COMMENTS

on

OMB PROPOSED BULLETIN ON GOOD GUIDANCE PRACTICES

Submitted by

THE GENERAL ELECTRIC COMPANY

January 9, 2006

I. Introduction

The General Electric Company (GE) welcomes the opportunity to comment on OMB's Bulletin on Good Guidance Practices (the "Bulletin"). We endorse OMB's effort to standardize agency guidance practices and promote quality, fairness, and accountability in the development of guidance. The Bulletin is an appropriate part of OMB's wider effort to ensure that agency disseminations meet high standards for quality, objectivity, and transparency. Agency guidance enables regulated entities to know agency interpretations of statutory and regulatory mandates and agency expectations for regulatory compliance. It is therefore vital that guidance development be transparent and accessible and that regulated entities be allowed to participate to the fullest extent practicable.

The development of agency guidance has not always been transparent to the regulated community, and agencies have misused guidance documents to create enforceable obligations without adhering to the process required for rulemaking under the Administrative Procedure Act. OMB cites *General Electric v. EPA*, 290 F.3d 377 (D.C. Cir. 2002), as one example of a court holding that agency guidance was in fact a legislative rule promulgated without prior notice and the opportunity for public comment. In that case, the EPA issued guidance for conducting risk assessments to support a risk-based PCB cleanup plan under the Toxic Substances Control Act. The court found that the guidance made clear that in reviewing applications for risk-based cleanups, EPA would not be open to considering approaches other than those prescribed in the guidance.

There are many other cases in which courts have found agency guidance to be legislative rules. *See* Robert A. Anthony, Interpretive Rules, Policy Statements,

Guidances, Manuals, and the Like – Should Federal Agencies Use Them To Bind the Public?, 41 *Duke L. J.* 1311 (1992). To highlight a few examples:

- In 2001, the Environmental Protection Agency (EPA) issued a press release informing the regulated community that it would not consider or rely on any third-party human studies in its regulatory decision making in evaluating the safety of pesticides. The court held that the language of the directive stated an obvious change in agency practice that created a binding norm, which required EPA to follow notice and comment procedures as provided for in the Food, Drug, and Cosmetic Act. *Croplife America v. EPA,* 329 F.3d 876 (D.C. Cir. 2003).

- The Occupational Safety and Health Administration (OSHA) issued a "Directive" pursuant to which employers in selected industries would be inspected unless a comprehensive safety and health program was adopted. The court held that although the Directive did not impose a binding norm in the sense that it gave rise to a legally enforceable duty, it nevertheless would have a substantial impact on all employers and was therefore, a substantive rule subject to the APA requirements of notice and comment rulemaking. *Chamber of Commerce of the United States v. Department of Labor,* 174 F.3d 206 (D.C. Cir. 1999).

- The Consumer Products Safety Commission, through a "statement of interpretation," eliminated an exclusion to its rule governing the use o small parts in children's products, which if violated, could invoke a range of civil and criminal penalties provided by statute. The court found that the statement did not interpret, but rather imposed, new duties having the force of law. *Jerri's Ceramic Arts, Inc. v. Consumer Prod. Safety Comm'n*, 874 F.2d 205 (4th Cir. 1989).

- Through an "order," the Federal Power Commission for the first time directed operators to pay compound interest on refunds the Commission ordered pursuant to its statutory authority. The court rejected the Commission's argument that the order was a policy statement and held that it was a legislative rule that imposed obligations on operators. *Texaco, Inc. v. Federal Power Comm'n*, 412 F.2d 740 (3d Cir. 1969).

Another example that never reached the courts demonstrates that an agency can impose regulatory obligations by simply responding to a request for clarification of the law. In a 1999 letter to a company, OSHA put employers on notice that they were responsible for ensuring that the homes of telecommuters and others who work at home meet OSHA safety standards. OSHA said that for employees who work from home, "the

employer is responsible for correcting hazards of which it is aware, or should be aware." Failing to do so could make the employer liable for safety violations and injuries resulting from safety violations. The letter sparked wide-spread criticism from both employers and employees. Members of Congress also registered their disapproval by introducing bills to prohibit OSHA from inspecting home offices. OSHA eventually withdrew the letter claiming that it had unintended consequences. Early public notice of intent to prepare such guidance might have prevented the controversy from arising (see section IV.A below).

These examples underscore the importance of the Bulletin providing a standardized approach to guidance development and use. We commend OMB for developing the Bulletin. Our recommendations principally involve expanding the Bulletin to provide for more public participation in guidance development and to make all agency guidance easily accessible.

We do not believe that the Bulletin will hamper agencies' ability to develop guidance. The OMB has modeled many of the Bulletin's provisions after the Food and Drug Administration's Good Guidance Practices, which the agency developed and Congress codified in the Food and Drug Administration Modernization Act of 1997. Congress directed the FDA to evaluate its guidance practices and then promulgate regulations specifying the agency's guidance practices. The OMB notes that FDA found that the procedures have been beneficial and effective in standardizing the agency's procedures for development, issuance, and use of guidance documents, and that FDA employees had generally followed the good guidance practices. *See* Proposed Bulletin at

3; 65 Fed. Reg. 7321. The Bulletin's good guidance practices will not only benefit the regulated community, but also agencies as well.

II. Definitions

The Bulletin's definition of a "significant guidance document" includes a document that may: "(i) reasonably be anticipated to lead to an annual effect of $100 million or more or adversely affect in a material way the economy or a sector of the economy; (ii) raise highly controversial issues related to interagency concerns or important Administration priorities; (iii) set forth initial interpretations of statutory or regulatory requirements, or changes in interpretation; or (iv) concern novel or complex scientific or technical issues." The definition addresses important criteria for determining significance but as written, some of the criteria are vague or limited in ways that undercut the Bulletin's objectives.

A. Provide Criteria for Economic Significance and Allow OMB to Designate Guidance as Economically Significant

The $100 million threshold for significance is consistent with the definition of a "significant regulatory action" in Executive Order 12866, which governs OIRA's oversight of agency rulemaking. Agencies must prepare a Regulatory Impact Analysis (RIA) for each regulation that OIRA or the agency designates as economically significant within the meaning of the Executive Order. The RIA must provide an assessment of benefits, costs, and potentially effective and reasonably feasible alternatives to the planned regulatory action. The RIA provides a means by which the agency and OIRA can validate the economic significance of a rule.

The Bulletin does not provide a mechanism by which OIRA can either designate agency guidance as significant or a way to validate whether proposed guidance will in

fact have a significant economic impact. Consequently, agencies may escape the requirements of the Bulletin by simply concluding that guidance will not have a significant economic impact. While a full RIA should not necessarily be developed for guidance, OMB should direct agencies to apply the principles that underlie a RIA in evaluating whether guidance is economically significant. OMB should also include in the Bulletin a provision that allows OIRA to designate agency guidance as significant and subject to the Bulletin's requirements. If, as suggested below, agencies prepare an annual agenda of guidance proposed for development, OIRA could review the agenda and address the economic significance of the guidance with the agency.

B. Broaden the Definition of Highly Controversial Issues

The Bulletin limits its definition of "highly controversial issues" only to those related to "interagency concerns or important Administration priorities." Highly controversial issues regarding regulatory requirements usually involve just one agency and seldom raise interagency concerns. As the definition is written, regulatory issues that are highly controversial and confined to one agency escape the reach of the Bulletin. We recommend that OMB broaden the definition to capture all highly controversial issues that might arise and for which guidance might be developed. This can be accomplished by deleting the terms "interagency concerns or important Administration priorities" and having section I.3(ii) state simply: "Raise highly controversial issues."

C. Do Not Limit Novel or Complex Issues to Only Those That Are Technical or Scientific

We commend OMB for including "scientific and technical issues" within its definition of "significant guidance." Agency guidance documents often set forth important technical and scientific requirements. The risk assessment guidance at issue in

General Electric v. EPA, is but one example. Such technical and scientific guidance may contain sampling techniques, monitoring requirements, or product specifications. They may also set important scientific standards for agency decision-making. For example, EPA's Integrated Risk Information System (IRIS) develops oral reference doses and inhalation reference concentrations (RfDs and RfCs, respectively) for chronic noncarcinogenic health effects and hazard identification, oral slope factors, and oral and inhalation unit risks for carcinogenic effects. These numerical, technically derived thresholds are used by the EPA and other agencies to inform regulatory standard-setting.

While it is important that the Bulletin capture technical and scientific issues, the Bulletin's reach should not be limited to these issues. Across the federal government numerous "novel and complex" issues arise that are neither scientific nor technical for which agency guidance is nevertheless necessary and appropriate. The government's array of social programs administered by numerous agencies is but one example. If OMB did not mean to limit "novel and complex" issues only to those that are "scientific or technical," it should clarify the definition. If it did intend such a limitation, we recommend that the definition be broadened. In either case, we recommend that the terms "related to interagency concerns or important Administration priorities" be deleted from the definition and section I.3(iv) state simply: "Concern novel or precedent-setting issues."

III. Basic Agency Standards

A. Direct Agencies to Develop Or Revise Their Own Guidance Guidelines To Incorporate The Provisions Of The Bulletin

The Bulletin provides that agencies shall maintain written procedures for the approval of significant guidance documents. It does not, however, direct agencies to

develop or revise their own guidance guidelines ("guidance guidance") to incorporate the provisions of the OMB Bulletin. Although agencies must observe the directives of the Bulletin, agency-specific regulations or guidance on guidance development should be amended to be consistent with the Bulletin. This will avoid confusion within agencies and provide a unified statement on how each agency intends to implement the Bulletin.

B. Include A Clear Disclaimer That Informs the Reader That the Guidance Represents Only The Agency's Interpretation Of, Or Policy Concerning A Statutory Or Regulatory Requirement And that It Does Not Establish Binding Requirements.

The Supreme Court has repeatedly defined interpretive rules, *i.e.,* agency guidance, as those "issued by an agency to advise the public of the agency's construction of the statutes and the rules which it administers." *See Shalala v. Guernsey Mem'l Hosp.,* 514 U.S. 87, 99 (1995) (quoting *Chrysler Corp. v. Brown,* 441 U.S. 281, 302 (1979)). As such, agency guidance should only "state what the administrative agency thinks the statute means, and only reminds affected parties of existing duties." *General Motors Corp. v. Ruckelshaus,* 742 F.2d 1561, 1565 (D.C.Cir.1984) (internal quotations omitted). Guidance should not spell out new obligations. *Id.* Thus, in section II.2, OMB has correctly recognized that guidance documents should not include mandatory language such as "shall, must, required, or requirement," unless the agency is using these terms to describe a statutory or regulatory requirement. The use of mandatory terms in guidance documents improperly suggests that the guidance sets forth binding requirements.

It is important that mandatory terms not be used in agency guidance, but it is equally if not more important that agency guidance unequivocally state that the document is not legally binding. Agency guidance should contain a clear disclaimer that informs the reader that the guidance represents only the agency's interpretation of, or policy

concerning, a statutory or regulatory requirement, and that the guidance does not establish binding requirements. OMB required a similar disclaimer in the Final Information Quality Bulletin for Peer Review to make clear that information distributed for peer review was excluded from the definition of information dissemination. A disclaimer in the Good Guidance Practices Bulletin should state:

> **THIS DOCUMENT IS INTENDED TO PROVIDE GUIDANCE. IT REPRESENTS THE AGENCY'S CURRENT THINKING ON THIS TOPIC. IT DOES NOT CREATE OR CONFER ANY RIGHTS FOR OR ON ANY PERSON AND DOES NOT OPERATE TO BIND THE [AGENCY] OR THE PUBLIC.**

C. OMB Should Direct Agencies to Refrain From Alleging That Activities Consistent With Guidance Documents Violate Regulatory Requirements

An important purpose of guidance documents is to provide regulated entities clear directions on how agencies interpret regulatory requirements. While guidance documents should not impose obligations, it is good public policy to recognize when regulated entities act in accordance with the agency's interpretation of the law. This is particularly true when agency guidance describes how to perform certain activities, *i.e.,* risk assessments. OMB therefore should direct agencies to refrain from alleging that activities that were consistent with the guidance violated the regulatory requirements that are the subject of the guidance.

D. Provide a Mechanism That Allows Regulated Entities to Obtain Concurrence That Complying With Regulatory Requirements In A Manner Different Than That Set Out In Agency Guidance Is Appropriate

The OMB should also direct agencies to develop a mechanism by which regulated entities can obtain agency concurrence that complying with regulatory requirements in a manner different than that set out in agency guidance is appropriate. For example, FDA

has provided in its guidance regulations a provision that informs regulated entities that the agency will discuss alternative approaches to regulatory compliance to ensure that the approach complies with relevant statutes and regulations. A similar provision in the Bulletin would be helpful to the regulated community.

IV. Internet Access

A. Direct Agencies To Maintain A Comprehensive List Of All Guidance Documents On Their Web Sites

In Section III.1, the Bulletin requires each agency to maintain on its Web site a current list of significant guidance documents and to update the list as new documents are created. This is an important provision that furthers the Bulletin's goal of transparency by providing easy access to agency documents. For the same reasons -- transparency and access -- it is equally essential to facilitate public access to all of an agency's guidance documents. If guidance exists and is relevant for a particular purpose, it should be easily accessible. In the Internet information age, this would not impose an unreasonable burden. Some agency guidance is obtainable already -- but not always -- by diligent, skillful search of an agency's website or the Internet. Thus, at a minimum, we recommend that the Bulletin include a provision that directs agencies to maintain a comprehensive list of all guidance documents on their Web sites in an organized form. The FDA provides such a list annually, organized by FDA centers. *See* http://www.fda.gov/opacom/morechoices/industry/guidedc.htm. FDA also publishes an annual comprehensive list of all guidance currently in use at the agency in the Federal Register. We recommend that OMB consider a similar requirement for all agencies.

B. Provide Notice To The Public That Non-Significant Guidance Documents Have Been Developed Or Revised And Are In Effect

The Bulletin does not provide a mechanism for public comment on "non-significant" guidance documents. We understand that mandating notice and comment on every guidance produced by an agency could be unduly burdensome and discourage agencies from issuing helpful guidance documents. We recommend, however, that the Bulletin include a provision that directs agencies to provide notice to the public that non-significant guidance documents have been developed or revised and are in effect. This could be accomplished by posting the guidance on agency Web sites, as recommended above, or through a notice in the Federal Register. Even though agencies may implement non-significant guidance without formal public comment, agencies should at least encourage public comment on the implemented guidance. Agencies may decide to revise the guidance as appropriate based on comments received.

C. Publish Annually A List of Guidance Under Development Or Proposed For Future Development Or Revision

Absent from the Bulletin is any mechanism to inform the public of guidance documents an agency proposes to develop or revise. The OMB's Peer Review Bulletin requires agencies to post on their Web sites a description of "highly influential scientific assessments" and "influential scientific information" that the agency proposes to develop, together with details of plans for peer review. The peer review agenda provides an important means to inform and allow stakeholders to participate in shaping the peer review of agency science. If one purpose of agency guidance to is assist the regulated community in understanding current agency thinking on regulatory issues, a proposed guidance agenda would be even more functional here than in the peer review context.

Facilitating early collaboration with the regulated community will ensure that guidance is meaningful and useful. Agency guidance is often written by agency staff who have little or no experience working in the industry for which the guidance is being developed, and who will not have to apply the guidance in industrial, commercial, or other settings. Consequently, guidance too often is written without an appreciation for the practical difficulties that might be encountered by those who have to implement the guidance. If a list of guidance proposed for development is made available for public comment, stakeholders could provide agencies with useful information such as the importance of a particular guidance, the issues that need to be addressed in the forthcoming guidance, the problems stakeholders have encountered fulfilling regulatory mandates, or ideas for developing effective guidance. The FDA publishes such an agenda, and we recommend that other agencies do so as well.

Accordingly, the Bulletin should contain a provision that states: "Once a year, each agency shall publish, both in the Federal Register and on the Internet, a list of guidance under development or proposed for future development or revision. Agencies should provide a mechanism for allowing the public to comment on the list of guidance topics."

V. Direct Agencies to Respond to Comments on Significant Guidance Documents

The Bulletin provides in section III.2 that agencies develop a means for the public to electronically submit comments on significant guidance documents, and to request that significant guidance documents be created, reconsidered, or modified. However, the Bulletin does not require an agency to respond to the comments. The Bulletin takes the view that the comments are only for the benefit of the agency.

Providing an opportunity for comment without any opportunity to obtain an agency response, reduces the agency's incentive to give comments due consideration and increases the chance that the final guidance will be the subject of a judicial challenge.

OMB should require agencies to respond to comments on "significant guidance documents." This would stimulate the agency to rethink its interpretation, leading to the development of better guidance. It would also provide the regulated community with a better understanding of an agency's basis for its interpretation of the law.

VI. Provide Notice and Comment for All Significant Guidance Documents

In Section IV, the Bulletin requires notice, the opportunity to comment, and agency response only on drafts of economically significant guidance documents, but does not provide a rationale for the limitation. Significant guidance documents that raise controversial issues, set forth initial interpretations of statutory or regulatory requirements, or concern novel or complex issues can have a significant effect on regulated entities -- especially small businesses -- even when it is not possible to demonstrate that the guidance will have "an annual effect of $100 million or more or adversely affect in a material way the economy or a sector of the economy." Consequently, if a guidance document is important enough to be deemed "significant" under the Bulletin, the public should have the opportunity to comment on the draft document, and the agencies should respond to those comments. OMB should revise the Bulletin to provide for notice and comment on all draft significant guidance documents.

A. Allow Adequate Time for Public Comment

The Bulletin should include a provision that establishes minimum time periods for public comment on significant guidance documents. Agencies can spend months, if not years, developing guidance and then, when public comment is solicited, provide only 30

days for affected entities to submit comments. Guidance documents are often highly technical and complex, and 30 days is often not enough time for commentors to analyze the document and provide meaningful comments. We recommend that OMB include in the Bulletin a provision that directs agencies to allow at least 60 days for comments on significant guidance documents, unless the agency can justify a shorter period of time by showing, for example, that the draft document was publicly circulated before the start of the comment period.

B. Provide for Dispute Resolution Procedures

While guidance is not intended to create legal obligations, agencies are generally committed to positions taken in guidance and will insist on following them. This can engender lengthy and expensive administrative or judicial proceedings.

We recommend that OMB include a provision in the Bulletin that directs agencies to create dispute resolution procedures to address complaints about the development or use of guidance. Congress directed FDA to create such a mechanism, and the agency has done so through directing affected entities to contact supervisory personnel in the responsible office and encouraging FDA staff to resolve the issue at the staff level. If a dispute cannot be resolved at the staff level, affected entities may move up the chain of command and ask the agency's chief mediator and ombudsman to become involved. A similar dispute resolution mechanism across agencies would help avoid entrenched positions that may ultimately be resolved only by the courts.

C. Discourage Agencies From Relying on Guidance Until It Is Finalized

Too often agencies publish draft guidance documents, receive critical comments, and rely upon the unrevised draft guidance documents without finalizing them. This

essentially allows agencies to ignore critical comments and it creates uncertainty in the regulated community. OMB should include a provision in the Bulletin that directs agencies not to rely upon guidance until it is finalized. It should also require that agencies post a clear notice on each draft document that states:

> **THIS GUIDANCE DOCUMENT IS ONLY A DRAFT. IT DOES NOT REPRESENT [THE AGENCY'S] FINAL INTERPRETATION OF STATUTORY OR REGULATORY REQUIREMENTS OR POLICY ON AN ISSUE. [THE AGENCY] WILL NOT RELY ON THE DOCUMENT UNTIL IT IS FINALIZED IN ACCORDANCE WITH AGENCY PROCEDURES.**