November 5, 2026

Lee Zeldin, Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: Initial Air Quality Designations for the 2024 Revised Primary Annual Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS) (Docket ID: EPA–HQ–OAR–2024–0078)[1]

Administrator Zeldin:

The undersigned health and medical organizations represent health professionals and patient advocates who work to prevent, identify and treat diseases caused or exacerbated by air pollution. Many of our organizations have long engaged in the NAAQS process for different criteria pollutants to ensure that EPA's regulatory processes in standard-setting and implementation are grounded in the Clean Air Act (CAA) and are truly protective of public health, particularly for children, seniors, people with lung disease and other more susceptible populations.

We are deeply troubled that EPA's proposed designations, as outlined in its 120-day letters to the states, depart from the central purpose of the designation process established by Congress. Under CAA Section 107(d), designations are intended to identify areas that attain and fail to attain the NAAQS. In places that fail to attain the standard, the designations trigger the statutory planning and emission reduction obligations needed to protect public health. Instead of proposing clear designation outcomes based on the best available evidence, EPA's letters consistently and repeatedly emphasize potential pathways through which areas with monitored violations may ultimately avoid nonattainment designation.

1. EPA identifies potential monitor violations but does not propose clear designation outcomes

In its 120-day letters, EPA identifies monitors in some areas that "may not meet" the revised annual primary $PM_{2.5}$ NAAQS based on current (2023-2025) design values (DVs). However, EPA does not propose definitive nonattainment determinations for those areas. Instead, the agency repeatedly states that attainment/unclassifiable,

[1] https://www.epa.gov/system/files/documents/2026-10/11650-03-oar_pmdesignationsnoa_20261002_0.pdf

nonattainment, or unclassifiable outcomes may all remain possible. This approach creates a fundamental inconsistency - if EPA has sufficient information to identify monitors with DVs that exceed the standard, it necessarily possesses sufficient information and capacity to determine the limits of nonattainment areas and to make preliminary designation determinations. Yet the agency does not clearly explain whether it has completed the full area-boundary (five-factor) analyses[2] normally used to support nonattainment designations. This lack of clarity makes it difficult for the public to determine how EPA intends to move from monitor-level findings to final area designations.

The CAA designation process in NAAQS implementation is intended to clearly identify which areas meet or do not meet the standard based on the data that is collected. In these letters, EPA is proposing to avoid reaching firm conclusions even where current monitoring data clearly indicate that the standard has not been met. This aspect of EPA's proposal is unlawful and arbitrary.

2. EPA is providing states extraordinary opportunities to avoid nonattainment consequences

EPA's 120-day letters invite states to submit additional information that could support attainment or unclassifiable outcomes. EPA specifically highlights exceptional-event (EE) demonstrations and other technical analyses that could reduce effective DVs or otherwise alter potential nonattainment designation outcomes.

EPA's repeated emphasis throughout its correspondence is on opportunities to avoid or mitigate nonattainment determinations, which goes well beyond the normal consideration of EEs and a neutral description of the administrative process. In enacting the CAA, Congress established the designation process so that areas failing to attain health-based national air quality standards could be identified and brought into compliance through CAA's statutory planning framework. The emphasis EPA's letters place on ways states could avoid nonattainment designations and attendant cleanup process undercuts the importance of designations as the mechanism Congress created to address unhealthy ambient air quality under the CAA.

3. EPA's exceptional events discussion substantially expands the universe of potential designation exclusions

EPA's current approach to EEs and regulatory exemptions extends far beyond the framework described in prior implementation materials and prior agency communications regarding exceptional events. EPA's 2024 $PM_{2.5}$ NAAQS implementation memo focused on EE demonstrations associated with wildfire smoke and specifically discussed the potential impact of Canadian wildfire smoke on DVs relevant to the designation process.[3]

But now the agency has not only expanded the scope of EE demonstrations and related analyses significantly (which may affect many monitors and site-days nationwide) but is actively encouraging and inviting state air agencies to evaluate whether such

[2] Particle Pollution Designations Data for the 2024 Revised Annual PM2.5 NAAQS | US EPA

[3] J. Goffman, EPA Assistant Administrator. (02/7/ 2024). MEMORANDUM: Initial Area Designations for the 2024 Revised Primary Annual Fine Particle National Ambient Air Quality Standard

demonstrations could affect designation outcomes of areas within their jurisdictions. The practical effect of EPA's approach risks creating an expansive set of potential mechanisms by which currently observed violations could be discounted or excluded before final designation decisions are made.

While the Exceptional Events Rule[4] is a tool to be used where legally and legitimately applicable, EPA should not structure the designation process around identifying opportunities to dismiss monitored violations for regulatory purposes. The primary question the agency needs to address is whether areas attain the NAAQS based on the best available evidence, not to encourage states to exclude as much data as possible.

4. EPA's discussion of timing is difficult to reconcile with the procedural history of this rulemaking

EPA repeatedly references an expedited schedule and the July 2026 court order requiring completion of designations by February 2027[5], even though it is now conducting designations almost a year later than the statutorily required deadline after the revision of the $PM_{2.5}$ NAAQS – a timeline prescribed by CAA and followed by the agency in all NAAQS implementations to-date. The agency has therefore had more time, not less, to evaluate monitoring data, emissions information, transport considerations, and states' recommendations in order to finalize its designations. Further, EPA's proposal demonstrates that it has already analyzed more recent monitoring data (2023-2025 DVs) compared to the data it had proposed to use (2022-2024 DVs) on the original timeline.[6] EPA's use of the most recent available DVs reflects an appropriate reliance on current information. The agency cannot credibly cite timing concerns as a justification for declining to propose firm designation outcomes while simultaneously relying on updated data and analyses that post-date both its own original approach to monitor data as well as state recommendations.

5. EPA's proposal risks undermining the purpose of the designation process

Air quality designations should be based on the most current evidence available to the agency at the time of its decision-making. We support EPA's decision to evaluate attainment and propose designations based on the most recent monitoring data available (2023-2025 Design Values). However, the value of the recent data is undercut by EPA's letters not including corresponding preliminary designation conclusions. EPA appropriately relies on current DVs and should use that data to propose clear designation outcomes.

6. EPA's treatment of Teledyne monitor issues raises additional concerns

EPA's 120-day letters flag concerns regarding measurements from certain Teledyne instruments and expressly note that states may submit information regarding their alleged positive measurement bias. EPA's current proposal expands the significance of

[4] https://www.epa.gov/sites/default/files/2018-10/documents/exceptional_events_rule_revisions_2060-as02_final.pdf
[5] Judge rules EPA failed to implement key part of the Clean Air Act | Courthouse News Service
[6] EPA Presentation: Designating Areas for the 2024 PM2.5 Standard

issues previously raised regarding Teledyne T640/T640X monitors[7] by expressly asking states to evaluate potential monitor bias and submit information that could support exclusion or adjustment of monitoring data used in designation decisions. The agency's reliance on such submissions as a potential basis for altering effective DVs underscores the importance of ensuring that any monitor-related determinations are scientifically robust, transparent, and fully supported by the record.

EPA's handling of this issue presents a broader concern. The agency repeatedly cites the possibility that monitor-specific analyses may support exclusion of data or alternative attainment conclusions, while simultaneously relying on the national monitoring network as the foundation of the designation process itself. To the extent EPA concludes that specific monitoring data are valid and suitable for designation purposes, those data should be treated consistently. Conversely, to the extent EPA believes particular measurements are sufficiently unreliable to warrant exclusion, the agency should transparently explain the basis for that conclusion and its implications for other affected monitors and areas. EPA should not selectively invoke monitoring concerns primarily as a mechanism for avoiding nonattainment determinations.

7. Missouri illustrates why EPA should not structure the designation process around avoiding nonattainment determinations

Missouri provides a useful example of the concerns raised by EPA's proposal. The Exceptional Events Rule provides a lawful mechanism for addressing qualifying events but it should not be used as a routine vehicle for avoiding accountability for unhealthy air quality or for delaying needed public health protections. The American Lung Association has previously opposed Missouri's efforts to exclude monitor data from regulatory determinations in areas where communities are already experiencing adverse health risks from air pollution.[8] This concern is particularly important in the St. Louis region, where residents already face substantial air quality burdens. The American Lung Association's prior comments have documented continuing concerns over levels of particulate matter and ozone pollution in the region, with residents experiencing respiratory disease burdens and asthma impacts from pollutant exposures. Communities in the region who continue to face significant air quality challenges should not be denied the benefits of timely and accurate implementation of $PM_{2.5}$ NAAQS through the exclusion, adjustment or discounting of monitored pollution data. The state continues to consider and permit major new combustion sources in the area[9] even as EPA has just identified three violating monitors in the region.[10] We also note that Missouri is among those states that have not submitted their designation recommendations to the EPA.

EPA's Missouri 120-day letter is emblematic of a broader national concern. Rather than

---

[7] American Lung Association. (03/15/2024). Comments on EPA's Proposed Update of $PM_{2.5}$ Data from T640/T640X PM Mass Monitors; Docket ID: EPA-HQ-OAR-2023-0642; Tracking #: ltt-2n5h-wdff - attached

[8] ALA comments. (10/17/2025). Exceptional Events Demonstration St. Louis Area, Missouri Department of Natural Resources - attached

[9] ALA comments. (10/30/2025). Big Hollow Energy Center development, Missouri Public Service Commission - attached

[10] $PM_{2.5}$ Designations Mapping Tool for the 2024 Annual Primary NAAQS, U.S. EPA (Public)

proposing a clear designation outcome based on the agency's current evaluation of available monitoring data, EPA emphasizes potential future EE demonstrations and other technical submissions that could alter effective DVs and support attainment or unclassifiable determinations. This has the effect of shifting the focus away from identifying whether communities are experiencing air pollution levels above the health-based standard and toward identifying mechanisms through which such exceedances may be recharacterized or excluded. Accurate nonattainment designations are therefore especially important to ensure that federal, state, and local decision makers receive a clear picture of current air quality conditions and the actions needed to protect public health.

Conclusion

Nonattainment designations serve a critical purpose under the Clean Air Act by initiating planning obligations and emission-reduction measures needed to achieve cleaner air. Areas experiencing unhealthy levels of $PM_{2.5}$ should be identified as such based on the most current available evidence. The designation process should not be structured around maximizing opportunities to exclude air pollution data.

Taken as a whole, EPA's proposal, as stated in its 120-day letters, effectively proposes that areas with monitors showing potential violations should be given additional opportunities to have that data excluded, potentially avoiding nonattainment consequences. That message is inconsistent with the structure and purpose of the Clean Air Act.

The designation process is intended to identify areas that attain the NAAQS and areas that do not. EPA has the necessary information and capacity to identify areas of concern. The agency has identified monitors that exceed the revised standard using updated monitoring data beyond those available when states submitted recommendations. Having done so, EPA should fulfill its statutory obligation by proposing clear, evidence-based designation outcomes rather than emphasizing mechanisms through which nonattainment determinations might ultimately be avoided.

For all the above reasons, we ask EPA to immediately issue transparent, supportable and definitive designations based on the best available evidence and to ensure that the designation process remains focused on its fundamental statutory purpose: identifying areas that do not meet the health-based annual $PM_{2.5}$ national air quality standard and initiating the actions necessary to achieve attainment to protect the health of communities across the country.

Attachments

1. American Lung Association comments to Missouri Department of Natural Resources on Exceptional Events Demonstration for St. Louis Area, (10/17/2025).
2. American Lung Association comments to Missouri Public Service Commission on Big Hollow Energy Center development (10/30/2025).
3. American Lung Association comments to EPA on Proposed Update of $PM_{2.5}$ Data from T640/T640X PM Mass Monitors; Docket ID: EPA-HQ-OAR-2023-0642 (03/15/2024).

Signed:

Alliance of Nurses for Healthy Environments

American Lung Association
American Public Health Association
American Thoracic Society
International Society for Environmental Epidemiology-North America Chapter
Medical Society Consortium on Climate and Health (MSCCH)
Physicians for Social Responsibility (PSR)
Oncology Advocates United for Climate and Health – International (OUCH-I)