COMMUNICATION 11
EXECUTIVE SUMMARY

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# Assessing Health Impact of Air Quality Regulations: Concepts and Methods for Accountability Research

Health Effects Institute
Charlestown Navy Yard
120 Second Ave, Boston MA 02129-4533
Phone: +1-617-886-9330 Fax: +1-617-886-9335
*www.healtheffects.org*

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The Health Effects Institute, established in 1980, is an independent and unbiased source of information on the health effects of pollutants from motor vehicles and other sources in the environment. Supported jointly by the US Environmental Protection Agency and industry, and periodically by other domestic and international partners, HEI provides science to inform decisions that are directly relevant to regulation. This HEI science includes:

*Research* about the health effects of all major air pollutants, including air toxics, carbon monoxide, diesel exhaust, nitrogen oxides, ozone, and particulate matter. HEI has funded more than 220 studies in North America, Europe, and Asia and has published more than 160 research reports and special reports.

*Special Reviews* of an entire area of scientific literature on key topics including asbestos, diesel exhaust, oxygenates in fuel, and research methods used by scientists to evaluate these and other pollutants.

*Reanalysis* of studies central to regulatory proceedings, such as the Harvard Six Cities Study and the American Cancer Society Study of the health effects of air pollution.

HEI also periodically communicates about other topics that are highly relevant to questions of science and regulation, including assessing the health impact of environmental regulations and its concepts and methods for accountability research, the subject of this Executive Summary.

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# Assessing Health Impact of Air Quality Regulations: Concepts and Methods for Accountability Research

## GROWING INTEREST IN ACCOUNTABILITY

Protecting public health from environmental risks involves taking regulatory and other actions on the basis of population statistics or patterns of clinical disease and tracking their consequences so that efforts can be redirected as indicated by subsequent evidence. As some indicators of environmental quality have improved for the United States, specific measures of progress in improving public health have been sought and questions have been raised as to whether public health goals have been met. These questions have emerged with particular force with regard to marked improvements in air quality in the United States in recent decades and ongoing efforts to further improve air quality.

Evaluating the extent to which air quality regulations improve public health is part of a broad effort—termed *accountability*—to assess the performance of all environmental regulatory policies. Air quality has improved substantially in the United States and western Europe in recent decades, with far less visible pollution and dropping concentrations of several major pollutants. In large part, these gains have been achieved through increasingly stringent air quality regulations that often require costly control measures to implement. For example, since 1980, measurements at thousands of monitoring stations across the United States have shown decreasing concentrations for all six criteria pollutants. This progress, of course, has come at a price. The US Environmental Protection Agency (EPA*) estimates that from 1970 to 1990 the annualized cost of air pollution control was about $25 billion per year—more than $500 billion over 20 years. Even as new research findings appear to have strengthened the evidence for health effects, many (including policy makers, legislators, industry, and the public) ask whether past efforts to reduce air pollution have yielded demonstrable improvements in public health and whether future efforts will continue to do so.

Although risk assessments estimate a substantial burden of premature mortality and excess morbidity even at current levels of ambient pollution, direct evidence is lacking about the extent to which control measures have improved health. This dearth has prompted efforts to assess and collect such evidence, including the recent US National Research Council (NRC) report, *Estimating the Public Health Benefits of Proposed Air Pollution Regulations* (NRC 2002); research funded by California Air Resources Board; and recent efforts by the EPA, the US Centers for Disease Control and Prevention (CDC), and other agencies to improve surveillance of the environment and public health. It is also the basis for an initiative by the Health Effects Institute, comprising epidemiologic studies of improvements in air quality and health, and this Communication: *Assessing Health Impact of Air Quality Regulations: Concepts and Methods for Accountability Research*, written by a multidisciplinary HEI Accountability Working Group. Communication 11 sets out a conceptual framework for accountability research and identifies types of evidence required and methods by which the evidence can be obtained.

## CHALLENGE OF MEASURING HEALTH IMPACT OF AIR QUALITY REGULATIONS

Consideration of accountability starts with assessment of the effectiveness of regulations for reducing emissions and whether reductions have affected ambient concentrations as intended. Assessments must then evaluate whether adverse health effects of air pollution have been reduced. Some national governments and public health agencies have attempted to quantify the past health impact of air quality improvements and to estimate future impact. To date, these attempts have used risk estimates from epidemiologic studies to calculate the impact of air pollution on public health in terms of disease burden under hypothetical air quality scenarios. These scenarios reflect either continuation of past patterns of exposure or future patterns of exposure under more stringent controls (EPA 1999). However, these estimates have not been extensively validated against studies of actual regulatory programs and other interventions.

Research on accountability is in its early stages, but even now considerable challenges in assessing the health impact of air quality regulations can be anticipated. Air quality regulations themselves are promulgated to take effect at different times and on multiple governmental levels. Therefore, diverse approaches are needed to evaluate the impact of interventions on human health at national, regional, and local levels and in various time frames. We can also expect the consequences of interventions to extend beyond changes in air quality. Whether or not an intervention improves air quality, it could result in changes in personal activities and behaviors or in economic activities that could in turn affect health. Therefore, the causal pathways from a regulation and its consequences for air quality to a change in its risk to health could be difficult to isolate. Additionally, adverse health effects that may be caused by exposure to air pollution can also be caused by other factors (some changing over the same time periods as air pollution concentrations).

Regulatory interventions to improve air quality, especially large national programs such as the US Clean Air Act, may not

* A list of abbreviations and other terms appears at the end of the Executive Summary.

This Executive Summary of Communication 11, *Assessing Health Impact of Air Quality Regulations: Concepts and Methods for Accountability Research*, was prepared by the Accountability Working Group of the Health Effects Institute. The entire Communication is available from *www.healtheffects.org* or from HEI.

immediately affect either air quality or public health. Once regulations are instated, changes in pollutant emissions, ambient pollutant concentrations, and human exposure to ambient concentrations may not be immediately or uniformly evident, and the biological processes of injury that underlie the health effects of air pollution may not be immediately evident. The longer the time between promulgation of regulations and their effects, the greater the possibility that other events may come into play and interfere with isolating effects of the interventions themselves. The level of enforcement may complicate the analysis by extending the anticipated time between intervention and effect. On the other hand, some interventions may produce relatively rapid changes in air quality, the impact of which may be measurable soon after. Recent studies of the health effects of air quality improvement programs implemented over short time frames in Ireland (Clancy et al 2002) and Hong Kong (Hedley et al 2002) are examples. Rapid changes reduce, but by no means eliminate, the possibility of confounding by other risk factors.

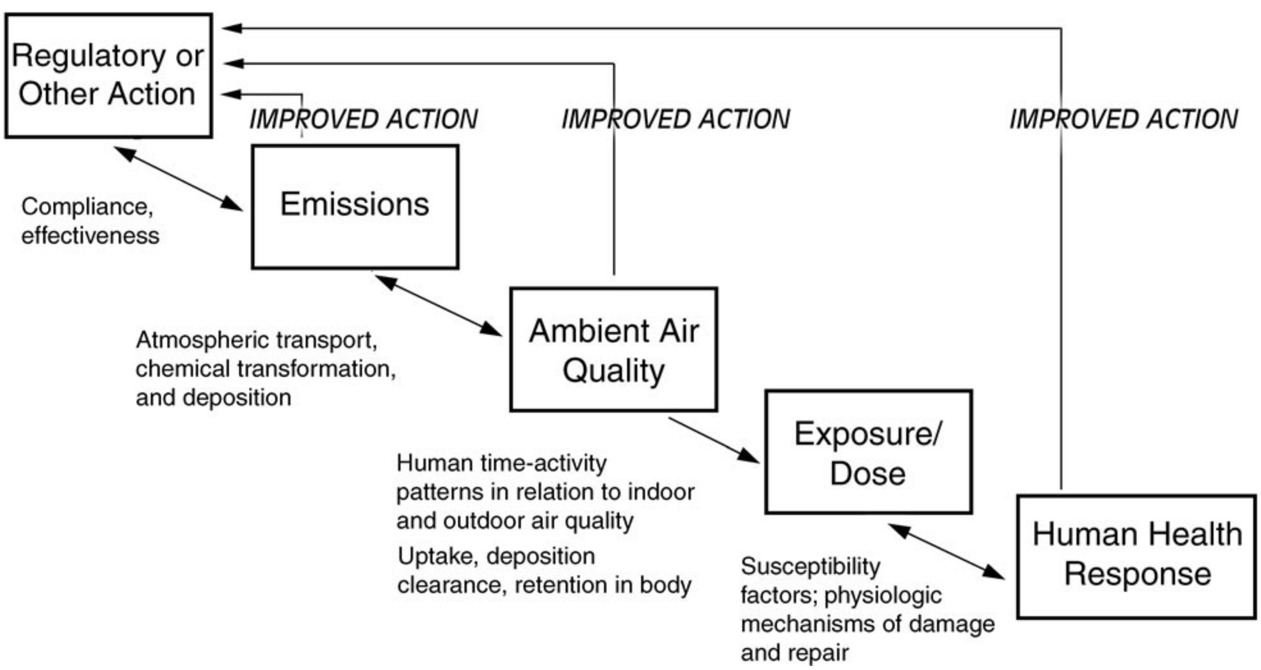
The need to measure the health impact of air quality regulations and other actions, and to improve the evidentiary basis for assessing the effectiveness of those actions, is clear. Whether and to what extent observational study designs can meet these challenges is the task before us. The inherent challenges are well documented in Communication 11, but recent advances in data collection and analytic techniques provide an unprecedented opportunity to improve our assessments of the impact of air quality actions. To this end, this Communication is intended to advance the concept of accountability and to foster development of accountability methods and research throughout the scientific and policy communities.

## THE CHAIN OF ACCOUNTABILITY: A FRAMEWORK FOR RESEARCH AND PUBLIC HEALTH ACTIVITY

Future efforts to measure the impact of air quality regulations will need to be based on a conceptual framework that identifies key relations to be estimated and the resources needed to do so. The NRC's Committee on Research Priorities for Airborne Particulate Matter (NRC 1998) set out a framework for linking air pollution sources to adverse health effects. This framework can be used to identify indicators for use in accountability assessment and leads to designation of the chain of accountability, which parallels the links from sources to health effects (Figure 1). The connections between the links correspond to typical points at which quantitative measures of accountability are possible.

Along the length of the chain of accountability, a number of indicators can be identified, and accountability questions addressed:

- **Regulatory action**: Have controls on source emissions been put into place?
- **Emissions**: Have the source controls reduced emissions? Have there been unanticipated and untoward consequences? Answers to these questions require evidence about how regulation has changed the practices of emitters and about what changes in emissions have resulted.
- **Ambient air quality**: Have concentrations of air pollutants declined consequent to source control and emissions reductions? Answers to this question require evidence based on the periodic standardized measurement of ambient concentrations of air pollution constituents, such as particles, ozone, and sulfur dioxide.




**Chain of accountability.** Each box represents a link between regulatory action and human health response to air pollution. Arrows connecting the links indicate possible directions of influence. Text below the arrows identifies general indices of accountability at that stage. At several stages, knowledge gained from accountability assessment can provide valuable feedback for improving regulatory or other action.

- **Personal exposure**: Has exposure to air pollution declined? For which groups in the population (particularly as defined with reference to susceptibility to the effects of air pollution)? For instance, have exposures been reduced for disadvantaged people, including racial and ethnic groups, who may experience disproportionately high exposures and may be more susceptible? The relation between concentration and exposure can be modified by time-activity patterns, and such modification may mean that declines in concentration do not lead to proportional declines in exposure. In assessing changes in exposure, two factors should be considered: how ambient concentrations have changed as a result of changes in emissions, and how the intervention may have changed the behavior (and thus exposure) of the population(s) it was intended to protect.
- **Dose to target tissues**: Have reductions in exposure led to reductions in dose? The relative consequences of a dose for a susceptible versus a nonsusceptible person may also be relevant.
- **Human health response**: Have health risks declined? This indicator requires evidence about changes in health endpoints that have resulted from changes in exposure. Research must address which health endpoints and measurement techniques are most directly attributable to air pollution exposure, and thus would be most useful for accountability assessments, as well as how the health endpoints should be defined and characterized for analysis.

At each link in the chain, the opportunity exists to collect evidence to either validate the assumptions that motivated intervention or identify ways in which those assumptions were incorrect. Using such evidence can thus ensure that future interventions are maximally effective.

This framework fits well with the approach taken in the United States for regulation of principal pollutants. Air pollution regulations for criteria pollutants specify National Ambient Air Quality Standards (NAAQS)—maximum concentrations of selected pollutants in air. Each standard specifies a pollutant, its concentration, the averaging time, and the proportion of time that the standard must be met. The concentration limits are met by source control and related reductions of emissions. This approach inherently assumes that source control and emissions reductions to meet target concentrations will reduce human exposure to targeted pollutants and, subsequently, reduce risks of adverse health effects. Assessing the health impact of programs such as the US Clean Air Act calls for a demonstration that implementation of measures to reach the NAAQS has in fact led to a reduced disease burden, which is the final step in the chain of accountability. In the general framework considered here, implementation of a NAAQS would ideally be followed by comprehensive surveillance for each indicator. Although the EPA tracks ambient pollutant concentrations with monitoring networks and requires the development of plans that specify emissions controls, there is currently no way to connect in a comprehensive fashion the sources at one end of the chain to adverse health effects at the other.

Ultimately, the framework for accountability assessment will need to be extended beyond targeted pollutants and associated health risks. The measures that are needed to reduce ambient concentrations of major pollutants may have broad consequences, some unintended and unanticipated, which could reduce or increase risks to public health. Wiener (1998) and others have advanced the concept of a so-called portfolio of effects of a regulation and argue that the full set of effects, not just the intended effects, needs to be evaluated. Although this Communication focuses primarily on measuring the health-related consequences of regulation, each link in the chain of accountability is placed in this broader context.

## METHODS FOR ACCOUNTABILITY STUDIES

The success of future accountability assessments will require further development and application of epidemiologic and biostatistical approaches in three areas: assessment of exposure and dose, selection of health outcomes, and study design and data analysis.

### ASSESSING POPULATION EXPOSURE AND DOSE

Policies to improve health of the population by controlling emissions will be successful only if the emissions reductions ultimately result in reduced population exposures to and doses of the air pollutant of concern. Several general strategies can be used to measure exposure or dose in accountability studies. One involves the use of large-scale, periodic, random monitoring surveys of the general population to document long-term trends in exposure or dose. Examples of the large-scale survey designs include periodic US National Health and Nutrition Examination Survey (NHANES) (US National Center for Health Statistics 2003) and the US National Human Exposure Assessment Study (NHEXAS) (EPA 2003a). On such a large scale, personal monitoring would be constrained by cost considerations as well as the need to limit the burden on participants. When practical, and if an appropriate biomarker is available, blood or other biospecimens could be collected for analysis. Another strategy involves smaller-scale studies of specific subpopulations to document exposure and dose before and after specific interventions. This strategy could yield richer data on personal exposure and biological dose measurements. Carefully designed and targeted small-scale field studies of personal exposures or doses could play a critical role in assessing interventions directed at reducing pollution and improving health. Such small-scale studies would complement large-scale surveys that aim to track long-term trends broadly across the population.

### SELECTING HEALTH OUTCOMES FOR ACCOUNTABILITY STUDIES

Air quality regulations are established with the primary purpose of protecting the public's health. Regulatory action is taken on the basis of evidence of a causal association between exposure to air pollution and health risk. The outcomes considered in assessments of accountability should, therefore, reflect the evidence on which estimates of health benefits and regulation are based.

To estimate the impact of specific regulations, however, certain outcomes may easier or harder to apply. The most serious health outcomes (such as mortality and increased morbidity from cardiovascular and respiratory diseases) are associated with not just one but several pollutants as well as other behavioral and environmental factors. Thus, although researchers planning studies of the health impact of air quality regulations have a variety of possible health outcomes from which to choose, none are associated uniquely with air pollution. In addition, a range of practical considerations will determine the feasibility of using specific endpoints for accountability research. For example, national databases currently exist for some endpoints of interest (eg, mortality via the US National Centers for Health Statistics, hospitalization via the US Health Care Finance Administration). But some data including baseline (preintervention) rates of some endpoints (eg, asthma prevalence in major cities across the United States) may be unavailable or limited.

Choice of health endpoints for assessments of the health impact of air quality regulations will depend critically on temporal relations among changes in pollutant emissions, concentrations, and exposure and on development of a detectable endpoint. Endpoints that might be detectable shortly after exposures change are counts of daily deaths and hospitalizations, certain clinical endpoints such as medication use, and subclinical indices (such as changes in pulmonary function that can be linked to adverse clinical conditions). Biomarkers of health response have the potential to predict the health impact of regulations without waiting for disease outcomes. Using biomarkers is challenging, however. For instance, relations among biomarkers and health endpoints must be demonstrated and biomarkers must be validated under field conditions.

Endpoints that might be appropriate for assessing the long-term impact of air quality regulations include long-term average rates of adult and infant mortality, effects on average population lifespan, incidence of chronic cardiovascular and respiratory disease, and biomarkers such as age-related growth and decline of lung function. Studies of long-term impact will probably need to use information on spatial variation in exposure resulting from regulatory interventions, as has been done in earlier epidemiologic studies. Existing cohorts may offer some opportunities for accountability assessments if the period of observation allows preintervention baselines to be established and the duration of follow up is long enough to allow observation of intervention-related long-term effects.

### MODEL DESIGN AND DATA ANALYSIS

Much evidence of health effects of air pollution comes from observational studies that relate changes in health indicators to changes in exposure to air pollution in space and time. The results of such studies are then used to estimate the expected benefits of current and future air pollution regulations. Interventions may be broadly viewed as any intentional (planned, such as a regulatory program) or unintentional (unplanned, such as a labor strike closing an industrial facility) change in air pollutant concentrations or exposures. Direct study of the effect of such interventions may be a more definitive approach to determining whether air pollution regulations actually result in health benefits. Compared with the usual observational studies, studies of interventions can disrupt links between confounding factors and exposures that may be unavoidable and cause bias in many observational studies of environmental factors and health.

Some might argue that assessing accountability depends only on better science—that scientific methods, in particular those of epidemiology and toxicology, could be enhanced to generate better evidence and provide a platform for decision making. Although improved science is, without question, central to both applications, new scientific methods alone would be insufficient to integrate evidence across the chain of accountability. As Figure 1 indicates, accountability assessment may incorporate evidence over a long, complex chain of relations. Therefore, its evaluation requires integrating information that is directly and indirectly related. Statistical synthesis is central to such integration. It should describe relations among the links of the chain of accountability, generate the statistical relations needed for evaluation, and identify gaps in data or research. Bayesian approaches that explicitly incorporate summaries of prior knowledge may be particularly valuable.

## DIRECTIONS FOR FUTURE RESEARCH

On the basis of this Communication, the Health Effects Institute plans to develop methods for accountability assessment and fund studies that address accountability. To that end, Communication 11 makes wide-ranging recommendations for an agenda to advance understanding and assessment of accountability. These recommendations fall into three general categories: (1) developing and implementing new study designs; (2) identifying targets of opportunity for accountability research; and (3) developing surveillance systems to track prospectively the health impact of air quality regulations. As HEI and other organizations move forward on accountability research, priorities among these opportunities will need to be set.

### OPPORTUNITIES

The continually changing regulation of air pollution in the United States, Europe, and elsewhere affords an immediate set of opportunities for accountability assessment on national, regional, and local scales. In the United States, possible targets include:

- **$PM_{2.5}$ and ozone NAAQS implementation**. The state implementation plan (SIP) process is now in its initial stages for the recently promulgated $PM_{2.5}$ (particulate matter less than 2.5 µm in aerodynamic diameter) and ozone NAAQS. Extensive data on nationwide $PM_{2.5}$ concentrations are now being collected from a new monitoring network, establishing baseline conditions against which future emissions reductions can be assessed. (Such data already exist for ozone concentrations.) The state implementation plan process for $PM_{2.5}$ and ozone could provide an opportunity for accountability assessments that address changes in emissions, ambient concentrations, and exposures or doses to the population.
- **EPA's Air Toxics Control Plan.** EPA is required to assess risks and, if necessary, control the 188 air pollutants now classified as hazardous. Relevant research for accountability might include longitudinal measurements of pollutant emissions and ambient concentrations and identification of health endpoints that could be tracked in the near term.

This approach is most applicable for hazardous air pollutants associated with short-term responses (eg, irritants).

- **Targets at local level.** Relatively rapid changes in ambient concentrations may occur in a local area as a result of a major change in local source emissions due to regulatory action. Numerous opportunities exist for studies of such interventions throughout the United States and elsewhere. For example, the New York City Metropolitan Transit Authority has plans to convert bus fueling and storage depots from diesel to natural gas, thereby possibly reducing neighborhood levels of elemental carbon and other diesel-related particle components. Control programs for major stationary pollution sources might also provide opportunities. Because these interventions occur over relatively short times and small areas, assessment studies aimed at documenting cause-effect relations between emissions changes and changes in exposure or health can be both economically and logistically feasible.

## STUDY DESIGNS

Success of future research requires systematic identification of research needs and opportunities and commissioned studies to address them. This research will probably entail both adaptation (or tuning) of existing methods to suit specific needs and development of long-term surveillance of both health outcomes and potential confounders. Both conceptual and methodologic issues need to be addressed, including the fundamental step of assuring a uniform concept of accountability among researchers and regulators. Needed activities include the following:

- Focused research planning and further elaboration of study designs to assess accountability. Planning may include workshops involving the many stakeholders concerned with accountability and moving toward a shared understanding of the concept.
- Review of available information and development of a mechanism for identifying possibly informative natural experiments and a process for following up on them. Reviewing information will include creating syntheses of studies relevant to accountability assessment in which different approaches are used to combine data across studies in order to properly gauge the weight of the evidence. A formal analysis could help identify the most important gaps in information which, if filled, would exert the most leverage on both scientific knowledge and public policy decisions.
- Analysis of model-based predictions of health impact to compare predicted and observed effects while accounting for model uncertainty. Findings from those analyses that appropriately address uncertainty can provide insight into the information required to make more accurate accountability assessments.
- Development of cooperative research models to anticipate settings that may be affected by changes in air pollution regulations or policies and that could provide opportunities for accountability assessment. Such mechanisms will likely require funding agencies to reach out to regulators and other governmental agencies and affected communities.
- Implementation of specific study designs:
    - Serial cross-sectional studies that could be completed within relatively short time frames and then repeated after an air pollution intervention. The timing of the repeated studies would be determined by the postulated latency period between any changes in exposure and health outcomes.
    - Randomized studies aimed at rigorously providing information about one or several connections in the chain of accountability. Randomizing exposure in real-life settings through randomized manipulation of behavior (eg, provision of air conditioners or indoor versus outdoor exercise regimens) is an example of providing information about the connection between the exposure and health effect links.
    - Cohort studies that may serve as the basis for accountability assessments. Ongoing cohort studies provide limited information for the windows of exposure applicable to study participants (eg, HEI 2001; Pope et al 2002). Insights from cohort studies might be improved by combining evidence from multiple cohorts to widen the exposure windows that could be assessed.

## NEED FOR SURVEILLANCE

Taking full advantage of these opportunities will require data collected through ongoing surveillance of major time-varying links in the chain of accountability, or at least those components dealing with exposure and health outcomes. Existing data on air pollution and precedents for using national databases for air pollution analyses (Samet et al 2000) suggest that the issues of air pollution and public health provide an excellent opportunity to pilot the use of emerging surveillance systems for informing decisions about public health interventions. Some elements of such a system already exist, such as the National Death Index of the US National Centers for Health Statistics, NHANES, and the EPA and state air monitoring networks.

A system for the long-term surveillance of the health impact of air quality regulations will initially require evaluation of the adequacy of these existing resources in the context of a proposed study design. This evaluation would also need to consider what kinds of information would be required for long-term evaluation of health impact, including goals for efficacy and effectiveness. Several recent and ongoing efforts have already made important contributions. These include the CDC Environmental Public Health Indicators Project, which is evaluating a range of health indicators that could be used to track changes in health outcomes caused by environmental factors, and two recently released EPA reports, *America's Children and the Environment* (EPA 2003b) and the *Draft Report on the Environment* (EPA 2003c). A Nationwide Health Tracking Act is being considered by the US Congress to develop a comprehensive system for identifying and monitoring chronic diseases and correlating their causes with environmental, behavioral, socioeconomic, and demographic risk factors. New funding is enabling CDC to begin to build such systems with the help of many states and three university-based Centers of Excellence. These systems would be a great asset for accountability research.

## CONCLUSIONS

Air quality in the United States and western Europe has improved considerably in recent decades, yet findings of continuing adverse health effects have prompted increasingly stringent air quality regulations. Demonstrating that these regulations are producing the desired health benefits will require creative and rigorous application of epidemiologic research methods and public health surveillance approaches within a conceptual framework for assessing accountability at each stage of the regulatory process. This Communication proposes such a framework and begins to identify opportunities to implement it. Improvement of our ability to measure the health impact of regulations will require new levels of collaboration among the research community and federal, state, and local agencies charged with protection of both the environment and public health.

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## ABBREVIATIONS AND OTHER TERMS

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| CDC | Centers for Disease Control and Prevention (US) |
| EPA | Environmental Protection Agency (US) |
| NAAQS | National Ambient Air Quality Standard(s) (US) |
| NHANES | National Health and Nutrition Examination Survey (US) |
| NRC | National Research Council (US) |
| $PM_{2.5}$ | particulate matter less than 2.5 µm in aerodynamic diameter |


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Health Effects Institute, Charlestown Navy Yard, 120 Second Ave, Boston MA 02129-4533. Phone: +1-617-886-9330 Fax: +1-617-886-9335. *www.healtheffects.org*.



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