMS will directly benefit this population by increasing the accuracy of the emissions data that are monitored and reported because the CEMS reflects batch-specific emission characteristics that are not accounted for with the brew ethanol correlation.

The EPA has determined that this rule does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples because the health risks based on actual emissions are low (below 2-in-1 million), the population exposed to risks greater than 1-in-1 million is relatively small (750 persons), and the rule maintains or increases the level of environmental protection for all affected populations.

The methodology and the results of the demographic analysis are included in the technical report, ''Risk and Technology Review—Analysis of Socio-Economic Factors for Populations Living Near Nutritional Yeast Manufacturing Facilities,'' which is available in the docket for this action (Docket ID No. EPA–HQ–OAR–2015–0730–0015).

G. What analysis of children's environmental health did we conduct?

The EPA assessed risks to infants and children as part of the health and risk assessments, as well as the proximity analysis conducted for this action. These analyses are documented in the

memoranda, ''Residual Risk Assessment for the Manufacturing of Nutritional Yeast Source Category in Support of the October, 2017 Risk and Technology Review Final Rule'' and ''Risk and Technology Review—Analysis of Socio-Economic Factors for Populations Living Near Nutritional Yeast Manufacturing Facilities,'' which are available in the docket for this action.

The results of the proximity analysis show that children 17 years and younger as a percentage of the population in close proximity to nutritional yeast manufacturing facilities and with an estimated cancer risk greater than or equal to 1-in-1 million is similar to the percentage of the national population in this age group (25 percent versus 24 percent, respectively). The difference in the absolute number of percentage points of the population 17 years old and younger from the national average indicates a 1-percent over-representation near nutritional yeast manufacturing facilities.

Consistent with the EPA's *Policy on Evaluating Health Risks to Children*,[6] we conducted inhalation risk assessments for the Manufacturing of Nutritional Yeast source category, considering risk to infants and children. Children are exposed to chemicals emitted to the atmosphere via two primary routes: Directly via inhalation or indirectly via ingestion or dermal contact with various media that have been contaminated with the emitted chemicals. The EPA considers the possibility that children might be more sensitive than adults to toxic chemicals, including chemical carcinogens. For each carcinogenic HAP included in this assessment that has a potency estimate available, the EPA calculated individual and population cancer risks by multiplying the corresponding lifetime average exposure estimate by the appropriate unit risk estimate (URE). This calculated cancer risk is defined as the upper-bound probability of developing cancer over a 70-year period (*i.e.,* the assumed human lifespan) at that exposure. Because UREs for most HAP are upper-bound estimates, actual risks at a given exposure level may be lower than predicted, and could be zero. For the EPA's list of carcinogenic HAP that act by a mutagenic mode-of action, we applied the EPA's *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens.*[7] This guidance has the effect of adjusting the URE by factors of 10 (for children aged 0–1), 3 (for children aged 2–15), or 1.6 (for 70 years of exposure beginning at birth), as needed in risk assessments. In this case, this has the effect of increasing the estimated lifetime risks for these pollutants by a factor of 1.6. With regard to other carcinogenic pollutants for which early-life susceptibility data are lacking, it is the EPA's long-standing science policy position that use of the linear low-dose extrapolation approach (without further adjustment) provides adequate public health conservatism in the absence of chemical-specific data indicating differential early-life susceptibility or when the mode of action is not mutagenicity. The basis for this methodology is also provided in the 2005 Supplemental Guidance.

Unlike linear dose-response assessments for cancer, non-cancer health hazards generally are not expressed as a probability of an adverse occurrence. Instead, hazard of non-cancer effects is expressed by comparing an exposure to a reference level as a ratio. The HQ is the estimated exposure divided by a reference level (*e.g.,* the reference concentration, RfC). For a given HAP, exposures at or below the reference level (HQ≤1) are not likely to cause adverse health effects. As exposures increase above the reference level (HQs increasingly greater than 1), the potential for adverse effects increases. For exposures predicted to be above the RfC, the risk characterization includes the degree of confidence ascribed to the RfC values for the compound(s) of concern (*i.e.,* high, medium, or low confidence) and discusses the impact of this on possible health interpretations. The reference levels used to determine the HQs incorporate generally conservative uncertainty factors that account for effects in the most susceptible populations including all life stages (*e.g.,* infants and children).

The EPA concludes that the standards provide an ample margin of safety to protect public health of all demographic groups, including children.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket. The EPA prepared an economic analysis of the potential costs and benefits associated with this action. This analysis, ''Economic Impact Analysis for the Manufacturing of Nutritional Yeast Risk and Technology Review (RTR),'' is available in the docket for this rule.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This rule is not subject to the requirements of Executive Order 13771 because this rule results in no more than *de minimis* costs.

C. Paperwork Reduction Act (PRA)

The information collection activities in this rule have been submitted for approval to OMB under the PRA. The ICR document that the EPA prepared has been assigned EPA ICR number 1886.03. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

Concurrent to the residual risk and technology reviews for the NESHAP, the EPA finalized amendments that change the form of the current emission limitations, require the use of VOC CEMS, require valid CEMS data from each hour of the batch monitoring period, require ongoing tests to evaluate the performance of the CEMS over time, require electronic reporting, and remove exemptions for malfunctions so that affected facilities would be subject to the emission standards at all times. This information collection request documents the recordkeeping and reporting requirements and burden imposed by the rule—both the requirements that were previously promulgated and retained, as well as the final amendments.

Respondents/affected entities: Manufacturers of nutritional yeast.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart CCCC).

Estimated number of respondents: Four facilities.

[6] *Policy on Evaluating Health Risks to Children,* U.S. Environmental Protection Agency, Washington, DC. May 2014. Available at *http://www2.epa.gov/sites/production/files/2014-05/documents/1995_childrens_health_policy_statement.pdf.*

[7] *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens.* Risk Assessment Forum, U.S. Environmental Protection Agency, Washington, DC. EPA/630/R–03/003F. March 2005. Available at *http://www.epa.gov/raf/publications/pdfs/childrens_supplement_final.pdf.*

Frequency of response: Initially and semiannually.

Total estimated burden: 1,370 hours (per year) for the responding facilities and 175 hours (per year) for the Agency. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $817,000 (per year), which includes $695,000 annualized capital and operation and maintenance costs for the responding facilities and $9,500 (per year) for the Agency to comply with all of the requirements in this NESHAP.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities.

This action is projected to affect four facilities, and none of these facilities is ultimately owned by a small entity. Details of the associated analysis are presented in the memorandum, ''Economic Impact Analysis for the Manufacturing of Nutritional Yeast Risk and Technology Review (RTR),'' which is available in the docket for this action. At the time of proposal for this action, there was one entity which was assumed to be a small business for the purpose of the analysis, as the complex ownership structure made it difficult to clearly determine the entity's size. However, between proposal and promulgation, this entity was sold to a company that owns other nutritional yeast manufacturing facilities, and which is not a small business.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments. The nationwide equivalent annualized net cost of this action for affected industrial sources is approximately $86,000 under a 3 percent discount rate, and $89,000 under a 7 percent discount rate. Details of the associated economic analysis are presented in the memorandum ''Economic Impact Analysis for the Manufacturing of Nutritional Yeast Risk and Technology Review (RTR),'' which is available in the docket for this action.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. No tribal facilities are known to be engaged in the nutritional yeast manufacturing industry that would be affected by this action. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in sections IV.A and V.G of this preamble.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The action is not related to the energy sector nor the supply, production, or price of energy.

J. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This action involves technical standards that are reasonably available and already widely used by industry. The EPA conducted a search to identify potentially applicable voluntary consensus standards. However, the Agency identified no available standards that were practical for use as alternates and none were brought to our attention in comments. Therefore, the EPA has decided to use EPA Method 25A of 40 CFR part 60, appendix A (Method) and EPA/600/R–12/531, EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards (Protocol). The Method is used to determine total gaseous organic concentration using a flame ionization analyzer. More information about the Method is available at: *https://www.epa.gov/emc/method-25a-gaseous-organic-concentration-flame-ionization.* The Protocol is used to certify calibration gases for continuous emission monitors and specifies methods for assaying gases and establishing traceability to National Institute of Standards and Technology reference standards. The Protocol and associated information is available at: *https://www.epa.gov/air-research/epa-traceability-protocol-assay-and-certification-gaseous-calibration-standards.*

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (58 FR 7629, February 16, 1994).

The documentation for this decision is contained in the proposal (81 FR 95824, December 28, 2016), section V.F of this preamble, and the technical report, ''Risk and Technology Review—Analysis of Socio-Economic Factors for Populations Living Near Nutritional Yeast Manufacturing Facilities,'' which is available in the docket for this action (Docket ID No. EPA–HQ–OAR–2015–0730–0015).

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedures, Air pollution control, Hazardous substances, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: September 29, 2017.

E. Scott Pruitt,

Administrator.

For the reasons set forth in the preamble, the Environmental Protection Agency amends 40 CFR part 63 as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

■ 2. Section 63.14 is amended by redesignating paragraphs (m)(5) through (m)(23) as (m)(6) through (m)(24), respectively; and adding a new paragraph (m)(5) to read as follows:

§ 63.14 Incorporations by reference.

* * * * *

(m) * * *

(5) EPA/600/R–12/531, EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards, May 2012, IBR approved for § 63.2163(b).

* * * * *

■ 3. Part 63 is amended by revising subpart CCCC to read as follows:

Subpart CCCC—National Emission Standards for Hazardous Air Pollutants: Manufacturing of Nutritional Yeast

What This Subpart Covers

Sec.

Subpart CCCC—National Emission Standards for Hazardous Air Pollutants: Manufacturing of Nutritional Yeast

What This Subpart Covers

§ 63.2130 What is the purpose of this subpart?

This subpart establishes national emission limitations for hazardous air pollutants (HAP) emitted from manufacturers of nutritional yeast. This subpart also establishes requirements to demonstrate initial and continuous compliance with the emission limitations.

§ 63.2131 Am I subject to this subpart?

(a) You are subject to this subpart if you own or operate a nutritional yeast manufacturing facility that is, is located at, or is part of a major source of HAP emissions.

(1) A manufacturer of nutritional yeast is a facility that makes yeast for the purpose of becoming an ingredient in dough for bread or any other yeast-raised baked product, or for becoming a nutritional food additive intended for consumption by humans. A manufacturer of nutritional yeast does not include production of yeast intended for consumption by animals, such as an additive for livestock feed.

(2) A major source of HAP emissions is any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit, considering controls, any single HAP at a rate of 9.07 megagrams (10 tons) or more per year or any combination of HAP at a rate of 22.68 megagrams (25 tons) or more per year.

(b) [Reserved]

§ 63.2132 What parts of my plant does this subpart cover?

(a) This subpart applies to each new, reconstructed, or existing ''affected source'' that produces *Saccharomyces cerevisiae* at a nutritional yeast manufacturing facility.

(b) The affected source is the collection of equipment used in the manufacture of the nutritional yeast species *Saccharomyces cerevisiae.* This collection of equipment includes fermentation vessels (fermenters), as described in paragraph (c) of this section. The collection of equipment used in the manufacture of the nutritional yeast species *Candida utilis* (torula yeast) is not part of the affected source.

(c) The emission limitations in this subpart apply to fermenters in the affected source that meet all of the criteria listed in paragraphs (c)(1) and (2) of this section.

(1) The fermenters are ''fed-batch'' as defined in § 63.2192.

(2) The fermenters are used to support one of the last three fermentation stages in a production run (*i.e.,* third-to-last stage, second-to-last stage, and last stage), which may be referred to as ''stock, first generation, and trade,'' ''seed, semi-seed, and commercial,'' or ''CB4, CB5, and CB6'' stages.

(d) The emission limitations in this subpart do not apply to flask, pure-culture, yeasting-tank, or any other set-batch (as defined in § 63.2192) fermentation, and they do not apply to any operations after the last dewatering operation, such as filtration.

(e) The emission limitations in Table 1 to this subpart do not apply to fermenters during the production of specialty yeast (defined in § 63.2192).

(f) An affected source is a ''new affected source'' if you commenced construction of the affected source after October 19, 1998, and you met the applicability criteria in § 63.2131 at the time you commenced construction.

(g) An affected source is ''reconstructed'' if it meets the criteria for reconstruction as defined in § 63.2.

(h) An affected source is ''existing'' if it is not new or reconstructed.

§ 63.2133 When do I have to comply with this subpart?

(a) If you have a new or reconstructed affected source, then you must comply with paragraph (a)(1) or (2) of this section.

(1) If you start up your affected source before May 21, 2001, then you must comply with this subpart no later than May 21, 2001.

(2) If you start up your affected source on or after May 21, 2001, then you must comply with this subpart upon startup of your affected source.

(b) If you have an existing affected source, then you must comply with this subpart no later than May 21, 2004.

(c) If you have an area source that increases its emissions, or its potential to emit, so that it becomes a major source of HAP, then paragraphs (c)(1) and (2) of this section apply.

(1) Any portion of the existing facility that is a new affected source or a new reconstructed source must be in compliance with this subpart upon startup.

(2) All other parts of the affected source must be in compliance with this subpart by no later than 1 year after it becomes a major source.

(d) You must meet the notification requirements in § 63.2180 according to the schedule in § 63.2180 and in subpart A of this part.

Emission Limitations

§ 63.2140 What emission limitations must I meet?

You must meet the applicable emission limitations in Table 1 to this subpart, according to the timeline provided in Table 7 to this subpart.

General Compliance Requirements

§ 63.2150 What are my general requirements for complying with this subpart?

(a) You must be in compliance with the applicable emission limitations in Table 1 to this subpart at all times, and demonstrate compliance according to paragraphs (a)(1) through (3) of this section.

(1) To demonstrate compliance with emission limitations by using the 98-Percent Option, you must follow the procedures of § 63.2171(b).

(2) To demonstrate compliance with emission limitations by using the Average Option, you must follow the procedures of § 63.2171(c).

(3) To demonstrate compliance with emission limitations by using the Batch Option, you must follow the procedures of § 63.2171(d).

(b) You must monitor VOC concentration continuously for each batch by using the applicable monitoring method in Table 8 to this subpart.

(c) If the date upon which you must demonstrate initial compliance as specified in § 63.2160 falls after the compliance date specified for your affected source in § 63.2133, then you must maintain a log detailing the operation and maintenance of the continuous emission monitoring systems and the process and emissions control equipment during the period between those dates.

(d) At all times, you must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require you to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether an affected source is operating in compliance with operation and maintenance requirements will be based on information available to the Administrator that may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the affected source.

Testing and Initial Compliance Requirements

§ 63.2160 By what date must I conduct an initial compliance demonstration?

(a) For each emission limitation in Table 1 to this subpart for which you demonstrate compliance using the Average Option, you must demonstrate initial compliance for the period ending on the last day of the month that is 12 calendar months (or 11 calendar months, if the compliance date for your affected source is the first day of the month) after the compliance date that is specified for your affected source in § 63.2133.

(b) For each emission limitation in Table 1 to this subpart for which you demonstrate compliance using the Batch Option, you must demonstrate initial compliance for the period ending June 30 or December 31 (use whichever date is the first date following the compliance date that is specified for your affected source in § 63.2133).

§ 63.2161 What performance tests and other procedures must I use if I monitor brew ethanol?

(a) You must conduct each performance test in Table 2 to this subpart that applies to you, as specified in paragraphs (b) through (f) of this section.

(b) You must conduct performance tests under such conditions as the Administrator specifies, based on representative performance of the affected source for the period being tested, and under the specific conditions that this subpart specifies in Table 2 to this subpart and in paragraphs (b)(1) through (4) of this section. You must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, you must make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

(1) You must conduct each performance test concurrently with brew ethanol monitoring to establish a brew-to-exhaust correlation as specified in paragraph (e) of this section.

(2) For each fermentation stage, you must conduct one run of the EPA Test Method 25A of 40 CFR part 60, appendix A–7, over the entire length of a batch. The three fermentation stages do not have to be from the same production run.

(3) You must obtain your test sample at a point in the exhaust-gas stream before you inject any dilution air. For fermenters, dilution air is any air not needed to control fermentation.

(4) You must record the results of the test for each fermentation stage.

(c) You may not conduct performance tests during periods of malfunction.

(d) You must collect data to correlate the brew ethanol concentration to the VOC concentration in the fermenter exhaust according to paragraphs (d)(1) through (3) of this section.

(1) You must collect a separate set of brew ethanol concentration data for each fed-batch fermentation stage while manufacturing the product that constitutes the largest percentage (by mass) of average annual production.

(2) You must measure brew ethanol as specified in § 63.2164 concurrently with conducting a performance test for VOC

in fermenter exhaust as specified in paragraph (b) of this section. You must measure brew ethanol at least once during each successive 30-minute period over the entire period of the performance test for VOC in fermenter exhaust.

(3) You must keep a record of the brew ethanol concentration data for each fermentation stage over the period of EPA Test Method 25A of 40 CFR part 60, appendix A–7, performance test.

(e) For each set of data that you collected under paragraphs (b) and (d) of this section, you must perform a linear regression of brew ethanol concentration (percent) on VOC fermenter exhaust concentration (parts per million by volume (ppmv) measured as propane). You must ensure the correlation between the brew ethanol concentration, as measured by the brew ethanol monitor, and the VOC fermenter exhaust concentration, as measured by EPA Test Method 25A of 40 CFR part 60, appendix A–7, is linear with a correlation coefficient of at least 0.90.

(f) You must calculate the VOC concentration in the fermenter exhaust for each batch using the brew ethanol concentration data according to Equation 1 of this section, and using the constants (CF and y) calculated by the applicable linear regression performed under paragraph (e) of this section.

$$BAVOC = BAE * CF + y \qquad \text{(Eq. 1)}$$

Where:

BAVOC = Batch-average concentration of VOC in fermenter exhaust (ppmv measured as propane), calculated for compliance demonstration

BAE = Batch-average concentration of brew ethanol in fermenter liquid (percent), measured by the brew ethanol monitor

CF = Constant established at performance test and representing the slope of the regression line

y = Constant established at performance test and representing the y-intercept of the regression line

§ 63.2162 When must I conduct subsequent performance tests if I monitor brew ethanol?

(a) For each emission limitation in Table 1 to this subpart for which compliance is demonstrated by monitoring brew ethanol concentration and calculating VOC concentration in the fermenter exhaust according to the procedures in § 63.2161, you must conduct an EPA Test Method 25A of 40 CFR part 60, appendix A–7, performance test and establish a brew-to-exhaust correlation according to the procedures in Table 2 to this subpart and in § 63.2161, at least once every year.

(b) The first subsequent performance test must be conducted no later than 365 calendar days after the initial performance test conducted according to § 63.2160. Each subsequent performance test must be conducted no later than 365 calendar days after the previous performance test. You must conduct a performance test for each 365 calendar day period during which you demonstrate compliance using the brew ethanol correlation developed according to § 63.2161.

§ 63.2163 If I monitor fermenter exhaust, what are my monitoring installation, operation, and maintenance requirements?

(a) You must install and certify a CEMS that generates a single combined response value for VOC concentration (VOC CEMS) according to the procedures and requirements in Performance Specification 8—Performance Specifications for Volatile Organic Compound Continuous Emission Monitoring Systems in Stationary Sources in appendix B to part 60 of this chapter.

(b) You must operate and maintain your VOC CEMS according to the procedures and requirements in Procedure 1—Quality Assurance Requirements for Gas Continuous Emission Monitoring Systems Used for Compliance Determination in appendix F to part 60 of this chapter, except with regard to provisions concerning relative accuracy test audit (RATA), cylinder gas audit (CGA), and relative accuracy audit (RAA) frequencies; out of control period definition; and CEMS data status during out of control periods; which are instead specified in this paragraph for frequencies; and § 63.8(c)(7) for the definition of and status of CEMS data during out of control periods.

(1) You must conduct a RATA at least once every 12 calendar quarters, in accordance with sections 8 and 11, as applicable, of Performance Specification 8.

(2) You must conduct a CGA or RAA in the calendar quarters during which a RATA is not conducted, but in no more than 11 quarters in succession.

(3) As necessary, rather than relying on citation 2 of Procedure 1 of appendix F to 40 CFR part 60, you must rely on EPA/600/R–12/531 (incorporated by reference, see § 63.14).

(4) Your affected source must meet the criteria of Performance Specification 8, section 13.2.

(c) You must use Method 25A in appendix A–7 to part 60 of this chapter as the Reference Method.

(d) You must calibrate your VOC CEMS with propane.

(e) You must set your VOC CEMS span at less than 5 times the relevant VOC emission limitation given in Table 1 of this subpart. Note that the EPA considers 1.5 to 2.5 times the relevant VOC emission limitation to be the optimum range, in general.

(f) You must complete the performance evaluation and submit the performance evaluation report before the compliance date that is specified for your affected source in § 63.2133.

(g) You must monitor VOC concentration in fermenter exhaust at any point prior to dilution of the exhaust stream.

(h) You must collect data using the VOC CEMS at all times during each batch monitoring period, except for periods of monitoring system malfunctions, required monitoring system quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments), and any scheduled maintenance.

(i) For each CEMS, you must record the results of each inspection, calibration, and validation check.

(j) You must check the zero (low-level) and high-level calibration drifts for each CEMS in accordance with the applicable Performance Specification of 40 CFR part 60, appendix B. You must adjust the zero (low-level) and high-level calibration drifts, at a minimum, whenever the zero (low-level) drift exceeds 2 times the limits of the applicable Performance Specification. You must perform the calibration drift checks at least once daily except under the conditions of paragraphs (j)(1) through (3) of this section.

(1) If a 24-hour calibration drift check for your CEMS is performed immediately prior to, or at the start of, a batch monitoring period of a duration exceeding 24 hours, then you are not required to perform 24-hour-interval calibration drift checks during that batch monitoring period.

(2) If the 24-hour calibration drift exceeds 2.5 percent of the span value in fewer than 5 percent of the checks over a 1-month period, and the 24-hour

calibration drift never exceeds 7.5 percent of the span value, then you may reduce the frequency of calibration drift checks to at least weekly (once every 7 days).

(3) If, during two consecutive weekly checks, the weekly calibration drift exceeds 5 percent of the span value, then you must resume a frequency of at least 24-hour interval calibration checks until the 24-hour calibration checks meet the test of paragraph (j)(2) of this section.

§ 63.2164 If I monitor brew ethanol, what are my monitoring installation, operation, and maintenance requirements?

(a) You must install, operate, and maintain each brew ethanol monitor according to the manufacturer's specifications and in accordance with § 63.2150(d).

(b) Each of your brew ethanol monitors must complete a minimum of one cycle of operation (sampling, analyzing, and data recording) for each successive 30-minute period within each batch monitoring period. Except as specified in paragraph (c) of this section, you must have a minimum of two cycles of operation in a 1-hour period to have a valid hour of data.

(c) You must reduce the brew ethanol monitor data to arithmetic batch averages computed from two or more data points over each 1-hour period, except during periods when calibration, quality assurance, or maintenance activities pursuant to provisions of this part are being performed. During these periods, a valid hour of data must consist of at least one data point representing a 30-minute period.

(d) You must have valid brew ethanol monitor data from all operating hours over the entire batch monitoring period.

(e) You must set the brew ethanol monitor span to correspond to not greater than 5 times the relevant emission limitation; note that we consider 1.5 to 2.5 times the relevant emission limitation to be the optimum range, in general. You must use the brew-to-exhaust correlation equation established under § 63.2161(f) to determine the span value for your brew ethanol monitor that corresponds to the relevant emission limitation.

(f) For each brew ethanol monitor, you must record the results of each inspection, calibration, and validation check.

(g) The gas chromatograph (GC) that you use to calibrate your brew ethanol monitor must meet the requirements of paragraphs (g)(1) through (3) of this section.

(1) You must calibrate the GC at least daily, by analyzing standard solutions of ethanol in water (0.05 percent, 0.15 percent, and 0.3 percent).

(2) For use in calibrating the GC, you must prepare the standard solutions of ethanol using the procedures listed in paragraphs (g)(2)(i) through (vi) of this section.

(i) Starting with 100-percent ethanol, you must dry the ethanol by adding a small amount of anhydrous magnesium sulfate (granular) to 15–20 milliliters (ml) of ethanol.

(ii) You must place approximately 50 ml of water into a 100-ml volumetric flask and place the flask on a balance. You must tare the balance. You must weigh 2.3670 grams of the dry (anhydrous) ethanol into the volumetric flask.

(iii) You must add the 100-ml volumetric flask contents to a 1000-ml volumetric flask. You must rinse the 100-ml volumetric flask with water into the 1000-ml flask. You must bring the volume to 1000 ml with water.

(iv) You must place an aliquot into a sample bottle labeled ''0.3% Ethanol.''

(v) You must fill a 50-ml volumetric flask from the contents of the 1000-ml flask. You must add the contents of the 50-ml volumetric flask to a 100-ml volumetric flask and rinse the 50-ml flask into the 100-ml flask with water. You must bring the volume to 100 ml with water. You must place the contents into a sample bottle labeled ''0.15% Ethanol.''

(vi) With a 10-ml volumetric pipette, you must add two 10.0-ml volumes of water to a sample bottle labeled ''0.05% Ethanol.'' With a 10.0-ml volumetric pipette, you must pipette 10.0 ml of the 0.15 percent ethanol solution into the sample bottle labeled ''0.05% Ethanol.''

(3) For use in calibrating the GC, you must dispense samples of the standard solutions of ethanol in water in aliquots to appropriately labeled and dated glass sample bottles fitted with caps having a Teflon® seal. You may keep refrigerated samples unopened for 1 month. You must prepare new calibration standards of ethanol in water at least monthly.

(h) You must calibrate the brew ethanol monitor according to paragraphs (h)(1) through (3) of this section.

(1) To calibrate the brew ethanol monitor, you must inject a brew sample into a calibrated GC and compare the simultaneous ethanol value given by the brew ethanol monitor to that given by the GC. You must use either the Porapak® Q, 80–100 mesh, 6′ x ⅛″, stainless steel packed column; or the DB Wax, 0.53 millimeter x 30 meter capillary column.

(2) If a brew ethanol monitor value for ethanol differs by 20 percent or more from the corresponding GC ethanol value, you must determine the brew ethanol values throughout the rest of the batch monitoring period by injecting brew samples into the GC not less frequently than once every 30 minutes. From the time at which you detect a difference of 20 percent or more until the batch monitoring period ends, the GC data will serve as the brew ethanol monitor data.

(3) You must perform a calibration of the brew ethanol monitor at least four times per batch.

§ 63.2165 How do I demonstrate initial compliance with the emission limitations if I monitor fermenter exhaust?

(a) You must demonstrate initial compliance with each emission limitation in Table 1 to this subpart that applies to you according to the methods in Table 3 to this subpart.

(b) You must submit the Notification of Compliance Status containing the results of the initial compliance demonstration according to the requirements in § 63.2180(f).

Continuous Compliance Requirements

§ 63.2170 How do I monitor and collect data to demonstrate continuous compliance?

(a) You must monitor and collect data according to this section and § 63.2163 or § 63.2164.

(b) Except for periods of monitoring system malfunctions, required monitoring system quality assurance or control activities (including, as applicable, calibration checks and required zero and span adjustments), and any scheduled maintenance, you must collect data using the CEMS or brew ethanol monitor, as applicable, at all times during each batch monitoring period.

(c) You may not use data recorded during monitoring malfunctions, associated repairs, and required quality assurance or quality control activities in data averages and calculations used to report emission or operating levels, or to fulfill a data collection requirement. You must use all the data collected during all other periods in assessing the operation of the control system.

(d) Any hour during the batch monitoring period for which quality-assured VOC CEMS data or brew ethanol monitor data, as applicable, are not obtained is a deviation from monitoring requirements and is counted as an hour of monitoring system downtime.

§ 63.2171 How do I demonstrate continuous compliance with the emission limitations?

(a) You must demonstrate continuous compliance with each emission

limitation in Table 1 to this subpart that applies to you according to the methods specified in Table 4 to this subpart and the applicable procedures of this section.

(b) To demonstrate compliance with emission limitations by using the 98-Percent Option, you must calculate the percentage of within-concentration batches (as defined in § 63.2192) for each 12-month calculation period by following the procedures in this paragraph and paragraphs (e)(1) and (2) of this section. At the end of each calendar month, you must determine the percentage of batches that were in compliance with the applicable maximum concentration in the 12-month calculation period. The total number of batches in the calculation period is the sum of the numbers of batches of each fermentation stage for which emission limitations apply. To determine which batches are in the 12-month calculation period, you must include those batches for which the batch monitoring period ended at or after midnight on the first day of the period and exclude those batches for which the batch monitoring period did not end before midnight on the last day of the period.

(c) To demonstrate compliance with emission limitations by using the Average Option, you must follow the procedures in this paragraph and paragraphs (e)(1) and (2) of this section. At the end of each calendar month, you must determine the average VOC concentration from all batches in each fermentation stage in a 12-month calculation period. To determine which batches are in a 12-month calculation period, you must include those batches for which the batch monitoring period ended at or after midnight on the first day of the period and exclude those batches for which the batch monitoring period did not end before midnight on the last day of the period.

(d) To demonstrate compliance with emission limitations by using the Batch Option, you must determine the average VOC concentration in the fermenter exhaust for each batch of each fermentation stage in a semiannual reporting period (*i.e.,* January 1 through June 30 or July 1 through December 31). To determine which batches are in the semiannual reporting period, you must include those batches for which the batch monitoring period ended at or after midnight on the first day of the period and exclude those batches for which the batch monitoring period did not end before midnight on the last day of the period.

(e) To demonstrate compliance with an emission limitation using a 12-month calculation period, you must follow the procedures in paragraphs (e)(1) and (2) of this section.

(1) The first 12-month calculation period begins on the compliance date that is specified for your affected source in § 63.2133 and ends on the last day of the month that includes the date 1 year after your compliance date, unless the compliance date for your affected source is the first day of the month, in which case the first 12-month calculation period ends on the last day of the month that is 11 calendar months after the compliance date.

(2) The second 12-month calculation period and each subsequent 12-month calculation period begins on the first day of the month following the first full month of the previous 12-month calculation period and ends on the last day of the month 11 calendar months later.

Notification, Reports, and Records

§ 63.2180 What notifications must I submit and when?

(a) You must submit all of the notifications in §§ 63.7(b) and (c); 63.8(e), (f)(4) and (6); and 63.9(b) through (h) that apply to you by the dates specified.

(b) If you start up your affected source before May 21, 2001, you are not subject to the initial notification requirements of § 63.9(b)(2).

(c) If you are required to conduct a performance test as specified in § 63.2161 to this subpart, you must submit a notification of intent to conduct a performance test at least 60 calendar days before the performance test is scheduled to begin as required in § 63.7(b)(1).

(d) If you are required to conduct a performance evaluation as specified in § 63.2163, you must submit a notification of the date of the performance evaluation at least 60 days prior to the date the performance evaluation is scheduled to begin as required in § 63.8(e)(2).

(e) If you are required to conduct a performance test as specified in Table 2 to this subpart, you must submit a Notification of Compliance Status according to § 63.9(h)(2)(ii).

(f) For each initial compliance demonstration required in Table 3 to this subpart, you must submit the Notification of Compliance Status no later than July 31 or January 31, whichever date follows the initial compliance period that is specified for your affected source in § 63.2160(a) or (b). The first compliance report, described in § 63.2181(b)(1), serves as the Notification of Compliance Status.

§ 63.2181 What reports must I submit and when?

(a) You must submit each report in Table 5 to this subpart that applies to you.

(1) On and after October 16, 2017, you must also comply with reporting for performance tests or for performance evaluations as specified in paragraphs (a)(1)(i) and (ii) of this section.

(i) Within 60 days after the date of completing each performance test as required by this subpart, you must submit the results of the performance test following the procedures specified in paragraphs (a)(1)(i)(A) through (C) of this section.

(A) For data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT Web site (*https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert*) at the time of the test, you must submit the results of the performance test to the EPA via the Compliance and Emissions Data Reporting Interface (CEDRI). (CEDRI can be accessed through the EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov/*).) Performance test data must be submitted in a file format generated through the use of the EPA's ERT or an alternate electronic file format consistent with the extensible markup language (XML) schema listed on the EPA's ERT Web site.

(B) For data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT Web site at the time of the test, you must submit the results of the performance test to the Administrator at the appropriate address listed in § 63.13, unless the Administrator agrees to or specifies an alternate reporting method.

(C) If you claim that some of the performance test information being submitted under paragraph (a)(1)(i)(A) of this section is confidential business information (CBI), you must submit a complete file generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT Web site, including information claimed to be CBI, on a compact disc, flash drive, or other commonly used electronic storage media to the EPA. The electronic media must be clearly marked as CBI and mailed to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same ERT or alternate file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described in paragraph (a)(1)(i)(A) of this section.

(ii) Within 60 days after the date of completing each continuous monitoring system performance evaluation (as defined in § 63.2), you must submit the results of the performance evaluation following the procedures specified in paragraphs (a)(1)(ii)(A) through (C) of this section.

(A) For performance evaluations of continuous monitoring systems measuring RATA pollutants that are supported by the EPA's ERT as listed on the EPA's ERT Web site at the time of the evaluation, you must submit the results of the performance evaluation to the EPA via the CEDRI. Performance evaluation data must be submitted in a file format generated through the use of the EPA's ERT or an alternate file format consistent with the XML schema listed on the EPA's ERT Web site.

(B) For any performance evaluations of continuous monitoring systems measuring RATA pollutants that are not supported by the EPA's ERT as listed on the EPA's ERT Web site at the time of the evaluation, you must submit the results of the performance evaluation to the Administrator at the appropriate address listed in § 63.13, unless the Administrator agrees to or specifies an alternate reporting method.

(C) If you claim that some of the performance evaluation information being submitted is CBI, then you must submit a complete file generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT Web site, including information claimed to be CBI, on a compact disc, flash drive or other commonly used electronic storage media to the EPA. The electronic storage media must be clearly marked as CBI and mailed to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same ERT or alternate file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph.

(b) Unless the Administrator has approved a different schedule for submission of reports under § 63.10(a), you must submit each report according to the schedule in Table 5 to this subpart and according to paragraphs (b)(1) through (5) of this section.

(1) The first compliance report must include the information specified in paragraph (c) of this section. If you are demonstrating compliance with an emission limitation using a 12-month calculation period (*e.g.,* the Average Option), then the first compliance report must cover the period beginning on the compliance date that is specified for your affected source in § 63.2133 and ending on either June 30 or December 31 (use whichever date is the first date following the end of the first 12 calendar months after the compliance date that is specified for your affected source in § 63.2133). If you are demonstrating compliance with an emission limitation using the Batch Option, then the first compliance report must cover the period beginning on the compliance date that is specified for your affected source in § 63.2133 and ending on either June 30 or December 31 (use whichever date is the first date following the compliance date that is specified for your affected source in § 63.2133).

(2) The first compliance report must be postmarked or delivered no later than July 31 or January 31, whichever date follows the end of the first compliance reporting period specified in paragraph (b)(1) of this section.

(3) Each subsequent compliance report must cover the semiannual reporting period from January 1 through June 30 or the semiannual reporting period from July 1 through December 31. Each subsequent compliance report must include the information specified in paragraph (c) of this section.

(4) Each subsequent compliance report must be postmarked or delivered no later than July 31 or January 31, whichever date is the first date following the end of the semiannual reporting period.

(5) For each affected source that is subject to permitting regulations pursuant to 40 CFR part 70 or part 71, and if the permitting authority has established dates for submitting semiannual reports pursuant to 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A), you may submit the first and subsequent compliance reports according to the dates the permitting authority has established instead of according to the dates in paragraphs (b)(1) through (4) of this section.

(c) The compliance report must contain the information listed in paragraphs (c)(1) through (8) of this section.

(1) Company name and address.

(2) Statement by a responsible official with that official's name, title, and signature, certifying the accuracy of the content of the report.

(3) Date of report and beginning and ending dates of the reporting period.

(4) For each 12-month calculation period ending on a calendar month that falls within a reporting period for which you are using the 98-Percent Option to comply, the percentage of batches that are within-concentration batches.

(5) For each 12-month calculation period ending on a calendar month that falls within a reporting period for which you are using the 98-Percent Option to comply and your affected source fails to meet an applicable standard, the information for each batch for which BAVOC exceeded the applicable maximum VOC concentration in Table 1 to this subpart and whether the batch was in production during a period of malfunction or during another period.

(6) For each 12-month calculation period ending on a calendar month that falls within a reporting period for which you are using the Average Option to comply or for any reporting period for which you are using the Batch Option to comply, and your affected source meets an applicable standard, the information in paragraph (c)(6)(i) or (ii) of this section, depending on the compliance option selected from Table 1 to this subpart.

(i) If you are using the Average Option to comply, the average BAVOC of all batches in each fermentation stage for each 12-month calculation period ending on a calendar month that falls within the reporting period that did not exceed the applicable emission limitation.

(ii) If you are using the Batch Option to comply, a certification that BAVOC for each batch manufactured during the reporting period did not exceed applicable emission limitations.

(7) For each 12-month calculation period ending on a calendar month that falls within a reporting period for which you are using the Average Option to comply or for any reporting period for which you are using the Batch Option to comply and your affected source fails to meet an applicable standard, the information in paragraph (c)(7)(i) or (ii) of this section, depending on the compliance option selected from Table 1 to this subpart.

(i) If you are using the Average Option to comply, the average BAVOC of all batches in each fermentation stage for each 12-month calculation period that failed to meet the applicable standard; the fermenters that operated in each fermentation stage that failed to meet the applicable standard; the duration of each failure; an estimate of the quantity of VOC emitted over the emission limitation; a description of the method used to estimate the emissions; and the actions taken to minimize emissions and correct the failure.

(ii) If you are using the Batch Option to comply, the fermenters and batches that failed to meet the applicable standard; the date, time, and duration of each failure; an estimate of the quantity of VOC emitted over the emission

limitation; a description of the method used to estimate the emissions; and the actions taken to minimize emissions and correct the failure.

(8) The total operating hours for each fermenter, the total hours of monitoring system operation for each CEMS or brew ethanol monitor, and the total hours of monitoring system downtime for each CEMS or brew ethanol monitor.

§ 63.2182 What records must I keep?

(a) You must keep the records listed in paragraphs (a)(1) through (3) of this section.

(1) A copy of each notification and report that you submitted to comply with this subpart, including all documentation supporting any Notification of Compliance Status and compliance report that you submitted, according to the requirements in § 63.10(b)(2)(xiv).

(2) Records of failures to meet a standard, specified in § 63.2181(c)(5) and (7).

(3) Records of performance tests and performance evaluations as required in § 63.10(b)(2)(viii) and (ix).

(b) For each affected source that monitors brew ethanol, you must keep records demonstrating the calculation of the brew-to-exhaust correlations specified in § 63.2161.

(c) For each CEMS and brew ethanol monitor, you must keep the records listed in paragraphs (c)(1) through (5) of this section.

(1) Records described in § 63.10(b)(2)(vi), (vii), (x), and (xi). The CEMS must allow the amount of excess zero (low-level) and high-level calibration drift measured at the interval checks to be quantified and recorded.

(2) Records described in § 63.10(c)(1) through (6).

(3) Records of the quality control program as specified in § 63.8(d), including the program of corrective action; the current version of the performance evaluation test plan, as specified in § 63.8(e)(3); and previous (*i.e.,* superseded) versions of the performance evaluation test plan for a period of 5 years after each revision to the plan.

(4) Requests for alternatives to RATA for CEMS as required in § 63.8(f)(6)(i).

(5) Records of each deviation from monitoring requirements, including a description of the time period during which the deviation occurred, the nature and cause of the deviation, the corrective action taken or preventive measures adopted, and the nature of repairs or adjustments to the monitoring system.

(d) You must keep the records required to show continuous compliance with each emission limitation that applies to you according to the requirements in Table 4 to this subpart.

(e) You must also keep the records listed in paragraphs (e)(1) through (3) of this section for each batch in your affected source.

(1) Unique batch identification number.

(2) Fermentation stage for which you are using the fermenter.

(3) Unique CEMS equipment identification number.

§ 63.2183 In what form and how long must I keep my records?

(a) Your records must be in a form suitable and readily available for expeditious review, according to § 63.10(b)(1).

(b) As specified in § 63.10(b)(1), you must keep each record for 5 years following the date of each occurrence, measurement, maintenance, corrective action, report, or record.

(c) You must keep each record on site for at least 2 years after the date of each occurrence, measurement, maintenance, corrective action, report, or record, according to § 63.10(b)(1). You may keep the records off site for the remaining 3 years.

(d) Any records required to be maintained by this part that are submitted electronically via the EPA's CEDRI may be maintained in electronic format. This ability to maintain electronic copies does not affect the requirement for facilities to make records, data, and reports available upon request to a delegated air agency or the EPA as part of an on-site compliance evaluation.

(e) You must keep written procedures documenting the CEMS quality control program on record for the life of the affected source or until the affected source is no longer subject to the provisions of this part, to be made available for inspection, upon request, by the Administrator.

Other Requirements and Information

§ 63.2190 What parts of the General Provisions apply to me?

Table 6 to this subpart shows which parts of the General Provisions in §§ 63.1 through 63.15 apply to you.

§ 63.2191 Who implements and enforces this subpart?

(a) We, the U.S. EPA, or a delegated authority such as your state, local, or tribal agency, can implement and enforce this subpart. If our Administrator has delegated authority to your state, local, or tribal agency, then that agency has the authority to implement and enforce this subpart. You should contact the U.S. EPA Regional Office that serves you to find out if this subpart is delegated to your state, local, or tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to a state, local, or tribal agency under 40 CFR part 63, subpart E, the authorities contained in paragraph (c) of this section are retained by our Administrator and are not transferred to the state, local, or tribal agency.

(c) The authorities that will not be delegated to state, local, or tribal agencies are listed in paragraphs (c)(1) through (4) of this section.

(1) Approval of alternatives to the non-opacity emission limitations in § 63.2140 under § 63.6(g).

(2) Approval of major alternatives to test methods under § 63.7(e)(2)(ii) and (f) and as defined in § 63.90.

(3) Approval of major alternatives to monitoring under § 63.8(f) and as defined in § 63.90.

(4) Approval of major alternatives to recordkeeping and reporting under § 63.10(f) and as defined in § 63.90.

§ 63.2192 What definitions apply to this subpart?

Terms used in this subpart are defined in the Clean Air Act, in 40 CFR 63.2, in the General Provisions of this part (§§ 63.1 through 63.15), and in this section as follows:

Batch means a single fermentation cycle in a single fermentation vessel (fermenter).

Batch monitoring period means the period that begins at the later of either the start of aeration or the addition of yeast to the fermenter; the period ends at the earlier of either the end of aeration or the point at which the yeast has begun being emptied from the fermenter.

BAVOC means the average VOC concentration in the fermenter exhaust over the duration of a batch (''batch-average VOC concentration'').

Brew means the mixture of yeast and additives in the fermenter.

Brew ethanol means the ethanol in fermenter liquid.

Brew ethanol monitor means the monitoring system that you use to measure brew ethanol to demonstrate compliance with this subpart. The monitoring system includes a resistance element used as an ethanol sensor, with the measured resistance proportional to the concentration of ethanol in the brew.

Brew-to-exhaust correlation means the correlation between the concentration of ethanol in the brew and the concentration of VOC in the

fermenter exhaust. This correlation is specific to each fed-batch fermentation stage and is established while manufacturing the product that comprises the largest percentage (by mass) of average annual production.

Emission limitation means any emission limit or operating limit.

Fed-batch means the yeast is fed carbohydrates and additives during fermentation in the vessel.

Monitoring system malfunction means any sudden, infrequent, and not reasonably preventable failure of the monitoring system to provide valid data. Monitoring system failures that are caused in part by poor maintenance or careless operation are not malfunctions. You are required to complete monitoring system repairs in response to monitoring system malfunctions and to return the monitoring system to operation as expeditiously as practicable.

1-hour period means any successive period commencing on the minute at which the batch monitoring period begins and continuing for 60 minutes, except for the last period, which may be less than 60 minutes.

Product means the yeast resulting from the final stage in a production run. Products are distinguished by yeast species, strain, and variety.

Responsible official means responsible official as defined in 40 CFR 70.2.

Set-batch means the yeast is fed carbohydrates and additives only at the start of the batch.

Specialty yeast includes, but is not limited to, yeast produced for use in wine, champagne, whiskey, and beer.

Within-concentration batch means a batch for which BAVOC is not higher than the maximum concentration that is allowed as part of the applicable emission limitation.

TABLE 1 TO SUBPART CCCC OF PART 63—EMISSION LIMITATIONS

For each fed-batch fermenter producing yeast in the following fermentation stage . . .	98-percent option: You must not exceed the following VOC emission limitation [a] according to the timeline in Table 7 to this subpart . . .	Average option: You must not exceed the following VOC emission limitation [a] according to the timeline in Table 7 to this subpart . . .	Batch option: You must not exceed the following VOC emission limitation [a] according to the timeline in Table 7 to this subpart . . .
Last stage	100 ppmv (measured as propane) for BAVOC for at least 98 percent of all batches in each 12-month calculation period described in § 63.2171(b) and (e).	95 ppmv (measured as propane) for the average BAVOC of all batches in this stage in each 12-month calculation period described in § 63.2171(c) and (e).	100 ppmv (measured as propane) for BAVOC for each batch.
Second-to-last stage	200 ppmv (measured as propane) for BAVOC for at least 98 percent of all batches in each 12-month calculation period described in § 63.2171(b) and (e).	190 ppmv (measured as propane) for the average BAVOC of all batches in this stage in each 12-month calculation period described in § 63.2171(c) and (e).	200 ppmv (measured as propane) for BAVOC for each batch.
Third-to-last stage	300 ppmv (measured as propane) for BAVOC for at least 98 percent of all batches in each 12-month calculation period described in § 63.2171(b) and (e).	285 ppmv (measured as propane) for the average BAVOC of all batches in this stage in each 12-month calculation period described in § 63.2171(c) and (e).	300 ppmv (measured as propane) for BAVOC for each batch.

[a] The emission limitation does not apply during the production of specialty yeast.

TABLE 2 TO SUBPART CCCC OF PART 63—REQUIREMENTS FOR PERFORMANCE TESTS IF YOU MONITOR BREW ETHANOL

For each fed-batch fermenter for which compliance is determined by monitoring brew ethanol concentration and calculating VOC concentration in the fermenter exhaust according to the procedures in § 63.2161, you must . . .	Using . . .	According to the following requirements . . .
Measure VOC as propane	Method 25A,[a] or an alternative validated by EPA Method 301 [b] and approved by the Administrator.	You must measure the VOC concentration in the fermenter exhaust at any point prior to the dilution of the exhaust stream.

[a] EPA Test Method 25A is found in appendix A–7 of 40 CFR part 60.
[b] EPA Test Method 301 is found in appendix A of 40 CFR part 63.

TABLE 3 TO SUBPART CCCC OF PART 63—INITIAL COMPLIANCE WITH EMISSION LIMITATIONS

For . . .	Average option: You have demonstrated initial compliance if . . .	Batch option: You have demonstrated initial compliance if . . .
Each fed-batch fermenter producing yeast in a fermentation stage (last, second-to-last, or third-to-last) for which compliance is determined by monitoring VOC concentration in the fermenter exhaust.	The average BAVOC of all batches in each fermentation stage during the initial compliance period described in § 63.2160(a) does not exceed the applicable concentration in Table 1 to this subpart.	BAVOC for each batch of each fermentation stage during the initial compliance period described in § 63.2160(b) does not exceed the applicable concentration in Table 1 to this subpart.

TABLE 4 TO SUBPART CCCC OF PART 63—CONTINUOUS COMPLIANCE WITH EMISSION LIMITATIONS

For . . .	98-percent option: You must demonstrate continuous compliance by . . .	Average option: You must demonstrate continuous compliance by . . .	Batch option: You must demonstrate continuous compliance by . . .
1. Each fed-batch fermenter producing yeast in a fermentation stage (last, second-to-last, or third-to-last) for which compliance is determined by monitoring VOC concentration in the fermenter exhaust.	Showing that BAVOC for at least 98 percent of the batches for each 12-month calculation period ending within a semiannual reporting period described in §63.2181(b)(3) does not exceed the applicable maximum concentration in Table 1 to this subpart.	Showing that the average BAVOC of all batches in each fermentation stage during each 12-month calculation period ending within a semiannual reporting period described in §63.2181(b)(3) does not exceed the applicable concentration in Table 1 to this subpart.	Showing that BAVOC for each batch within a semiannual reporting period described in §63.2181(b)(3) does not exceed the applicable concentration in Table 1 to this subpart.
2. Each fed-batch fermenter producing yeast in a fermentation stage (last, second-to-last, or third-to-last) for which compliance is determined by monitoring brew ethanol concentration and calculating VOC concentration in the fermenter exhaust according to the procedures in §63.2161 [a].			

[a] Monitoring brew ethanol concentration to demonstrate compliance is not allowed on and after October 16, 2020, as specified in Table 8 to this subpart.

TABLE 5 TO SUBPART CCCC OF PART 63—REQUIREMENTS FOR REPORTS

You must submit a . . .	The report must contain . . .	You must submit the report . . .
1. Compliance report	a. The information described in §63.2181(c), as appropriate.	Semiannually according to the requirements in §63.2181(b).
	b. If you fail to meet an applicable standard during the reporting period, then the compliance report must include the information in §63.2181(c)(5) or (7).	Semiannually according to the requirements in §63.2181(b).
2. Performance test report	The results of the performance test, including the information described in §63.7(g).	At least once every 365 calendar days and according to the requirements in §63.2181(a)(1)(i).
3. Performance evaluation report.	The results of the performance evaluation, including information from the performance evaluation plan at §63.8(e)(3).	At least once every twelve calendar quarters and according to the requirements in §§63.2163(f) and 63.2181(a)(1)(ii).

TABLE 6 TO SUBPART CCCC OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART CCCC

Citation	Subject	Applicable to subpart CCCC?
§63.1	Applicability	Yes.
§63.2	Definitions	Yes.
§63.3	Units and Abbreviations	Yes.
§63.4	Prohibited Activities and Circumvention	Yes.
§63.5	Construction and Reconstruction	Yes.
§63.6	Compliance With Standards and Maintenance Requirements.	1. §63.6(e)(1)(i) does not apply, instead specified in §63.2150(d). 2. §63.6(e)(1)(ii), (e)(3), (f)(1), and (h) do not apply. 3. Otherwise, all apply.
§63.7	Performance Testing Requirements	1. §63.7(a)(1) and (2) do not apply, instead specified in §63.2162. 2. §63.7(e)(1) and (e)(3) do not apply, instead specified in §63.2161(b). 3. Otherwise, all apply.
§63.8	Monitoring Requirements	1. §63.8(a)(2) is modified by §63.2163. 2. §63.8(d)(3) is modified by §63.2182(c)(3) and §63.2183(e). 3. §63.8(a)(4), (c)(1)(i), (c)(1)(iii), (c)(4)(i), (c)(5), (e)(5)(ii), and (g)(5) do not apply. 4. §63.8(c)(6), (c)(8), (e)(4), (g)(1), and (g)(3) do not apply, instead specified in §§63.2163(b) and (j), 63.2164(c), and 63.2182(c)(1) and (5). 5. Otherwise, all apply.
§63.9	Notification Requirements	1. §63.9(b)(2) does not apply because rule omits requirements for initial notification for affected sources that start up prior to May 21, 2001. 2. §63.9(f) does not apply. 3. Otherwise, all apply.
§63.10	Recordkeeping and Reporting Requirements.	1. §63.10(b)(2)(ii) does not apply, instead specified in §63.2182(a)(2) and (c)(5). 2. §63.10(b)(2)(i), (b)(2)(iv), (b)(2)(v), (c)(15), (d)(3), (e)(2)(ii), and (e)(3) and (4) do not apply. 3. §63.10(d)(5) does not apply, instead specified in §63.2181(c)(5) and (7). 4. Otherwise, all apply.
§63.11	Flares	No.
§63.12	Delegation	Yes.
§63.13	Addresses	Yes.

TABLE 6 TO SUBPART CCCC OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART CCCC—Continued

Citation	Subject	Applicable to subpart CCCC?
§ 63.14	Incorporation by Reference	Yes.
§ 63.15	Availability of Information	Yes.

TABLE 7 TO SUBPART CCCC OF PART 63—EMISSION LIMITATION APPLICABILITY TIMELINE

For each . . .	During this time frame . . .	You must comply with the emission limitations in Table 1 to this subpart using the . . .
Existing affected source	Before 10/16/2017	98-Percent Option.
	Between 10/16/2017 and October 16, 2018	98-Percent Option, Average Option, or Batch Option.
	On and after October 16, 2018	Average Option or Batch Option.
New or reconstructed affected source that you start up prior to 10/16/2017.	Before 10/16/2017	98-Percent Option.
	Between 10/16/2017 and October 16, 2018	98-Percent Option, Average Option, or Batch Option.
	On and after October 16, 2018	Average Option or Batch Option.
New or reconstructed affected source that you start up after 10/16/2017.	After 10/16/2017	Average Option or Batch Option.

TABLE 8 TO SUBPART CCCC OF PART 63—MONITORING SYSTEM REQUIREMENTS TIMELINE

For each . . .	During this time frame . . .	You must monitor VOC concentration by . . .
Existing affected source	Before 10/16/2017	Monitoring fermenter exhaust using a CEMS or by monitoring brew ethanol concentration using a brew ethanol monitor.
	Between 10/16/2017 and October 16, 2020	Monitoring fermenter exhaust using a VOC CEMS or by monitoring brew ethanol concentration using a brew ethanol monitor.
	On and after October 16, 2020	Monitoring fermenter exhaust using a VOC CEMS.
New or reconstructed affected source that you start up prior to 10/16/2017.	Before 10/16/2017	Monitoring fermenter exhaust using a CEMS or by monitoring brew ethanol concentration using a brew ethanol monitor.
	Between 10/16/2017 and October 16, 2020	Monitoring fermenter exhaust using a VOC CEMS or by monitoring brew ethanol concentration using a brew ethanol monitor.
	On and after October 16, 2020	Monitoring fermenter exhaust using a VOC CEMS.
New or reconstructed affected source that you start up after 10/16/2017.	After 10/16/2017	Monitoring fermenter exhaust using a VOC CEMS.

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