

Particulate Matter: The Marines, EPA, And Air Quality

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In the film "A Few Good Men" Marine Corps Col. Nathan R. Jessep (Jack Nicholson) defends against Castro's bullets entering U.S. air space over a literal 'wall' at the Guantanamo Bay, Cuba Marine Base. Like the U. S. Marines, the U.S. Environmental Protection Agency (EPA) must defend a more figurative 'wall' against smaller, more insidious forms of airborne particulate matter (PM) entering U. S. breathing air space from EPA-regulated commercial and industrial sources. Jessep's mission to defend U. S. air is simple and unambiguous (at least in the movie), whereas EPA's mission to defend Americans' breathing air is based upon complex analyses in a 'PM Criteria Document' culminating in a detailed 'Integrative Synthesis'. The *Integrative Synthesis* then informs a US EPA 'Staff Paper' prepared by staff of EPA's Office of Air Quality Planning and Standards (OAQPS). The *Staff Paper* presents the EPA Administrator with regulatory risk management policy options to defend American air to the satisfaction of American lungs.

American lungs have been waiting more than six years as the PM Criteria Document has been formulated and reformulated by more than a few good men and women, and under judicial scrutiny arising from a lawsuit initiated by the American Lung Association, *et al.* in 1995 (7). The outcome of the lawsuit compels EPA to revisit the PM National Ambient Air Quality Standard (NAAQS) in compliance with Court-specified time frames. Indeed, the U.S. District Court of Arizona initially had ordered EPA to publish its final decision on the review of the PM NAAQS by 19 July 1997, but this deadline subsequently was modified. Under the current consent agreement, according to EPA's Lester Grant, Director of EPA's National Center for Environmental Assessment (NCEA), EPA must publish the final PM Criteria Document by 29 October, and further extensions will not be granted.

Later performance deadlines, according to Karen Martin of EPA's OAQPS, are the subject of ongoing discussions among EPA, Plaintiffs, and the Court. Current target dates call for a revised draft *Staff Paper* to be issued by the end of January 2005, and reviewed by the Clean Air Science Advisory Committee (CASAC) by the spring. The new PM standard, with or without changes to the current standard, then should be proposed by EPA about three months after that, perhaps in the fall of 2005, with a public comment period to follow. Ongoing discussions should narrow those approximate time frames.

Criteria Document drafts, peer reviewed by the EPA Science Advisory Board's CASAC, have been contentious. EPA finally received approval from CASAC on Chapters one through eight this past August. The latest version of Chapter 9, the *Integrative Synthesis* of chapters one through eight, also was released this past August. EPA received 'closure' in a publicly accessible telephone meeting held even more recently, on 21 September.

The approved product, available at EPA's web site (www.epa.gov), in my view dismisses one of the most important emerging issues in PM toxicology and epidemiology. Specifically, it mentions but gives short shrift to short-term PM 'excursions', that is, brief PM spikes producing high airborne PM concentrations ranging in duration from the metric equivalent of moments to the metric equivalent of a few good hours.

Mentioning a few studies of this type, the *Integrative Synthesis* dismisses them as follows: "more rigorous characterizations of dose-response relationships with environmentally relevant levels and species of PM will be necessary to evaluate more fully cardiovascular risks posed by ambient PM exposures" (*Integrative Summary*, page 9-65).

To understand why this statement is dismissive one must understand that it is likewise true of longer-term exposures that already are regulated in the current PM NAAQS. To the consternation of everyone, the dose-response curve for 24-hour exposure and for annual exposure both also vary among PM species. That's part of the territory in the PM world because, unlike ozone or chlorine gas, PM is diverse, not a single chemical substance. Yet, EPA does what it can, and must, to protect public health by incorporating reasonable 24-hour and annual average PM levels into the NAAQS, as it should consider also doing for one-hour PM averages. This is possible because only the approximate exposure threshold for an effect, not the detailed shape of the dose-response curve over a wide range of 'environmentally relevant' exposure levels, must be known to enable its prevention via regulatory risk management.

Based upon the above considerations, the *Integrative Synthesis* and, indeed, the entire PM Criteria Document, raise three issues, as follows:

— Did OAQPS policy influence NCEA science and, if so, how?

— Was CASAC influence on NCEA science purely objective? and

— Has regulation lagged too far behind advances in PM measurement technology?

— Did OAQPS policy influence NCEA science?

Policy options to manage potential risks to public health and welfare posed by airborne PM should be developed in EPA's OAQPS *Staff Paper* based upon science in EPA's NCEA *Criteria Document*, and especially in its *Integrative Synthesis*. In contrast, OAQPS should not reciprocally influence NCEA; that is, neither OAQPS nor its *Staff Paper* should determine the content of the *Criteria Document*. Indeed, under ordinary (non-litigation) circumstances, the *Staff Paper* should not exist as a public document until after completion of the *Criteria Docu-*

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ment. Notwithstanding the incompleteness of the *Criteria Document* until as recently as 21 September, however, the *Staff Paper* indeed has existed for years, and indeed has exerted its influence for years, albeit in sequentially revised form.

In an ideal world, each *Staff Paper* revision faithfully would reflect changes to the *Criteria Document*, not the reverse. People residing in the far-from-ideal real world, however, must pose the question of whether, and to what degree, EPA's OAQPS *Staff Paper* might map the boundaries of the EPA Administrator's regulatory flexibility (or inflexibility). Might it also reflect the priorities of the U. S. President, who is Commander-In-Chief not only of the US Military but also of the US EPA?

In short, the question must be posed whether an inappropriate policy feedback loop to the scientific content of the *Criteria Document* has been created. If so, has it unduly influenced that properly science-driven document? This issue was addressed in greater detail in a *Risk Policy Report Commentary* in 1997 (5). That *Commentary* called attention to a possible 'reversal of the arrow of time', in which a result influences the factors ostensibly causing it . . . an impossible violation in physics, but apparently not in environmental regulation or regulatory politics.

Was CASAC influence on NCEA science purely objective?

The relevance of the arrow-of-time issue has persisted unabated since 1996, but it has taken multiple forms. Indeed, within the past several years I was invited by EPA's NCEA to Research Triangle Park, North Carolina to present findings of my own and of coworkers and colleagues on the significance of risks potentially posed by short-term PM excursions (see, for example, 1-6). I also was invited to submit comments on drafts of the *Criteria Document*. Publications of mine and of others addressing health impacts and risks potentially posed by short-term exposure to PM were cited by NCEA in the *Criteria Document*. Within the past several years, however, CASAC-driven revisions to the *Criteria Document* also have seen such citations expunged mysteriously from the *Literature Cited* section, and the entire short-term exposure issue discussed only dismissively.

Removal of citations of peer-reviewed reports on short-term exposure to PM from the *Criteria Document* must be explainable, and should be explained in the context of the apparent appreciation of their importance among NCEA staff in recent years. One conceivable basis for excluding my reports from the *Criteria Document* is that they relied upon clinical or epidemiological data gathered and reported by others. In accordance with scientific norms, however, studies commonly have been reevaluated in a new context by PM researchers, including EPA staff and CASAC members. Thus, the research could not possibly have been deemed inadmissible for consideration in the *Criteria Document* by virtue of having been deemed secondary rather than primary.

Perhaps the research was considered speculative and therefore unusable. However, it had been peer-reviewed, and found to be substantive, not speculative. Perhaps the health effects

reported were deemed to be clinically insignificant, or to have occurred to a clinically insignificant degree of seriousness among study subjects. That is unlikely, given that life-threatening effects were reported.

Perhaps, notwithstanding the above considerations, technical rationales indeed do justify repudiation of the findings made and/or conclusions drawn by peer-reviewed reports addressing the short-term exposure issue (most notably 2, 3, 4, 6). The *Criteria Document*, however, is inscrutable regarding these reports. Except as quoted above, it also is essentially inscrutable regarding the vastly larger body of peer reviewed literature cited in those reports, documenting clinically significant effects caused by short-term exposure to airborne PM. The proper approach for the *Criteria Document* is to address, not dismiss, this body of literature—whether the technical result turns out to be acceptance, technically justified repudiation, or something between.

Why, then, was peer-reviewed literature initially cited by NCEA later expunged from the *Criteria Document* without explanation in the course of peer review by CASAC? Some have attributed this EPA action to a CASAC bias favoring the research interests and reputations of its members, preponderantly involving 24-hour and annual average exposure levels rather than real-time PM concentration excursions and fluctuations. EPA's staff in NCEA worked feverishly and heroically in a shifting scientific and judicial landscape to complete work in a timely manner. Issues initially raised because of their apparent significance simply may have fallen through the cracks later, as issues of greater immediacy arose.

Has regulation lagged too far behind technology?

EPA inattention to the short-term exposure issue is unjustified in the context of public health protection. For a decade or more technology has existed to measure and routinely monitor airborne PM fluctuations in real time. Such technology already has been embraced globally for measuring airborne PM, including in the U. S., in part because the instruments operate remotely and economically rather than labor-intensively and uneconomically. Research already had shown that PM exposures over short time frames (usually an hour or less) can elicit clinically significant adverse effects in people, especially in volunteer study subjects such as exercising asthmatics. More recent epidemiology studies enabled by technologies mentioned above have extended such findings to ambient PM levels in cities, most notably in the U. S. and Australia.

The above considerations do not mean that a one-hour PM average already should be in place in the PM NAAQS. I could support such a standard and, as a *Risk Policy Report Commentary* noted in 2001, so could many in corporate America (1). EPA would do well to address the issue, substantively, not dismissively. Thus, a legitimate question is whether EPA diligently considered regulation of PM over a one-hour averaging time now that technology enables routine compliance monitoring. The opportunity to do so awaits, as does the responsibility.

A legitimate question is whether EPA diligently considered regulation of PM over a one-hour averaging time now that technology enables routine compliance monitoring.

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