§ 80.1426 How are RINs generated and assigned to batches of renewable fuel by renewable fuel producers or importers?

(f) * * *

(1) * * *

TABLE 1 TO § 80.1426—APPLICABLE D CODES FOR EACH FUEL PATHWAY FOR USE IN GENERATING RINS

<table>
<thead>
<tr>
<th>Entry</th>
<th>Fuel type</th>
<th>Feedstock</th>
<th>Production process requirements</th>
<th>D-code</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>F</td>
<td>Biodiesel, renewable diesel, jet fuel and heating oil, biodiesel.</td>
<td>Soy bean oil; Oil from annual covercrops; Oil from algae grown photosynthetically; Biogenic waste oils/fats/greases; Non-food grade corn oil; Camelina sativa oil; Distillers sorghum oil.</td>
<td>One of the following: TransEsterification, Hydrotreating</td>
<td>4</td>
</tr>
<tr>
<td>H</td>
<td>Biodiesel, renewable diesel, jet fuel and heating oil.</td>
<td>Soy bean oil; Oil from annual covercrops; Oil from algae grown photosynthetically; Biogenic waste oils/fats/greases; Non-food grade corn oil; Camelina sativa oil; Distillers sorghum oil.</td>
<td>One of the following: TransEsterification, Hydrotreating</td>
<td>5</td>
</tr>
<tr>
<td>I</td>
<td>Naphtha, LPG</td>
<td>Camelina sativa oil; Distillers sorghum oil.</td>
<td>Hydrotreating</td>
<td>5</td>
</tr>
</tbody>
</table>

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[FR Doc. 2017–27946 Filed 12–26–17; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY


RIN 2040–AF69

Water Quality Standards for the State of Missouri’s Lakes and Reservoirs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) proposes to establish federal nutrient criteria to protect designated uses for the State of Missouri’s lakes and reservoirs. On August 16, 2011, EPA disapproved most of the numeric criteria for total nitrogen, total phosphorus, and chlorophyll a that the State submitted to EPA in 2009. EPA acknowledged the importance of Missouri’s proactive efforts to address nutrient pollution by adopting numeric nutrient criteria. However, EPA concluded that the Missouri Department of Natural Resources (MDNR) had failed to demonstrate the criteria would protect the State’s designated uses and were not based on a sound scientific rationale. The Clean Water Act (CWA) directs EPA to promptly propose water quality standards (WQS) that meet CWA requirements if a state does not adopt WQS addressing EPA’s disapproval. On February 24, 2016, the Missouri Coalition for the Environment (MCE) filed a lawsuit alleging that EPA failed to satisfy its statutory obligation to act “promptly.” On December 1, 2016, EPA entered into a consent decree with MCE committing to sign a notice of proposed rulemaking by December 15, 2017 to address EPA’s 2011 disapproval, unless the State submits and EPA approves criteria that address the disapproval on or before December 15, 2017. As of the date of this proposed rule, Missouri has not submitted new or revised standards to address EPA’s 2011 disapproval and EPA has not approved such water quality standards. Therefore, under the terms of the consent decree, EPA is signing a notice of proposed rulemaking that proposes new water quality standards addressing EPA’s August 16, 2011 disapproval. In this proposal, EPA seeks comment on two primary alternatives. Under the first alternative, EPA proposes nutrient protection values and eutrophication impact factors in a combined criterion approach. Under the second alternative, EPA proposes a similar combined criterion approach that would mirror the State of Missouri’s October 2017 proposal for lake nutrient water quality standards. EPA will not proceed with final rulemaking (or will withdraw its final rule, if applicable) to address its 2011 disapproval if Missouri adopts and submits criteria to address EPA’s 2011 disapproval and EPA approves them as meeting CWA requirements.

DATES: Comments must be received on or before February 26, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OW–2017–0010, at http://www.regulations.gov. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from regulations.gov. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit http://www2.epa.gov/dockets/commenting-epa-dockets.

EPA is offering two online public hearings so that interested parties may provide verbal comments on this proposed rule. The first public hearing

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will be on February 7, 2018. The second public hearing will be on February 8, 2018. For more details on the public hearings and a link to register, please visit https://www.epa.gov/wqs-tech/proposed-nutrient-criteria-missouri-lakes-and-reservoirs.

FOR FURTHER INFORMATION CONTACT:
Mario Sengco, Standards and Health Protection Division, Office of Water, Mailcode: 4305T, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: 202–566–2676; email address: sengco.mario@epa.gov.

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I. General Information
A. Does this action apply to me?

Citizens concerned with water quality in the State of Missouri may be interested in this proposed rulemaking. Entities discharging nitrogen or phosphorus to lakes and reservoirs, or to flowing waters emptying into lakes or reservoirs, could be affected directly or indirectly by this rulemaking because WQS are used in determining National Pollutant Discharge Elimination System (NPDES) permit effluent limits. Stakeholders that rely on lakes and reservoirs for recreation or as a source of drinking water likewise may be interested in the proposed criteria. Table 1 lists categories that ultimately may be affected by this proposal.

### Table 1—Categories Potentially Affected by Proposed Criteria

<table>
<thead>
<tr>
<th>Category</th>
<th>Examples of potentially affected entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry</td>
<td>Factories discharging pollutants to lakes/reservoirs or flowing waters emptying into downstream lakes/reservoirs in Missouri.</td>
</tr>
<tr>
<td>Municipalities</td>
<td>Publicly-owned treatment works discharging pollutants to lakes/reservoirs or flowing waters emptying into downstream lakes/reservoirs in Missouri.</td>
</tr>
<tr>
<td>Stormwater Management Districts</td>
<td>Entities responsible for managing stormwater runoff in Missouri.</td>
</tr>
</tbody>
</table>

This table is not intended to be exhaustive; rather, it provides a guide for entities that may be affected directly or indirectly by this action. Nonpoint source contributors and other entities not listed in the table also could be affected indirectly. Any party or entity that conducts activities within the watersheds affected by this rule, or that relies on, depends upon, influences, or contributes to the water quality of the lakes, reservoirs and flowing waters of Missouri, also may be affected by this rule. To determine whether your facility or activities may be affected by this action, you should carefully examine this proposed rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding FOR FURTHER INFORMATION CONTACT section.

B. What action is EPA taking?

The EPA is proposing two alternatives to establish federal nutrient criteria to protect designated uses for the State of Missouri’s lakes and reservoirs. Under the first alternative, EPA proposes nutrient protection values (total nitrogen, total phosphorus, chlorophyll a) and eutrophication impact factors in a combined criterion approach. Under the second alternative, EPA proposes a combined criterion approach that would mirror the State of Missouri’s October 2017 proposal for lake nutrient water quality standards. This action fulfills EPA’s obligation under its consent decree entered on December 1, 2016 to prepare and publish proposed regulations for nutrient criteria to address the Agency’s August 16, 2011, disapproval of the State’s nutrient criteria by December 15, 2017.

II. Background

A. Nutrient Pollution

1. What is nutrient (i.e., nitrogen and phosphorus) pollution?

Excess loading of nitrogen and phosphorus compounds is one of the most prevalent causes of water quality impairment in the United States. Nitrogen and phosphorus pollution problems have been recognized for some time in the U.S. For example, a 1969

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1 To be used by living organisms, nitrogen gas must be fixed into its reactive forms; for plants, this generally includes either nitrate or ammonia (Boyd, C.E. 1979. Water Quality in Warmwater Fish Ponds. Alabama Agricultural Experiment Station, Auburn, AL). Eutrophication is defined as the natural or artificial addition of nitrogen/phosphorus to bodies of water and to the effects of added nitrogen/phosphorus (National Academy of Sciences (U.S.). 1969. Eutrophication: Causes, Consequences, Correctives. National Academy of Sciences, Washington, DC).
phosphorus in water bodies come from many sources, which can be grouped into five major categories: (1) Urban stormwater runoff—sources associated with urban land use and development, (2) municipal and industrial waste water discharges, (3) row crop agriculture, (4) livestock production, and (5) atmospheric deposition from the production of nitrogen oxides in electric power generation and internal combustion engines.  

2. Adverse Impacts of Nitrogen and Phosphorus Pollution on Aquatic Life, Human Health, and the Economy  

The causal pathways that lead from human activities to excess nutrients to impacts on designated uses in lakes and reservoirs are well established in the scientific literature (e.g., Vollenweider, 1968; NAS, 1969; Schindler et al., 1973; Schindler, 1974; Vollenweider, 1976; Carlson, 1977; Paerl, 1988; Elser et al., 1990; Smith et al., 1999; Downing et al., 2001; Smith et al., 2006; Elser et al., 2007). When excessive nitrogen and phosphorus loads alter a waterbody’s complement of algal and plant species, the corresponding changes in habitat and available food resources can induce cascading effects on the entire food web. Algal blooms block sunlight that submerged plants need to grow, leading to a decline in the availability of submerged aquatic vegetation and a reduction in habitat for juvenile fish and some other aquatic organisms. Algal blooms can also increase turbidity and impair the ability of sight-feeding fish and other aquatic life to find food.9 Large concentrations of algae can also damage or clog the gills of fish and certain invertebrates.9 Excessive algal blooms can lead to shifts in a waterbody’s productive capacity and consumption of dissolved oxygen (DO) resulting in reduced DO levels that are sufficiently low to harm or kill important recreational species such as walleye, striped bass, and black bass.  

Excessive algal growth also contributes to increased oxygen consumption associated with decomposition (e.g., large quantities of senescing and decaying algal cells), in many instances reducing oxygen to levels below that needed for aquatic life to survive and flourish.10,11 Mobile species, such as adult fish, can sometimes survive by moving to areas with more oxygen. However, migration to avoid hypoxia depends on species mobility, availability of suitable habitat (i.e., refugia), and adequate environmental cues for migration. Less mobile or immobile species, such as mussels, cannot move to avoid low oxygen and are often killed during hypoxic events.12 While certain mature

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aquatic animals can tolerate a range of dissolved oxygen levels that occur in the water, younger life stages of fish and shellfish often require higher levels of oxygen to survive.\textsuperscript{13} Sustained low levels of dissolved oxygen cause a severe decrease in the amount of aquatic life in hypoxic zones and affect the ability of aquatic organisms to find necessary food and habitat.

In freshwater lakes and reservoirs, blooms of cyanobacteria (sometimes referred to as blue-green algae),\textsuperscript{14} can produce toxins that have been implicated in the cause of a number of fish and bird mortalities.\textsuperscript{15} These toxins have also been tied to the death of pets and livestock that may be exposed through drinking contaminated water or grooming themselves after bodily exposure.\textsuperscript{16} Cyanobacterial toxins can also pass through normal drinking water treatment processes and pose an increased risk to humans or animals.\textsuperscript{17}

Elevated nitrogen and phosphorus levels in lakes and reservoirs can impact human health and safety and otherwise detract from the outdoor recreational experience. For example, nutrient pollution in lakes typically promotes higher densities of phytoplankton, which can reduce the clarity of the water column to the detriment of swimmer safety. Cyanobacterial blooms frequently result in high algal toxin (e.g., microcystin) concentrations, leading to swimming beach closures and issuance of health advisories/warnings. In areas where recreation is determined to be unsafe because of algal blooms, warning signs are posted to discourage human contact with the affected waters. Many other states, and countries for that matter, are experiencing problems with harmful algal blooms (HABs).\textsuperscript{18,19} Scientific assessments and numerous studies have shown an increase of HAB occurrence, distribution and persistence in the U.S. and globally in recent years.\textsuperscript{20,21,22} In a recent scientific assessment, reviewers found that observed increases in water temperatures alter the seasonal windows of growth and the geographic range of suitable habitat for freshwater toxin-producing harmful algae and marine toxin-producing harmful algae.\textsuperscript{23} These changes may increase the risk of exposure to waterborne pathogens and algal toxins that can cause a variety of illnesses. In addition, runoff from more frequent and intense extreme precipitation events may increasingly compromise recreational waters, shellfish harvesting waters, and sources of drinking water through increased prevalence of toxic algal blooms. An example of an algal bloom event occurred on August 10, 2017,\textsuperscript{24} when officials from the Oakland County Health Division located near Detroit, Michigan issued a warning for residents and their pets to avoid two local lakes due to the presence of an algal bloom. People were advised to avoid contact with the water through recreation and to avoid drinking the water. In a July 7, 2017 article,\textsuperscript{25} the number of reports of harmful algal blooms affecting lakes and ponds in New York, as tracked by the New York State Department of Environmental Conservation, were increasing early in the season. Reducing nutrient input is one of the strategies lake managers are employing throughout the State to address the growing problem of algal blooms. Species of cyanobacteria commonly associated with freshwater algal blooms include: Microcystis aeruginosa, Anabaena circinalis, Anabaena flos-aquae, Aphanizomenon flos-aquae, and Cyanothecae cucullus. Under certain conditions, some of these species can release neurotoxins (affect the nervous system), hepatotoxins (affect the liver), lipopolysaccharide compounds inimical to the human gastrointestinal system, and tumor promoting compounds.\textsuperscript{26} One study showed that at least one type of cyanobacteria has been linked to cancer and tumor growth in animals.\textsuperscript{27}

Human health also can be impacted by disinfection byproducts (DBPs), formed when disinfectants such as chlorine used to treat drinking water react with organic carbon produced by algae in source waters. Some DBPs have been linked to rectal, bladder, and colon cancers; reproductive health risks; and liver, kidney, and central nervous system problems.\textsuperscript{28,29} In their study of 21 water supply lakes and reservoirs in New York, Callinan et al. (2013) concluded that “autochthonous [algal] precursors contribute substantially to the DBP precursor pool in lakes and reservoirs and the……establishment of [numeric nutrient criteria] for the protection of [potable water supply] source waters is warranted and feasible.”\textsuperscript{30}


Implementation of nutrient criteria help to protect lakes and reservoirs from the negative effects of nutrient pollution, which frequently include, but are not limited to (a) the occurrence and spread of toxic algae, (b) the proliferation of certain fish species that are less desirable to sport anglers (i.e., “rough” fish), (c) a general decline in sensitive aquatic plant and animal populations, (d) the occurrence of taste and odor problems in drinking water derived from lakes and reservoirs, (e) Safe Drinking Water Act violations related to the occurrence of disinfection by-products (e.g., trihalomethanes, haloacetic acids) in finished drinking water, (f) a decline in waterbody transparency with accompanying recreational safety concerns, (g) the occurrence of unsightly scums and objectionable odors, (h) the depreciation of lakefront property values,31 and (i) an occurrence of unsightly scums and recreational safety concerns, (g) the occurrence of unsightly scums and objectionable odors, (h) the depreciation of lakefront property values,31 and (i) an overall reduction in the functional life expectancy of reservoirs, with a corresponding loss of return on society’s economic investment in these systems.

3. Nutrient Pollution in Missouri Lakes and Reservoirs

Lake water quality impairments attributable to nutrient pollution have not been quantified with any degree of precision in Missouri. Long-term monitoring data are available for about 10 percent of the State’s classified lakes and reservoirs (representing approximately 90 percent of overall lake acreage), and about 15 percent of these monitored waters already have EPA-approved numeric nutrient criteria.

Missouri adopted site-specific chlorophyll a, total phosphorus and total nitrogen criteria for 25 lakes and reservoirs on July 1, 2009, which were approved by EPA on August 16, 2011. Currently, eleven of these waterbodies (44 percent) are listed for nutrient pollution-related impairments. This percentage is consistent with nationwide estimates of lakes in the most disturbed category obtained through the 2012 National Lakes Assessment (NLA). Specifically, the NLA estimates that 40 percent of all lakes and reservoirs in the conterminous U.S. are considered most disturbed based on elevated phosphorus concentrations, and 35 percent are considered most disturbed based on elevated nitrogen concentrations (https://www.epa.gov/national-aquatic-resource-surveys/nla).

MDNR acknowledges that lake and reservoir eutrophication is occurring at a detectable rate throughout much of the state.32 Over the past 20 or more years, chlorophyll a levels in monitored waterbodies have increased by an average of 3.5, 13, 28 and 2.6 μg/L in the Glaciated Plains, Osage Plains, Ozark Border and Ozark Highlands, respectively.33

B. Statutory and Regulatory Background

Section 303(c) of the CWA (33 U.S.C. § 1313(c)) directs states and authorized tribes to adopt WQS for their navigable waters. Section 303(c)(2)(A) and EPA’s implementing regulations at 40 CFR part 131 require, among other things, that state WQS include the designated use or uses to be made of the waters and criteria that protect those uses. EPA regulations at 40 CFR § 131.11(a)(1) provide that states and authorized tribes shall “adopt those water quality criteria that protect the designated use” and that such criteria “must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use. For waters with multiple use designations, the criteria shall support the most sensitive use.”

Additionally, 40 CFR § 130.10(b) provides that “[i]n designating uses of a waterbody and the appropriate criteria for those uses, the state shall take into consideration the water quality standards of downstream waters and ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters.”

States and authorized tribes also are required to hold one or more public hearings consistent with 40 CFR § 25.5 to review their WQS at least once every three years and, as appropriate, modify or adopt new standards and to hold public hearings when revising or adopting new WQS. (See 33 U.S.C. § 1313(c)(1) and 40 CFR § 131.20). Any new or revised WQS must be submitted to EPA for review and approval or disapproval. 33 U.S.C. § 303(c)(2)(A), (3)). If EPA determines a state’s new or revised standard does not meet the requirements of the CWA, EPA “must

C. Deriving and Expressing Numeric Nutrient Criteria

Under CWA section 304(a), EPA periodically publishes criteria recommendations for use by states and authorized tribes in setting water quality criteria for particular parameters to protect the designated uses for their surface waters. Where EPA has published nationally-recommended criteria, states and authorized tribes have the option of adopting water quality criteria based on EPA’s CWA section 304(a) criteria guidance, section 304(a) criteria guidance modified to reflect site-specific conditions, or other scientifically defensible methods. (See 40 CFR 131.11(b)(1)). For nitrogen and phosphorus pollution, EPA finalized in 2001–2002 numeric nutrient criteria recommendations (i.e., total nitrogen, total phosphorus, chlorophyll a, and turbidity) for lakes and reservoirs, and for rivers and streams for most of the aggregated Level III Ecoregions in the United States. These were based on EPA’s previously published series of peer-reviewed, water body specific technical guidance manuals regarding the development of numeric criteria for lakes and reservoirs35 and rivers and streams.36

In general, there are three types of empirical analyses that provide distinctly different, independent and scientifically defensible, approaches for deriving nutrient criteria from field data. These include (1) the “reference condition approach,” which derives criteria based on the observed water quality characteristics of minimally disturbed or least disturbed waterbodies, (2) the “mechanistic modeling approach,” which employs mathematical representations of ecological systems, processes and parameters using equations that can be calibrated using site-specific data, and (3) the “stressor-response-based


33 Id.

34 Hereafter referred to as “states and authorized tribes”.


modeling approach,"37 which uses available data to estimate statistical relationships between nutrient concentrations and response (ecological, recreational, human health) measures relevant to the designated use to be protected. Each of these approaches is appropriate for deriving scientifically defensible numeric nutrient criteria. Other approaches may be appropriate depending on specific circumstances. Numeric nutrient criteria also may be based on well-established (e.g., peer-reviewed, published, widely recognized) nutrient response thresholds relating to the protection of a given designated use.38

EPA has long recommended that states adopt numeric criteria for total nitrogen (TN) and total phosphorus (TP),39 the nutrients that in excess can ultimately cause adverse effects on designated uses. For this reason, TN and TP are often referred to as “causal” parameters. However, EPA recognizes that the specific levels of TN and TP that adversely affect designated uses, including harm to aquatic life as indicated by various measures of ecological responses, may vary from waterbody to waterbody, depending on many factors, including geomorphology and hydrology among others. As a result, EPA has worked with several states as they developed a combined criterion approach that allows a state to further consider whether a waterbody is meeting designated uses when elevated TN and TP levels are detected. Under this approach, an exceedance of a causal variable, acts as a trigger to consider additional physical, chemical, and biological parameters that serve as indicators to determine protection or impairment of designated uses; these additional parameters are collectively termed “response” parameters.

EPA’s articulation of this combined criterion approach 40 is intended to apply when states wish to rely on response parameters to determine whether a designated use is impaired, once a causal variable has been found to be above an adopted threshold. As with any criteria, states should make clear at what point it has determined that a waterbody is meeting or not meeting its designated use. EPA has expressed that numeric values for all parameters must be set at levels that protect these uses (i.e., before adverse conditions occur that would require restoration).41

EPA has worked extensively with states that have adopted a combined criterion approach, resulting in CWA section 303(c) approvals of combined criterion approaches for Florida’s streams,42 Minnesota’s rivers and streams,43 and Vermont’s lakes and reservoirs.44 Although each of these combined criterion approaches differ from one another in terms of the applicable causal parameters and suite of response parameters as applied to various waterbody types, the combined criterion construction can provide greater precision when there is heightened variability in waterbodies’ responses to nutrients.

EPA notes that once appropriate numeric criteria are developed, assessment of the impairment status of individual water bodies is dependent on data; this is true for any set of numeric criteria addressing any pollutant. EPA further recognizes that it is the responsibility of States to determine the pace and prioritization of data collection, as this is primarily an implementation issue rather than a criteria development issue. However, EPA recommends that states consider such implementation issues at the time of criteria development as this may lead to a more successful water quality standards program generally. In the case of nutrient criteria, EPA has recommended that states interested in this approach develop a biological assessment program that can measure biological responses and other nutrient-related response parameters, with confidence through a robust monitoring program to account for spatial and temporal variability to document the effects of nutrient pollution. EPA reiterates, however, that States have significant discretion in determining the appropriate pace and prioritization of such a monitoring program.

In developing combined criteria, States and EPA have previously identified the following as response parameters that are indicative of nutrient pollution in streams: measures of primary productivity (e.g. benthic chlorophyll a, percent cover of macrophytes), measures of algal assemblage (e.g. algal assemblage indices), and measures of ecosystem function (e.g. continuously monitored pH and dissolved oxygen). EPA recognizes that this may not be an exhaustive list of appropriate response parameters. The approach is generally applicable to lakes and reservoirs, as well as other waterbody types. For lakes and reservoirs, chlorophyll a has typically been measured as sestonic (open water) concentration rather than as a benthic (bottom surface) concentration. Appropriate biological response parameters should directly link nutrient concentrations to the protection of designated uses. The appropriate type and quantity of response parameters may vary by state, ecosystem, and waterbody type.

In previous guidance, EPA has recommended that a combined criterion approach should make clear the impairment status of water bodies in the following situations.46 Specifically, EPA has recommended that if all causal and response parameters are met, then the water quality criterion is met and the waterbody is deemed to be meeting its designated uses. If all response parameters are met, but one or more of the causal parameters is exceeded, then the criterion is met and the waterbody is deemed to be meeting its designated uses (though the state may wish to flag this water body for further scrutiny in the future). If a causal parameter is exceeded and any applicable response parameter is exceeded, then the criterion is not met and the waterbody is deemed to not be meeting its designated uses. If a causal parameter is exceeded and data are unavailable for any applicable response parameters, then the criterion is not met and the waterbody is deemed to not be meeting its designated uses. If a causal parameter is not exceeded but an applicable response variable is exceeded, then the criterion is not met and the waterbody is deemed to not be meeting its designated uses (in this scenario, further


39 USEPA. Letter from James D. Giattina, Director, Water Protection Division, EPA Region 4, to Herschel T. Vinyard, Secretary, Florida Department of Environmental Protection, November 30, 2012.

40 USEPA. Letter from James D. Giattina, Director, Water Protection Division, EPA Region 4, to Herschel T. Vinyard, Secretary, Florida Department of Environmental Protection, June 27, 2013.

41 USEPA. Letter from Tinka Hyde, Director, Water Division, EPA Region 5, to Commissioner John Line Stine, Minnesota Pollution Control Agency. September 15, 2015.

42 USEPA. Guiding Principles on an Optional Approach for Developing and Implementing a Numeric Nutrient Criterion that Integrates Causal and Response Parameters. September 2013.

43 USEPA. Guiding Principles on an Optional Approach for Developing and Implementing a Numeric Nutrient Criterion that Integrates Causal and Response Parameters. September 2013.
investigation may be warranted to determine if nutrient pollution is the cause).

One situation deserves special consideration. If a causal parameter is exceeded and data are unavailable for any applicable response parameters, EPA has previously recommended that the criterion be deemed not met and the waterbody be deemed to not be meeting its designated uses. Under one of EPA’s co-proposed approaches (which mirrors the State’s 2017 proposal), such waterbodies would be deemed “undetermined” with respect to impairment status. Under the other co-proposed approach, which matches EPA’s prior recommendations, the water body is deemed to be impaired, until all response variables have been assessed, at which point the water body status may be changed to non-impaired if no response variable is exceeded. EPA has recommended this approach in the past on the grounds that an exceedance of a causal variable will generally correlate with impairment of aquatic life uses, but we preserve the flexibility for states to conclude that a waterbody is not impaired if information indicates the absence of a response in the waterbody supporting the conclusion that the use is being protected. EPA recognizes there are alternative views of how this comports with requirements that criteria be based on a sound scientific rationale and protective of designated uses, believing if data on some response variables are missing, then it may not be known whether the water body is meeting its designated use or not, and an “undetermined” status with respect to impairment may be appropriate. EPA solicits comment on whether response variables are the best indicators of impairment or non-impairment, and the science policy considerations relevant to determining whether a water body is meeting its designated use if data on some or all response variables are missing.

The approach described above ensures protection of designated uses by taking into account critical information about the pollutant load in the waterbody, as well as the response. Although the terminology of the combined criterion approach more closely aligns with assessment and listing terminology, the combined criterion is also the applicable WQS for NPDES permitting purposes whereby permits must contain limits for any pollutant parameters that are or may be discharged at levels that will cause, have reasonable potential to cause, or contribute to an excursion above any WQS (40 CFR 122.44(d)(1)).

D. Missouri’s 2009 Nutrient Criteria Submission and EPA’s Clean Water Act Section 303(c) Action

On November 5, 2009, Missouri submitted revised WQS containing nutrient criteria for a large subset of the State’s classified lakes and reservoirs. These standards contained the following language at 10 CSR 20–7.031(4)(N)2: “This nutrient criteria rule applies to all lakes and reservoirs that are waters of the state and that are outside the Big River Floodplain Ecoregion and have an area of at least ten (10) acres during normal pool.” Table G in Missouri’s WQS regulations listed 453 classified lakes and reservoirs, 25 of which were deemed “high quality” and were assigned site-specific nutrient criteria separately in Table M. Of the remaining waters, 96 were smaller than ten acres and/or located in the Big River Floodplain Ecoregion and exempted from the application of nutrient criteria under 10 CSR 20–7.031(4)(N)2. Conversely, 332 lakes and reservoirs not listed in Table M were subject to the application of nutrient criteria under 10 CSR 20–7.031(4)(N)2 and (4)(N)3 at the time Missouri submitted its nutrient criteria to EPA. On August 16, 2011, EPA approved all nutrient criteria assigned to the 25 waterbodies listed in Table M but disapproved nutrient criteria that would have applied to the remaining waterbodies. Additionally, EPA disapproved site-specific criteria for total phosphorus assigned to the tributary arms of two large reservoirs (Lake of the Ozarks and Table Rock Lake) per 10 CSR 20–7.031(4)(N)3.a.IV. The disapproved water quality standards defined “prediction values,” “reference values” and “site specific-values” and derived total phosphorus (TP) criteria based on how these values compared to one another. This approach involved a set of input variables and site-specific data requirements. For example, the regulation established that TP prediction values for lakes and reservoirs in the Plains must be calculated based on site-specific coefficients for the (a) percentage of watershed originally in prairie, (b) hydraulic residence time in years, and (c) dam height in feet. To apply the appropriate TP criterion, the State would have had to know how the TP prediction value compared to both the TP reference value and the actual (empirically determined) TP concentration. Total nitrogen (TN) and chlorophyll a criteria were calculated as multiples of the selected TP criterion. EPA’s action was based on a determination that Missouri’s proposal did not include the data and other necessary information needed for EPA to independently reproduce the State’s work and that the State had failed to demonstrate that the criteria would protect the designated aquatic life support and recreational uses as required by 40 CFR 131.6(b) and (c). On March 19, 2014, Missouri submitted revised water quality standards (the designated uses component) that incorporated, for the first time, the Missouri Use Designation Dataset (MUDD) (10 CSR 20–7.031(2)(E); see also Table G of WQS which references the MUDD). This dataset assigned designated uses to the State’s classified lakes and reservoirs (and streams) and was approved by EPA on October 22, 2014. Altogether, MUDD identified 3,081 waterbody segments, including 2,757 lakes and reservoirs, and assigned the following designated uses to these waters: aquatic life support, whole body contact recreation, secondary contact recreation, fish consumption, livestock and wildlife watering, irrigation, and industrial water supply. In addition to these uses, 123 lakes and reservoirs are also designated in the 2014 MUDD dataset for drinking water supply. Missouri also revised its water quality standards to provide that its specific criteria applies to all waters consistent with the designated uses identified in Table G and MUDD. 10 CSR 20–7.031(5). EPA approved this change on November 17, 2015. EPA’s proposed rule addresses the same generic class of waters included in Missouri’s disapproved rule. However, consistent with Missouri’s subsequent actions, EPA’s proposal would apply to a larger group of enumerated lakes and reservoirs, specifically those in Table G and MUDD that are ten acres or more, not located in the Big River Floodplain Ecoregion, and not otherwise listed in Table M of the WQS. This includes 967 waterbodies. EPA requests comment on whether this scope is appropriate for the current rule.

E. Missouri Coalition for the Environment (MCE) Lawsuit and Consent Decree

On February 24, 2016, the Missouri Coalition for the Environment Foundation (MCE) filed a lawsuit alleging that EPA failed to perform its

47 US EPA. (2011) Letter to Sara Parker Pauley (Director, Missouri Department of Natural Resources) from Karl Brooks (USEPA Region 7), Decision document on Missouri Water Quality Standards, August 16, 2011. 48 The Water Body Name, Missouri Use Designation Dataset Version 1.0, August 20, 2013 (8202013 MUDD V1.0), refers to all lakes in the Missouri Use Designation Dataset Version 1.0, August 20, 2013, that are not otherwise listed in Table G.
nondiscretionary duty to propose and promulgate new or revised water quality standards for lakes and reservoirs in Missouri after disapproving the State’s submission in 2011. On December 1, 2016, EPA entered into a consent decree with MCE that stipulates that EPA shall sign a notice of proposed rulemaking by December 15, 2017, to address EPA’s 2011 disapproval, unless the State submits and EPA approves new or revised standards that address the disapproval on or before December 15, 2017; and that EPA shall sign a notice of final rulemaking on or before December 15, 2018, unless the State submits and EPA approves new or revised standards that address the disapproval. In the years following the 2011 disapproval action, EPA has endeavored to work closely with Missouri to develop approvable nutrient criteria.

F. Missouri’s 2017 Proposed Nutrient WQS

On October 16, 2017, MDNR continued to develop revised numeric nutrient criteria and formally issued its proposed WQS that are intended to address EPA’s August 16, 2011 disapproval. Based on EPA’s examination of the State’s proposed rule, Missouri has characterized its revised nutrient WQS as a combined criterion. Missouri’s proposed rule applies to lakes and reservoirs.49 The State’s lakes and reservoirs are impounded and have been assigned an aquatic life use of either: Warm water habitat, cool water habitat, or cold water habitat. Each subcategory is defined as “waters in which naturally-occurring water quality and habitat conditions allow [for] the maintenance of a wide variety of [warm, cool or cold water] biota.”50 The State takes the position that “health of sport fish populations can be interpreted as an indicator of overall ecosystem health and the presence of a “wide variety” of aquatic biota.”51 Missouri’s proposed rule establishes three ecoregions and sets forth for each ecoregion chl-a criteria above which waters would be deemed impaired, and a combination of TN, TP, and chl-a “screening values” and five “eutrophication impacts” (i.e., response parameters) where a waterbody would be deemed impaired if at least one screening value and at least one eutrophication impact are exceeded in the same year. When data are unavailable for the eutrophication impacts despite information indicating that at least one screening value is exceeded, Missouri intends waters to be listed on Category 3 of the 305(b)/303(d) Integrated Report, meaning there is insufficient information to determine impairment status. In Missouri’s expression of the combined criterion approach, the chl-a parameter functions as both a screening value, requiring evaluation of the eutrophication impacts, and at a higher level as a standalone criterion that would determine in and of itself that a waterbody is impaired, without the need to further assess eutrophication impacts. If chl-a is exceeded at the screening level but there is inadequate information on the other response variables, the water is placed in category 3 and not listed as impaired.

Table 2. Excerpts From Missouri’s October 16, 2017 Nutrient Proposal

<table>
<thead>
<tr>
<th>Lake Ecoregion</th>
<th>Chl-a Criterion</th>
<th>Screening Values (μg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>TP</td>
</tr>
<tr>
<td>Plains</td>
<td>30</td>
<td>49</td>
</tr>
<tr>
<td>Ozark Border</td>
<td>22</td>
<td>40</td>
</tr>
<tr>
<td>Ozark Highland</td>
<td>15</td>
<td>16</td>
</tr>
</tbody>
</table>

5. Lakes with water quality that exceed Nutrient Criteria identified in Tables L and M are to be deemed impaired for excess nutrients.
6. Lakes with water quality that exceed screening values for Chl-a, TN, or TP are to be deemed impaired for excess nutrients if any of the following eutrophication impacts are documented for the respective designated uses within the same year. Eutrophication impacts for aquatic life uses include:
   (I) Occurrence of eutrophication-related mortality or morbidity events for fish and other aquatic organisms;
   (II) Epilimnetic excursions from dissolved oxygen or pH criteria;
   (III) Cyanobacteria counts in excess of 100,000 cells per milliliter (cells/ml);
   (IV) Observed shifts in aquatic diversity attributed to eutrophication; and
   (V) Excessive levels of mineral turbidity that consistently limit algal productivity during the period May 1—September 30

At the time of this proposal, Missouri’s proposal is still under consideration and the State has not submitted to EPA for CWA 303(c) review a final rule with supporting information to address EPA’s 2011 disapproval.

III. Proposed Nutrient Combined Criterion for Lakes and Reservoirs in Missouri

A. Proposed Combined Criterion Approaches

Today EPA is proposing two alternatives to establish nutrient criteria in a combined criterion approach to address its 2011 disapproval. Under the first alternative, EPA proposes nutrient protection values and eutrophication impact factors in a combined criterion approach. Under the second alternative, EPA proposes a combined criterion approach that would mirror the State of Missouri’s October 2017 proposal for lake nutrient water quality standards. EPA seeks public comment on the two alternatives described below in light of the federal regulations at 40 CFR part 131.11 requiring that criteria must be based on a sound scientific rationale and protective of the designated uses of the waters.

B. Proposed Combined Criterion

Alternative 1

Alternative 1 is presented in Table 3 below and appears as regulatory text at the end of this proposal.

49 See 10 CSR 20–7.031(5) and the October 2017 draft language proposed for 10 CSR 20–7.031(5)(N)(2) (“This rule applies to all lakes that are waters of the state and have an area of at least ten (10) acres during normal pool conditions. Big River Floodplain lakes shall not be subject to these criteria.”).
50 10 CSR 20–7.031(1)(C)1.A, VI, B, V and C.V.
Alternative 1 is comprised of nutrient protection values and eutrophication impacts. Nutrient protection values are defined similarly as Missouri defines their "screening values": maximum ambient concentrations of TP, TN, and chl-α based on the three-year rolling average geometric mean of nutrient data collected April through September. EPA has chosen the term "protection values," rather than "causal" or "screening" values, to emphasize that in general, lakes and reservoirs that do not exceed these values may be assumed to meet designated uses without further assessment of eutrophication impacts. However, EPA recognizes, consistent with the logic of the combined criteria approach, that exceedance of such values does not necessarily mean that a water body is impaired. Alternative 1 uses nutrient protection values for TN, TP, and chl-α derived using a reference condition approach for the Plains ecoregion and a combined Ozarks ecoregion described in detail in the following section. These values are based on a reference condition approach using the 75th percentile of a distribution of values from a population of least disturbed lakes in each of the two ecoregions (Plains and Ozarks). The nutrient protection values for chl-α in Alternative 1 function as stand-alone criteria independent from the TN and TP protection values and other eutrophication impact factors. This approach gives additional weight to chl-α as a key early response indicator of adverse impact from excess nitrogen and phosphorus.

Under Alternative 1, lake and reservoir water quality must not exceed protection values for TN or TP unless each of the eutrophication impacts are evaluated and data demonstrate that none occur within the same three-year rolling average period as a TN or TP exceedance. EPA included this presumption to address potential for data gaps for response parameters.52 As

### Table 3—Alternative 1 Lake Ecoregion Nutrient Protection Values (µG/L) and Eutrophication Impacts

<table>
<thead>
<tr>
<th>Lake Ecoregion</th>
<th>TP</th>
<th>TN</th>
<th>Chl-a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plains</td>
<td>44</td>
<td>817</td>
<td>14</td>
</tr>
<tr>
<td>Ozarks</td>
<td>23</td>
<td>500</td>
<td>7.1</td>
</tr>
</tbody>
</table>

(1) Lake and reservoir water quality must not exceed nutrient protection values for chlorophyll-a. (2) Lake and reservoir water quality must also not exceed nutrient protection values for total nitrogen and total phosphorus unless each of the following eutrophication impacts are evaluated and none occur within the same three-year rolling average period: (I) Eutrophication-related mortality or morbidity events for fish and other aquatic organisms; (II) An excursion from the DO or pH criteria in Missouri water quality standards applicable for Clean Water Act purposes; (III) Cyanobacteria counts equal to or greater than 100,000 cells per ml; (IV) Observed shifts in aquatic diversity directly attributable to eutrophication; or (V) Excessive levels of mineral turbidity that consistently limit algal productivity during the period May 1–September 30, or Secchi disk measurements of turbidity equal to or less than EPA’s recommended Level III Ecoregions IX (1.53 m) or IX (2.86 m).

C. Derivation of Nutrient Protection Values for Alternative 1

EPA requests comment on a set of nutrient protection values as derived below. This methodology considered the water quality characteristics of lakes and reservoirs located in watersheds with comparatively low levels of human disturbance. This methodology, known as the reference condition approach, comport with longstanding Agency guidance54 and builds on earlier collaborative efforts in the four-state region. This approach could be implemented using the State’s existing water quality dataset56 and key geographical concepts and interpretations supported previously by the State.57 Protecting a waterbody at reference conditions should inherently protect all designated uses, and therefore, should support the most sensitive use.58 EPA further supported by the data used to derive reference condition values. A third set of alternatives appears in the Technical Support Document accompanying this rule describing reference condition values for Missouri lakes.

56 Oblecht, D. 2015. Statewide Lake Assessment Program. Quality assurance project plan. School of Natural Resources, University of Missouri, Columbia, MO.
57 Thorpe, A. 2015. The Lakes of Missouri Volunteer Program. Quality assurance project plan. School of Natural Resources, University of Missouri, Columbia, MO.
is unaware of compelling scientific evidence that would suggest that the reference condition approach employed here would not protect Missouri’s aquatic life, recreation, and drinking water designated uses, though EPA is not suggesting that there are no other approaches to protect applicable designated uses. EPA believes that the reference condition approach described here also comports with the State’s regulatory definition for the aquatic life support use. This definition recognizes three subcategories under the aquatic life support criterion: Warm water habitat, cool water habitat, and cold water habitat. Each subcategory is described as “waters in which naturally-occurring water quality and habitat conditions allow for the maintenance of a wide variety of [warm, cool or cold water] biota.” This description is explicitly applied to lakes and reservoirs (10 CSR 20–7.031(1)(C)). The same nutrient criteria apply to all three subcategories based on the way EPA aggregated data to account for less than twenty percent of the watershed was covered by grassland. In applying this threshold, EPA considered grassland and all other forms of native land cover (e.g., forest, marshland). If located in the Ozark Highlands, more than fifty percent of the watershed was forested. Forests in the Ozark Highlands are the equivalent to grasslands in the Plains in terms of native land cover and associated nutrient delivery. This selection criterion was applied by EPA to the Ozark Highlands and the adjoining Ozark Border, which collectively comprise the Ozarks Ecoregion.

In order to identify waters meeting this initial screening criteria, EPA obtained digital watershed polygons from USGS’s National Hydrography Dataset and a separate dataset maintained by the University of Missouri-Columbia. In about five cases, polygons were not available in either dataset and had to be digitized in ArcGIS. NHDPlus-V2 flowlines and medium resolution NHD (1:100,000 scale) elevation-derived catchments were used to identify the watersheds for each lake/reservoir. In cases where a watershed was represented by more than one catchment, the catchments were dissolved into one polygon. For many of the smaller lakes/reservoirs, watersheds were defined using the Water Erosion Prediction Project.
explained the noted hypertrophic condition. The other two instances involved state-managed fishing lakes, one situated in a formerly cultivated field and the other situated in a watershed extending into the heavily cultivated Big River Floodplain. A few other lakes on state-managed lands were disqualified based on disturbance related to reported sedimentation and algal bloom issues. EPA ultimately identified 21 reference lakes and reservoirs in the Plains and 27 in the Ozarks that met the criteria discussed above. EPA calculated seasonal geometric mean TN, TP, and chlorophyll a concentration values for each waterbody, and calculated the long-term median seasonal geometric means for each parameter/waterbody combination. These medians were partitioned by ecoregion, ranked, and used in the calculation of appropriate concentration percentiles. EPA invites public comment on the methodology to select reference lakes and reservoirs for this alternative’s methodology.

To assist in the identification of appropriate concentration percentiles, land cover disturbance patterns in the three ecoregions were compared to patterns reported for the conterminous United States using ArcGIS. This comparison indicated that cropland and developed (urban) land collectively comprised 21.1 percent of the cover in the lower 48 states. This is comparable to the percentage reported for the Ozark Border (22.2 percent), higher than the percentage reported for the Ozark Highlands (6.9 percent), and lower than the percentage reported for the Plains (39.9 percent). Based on its review of the applicable federal guidance, EPA interpreted this to mean that application of the standard 75th percentile nutrient concentration would be appropriate for the Ozark Border, because this region has experienced a degree of land cover disturbance typifying that of the nation as a whole (excluding Alaska and Hawaii). The 75th percentile also was selected for the Ozark Highlands, and therefore appropriate for the combined Ozark ecoregion. In choosing this percentile, EPA was mindful of the limited number of potentially suitable reference waters in this region, and in turn, the difficulty in accurately estimating a higher percentile. EPA recognizes that there are higher levels of land cover disturbance in the Plains region relative to other locations in Missouri and most of the United States and considered using the 50th percentile for the Plains. However, EPA concluded that the screening criteria for reference sites (described above), already appropriately accounted for these differences by including the allowable percent of cropland and urban land in the lake watershed, is the same for each ecoregion. EPA decided to use the 75th percentile for all ecoregions. EPA invites public comment on whether the use of the 75th percentile for these ecoregions was appropriate. EPA notes that using the 75th percentile of reference lakes to derive protection values implies that 25 percent of reference lakes would be deemed to exceed the protection values if assessed using the data used to derive the criteria. This could be interpreted to mean that 25 percent of the lakes meeting the reference condition selection criteria described above would none-the-less be determined to be impaired. This could also be interpreted as appropriately ensuring that high levels of nutrient parameters for lakes that, in fact, may or may not meet designated uses are not identified as protective for the vast majority of lakes that have much lower levels of nutrient parameters. A higher percentile value, such as the 90th or 95th percentile, would ensure that, at least based on the data used to derive the criteria, all or most of the reference lakes would in fact be found to meet designated uses. EPA invites public comment on whether the use of a higher percentile would be appropriate in the context of the selection criteria used by EPA to identify reference lakes and reservoirs for the purpose of calculating protective values indicative of meeting designated uses.

In this alternative, these concentration percentiles would serve as nutrient protection values as part of a combined criterion approach for all classified lakes and reservoirs in Missouri that (1) are listed in Table G of the State’s WQS and the Missouri Use Designation
Three-year rolling averages. EPA invites public comment on the use of moving averages versus fixed averaging periods.

As described in the Technical Support Document accompanying this proposal, the resulting values are comparable in magnitude to those recommended by the Regional Technical Assistance Group (RTAG) for the four-state region, to criteria developed or adopted in neighboring Kansas, Nebraska and Oklahoma, and to TMDL targets adopted previously in Missouri. As such, EPA is confident that the nutrient protection values are protective of downstream lakes and reservoirs, though EPA emphasizes that this is not the only way of developing protective values. For protection of downstream rivers and streams, lakes often act as a “sink” for nutrients because of the relatively longer water residence time and associated physical processes and biochemical cycling. As such, lakes retain nutrients and outflow nutrient concentrations are generally lower than inflow nutrient concentrations. In terms of level of protection needed, nutrient criteria for lakes and reservoirs are generally lower than nutrient criteria for rivers and streams in the same ecoregion (see, for example, EPA’s criteria published in 2000 for Ecoregion IX). For these reasons, EPA concludes that the values are protective of downstream waters and their assigned uses. EPA invites public comment on the derivation of EPA’s proposed nutrient protection values based on least disturbed reference conditions. EPA specifically requests comments on the use of the 75th percentile of the reference lake values to establish the TN, TP, and chl-a nutrient protection values proposed for Alternative 1.

D. Proposed Combined Criterion Alternative 2

Alternative 2 is presented in Table 4 below.

TABLE 4—ALTERNATIVE 2 LAKE ECOREGION CHL-a CRITERIA, NUTRIENT SCREENING VALUES (μG/L), AND EUTROPHICATION IMPACTS

<table>
<thead>
<tr>
<th>Lake ecoregion</th>
<th>Chl-a criteria</th>
<th>Screening Values (μG/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plains</td>
<td>30</td>
<td>49 843 18</td>
</tr>
<tr>
<td>Ozark Border</td>
<td>22</td>
<td>40 733 13</td>
</tr>
<tr>
<td>Ozark Highland</td>
<td>15</td>
<td>16 401 6</td>
</tr>
</tbody>
</table>

Lakes with water quality that exceed Chl-a Criteria are to be deemed impaired for excess nutrients. Lakes with water quality that exceed screening values for Chl-a, TN, or TP are to be deemed impaired for excess nutrients if any of the following eutrophication impacts are documented for the respective designated uses within the same year. Eutrophication impacts for aquatic life uses include:

(I) Occurrence of eutrophication-related mortality or morbidity events for fish and other aquatic organisms;

(II) Epilimnetic excursions from dissolved oxygen or pH criteria;

(III) Cyanobacteria counts in excess of 100,000 cells per milliliter (cells/ml);

(IV) Observed shifts in aquatic diversity attributed to eutrophication; and

(V) Excessive levels of mineral turbidity that consistently limit algal productivity during the period May 1–September 30.

As of the date of this proposal, Missouri has not finalized, and EPA has not made any determination with respect to Missouri’s proposed standards. Notwithstanding this, EPA believes it is appropriate to propose standards for consideration that are essentially identical to the proposed state standards, and is doing so in Alternative 2. Alternative 2 includes chl-a criteria for three ecoregions (Plains, Ozark Border, and Ozark Highland) that determine impairment independent of the screening values and eutrophication impact factors.

Alternative 2, similarly to Alternative 1, includes screening values for TN, TP, and chl-a (at a lower level than the criteria for chl-a) that operate in coordination with five eutrophication impact factors to determine impairment. However, as explained above, one significant distinction is that Alternative 1 would treat the lower chl-a screening value (called a “protection value” in Alternative 1) as stand-alone criteria and deem any exceedance of this value as indicative of impairment without assessment of additional eutrophication impacts. Alternative 2 includes a qualifier of “epilimnetic” with respect to excursion of DO or pH criteria to mirror the State’s proposal. EPA seeks comment on limiting application of DO and pH criteria to the epilimnion (surface layer) of lakes.

The State of Missouri has documented a supporting rationale for the values proposed in Alternative 2 as part of a combined criterion structure. This document includes maps of the three ecoregions (Plains, Ozark Border, and Ozark Highland). This in turn leads Missouri to describe how it considered input from a stakeholder group and “decided on an approach that provided for the most scientifically defensible protections for the underlying designated uses.” Missouri indicates that its approach “focuses on the biological response, considers ecoregional differences and existing trophic levels, and supplements criteria with conservative screening values coupled with weight of evidence analysis to better support determinations of impairment.” Missouri indicates that it reviewed several different sources of information to derive reservoir numeric nutrient criteria, including recent numeric nutrient criteria development activities in other states, Missouri-specific reservoir water chemistry data, literature reviews, and expert opinion.

Missouri indicated the stand-alone independent chl-a criterion for the Plains “is conservatively set to support sport fisheries rather than maximizing...
sport fish harvest. Missouri maintains that using sport fishery status as an indicator of aquatic life use protection is ecologically justified because sport fish are generally apex predators in reservoir systems. Therefore, the health of sport fish populations can be interpreted as an indicator of overall ecosystem health and the presence a ‘wide variety’ of aquatic biota, as defined in the existing regulations”.\textsuperscript{79} For the Ozark Highlands, Missouri identified “a lower chlorophyll concentration of 15 µg/L, which reflects the regional pattern of reservoir fertility associated with the different physiographic regions of the state”.\textsuperscript{80} Because the Ozark Border section represents a transition zone between the Plains and Ozark Highlands, Missouri identified a chl-α screening criterion intermediate to the other two sections. Missouri proposed chl-α screening values equal to the 50th percentile of the distribution of growing season chlorophyll data for each ecoregion, and back calculated TN and TP screening values using regression relationships with chl-α presented in their rationale document.

EPA is seeking comment on whether the chl-α criteria in Alternative 2 would protect the State’s designated uses for these lakes. EPA seeks comment on whether a different (i.e., more protective) level of chl-α as a eutrophication impact factor is necessary to protect the designated uses for these lakes. EPA further seeks comment on whether or not the hypothetical scenario pursuant to Alternative 2 is scientifically supportable as protecting the designated use: Not identifying a lake as impaired when it (1) exceeds a screening value for TP or TN, (2) exceeds a screening value for chl-α, and (3) there are no documented eutrophication impacts. In other words, EPA seeks comment on whether it is sufficient or insufficient to identify impairment if a water body exceeds a screening value for TN or TP and also exceeds a screening value for chl-α.

The combined criterion could function in the manner proposed for Alternative 1, where a lake with water quality that exceeds a screening value for TN, TP, or chl-α (at a “screening” level) is deemed impaired for excess nutrients only if one or more of the eutrophication impacts are documented to occur within the same year. Using this Alternate 2 expression, a lake exceeding screening values for TN, TP, or chl-α (at a “screening” level) would not be considered to be impaired unless and until additional information is collected and evaluated to confirm the impairment. EPA has not separately prepared supporting documentation for Alternative 2 at the same level of detail as for Alternative 1, because as noted above, Alternative 2 is intended to closely mirror the State’s 2017 proposed rule. Accordingly, EPA has placed documentation as provided by the State, in its own docket as an integral part of the supporting documentation for Alternative 2. EPA is asking for comment on this approach.

EPA also has not provided proposed regulatory text for Alternative 2, because the regulatory text for this option would be largely identical to the regulatory text in the State’s 2017 proposed rule. Rather, the Agency is providing notice of its consideration of Alternative 2 in the preamble to today’s proposed rule. The Agency recognizes that, if the Agency were to adopt this alternative in the final rule, there may need to be formatting changes to the State regulatory text to conform to requirements applicable to codification in the Code of Federal Regulations.

E. Additional Alternative Approaches Considered

This federal action fulfills EPA’s commitment under the consent decree with MCE to propose criteria addressing its 2011 disapproval by December 15, 2017. EPA acknowledges that the alternatives in the current proposal are not the only possible options that EPA could promulgate or Missouri could adopt to address the 2011 disapproval action. When promulgating federal water quality standards for a state, EPA’s preference is to rely on state-specific data, where available, to derive criteria to protect the state’s applicable designated uses. EPA solicits comment from the public and stakeholders on the Agency’s co-proposals, in addition to other scientifically defensible options, to support a well-informed and robust final rule that reflects thoughtful consideration of Missouri’s regulatory structure and implementation mechanisms.

EPA considered several alternatives to the two alternatives proposed combined criterion approaches, component nutrient protection (or screening) values, and eutrophication impacts, and is interested in public comment on these approaches. First, EPA considered proposing the reference condition-derived nutrient protection values as stand-alone nutrient criteria (i.e., in absence of a combined criterion structure). However, given Missouri’s interest in the combined criterion approach and EPA’s position that such an approach can be appropriate and protective, EPA elected to structure the two alternatives in this proposal in a similar fashion. Second, EPA considered relying on fewer response parameters to avoid use of factors that may be onerous to routinely measure and assess, may be subject to various interpretations, and may not be necessary to indicate adverse impact. For example, EPA considered using only chl-α, DO, and pH as eutrophication impacts. EPA instead elected to include the full set Missouri identified in recognition that Missouri had concluded each was an appropriate eutrophication impact to be included in the State’s proposed rule. Lastly, for Alternative 1, EPA considered using the 50th percentile of the data from reference lakes in the Plains ecoregion for deriving nutrient protection values; these values are 9.8 µg/L chl-α, 39 µg/L TP, and 690 µg/L TN. EPA decided to use the 75th percentile for the Plains ecoregion for this proposal because reference lakes in both ecoregions could have no greater than 20 percent cropland and urban land in their watershed based on EPA’s screening procedure. EPA specifically solicits comment on using a higher percentile, such as 90th or 95th.

F. Applicability of Combined Criterion When Final

Unless EPA approves water quality standards addressing EPA’s 2011 disapproval. EPA’s proposed nutrient combined criterion for Missouri’s lakes and reservoirs would be effective for CWA purposes 60 days after publication of a final rule. The proposed combined criterion in this rule, if finalized, would be subject to Missouri’s general rules of applicability in the same way and to the same extent as are other state-adopted criteria.

EPA’s proposed nutrient combined criterion, if finalized, would serve as a basis for development of new or revised National Pollutant Discharge Elimination System (NPDES) permit limits in Missouri for regulated dischargers found to have reasonable potential to cause or contribute to an
excursion of the proposed nutrient combined criterion. Although EPA cannot be certain of whether a particular direct or indirect discharger would change their operations if these proposed criterion were finalized, EPA acknowledges that point source dischargers would need to be assessed to determine if they have a reasonable potential for the discharge to cause or contribute to an excursion of the water quality standard, and could well be subject to additional water quality-based effluent limits as a result. Nonpoint dischargers could also be subject to additional control requirements under Missouri law, perhaps in conjunction with a TMDL. Missouri has NPDES permitting authority, and retains discretion in issuing permits consistent with CWA permitting regulations, which require that permit limits be established such that permitted sources do not cause or contribute to a violation of water quality standards, including numeric nutrient criteria.

IV. Tributary Arms

As part of its efforts to establish its water quality standards, the State of Missouri established water quality criteria in its 2009 WQS submission to address nutrient-related pollutants for certain lakes, reservoirs and tributary arms. As mentioned previously, on August 16, 2011, EPA disapproved most numeric criteria for TN, TP, and chl-a for Missouri lakes and reservoirs and also disapproved TP criteria for tributary arms Grand Glaize, Gravois, and Nianga to the Lake of the Ozarks, and tributary arms James River, Kings River, and Long Creek to Table Rock Lake. In Missouri’s disapproved rule (10 CSR 20–7.0314)(N)(1)(D) and current proposed rule (10 CSR 20–7.031(N)(1)(E)), it considers a tributary arm to be a substantial segment of a Class L2 lake that is primarily discharged by a source or sources other than the main channel of the lake. EPA requests public comments on applying Alternative 1, Alternative 2, or any other appropriate alternative to the respective tributary arms to address EPA’s 2009 disapproval. EPA invites the public to provide any data or scientific information to inform decision-making towards this option.

V. Endangered Species Act

Section 7(a)(2) of the Endangered Species Act (ESA) requires the EPA, in consultation with the U.S. Fish and Wildlife Service (USFWS) and/or the National Marine Fisheries Service (NMFS), to determine if any action authorized by the Agency is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat for such species.

Pursuant to this section, EPA intends to initiate consultation with USFWS regarding the effects that finalizing this rulemaking would have on federally-listed threatened and endangered species and designated critical habitat. EPA will subsequently conduct a biological evaluation to determine whether any federally-listed threatened or endangered species or their critical habitat are likely to be adversely affected by the finalization of this rulemaking.

VI. Under what conditions will federal standards be either not finalized or withdrawn?

Under the CWA, Congress gave states primary responsibility for developing and adopting WQPs for their navigable waters. See CWA section 303(a)–(c). Although EPA is proposing nutrient criteria for Missouri’s lakes and reservoirs, the State has the option of adopting and submitting revised nutrient criteria for these waters consistent with CWA section 303(c) and implementing regulations at 40 CFR part 131. Consistent with CWA section 303(c)(4) and the consent decree discussed in Section II, if Missouri adopts water quality criteria to address EPA’s 2011 disapproval, and if EPA approves such criteria prior to the December 15, 2018 consent decree deadline to publish the final rule, EPA will not proceed with the final rulemaking.

Pursuant to 40 CFR 131.21(c), if EPA does promulgate final criteria, they would be applicable for the purposes of the CWA. EPA could eventually withdraw any federally promulgated criteria through a rulemaking. EPA would undertake a withdrawal action if Missouri adopts and EPA approves water quality criteria to address EPA’s 2011 disapproval as meeting CWA requirements.

VII. WQS Regulatory Approaches and Implementation Mechanisms

The Federal water quality standards regulation at 40 CFR part 131 provides several tools that Missouri has available to use at its discretion when implementing or deciding how to implement these numeric nutrient criteria, if finalized. Among other things, EPA’s WQS regulation: (1) Specifies how states and authorized tribes establish, modify or remove designated uses, (2) specifies the requirements for establishing criteria to protect designated uses, including criteria modified to reflect site-specific conditions, (3) authorizes and provides requirements for states and authorized tribes to adopt WQS variances that provide time to achieve the underlying WQS, and (4) allows states and authorized tribes to authorize the use of compliance schedules in NPDES permits to meet Water Quality Based Effluent Limits (WQBELs) derived from the applicable criteria. Each of these approaches is discussed in more detail in the next sections.

A. Designating Uses

Federal regulations at 40 CFR 131.10 provide regulatory requirements for establishing, modifying, and removing designated uses. If Missouri removes or modifies the aquatic life or recreational designated uses of a lake or reservoir subject to EPA’s proposed nutrient criteria and adopts the highest attainable use,81 the state must also adopt criteria to protect the newly designated highest attainable use consistent with 40 CFR 131.11. Any designated use change must meet the requirements of 40 CFR part 131 and obtain EPA approval. If EPA finds removal or modification of the designated use, the adoption of the highest attainable use and criteria to protect that use is consistent with CWA section 303(c) and the implementing regulation at 40 CFR part 131 and thus approves the revised WQS, then the new or revised use and criteria would become effective for CWA purposes. As an additional step, EPA would initiate rulemaking to withdraw its promulgation of nutrient criteria in Missouri if the criteria to protect the new use is something other than the federally promulgated criteria.

B. Site-Specific Criteria

The regulation at 40 CFR 131.11 specifies requirements for modifying water quality criteria to reflect site-specific conditions. In the context of this rulemaking, a site-specific criterion (SSC) is an alternative to a federally promulgated nutrient criterion that would be applied on a watershed, area-wide, or water body-specific basis.

81 If a state or authorized tribe adopts a new or revised WQS based on a required use attainability analysis, then it must also adopt the highest attainable use (40 CFR 131.10(g)). Highest attainable use is the modified aquatic life, wildlife, or recreational use that is closest to the uses specified in section 101(a)(2) of the Act and attainable, based on the evaluation of the factor(s) in 40 CFR 131.10(g) that preclude(s) attainment of the use and any other information or analyses that were used to evaluate attainability. There is no required highest attainable use where the state demonstrates the relevant use specified in section 101(a)(2) of the Act and sub-categories of such a use are not attainable (See 40 CFR 131.3(m)).
provided this alternative is protective of the designated use, is scientifically defensible, and provides for the protection and maintenance of downstream water quality. A SSC may be more or less stringent than the otherwise applicable federal criterion. A SSC may be appropriate when further scientific data and analyses more precisely define the concentration of a pollutant that is protective of the designated uses of a particular watershed, region, or water body. If Missouri adopts, and EPA approves, a SSC that fully meets the requirements of both section 303(c) of the CWA and EPA's implementing regulation at 40 CFR part 131, EPA would undertake a rulemaking to withdraw the corresponding federal criterion for the water(s) affected by the SSC.

C. WQS Variances

Federal regulations at 40 CFR 131.14 define a WQS variance as a time-limited designated use and criterion, for a specific pollutant, water quality parameter, that reflects the highest attainable condition during the term of the WQS variance. WQS variances adopted in accordance with 40 CFR 131.14 (including a public hearing consistent with 40 CFR 25.5) provide a flexible but defined pathway for states and authorized tribes to meet their NPDES permit obligations by allowing dischargers the time they need (as demonstrated by the state or authorized tribe) to make incremental progress toward meeting WQS that are not immediately attainable but may be in the future. When adopting a WQS variance, states and authorized tribes specify the interim requirements of the variance by identifying a quantitative expression that reflects the highest attainable condition (HAC) during the term of the variance, defining the term of the variance, and describing the pollutant control activities to achieve the HAC during the term of the variance. WQS variances will help states and authorized tribes focus on improving water quality, rather than pursuing a downgrade of the underlying water quality goals through modification or removal of a designated use, as a variance cannot lower currently attained water quality. As water quality standards, variances are submitted to EPA for review and approval under CWA section 303(c) which provides legal avenue by which NPDES permit limits can be written to derive from, and comply with, the WQS variance rather than the underlying WQS for the WQS variance. If dischargers are still unable to meet the WQBELs derived from the applicable WQS once a variance term is complete, the regulation allows the state to adopt a subsequent variance if it is adopted consistent with 131.14.

EPA’s proposed nutrient criterion applies to use designations that Missouri has already established. Missouri may adopt time-limited designated uses and criteria to apply for the purposes specified in 40 CFR 131.14(a)(3).

D. NPDES Permit Compliance Schedules

EPA’s regulations at 40 CFR 122.47 and 40 CFR 131.15 address how states and authorized tribes include permit compliance schedules in their NPDES permits if dischargers need additional time to meet their WQBELs based on the applicable WQS. EPA’s updated regulations at 40 CFR 131.15 require that states and authorized tribes that wish to allow the use of permit compliance schedules adopt specific provisions authorizing their use and obtain EPA approval under CWA section 303(c) to ensure that a decision to allow permit compliance schedules is transparent and allows for public input (80 FR 51022, August 21, 2015). On December 11, 2012, Missouri submitted a revised compliance schedule authorizing provision at 10 CSR 20–7.031(10). This revision was partly approved by EPA on January 25, 2015. Missouri is authorized to grant permit compliance schedules, as appropriate, to permitted facilities impacted by federally promulgated numeric nutrient criteria as compliance schedules are consistent with EPA’s permitting regulation at 40 CFR 122.47.

VIII. Economic Analysis

At this time, EPA has prepared only a preliminary economic analysis specifically for Alternative 1. This analysis will be further refined and an updated more comprehensive economic review will be put out for comment in a Notice of Data Availability at a later time. At that time, to best inform the public of the potential impacts of this rule, EPA will evaluate the potential benefits and costs associated with implementation of EPA’s proposed criterion.

The analysis of acres with BMPs to address nonpoint sources of nutrients was conducted at the HUC–12 level of resolution. Many of the potentially incrementally impaired lakes in Missouri are small, and their watersheds are smaller than the HUC–12 watershed in which they are located, thus, the benefits that these WQBELs may be overstated. However, EPA did not initially include any costs for watersheds for which it does not have data. Thus, at least some likely costs were not included in the preliminary analysis. Due to these and other limitations, EPA believes that its current draft analysis is too preliminary to adequately inform public comment on the rule. EPA will address these issues in the updated analysis provided in the NODA.

EPA also preliminarily estimated the benefits from water quality improvements resulting from implementing the nutrient protection values in Missouri Lakes and reservoirs. However, due to data and resource limitations and other challenges, EPA believes that this benefits analysis is also too preliminary to be presented at this time. EPA will also include an updated analysis of benefits in the NODA.

EPA seeks public comment to inform EPA’s economic analysis. EPA is interested in public comment regarding how likely it is that lakes without water quality data may trigger the screening criteria; what practices the agricultural sector and cities may take to reduce nonpoint source discharges and the likelihood that such practices are implemented; what unit costs EPA should consider using in conducting this analysis; and what assumptions EPA should consider using for expected nutrient load reductions.

EPA intends to make the revised analysis, including pre-publication peer review, available for public comment no later than six months after the date of publication of this proposed rule. In no circumstances will EPA issue a final rule without providing an economic analysis sufficiently in advance of the final rule for public comment on the analysis to meaningfully inform EPA’s development of the rule.

IX. Statutory and Executive Order Reviews

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

This action is an economically 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. (Docket Id. No. EPA–HQ–OW–2009–0596) is available in the docket. A summary of the report can be found in Section VIII of this preamble.
B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This action is expected to be an Executive Order 13771 regulatory action. Details on the estimated costs of this proposed rule will be available for public comment in a subsequent Notice of Data Availability to be published no later than six months after this proposed rule (See summary at Section VIII. Economic Analysis, and full economic analysis report in the docket for this proposed rule).

C. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the PRA, 44 U.S.C. 3501 et seq. Burden is defined at 5 CFR 1320.3(b). This action does not include any information collection, reporting, or record-keeping requirements.

D. Regulatory Flexibility Act

For purposes of assessing the impacts of this action on small entities, a small entity is defined as: (1) A small business as defined by the Small Business Administration’s (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise that is independently owned and operated and is not dominant in its field.

Under the CWA, states must adopt WQS for their waters and submit these standards to EPA for approval. If the Agency disapproves a submitted standard and the state does not adopt revisions to address EPA’s disapproval, EPA must promulgate standards consistent with the CWA requirements. State standards (or EPA-promulgated standards) are implemented through various water quality control programs including the NPDES program, which limits discharges to navigable waters except in compliance with an NPDES permit. The CWA requires that all NPDES permits include any limits on discharges that are necessary to meet applicable WQS. Thus, under the CWA, EPA’s promulgation of WQS establishes standards that the state implements through the NPDES permit process. The State has discretion in developing discharge limits, as needed to meet the standards. This proposed rule, as explained earlier, does not itself establish any requirements that are applicable to small entities. As a result of this action, the State of Missouri will need to ensure that permits it issues include any limitations on discharges necessary to comply with the standards established in the final rule. In doing so, the state will have a number of choices associated with permit writing. While Missouri’s implementation of the rule may ultimately result in new or revised permit conditions for some dischargers, including small entities, EPA’s action, by itself, does not impose any of these requirements on small entities; that is, these requirements are not self-implementing. Thus, I certify that this rule will not have a significant economic impact on a substantial number of small entities under the RFA.

E. Unfunded Mandates Reform Act

This proposed rule contains no federal mandates (under the regulatory provisions of Title II of the UMRA) for state, local, or tribal governments or the private sector.

EPA determined that this proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments. Moreover, WQS, including those proposed here, apply broadly to dischargers and are not uniquely applicable to small governments. Thus, this proposed rule is not subject to the requirements of section 203 of UMRA.

F. Executive Order 13132 (Federalism)

This action does not have federalism implications as that term is used in EO 13132. Although section 6 of Executive Order 13132 does not apply to this action, EPA had extensive communication with the State of Missouri to discuss EPA’s concerns with the State’s previously submitted and disapproved criteria and the federal rulemaking process. In the spirit of Executive Order 13132, and consistent with EPA’s policy to promote communications between EPA and state and local governments, EPA specifically solicits comment on this proposed rule from state and local officials.

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

This action does not have any tribal implications as specified by Executive Order 13175. As there are no federally-recognized tribes in the State of Missouri, this executive order does not apply. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045 (Protection of Children from Environmental Health and Safety Risk)

Executive Order 13045 (62 FR 19885, April 23, 1997) requires agencies to identify and assess health and safety risks that may disproportionately affect children and ensure that activities address disproportionate risks to children. This action not subject to Executive Order 13045 because the EPA does not believe the environmental health risks or safety risks addressed by this action present a disproportionate risk to children.

I. Executive Order 13211 (Actions That Significantly Affect Energy Supply, Distribution, or Use)

This rule 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.

J. National Technology Transfer Advancement Act of 1995

EPA is not aware of any voluntary consensus standards that address the numeric nutrient criteria in this proposed rule.

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

EPA has determined that this proposed rule does not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it would afford a greater level of protection to both human health and the environment if these nutrient criteria are promulgated in the State of Missouri.

List of Subjects in 40 CFR Part 131

Environmental protection, water quality standards, nutrients, Missouri.


E. Scott Pruitt, Administrator.

For the reasons set out in the preamble, EPA proposes to amend 40 CFR part 131 as follows:

PART 131—WATER QUALITY STANDARDS

§ 131.47 Missouri.

(a) Scope. This section promulgates a combined criterion for designated uses for all lakes and reservoirs in the State of Missouri that (1) are listed in Table G and the Missouri Use Designation Dataset in the State’s water quality standards (WQS) (10 CSR 20–7.031), (2)
equal or exceed ten acres, (3) are located outside of the Big River Flood Plain Ecoregion and (4) are not listed as having site-specific criteria in Table M of the State’s WQS. (b) Combined Criterion for Missouri lakes and reservoirs. In all instances, nutrient protection values are maximum ambient concentrations expressed as seasonal (April through September) geometric mean values on a three-year rolling average basis.

<table>
<thead>
<tr>
<th>Lake Ecoregion</th>
<th>TP</th>
<th>TN</th>
<th>Chl-a</th>
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*Table 1 also applies to tributary arms Grand Glaise, Gravois, and Nianga to the Lake of the Ozarks, and tributary arms James River, Kings River, and Long Creek to Table Rock Lake.

1. Lake and reservoir water quality must not exceed nutrient protection values for chlorophyll a.
2. Lake and reservoir water quality must also not exceed nutrient protection values for total nitrogen and total phosphorus unless each of the following eutrophication impacts are evaluated and none occur within the same three-year rolling average period: (I) Eutrophication-related mortality or morbidity events for fish and other aquatic organisms, (II) An excursion from the DO or pH criteria in Missouri water quality standards applicable for Clean Water Act purposes, (III) Cyanobacteria counts equal to or greater than 100,000 cells per ml, (IV) Observed shifts in aquatic diversity directly attributable to eutrophication, or (V) Excessive levels of mineral turbidity that consistently limit algal productivity during the period May 1—September 30, or Secchi disk measurements of turbidity equal to or less than EPA’s recommended Level III Ecoregions IX (1.53 m) or IX (2.86 m).

3. By hand or courier. If you prefer, you may deliver your written comments by hand or courier before the close of the comment period to Patrice Drew, Office of Inspector General, Department of Health and Human Services, Cohen Building, Room 5541C, 330 Independence Avenue SW, Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 619–1368.

For information on viewing public comments, please see the SUPPLEMENTARY INFORMATION section.


SUPPLEMENTARY INFORMATION: Submitting Comments: We welcome comments from the public on recommendations for developing new or revised safe harbors and Special Fraud Alerts. Please assist us by referencing the file code OIG–127–N.

Inspection of Public Comments: All comments received before the end of the comment period are available for viewing by the public. All comments will be posted on http://www.regulations.gov after the closing of the comment period. Comments received in a timely manner will also be available for public inspection as they are received at the Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW, Washington, DC 20201, Monday through Friday, from 10 a.m. to 5 p.m. To schedule an appointment to view public comments, phone (202) 619–1368.

I. Background

A. OIG Safe Harbor Provisions

Section 1128B(b) of the Social Security Act (the Act) (42 U.S.C. 1320a–7b(b)) provides criminal penalties for individuals or entities that knowingly...