Statement of Annette C. Rohr, ScD, DABT
Electric Power Research Institute

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Good morning, and thank you for the opportunity to provide comments today. I am Annette Rohr, an environmental health scientist and board-certified toxicologist, and am speaking on behalf of the Electric Power Research Institute. My statement today summarizes the main points in EPRI's written comments on the PM Policy Assessment (PA), which will be submitted to the docket on November 11th.

EPRI has three primary comments, all of which relate to treatment of uncertainty in the PA. These comments are: (1) uncertainty regarding the underlying epidemiological evidence due to confounding; (2) uncertainty in exposure assessment in PM epidemiological studies; and (3) uncertainty in the risk estimates presented in the risk-based considerations section of the PA. I will briefly describe each of these comments.

Although confounding in epidemiological studies is a key source of uncertainty, EPRI finds that EPA has not adequately addressed how confounding may impact the overall epidemiological evidence. In fact, the PA fails to mention a body of work related to a novel method for evaluating confounding in long-term studies. This body of work, which began with an analysis conducted by Greven et al. (2011), has been expanded with EPRI support to include two additional studies by Pun et al. (2017) and Eum et al. (2018). The method decomposes PM association estimates into a "global" estimate that reflects the association between national trends in PM and mortality, and a "local" estimate that measures the location-specific trends adjusted for the national trends. Results from the EPRI research suggest that unmeasured confounding may be present in long-term studies of PM, ozone, and NO_2. Furthermore, in separate analyses that controlled for time, mortality risk estimates for PM were reduced by about 50%, suggesting that temporal confounding is important in long-term studies. *Overall, EPRI believes that EPA's consideration of the contribution of unmeasured confounding to overall uncertainty in the long-term epidemiological evidence is technically inadequate; such confounding could result in significant variability in mortality risk. EPRI recommends that the Agency incorporate the findings of Greven et al., Pun et al., and Eum et al. into the PA.*

Exposure assessment is another important source of uncertainty, and the field of air pollution epidemiology is rapidly evolving to incorporate more and more complex exposure estimation methods. While the PA does address performance of exposure assessment approaches to a limited extent, EPRI finds the evaluation inadequate, particularly with respect to how the noted methodological limitations relate to the epidemiological evidence base. The PA cites an EPRI-supported study by Yu and colleagues (2018) that evaluated 14 exposure assessment approaches for multiple pollutants, including PM components. Results indicated wide variability in performance. To the extent that PM composition varies spatially, the selection of method may have important implications for exposure estimation accuracy. In the same vein, the differential

availability and density of observational data is problematic. The reduced ability of exposure assessment methods to accurately predict low concentrations (because of lack of monitoring data) may lead to differential exposure misclassification by concentration, which could bias epidemiological results. *Overall, EPRI recommends that EPA conduct a more comprehensive evaluation of uncertainty in exposure assessment in the epidemiological studies underpinning the PA.*

Finally, EPRI finds that uncertainty in the risk estimates presented in the PA is inadequately characterized. EPA states that it characterized variability and uncertainty by inclusion of 95 percent confidence intervals, sensitivity analyses, and qualitative uncertainty assessment. EPRI finds that a more rigorous approach is needed. EPRI has been conducting research on the incorporation of uncertainty into risk assessment since 2012. EPRI notes that only a small subset of the available literature was used to provide concentration-response functions used in the PA. Previous EPRI-sponsored research by Smith and Gans (2015) highlighted the fact that CR functions vary widely between and within studies, and that EPA's BenMAP tool does not include all appropriate functions. This paper was not cited in the PA. Further, in response to an NAS report in 2002 that recommended the Agency conduct more comprehensive uncertainty analysis, EPRI has supported research to apply Integrated Uncertainty Assessment, or IUA, to air pollution health risks. This approach combines multiple sources of uncertainty, each with its own probability distribution, into one analysis. EPRI work has demonstrated the feasibility and value of this approach for both ozone and PM (Smith and Glasgow [2018] and Smith [2019], respectively) and highlighted the fact that uncertainty is greater using the IUA approach than a simple deterministic approach. *Overall, EPRI recommends that the Agency more fully integrate quantitative uncertainty assessment into the risk calculations contained within the PA to provide a more robust and meaningful assessment of the inherent uncertainty in risk estimates.*

Thank you.