A HANDY "RULEMAKING VERSUS GUIDANCE" CHECKLIST FOR FEDERAL AGENCY COUNSEL

by Richard G. Stoll, James C. Conrad, and Katherine E. Lazarski

A "Rulemaking Versus Guidance" Problem Comes Your Way

Assume you are an attorney in the general counsel's office of a federal regulatory agency. A client from one of your program offices approaches you. The program office has been receiving lots of inquiries from the public, as well as the agency's own regional personnel, as to what types of activities would be allowed and/or prohibited under a statute that your agency administers. In fact, regional offices have begun taking inconsistent positions.

The program personnel have deliberated over the issues and have agreed upon the positions they should take. Your client now wants to commit these positions to some form of writing, and in fact shows you a draft his staff has prepared.

Your client dreads initiating a rulemaking process. Considering the internal agency and OMB hoops, he can see at least a year of work involving dozens of agency personnel from various offices even to reach the proposed rule stage. He can also envision at least another year to finalize the rule. If he could convert his draft into a "guidance" memorandum and get his boss to sign the memo, all his problems would be solved within a few days.

Your client remembers hearing, however, that a court threw out a "guidance" issued by a program office just down the hall on the grounds that its contents should have been subject to APA notice-and-comment rulemaking. Your client is concerned.

You are sympathetic with your client's concerns for resources and expedition, but are also mindful that the federal courts – especially in the last few years – have been aggressive in disapproving (and vacating) agency "guidances" issued in the form of policy memoranda, manuals, letters, etc. Especially in the U.S. Court of Appeals for the D.C. Circuit (where a judicial challenge alleging your agency had violated APA rulemaking requirements would probably be heard) there have been several significant cases nullifying "guidance" documents on the grounds that they were in effect "rules" under the APA.

Approaches to Addressing the Problem

We are presenting a "checklist" of questions and factors to consider when you address this problem in a particular situation.

Part I covers factors that bear on whether a court might overturn "guidance" as an illegal rule. We will describe situations in which the courts might be more or less likely to be suspicious of "guidance."

But a stern warning: there are no easy answers. Even more than most areas of federal administrative law, this issue area is evolving – and it is evolving inconsistently and unpredictably. We can only provide our own "guidance," therefore, that might at least point you in the right direction.

Part II addresses new requirements from the Executive Office of the President (EOP) regarding guidance documents. As we will discuss, certain types of "guidance" – even truly legitimate guidance – must now go through new internal and external hoops. As the process for issuing some types of guidance becomes more burdensome, these new requirements could sometimes tilt you in the direction of rulemaking when considering your options.

Part III presents "best practice/prudential" factors that might be considered regardless of what a court or the EOP may require in a specific situation. Finally, we offer a table of significant recent cases, and a bibliography of relevant articles, if you want to pursue these issues in greater detail.

Part I – How Likely Would a "Guidance" Survive Judicial Review?

Question 1: What does the statute say? (This is a good first question in almost any administrative law issue.)

a. Does the statute explicitly direct the agency to address certain issues by issuing regulations?

In many statutes, Congress includes a broad, general delegation to the agency for issuing regulations. An example is contained in § 301(a) of the Clean Air Act: "The Administrator is authorized to prescribe such regulations as are necessary to carry out his functions under this chapter." Statutes containing such broad delegations commonly include additional delegations that may be somewhat more focused. An example is the authorization in § 3002 of the Solid Waste Disposal Act for EPA to issue "regulations establishing such standards applicable to generators of hazardous waste . . . as may be necessary to protect human health and the environment."

But sometimes a statute might have a much more specific delegation in lieu of, or in addition to, such general types of delegations. It is highly risky to issue a guidance document on a topic covered by such a specific delegation, as illustrated by the D.C. Circuit's decisions in *MST Express v. DOT*[1] and *Ethyl Corporation v. EPA*.[2]

In *MST*, the Motor Carrier Safety Act directed DOT to "prescribe regulations establishing a procedure to decide on the safety fitness of owners and operators of commercial motor

[1] 108 F.3d 401 (D.C. Cir. 1997).

[2] 306 F.3d 1144 (D.C. Cir. 2002).

vehicles." The statute further specified that the regulations include "a means of deciding whether the owners, operators, and persons meet the safety fitness requirements."[3]

DOT had issued regulations providing a framework for decisionmaking, but DOT utilized guidance instead of regulations to prescribe the tests for deciding whether vehicles met safety fitness requirements. The Court rejected DOT's approach because the agency "failed to carry out its statutory obligation to *establish by regulation* a means of determining whether a carrier has complied with the safety fitness requirements."[4]

The Court similarly rejected EPA's approach in *Ethyl*, where the statutory delegation provided that EPA must "by regulation establish methods and procedures" for determining whether a motor vehicle's emissions will comply with certain federal standards. CAA § 206(d).

These cases show that a court would view as highly suspect an agency guidance document that appears to perform a function that Congress has specifically authorized or directed the agency to perform through issuance of regulations.

b. Conversely, does the statute even *authorize* regulations on the subject matter of interest?

The Patent Act, for instance, contains provisions authorizing PTO to issue regulations governing procedures and practice before the agency.[5] But the Patent Act contains no delegation of authority for the agency to issue substantive regulations defining such key patentability concepts as prior art, obviousness, or prior publication. It also contains no broad, general grant of the type described above for the agency to issue regulations "as may be necessary" to carry out the agency's functions.

In *Kelley v. EPA*[6] the D.C. Circuit vacated an EPA regulation because the Court found no Congressional delegation for that type of regulation expressed in the relevant statute (the Comprehensive Environmental Response, Compensation and Liability Act or CERCLA). Interestingly, the court reached this conclusion notwithstanding CERCLA's general delegation to EPA, in Section 115, for regulations "necessary to carry out the provisions of this subchapter."[7]

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[3] 49 U.S.C. §31144(a)(1).

[4] 108 F. 3d at 406 (emphasis added).

[5] *E.g.*, 35 U.S.C. §§ 2(b)(2), 23, 41, 118.

[6] 15 F. 3d 1100 (D.C. Cir. 1994).

[7] 42 U.S.C. § 9615.

EPA's regulations had attempted to resolve statutory ambiguity and conflicting judicial opinions by defining the extent lenders would be liable for contaminated sites in which they held a security interest. The Court reasoned that since CERCLA established a liability scheme in which private parties might often litigate against each other, it could not assume Congress intended to allow EPA to define liabilities through regulations, and the Court found the general language of CERCLA Section 115 insufficient evidence of such intent.

Thus, getting back to your client's question, if the statute does not even authorize the issuance of regulations on the subject at hand, your client may have no option other than issuing a guidance document. Care must be taken, however, to draft guidance in a manner that does not have the effect of being a rule under the criteria discussed in the next sections, or a Court might still decide to vacate the "guidance" if challenged.[8]

c. Does the statute authorize regulations on the subject but contain no explicit direction for the agency to address specific issues through regulations?

This is the more common scenario which has spawned the most litigation in recent years. The rest of our checklist is directed primarily to this scenario.

Question 2: Do the style and verbiage of your client's draft sound like it is stating definitive requirements or prohibitions, or is it "soft" enough to sound like it is merely offering thoughts for consideration?

Generally, guidances are not allowed to have "binding effect" on either the agency or a regulated party. Guidances that appear to "command" and "dictate" have been struck down because they were written with "binding"-sounding language.[9] Alternatively, "softer" language has moved a court in some cases to conclude that the guidance is not a rule. Phrases such as "in general" or "in some cases it may be permissible" have moved courts to conclude that guidance is not a rule.[10]

Some agency lawyers accordingly may edit "guidance" documents – in hopes of saving them on judicial review – by changing all the "shall"s and "must"s to "may"s, and adding words like "suggest" and "recommend" all over the place. This may or may not be effective, depending upon other factors discussed below.

Question 3: Would your client include a "disclaimer" stating that the agency does not intend for the document to have any binding effect, and that the document is simply guidance that need not be followed?

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[8] For instance, in *Kelley v. EPA*, the Court rejected EPA's alternative argument that its regulation could at least be sustained as an interpretive rule that would be entitled to deference. 15 F.3d 110, 1108-09 (D.C. Cir. 1994).

[9] *E.g., Appalachian Power Company v. EPA*, 208 F. 3d 1015, 1023 (2000).

[10] *E.g., Center for Auto Safety v. NHTSA*, 452 F. 3d 798, 808-809 (D.C. Cir. 2006).

In some cases, courts have given substantial credence to an agency's own characterization of its action. For example, in a 2006 opinion, the D.C. Circuit found that a guidance document was not a rule because, in part, the agency labeled the document "policy guidelines" and the agency did not publish the document in the Code of Federal Regulations.[11]

But courts have frequently disregarded such disclaimers as "mere boilerplate" or even a "charade" where the court believed the guidance had the practical effect of governing conduct.[12]

Thus, if you decide to pursue the "guidance" option, by all means include a "disclaimer" and utilize the softest language possible. But recognize that the guidance may still be vacated on judicial review for the reasons discussed below.

Question 4: Would your client's document have the "practical effect" of imposing requirements, prohibitions, or a standard?

As a general matter, a court will look at real world evidence as to how an agency and the interested public and perceive and treat a document. Here the case law gets very inconsistent; the best we can do is give you a checklist of points to consider that have moved courts in one direction or the other.

a. Will the agency act as if a document issued by headquarters is controlling in the field?

b. Will the agency treat the document the same as it treats a rule?

c. Will the document lead parties or permitting authorities to believe the agency will disapprove permit applications unless they comply with terms of the document?

d. Will the agency base enforcement actions on policies or interpretations formulated in the document?

These four questions were posed by the D.C. Circuit in *Appalachian Power Co. v. EPA*[13] in 2000. The Court engaged in a similar inquiry in *Croplife America v. EPA*.[14]

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[11] *Id.* at 808.

[12] *Appalachian Power*, 208 F.3d at 1022-23.

[13] *Id.* at 1021.

[14] 329 F. 3d 876, 883 (D.C. Cir. 2003).

If the answer to any of these is yes, a court may view the document as having the "practical effect" of imposing requirements or restrictions – the more "yes"s, the more suspicious a court is likely to be. We note that a "yes" under (d) alone may not be problematic, so long as the agency publicizes the new guidance (*i.e.*, gives "fair notice") to affected parties and seeks to enforce consistent with that new guidance only in a *prospective* manner.[15]

Question 5: Would the guidance have the practical effect of adding to or reducing obligations, burdens, prohibitions, or restrictions in ways that could not be reasonably ascertained from the text of the statute or existing regulations?

In such situations, a court would be highly suspicious of the guidance.

Example #1: An existing regulation says: "No widget maker can emit sulfur dioxide at levels of greater than 240 units per day." Then the agency issues "guidance" saying that, to assure compliance with this 240 unit per day limit, the agency will assume any widget maker found emitting sulfur dioxide at levels of greater than 10 units per hour will be deemed in violation. The effect of this guidance would be to impose significant restrictions on operations of a typical widget maker or add greatly to costs of compliance.

Example #2: After reading the text of a regulation, a party would fairly assume compliance with the regulation at his facility should cost in the range of $50,000-$100,000, but compliance with the provisions in the guidance would cost in the range of $500,000-$1,000,000.

Question 6: Does the document have the practical effect of establishing a norm of conduct, or a standard by which an agency would judge compliance, which norm or standard could not be reasonably ascertained from the text of the statute or existing regulation?

In such a situation a court would be highly suspicious of the document.

Example #3: The text of a statute and the text of a regulation provide that in cleaning up contaminated soil, the agency should assure that concentrations of a certain chemical compound should be reduced to a level the administrator finds protective of human health. In guidance issued by the agency, the agency states that it will generally accept cleanups of chemical compound where the concentrations are reduced to 4 ppm.[16]

Question 7: Does the document reverse course or terminate a policy or practice that had previously been established and relied upon by interested parties (whether or not that policy or practice had been established through regulations)?

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[15] *U.S. v. Chrysler Corp*., 158 F.3d 1350 (D.C. Cir. 1998).

[16] *See General Electric Co. v. EPA*, 290 F.3d 377, 382-85 (D.C. Cir. 2002).

If so, a court could be suspicious of the document.

Example: An agency has, through years of practice, accepted a certain type of test as relevant support in an application for approval of a product. The agency issues a document declaring that it will no longer accept that type of test. The D.C. Circuit has ruled that even a press release reflecting such a reversal was a rule and vacated the press release because it was not issued through APA rulemaking.[17]

Special note: Be aware that DC Circuit cases – even quite recent ones – have ruled that an agency changing or reversing course regarding a policy on which parties have had notice and relied upon must do so through APA rulemaking *even if* the original policy was only embedded in non-rulemaking guidance.[18]

Question 8: Who will sign the document?

There is very inconsistent case law here. At least some cases indicate if a guidance document is signed by an agency official who does not actually have authority to sign rules, the guidance cannot for that reason be deemed to be a rule.[19] Other cases, however, have rejected such logic either implicitly or explicitly.[20]

Question 9: Has your agency previously addressed this subject through rulemaking (or said it would do so)? Has your agency committed to develop regulations on the issue in its semi-annual Regulatory Agendas?

If an agency has proposed a specific rule, but then never finalizes it but instead issues "guidance" that appears to answer questions left hanging by the proposed rule, a court might obviously be quite suspicious of the "guidance."[21] Suspicions could also be aroused if the agency has announced plans to address a topic through rulemaking in its Regulatory Agenda, but then issues "guidance" on the topic with no rulemaking.

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[17] *Croplife America v. EPA*, 329 F.3d 876 (D.C. Cir. 2003).

[18] *See Envtl. Integrity Project v. EPA*, 425 F.3d 992, 997 (D.C. Cir. 2005); *.Alaska Professional Hunters Ass'n v. FAA*, 177 F.3d 1030 (D.C. Cir. 1999).

[19] *See Amoco Production Co. v. Watson*, 410 F.3d 722, 732 (D.C. Cir. 2005); *Center for Auto Safety v. NHTSA*, 452 F. 3d 798, 810 (D.C. Cir. 2000).

[20] *See, e.g., Appalachian Power*, 208 F.3d at 1021 n. 10.

[21] *Appalachian Power*, 208 F.3d at 1025-26.

Part II – New EOP Requirements for "Significant" Guidance Documents

On January 18, 2007, the President issued Executive Order 13422,[22] amending Executive Order 12866, which had been issued by President Clinton in 1993. President Clinton's Order had imposed process requirements on agencies undertaking rulemaking actions. President Bush's new Order, along with a new OMB "Final Bulletin for Agency Good Guidance Practices" issued the same day, [23] creates a similar set of process requirements for agencies issuing "significant" guidance documents.

The new Order and Bulletin define "significant" guidance documents as follows:

> A guidance document disseminated to regulated entities or the general public that may reasonably be anticipated to:
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> (i) Lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
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> (ii) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
>
> (iii) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
>
> (iv) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866, as further amended.[24]

Note the "or" connecting these four criteria. Moreover, if a document meets criterion (i), it is defined as an "economically significant guidance document."

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[22] 72 Fed. Reg. 2763 (Jan. 23, 2007).

[23] 72 Fed. Reg. 3432 (Jan. 25, 2007).

[24] 72 Fed. Reg. 3439. The following are exempt from the definition of "significant" guidance documents: legal advisory opinions for internal Executive Branch use and not for release; briefs and other positions taken by agencies in investigations, pre-litigation, litigation, or other enforcement proceedings; speeches; editorials; media interviews; press materials; Congressional correspondence; documents pertaining to a military or foreign affairs function of the United States (other than guidance on procurement or the import or export of non-defense articles and services); grant solicitations; warning letters; case or investigatory letters responding to complaints involving fact-specific determinations; purely internal agency policies; guidance documents that pertain to the use, operation or control of a government facility; internal guidance documents directed solely to other Federal agencies; and any documents exempted by an agency head in consultation with the OIRA Administrator.

One of the purposes of the new Bulletin is to give effect to some of the case law discussed above, as well as consensus among administrative law scholars, so that agencies can more confidently issue and apply significant guidance documents that stay within their proper bounds. The Bulletin provides that:

> (i) Guidance documents must include the term "guidance" or its functional equivalent, and cannot contain mandatory language such as "shall" and "must";[25]
>
> (ii) Agencies must establish written procedures requiring, among other things, that senior officials approve each document;[26]
>
> (iii) Agency employees should not depart from significant guidance documents without appropriate justification and supervisory concurrence;[27] and
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> (iv) Conversely, agency employees must not treat a significant guidance document as foreclosing consideration by the agency of positions advanced by affected private parties.[28]

The new Order and Bulletin also impose a number of new process requirements on "significant" guidance documents – especially for "economically significant" guidance documents – that begin to approach the process requirements for APA rulemaking:

> (i) The Bulletin requires agencies to post all significant guidance documents on their websites and provide a procedure for the public to submit comments on them through those websites, including requests for rescission or revision. No response to comments is mandated.[29]
>
> (ii) For economically significant guidance documents, the Bulletin requires an agency to announce availability of a draft in the *Federal Register* as well as its website. The agency must not only solicit public comments but also prepare a response to them.[30]
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> (iii) The Order requires agencies to give OMB advance notice of any significant guidance document they plan to issue. OMB may invoke the right to review and

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[25] § II.2.h, 72 Fed. Reg. 3440.

[26] § II.1.a, *id*.

[27] § II.1.b, *id*.

[28] § II.2.h, id.

[29] § III, *id*.

[30] § IV, *id*.

consult with the agency regarding any such documents before they are issued, even in draft form.[31]

Once effective,[32] these new mandates may factor into your equation in deciding whether to advise your client to proceed by rulemaking or by guidance. Now that the process for some guidance will be approaching the degree of process for APA rulemaking, this might help tip your balance in favor of rulemaking in some situations.

Part III -- Best Practice/Prudential Recommendations

Finally, we offer the following recommendations that go beyond the issues of what a court or OMB might require in a given situation.

1. It is almost always better to allow for some sort of public input**.**

Regulated entities generally are closer to the subject matter of their businesses than are regulators, and information from these entities can improve guidance by tailoring it more precisely and averting unintended consequences. Similarly, public interest groups that track certain issues closely may provide valuable insights and catch things agency staff may not have thought of. An opportunity to comment also minimizes feelings of being blindsided, which should not be underestimated.

2. If highly controversial legal calls are at issue, it may be better to go through rulemaking.

Faced with politically sensitive issues of law with aggressive advocates on both sides, agencies are often tempted to craft compromise positions in guidances that are frequently "draft" or "interim." This can justifiably fuel suspicion that an agency is attempting to circumvent its legal obligations and/or avoid judicial review through guidance. Yet questions that primarily involve legal issues – as opposed to factual ones – are usually the easiest for an agency to address through rulemaking. Public comments are more in the nature of legal briefs than the voluminous, fact-laden filings of typical rulemakings.

3. If the subject, or the agency's understanding of the subject, is evolving rapidly, it may be better to utilize guidance.

Particularly in highly technical areas where the subject, or the agency's understanding of it, is changing rapidly, it may make sense for the agency to proceed by guidance. Thus, as events and agency knowledge progress, the agency can more easily and quickly update the material. Imagine if software had to be promulgated by regulation -- it would be outdated

[31] § 9, 72 Fed. Reg. 2764.

[32] The Bulletin becomes effective on July 24, 2007. The requirement of the Order regarding OIRA review of significant guidance documents becomes effective at OIRA's specification.

before it was ever finalized. (We are not suggesting, however, that highly-technical, rapidly evolving subject matter can provide an excuse for avoiding APA rulemaking where the effect of guidance would not pass muster under questions 4-7 in Part I.)

CASES

Community Nutrition Institute v. Young, 818 F.2d 943 (D.C. Cir. 1987)(court vacated FDA determination of an action level for aflatoxin in corn because it should have been subject to notice and comment).

Paralyzed Veteran's of America v. D.C. Arena L.P., 117 F.3d 579 (D.C. Cir. 1997)(Department of Justice interpretation of Americans with Disabilities Act was exempt from notice and comment procedures).

Syncor International v. Shalala, 127 F.3d 90 (D.C. Cir. 1997)(FDA guidance document should have been subject to notice and comment).

Appalachian Power Co. v. EPA, 208 F. 3d 1015 (D.C. Cir. 2000)(Periodic Monitoring Guidance under the Clean Air Act should have been subject to notice and comment).

General Electric Company v. EPA, 290 F.3d 377 (D.C. Cir. 2002)(PCB Risk Assessment Review Guidance should have been subject to notice and comment).

Croplife America v. EPA, 329 F.3d 876 (D.C. Cir. 2003)(EPA directive on use of third-party human studies should have been subject to notice and comment).

Theiss v. Principi, 18 Vet. App. 204 (2004)(VA interpretation of "educational institution" should have been subject to notice and comment).

Erringer v. Thompson, 371 F.3d 625 (9th Cir. 2004)(guidance documents on eligibility for Medicare were not subject to notice and comment).

National Association of Home Builders v. United States Army Corps of Engineers, 417 F.3d 1272 (D.C. Cir. 2005)(Clean Water Act "general permits" subject to notice and comment and other provisions of APA).

Amoco Production Co. v. Watson, 410 F.3d 722 (D.C. Cir. 2005)(letter from the Interior Department regarding calculation of royalty payments was not subject to the APA notice and comment requirements).

The Wilderness Society v. Norton, 434 F.3d 584 (D.C. Cir. 2006)(National Park Service management policies did not create enforceable regulations or modify existing legal rights).

Center for Auto Safety v. National Highway Traffic Safety Administration, 452 F. 3d 798 (D.C. Cir. 2006)(policy guidelines regarding regional recalls did not establish binding rules and were not final reviewable agency actions).

ARTICLES

Robert Anthony, *Interpretive Rules, Policy Statements, Guidance, Manuals and the Like – Should Federal Agencies Use them to Bind the Public?* 41 Duke L. J. 1311 (1992).

Peter Strauss, *The Rulemaking Continuum*, Duke L. J. 1465 (1992).

Ronald Levin, *Nonlegislative Rules and the Administrative Open Mind*, 41 Duke L. J. 1498 (1992).

Robert Anthony, *"Interpretive" Rules, "Legislative" Rules and "Spurious" Rules: Lifting the Smog*, 8 Admin. L.J. Am. U. 1 (1994).

Michael Asimow & Robert Anthony, *A Second Opinion? Inconsistent Interpretive Rules*, 25 Admin. & Reg. L. News 16 (Winter 2000).

Peter Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 Admin. L. Rev. 803, 809 (2001).

William Funk, *A Primer on Nonlegislative Rules*, 53 Admin. L. Rev. 1321 (2001).

William Funk, *When is a "Rule" a Regulation? Marking a Clear Line Between Nonlegislative Rules and Legislative Rules*, 54 Admin. L. Rev. 659 (2002).

Leslie MacRae and Kenneth Nicely, *Break the Rules and Run an Industry: Guidance Manuals More Destructive of the Rule of Law than Bad Accounting*, 11 U. Balt. J. Envtl. L. 1 (2003).