A Path Through the Forest - The Role of Agency Guidance in Developing Regulatory Compliance Programs

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Abstract
Counsel involved in developing regulatory compliance programs know that merely looking at the statute and regulations is not enough. They need to look to multiple sources of information to determine how the agency interprets the laws and regulations, and to understand agency expectations. Agency guidance documents play an important role in obtaining this information. This paper identifies the types of materials available and how they can be used. It also touches on the problems with these materials, including their nonbinding nature, and the benefits of using them.

1.0 Introduction
In 2000, Judge Raymond Randolph issued a lament that resonates with regulatory counsel. Deciding the case of Appalachian Power Company v Environmental Protection Agency1, Judge Randolph wrote:

“The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in the regulations. One guidance document may yield another and then another and so on. Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations. With the advent of the Internet, the agency does not need these official publications to ensure widespread circulation; it can inform those affected simply by posting its new guidance or memoranda or policy statement on its web site. An agency operating in this way gains a large advantage.”

This description forcefully states one of the quandaries facing regulatory counsel as they seek to develop compliance programs to address United States regulatory requirements. In order to understand the regulatory requirements applicable to their clients, and best advise them how to proceed, counsel seek ways to look beyond the wording of the statutes and regulations. Even a brief foray into this area reveals a host of materials that counsel can use to obtain insight into agency expectations.

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Legal commentators have spent almost all of their efforts addressing the questions of legitimacy and enforceability for these materials\(^2\). However, the reality is that these types of materials fulfil a number of needs. In some cases, as reflected by materials such as policy statements, training programs and procedure manuals, they are an inherent necessity for agency operation. In other cases, such as opinion letters and FAQ documents, they reflect agency efforts to respond to requests for assistance from the regulated entities, and even their own staff. Ultimately, whether sanctioned or not, they probably are here to stay.

This article will look at these materials from the perspective of their role in helping to develop programs to comply with United States regulatory requirements. It will provide a brief overview of the statutory structure, in order to place them in context. It will then identify the types of materials that are available, and briefly touch on ways they can be used. Finally, the article will discuss the benefits of having these materials available.

### 2.0 What are guidance documents?

First, a bit of definition is in order. In the regulatory context, the term ‘guidance document’ tends to be used in different ways and in various contexts. For example, at a formal level, in 2007 the Federal Office of Management and Budget issued a bulletin describing agency ‘Good Guidance Practices’. That bulletin defined a ‘guidance document’ as ‘an agency statement of general applicability and future effect…that sets forth a policy on a statutory, regulatory or technical issue or an interpretation of a statutory or regulatory issue’\(^3\).

Informally, however, the term is broadly used to refer generically to a broad range of materials that provide (1) insight into how an agency intends to interpret and apply the statutory and regulatory requirements or (2) assistance in addressing the regulatory requirements. The first category includes, for example, materials that explain how the agency defines specific terms, resolves ambiguities, or applies listed criteria. The second category includes materials that help regulated entities establish compliance programs, such as descriptions of best practices, samples of completed forms, and training programs. While some of these materials may have been opened up for public comment, many others are developed solely within the agency.

This article uses the term in its informal sense. Thus a guidance document includes any material that falls within either of the two categories described above, regardless of its nature or source. This approach allows a wider view of the range of materials available, and captures categories of material that otherwise would be excluded.

### 3.0 The underlying legal structures

This article is not about the agency rulemaking process. However, in order to understand how these materials fit into the compliance structure, it is helpful to first understand the underlying legal structure.

In the United States\(^4\), this inquiry begins with the ‘APA’, the Federal Administrative Procedure Act\(^5\). One of the key elements of the APA is the requirement for regulations to

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\(^2\) See, for example, Robert A. Anthony, ‘Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like – Should Federal Agencies Use them to Bind the Public’, Duke Law Journal, Volume 41, Page 1311 (June 1992), which provides an excellent listing of the impact of agency actions taken based on guidance documents.

\(^3\) Federal Register, Volume 72, Number 16, January 25, 2007 at Page 3439.

\(^4\) It is worth noting here that in January, 2013, the European Parliament adopted a resolution calling for a regulation on a European Law of Administrative Procedure.

\(^5\) The APA can be found at 5 USC 501, et. seq.
be developed and adopted using a ‘notice and comment’ rulemaking process\(^6\). The process is simply summarized as containing three elements.

- First, prior to adopting any regulation, the agency must publish notice of the proposed rule and describe in some form its authority to adopt the rule, the reasons for the rule, and what it intends to accomplish. In some cases, the agency must also discuss the costs and benefits of the rule and explain why it is the ‘least burdensome approach’ to addressing the issues the rule is targeting.
- Second, the agency must provide an opportunity for the affected members of the public to comment on the proposal. Comments can be in writing or the agency can provide an opportunity to present them orally at one or more public hearings. In each case, the agency must provide sufficient time for the public to evaluate the proposal and submit their comments.
- Third, the agency must actually review the comments and respond to them when it adopts the final rule. Where it has rejected recommendations, it must explain why the recommendation was not acceptable.

Regulations, once adopted, have the force of law. Consequently, this three step process tries to ensure that regulations are adopted with a level of scrutiny and debate that is equivalent to the legislative process.

In the United States, regulations adopted through this process also receive an additional benefit – deference by the courts. Broadly stated, the courts have stated that, as a general rule, when evaluating regulations and their interpretation they will defer to the agency’s decisions\(^7\). The corollary to this rule, of course, is that agency interpretations outside of the notice and comment process will receive much less deference and much closer scrutiny.

While notice and comment rulemaking is the basic requirement of the APA, it does contain some important exceptions. In particular, the APA excludes from the notice and comment process ‘interpretive rules’, ‘general statements of policy’, and ‘rules of agency organization, procedure, or practice’. The interpretation and application of these exceptions has been the subject of numerous court decisions and legal commentaries, since they provide agencies with an opportunity to legitimately adopt materials without going through the notice and comment process. Many, but not all, of the materials discussed in this article fall within these categories, and while the debate around their use is interesting from a theoretical perspective, in practical terms the availability of these materials is critical to developing compliance programs.

### 4.0 Types of guidance

The list of guidance materials provided below identifies the most common and useful forms of guidance. It is not definitive, and certainly there are other sources of information available\(^8\). However, the list should provide counsel with a good starting point.

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\(^6\) 5 USC Section 553

\(^7\) See Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). The subject of deference is outside of the scope of this article; however a quick search by anyone interested in the subject will turn up numerous court cases and journal articles discussing the concept and its application

\(^8\) Obviously, there are also many sources external to the agency, such as former agency personnel acting as consultants, materials prepared by trade associations and bar associations, and colleagues who have addressed similar issues.
4.1 Notice and comment rulemaking supporting materials

As the discussion above notes, agencies engaged in notice and comment rulemaking must provide a fair amount of information about the proposed and final rule. This information is not part of the regulation and consequently qualifies as guidance. However, this material, which can cover several hundred pages, often provides detailed explanations of the types of technical and policy choices the agency made when drafting the proposed rule and responding to comments. Counsel seeking to develop a compliance program for a new regulation or determine what changes need to be made to a compliance program after significant modifications to an existing regulation, should consult these materials.

4.2 Formal guidance documents

These materials are the ones that typically fall under the formal definition of ‘guidance document’ discussed above. Often they are specifically called ‘guidance’ or some similar equivalent term. Guidance documents may be issued unilaterally by the agency, but often agencies will accept comments in some form, although the opportunity to comment may not come until after the document has been issued.

Guidance documents are extremely useful. While some merely paraphrase the regulations; others are much more detailed, providing a great deal of information about agency expectations and how to comply with specific regulatory requirements. In highly technical areas they frequently address the underlying scientific issues and provide clear directions for presenting technical information to the agency.

They do, however, raise a number of problems. In many cases, in an attempt to avoid running afoul of the APA’s notice and comment requirements, the agency will designate these documents as ‘nonbinding’ or ‘advisory only’, raising the question of whether there is any safety in following them. In addition, the agency may designate the documents as ‘reflecting current thinking’, keeping the door open to adopting new or alternative approaches, sometimes without warning or notice.

The agency may also say that alternative forms of compliance are acceptable. However, along with this statement the agency may take the position, or state specifically, that the regulated entity carries the burden of showing that its alternative form of compliance is at least as good as the agency’s suggested actions. This burden can be substantial when facing regulators who have been trained to expect to see the guidance document recommendations followed and may not have been provided with tools to evaluate alternative approaches. In addition, in some cases the regulated entity may not be able to defend its alternative approach until the agency takes enforcement action. These factors tend to discourage the use of alternative forms of compliance, driving companies toward the agency’s ‘preferred’ methods of compliance.

Despite the problems with the materials, they usually represent the best source of information for counsel to use. When establishing a compliance program, counsel should look for these types of materials immediately. Understanding what is available is a critical first step.

4.3 ‘Frequently Asked Questions’

From time to time, agencies may issue documents designated as responses to ‘frequently asked questions’ (or ‘FAQs’). These materials represent compendia of agency responses to the most common questions it receives. This approach benefits the agency by eliminating the need to repeatedly answer the same questions. It benefits counsel by providing insight into how the agency approaches specific factual questions.
In some cases, what appear to be FAQs are actually agency efforts to present formal guidance documents in a more informal question and answer format. Usually, the nature of the information presented will indicate the agency is following this approach or the agency itself will clarify somewhere in the materials that it is following this approach. Either way, the materials are useful.

4.4 Procedure manuals
Internal agency procedure manuals are a key source of informal guidance. These manuals typically are prepared to provide guidance to agency staff on how to address various aspects of their responsibilities. The scope of information can range from instructions on how to prepare expense reports, to summaries of the law prepared by agency legal staff, to specific steps to be followed in taking actions such as evaluating permit applications, conducting inspections, or referring matters for enforcement action. They may also identify issues that may come up and identify the laws and regulations that address these issues.

These materials offer valuable information on how to approach compliance. Companies can use manuals that guide agency inspectors to see how the inspector has been instructed and trained to approach the inspection and what types of information the inspector will be looking for. The company can then use this information to conduct its own focused compliance audit. Similarly, a manual providing instructions on how to review and evaluate an application for a permit or license may list the specific steps to be followed, the types of information the evaluator needs to have in the file, and how the reviewer is to evaluate the information provided. The company can use this information to double check its application before submission to make sure it is complete and addresses all of the reviewer’s expectations. The company can also use the manual to obtain context for questions the reviewer may be asking.

4.5 Compliance policy guides
Compliance Policy Guides can take various forms, but typically are short statements of the agency’s policy decisions regarding the interpretation of specific portions of the laws and regulations. They may be freestanding compendia or set out in internal memoranda issued by agency management. Often they clarify elements of the law or regulation that are vaguely worded or subject to multiple interpretations. Since they are narrowly focused, they tend to be most useful when reviewed in the context of other materials on the same subject.

4.6 Internal and interagency memoranda
As was noted above, the APA specifically exempts communications within and between agencies from the notice and comment process. They can include communications from the head of the agency to agency staff setting out broad policy priorities, goals, and objectives. They can also include communications from department heads to their staff identifying how to address specific issues that have come up recently. Finally, communications between staff of two different agencies can offer insight into how the agencies have decided to allocate responsibilities when both of them have jurisdiction over a subject.

4.7 Training materials
Like newly hired company staff, newly hired agency staff need training in how to perform their jobs. In addition, experienced staff need refresher training as well as training on new requirements and changes in the rules. Agency training materials, like procedure manuals, offer insight into how the agency is telling its staff to interpret and apply the law and regulations. In addition, they can be used to develop materials for companies to use in providing training to their own employees. It is worth noting here
that many agencies put on training programs that are open to the public. Counsel should be aware of these programs and use them as part of the company’s own training activities.

4.8 Opinion letters
Agency opinion letters contain agency responses to specific questions they have been asked. Unlike the other materials discussed, which tend to be generic, opinion letters offer useful insight into how the agency has addressed specific situations and fact patterns. They may not be binding on the agency beyond the specific party and fact pattern involved, but they do offer insight into how the agency approaches specific problems and applies the law and regulations to specific facts. They can also be used by counsel considering asking the agency for an opinion to see how others have approached similar subjects and how the agency has responded.

4.9 Adjudicatory rulings
Adjudicatory rulings, like opinion letters, show how the agency applies the law and regulations to the facts. Under the APA, these proceedings usually take place before an independent administrative law judge. As with any adjudicative proceeding, they require the agency to articulate a clear position regarding application of the law to the facts of the specific case. Consequently, they offer additional insight into agency thinking. In addition, the ruling by the administrative law judge offers insight into how an independent reviewer interprets the law and regulations, although that ruling may have limited precedential effect.

4.10 Speeches and speaker’s notes
Agency officials are popular invitees to speak at a variety of events. These may be in their ‘official’ capacity, such as testimony before a Congressional committee, or in a more ‘informal’ setting, such as industry conferences and educational programs. When speaking in informal settings, agency officials usually begin by stating that their remarks represent their opinions only and not those of the agency. Nevertheless, it is unlikely that they are going to deliberately misstate the positions of the agency and, as with other forms of communication, their statements offer insight at least into what their point of view may be. This information can be particularly useful if the speaker holds a senior position in a division or function that the company regularly deals with. For example, statements by a regional director about inspectional priorities have more value to companies located in that region than the usually generally worded statements of more senior officials.

4.11 Enforcement proceeding materials
Many agencies have at least some authority to initiate internal enforcement actions against companies who are out of compliance. These proceedings may be as limited as simply assessing penalties, or as complex as involving adjudicatory hearings before administrative law judges. Regardless of the nature of the proceedings, how and when agencies bring them provides important information about agency expectations.

While some violations routinely trigger enforcement proceedings, most agencies have limited resources, actively seek voluntary compliance, and are willing to work with companies who clearly demonstrate their intent to fix identified problems and operate in compliance with the laws. Therefore, the agency initiates proceedings only when it either sees a lack of good faith effort or the level of noncompliance is so egregious that the agency has no choice but to initiate proceedings. Looking at past enforcement actions can tell companies where these lines are, as well as what types of penalties the agency would seek for various types of noncompliance.
In addition, enforcement proceedings, like criminal prosecution, are intended in part to deter future behavior by showing the effects of noncompliance. Consequently, in some contexts enforcement proceedings are the best source of information about the agency’s true expectations, and, more importantly, where the limits of acceptable noncompliance are located. This information can be used together with the company’s own willingness to accept risk to help decide how compliance programs will be structured and what resources are needed to establish and maintain them.

4.12 Court filings
A final source of information comes from agency statements in court proceedings. These proceedings may be part of an enforcement action or represent challenges to agency demands for action initiated by regulated entities. Documents such as charging papers, briefs, evidence submitted, and settlement agreements can provide insight into how the agency interprets and applies the law and regulations, and approaches the enforcement process.

Unlike the majority of the sources of guidance discussed above, agency statements in legal proceedings offer the closest possible approach to a fixed position. Whether the agency is providing the statements in its own proceeding or as amicus, it is telling the court what it believes is the proper interpretation of the laws and regulations. If the court adopts the position stated, it becomes difficult for the agency to take a different position in a later proceeding without good rationale.

5.0 Benefits and Risks of guidance
The use of guidance offers a number of benefits to both the agency and the regulated community. One often mentioned benefit is that the use of guidance documents allows agencies to address new developments and social and technological changes quickly and at a reasonable cost. Considering the speed at which technology moves at times, it would be impossible for agencies to keep up with the changing environment if they had to go through notice and comment rulemaking to address each change.

Possibly a more compelling argument for the benefits of guidance is its ability to address specific situations with more clarity. Laws and regulations by design are general. They prohibit or require certain behavior, but don’t often address whether specific acts fall within or outside what is required or prohibited. This problem becomes particularly acute when the agency’s regulations create performance standards rather than setting out command and control requirements. Command and control regulations tell the regulated entity specifically what to do and what the acceptable variations are. They offer specificity and certainty. A regulated entity knows that if it does what the rule says, it will be in compliance.

Performance standards, on the other hand, set out general, and often broadly stated goals to be accomplished. Performance standards offer regulated entities the benefit of being able to choose the means and method for accomplishing the goal in light of their own specific industry and capabilities. With this benefit comes the risk that the agency will find that the actions taken do not or will not accomplish the stated goal. This risk is compounded if the entity’s first indication that it is not in compliance is the initiation of an enforcement action. While some companies are comfortable with this level of uncertainty and the risk inherent in it; others balk and ask for help in determining what is needed.

Agency guidance meets this need by allowing the agency to address specific scenarios and specific situations. Opinion letters allow agencies to respond to specific questions regarding compliance. Frequently asked questions’ documents allow agencies to compile commonly asked questions into a package that companies can access easily. Guidance
documents allow agencies to address specific situations and discuss specific compliance mechanisms in more detail than a regulatory statement would allow. They also allow the agency to quickly address changes in technology.

Treating enforcement actions, adjudicatory proceedings, and agency statements in briefs and litigation filings, as guidance, falls within this scope. The information provided by these activities is part of the mosaic of information available to obtain insight into agency expectations.

Guidance documents offer one additional benefit to agencies, the ability to experiment. Laws and regulations, even if the regulations are performance standards, lock the agency into a particular position. If rulemaking is more expensive and time consuming than adopting guidance, then modifying the rules is equally as expensive and time consuming.

Guidance, on the other hand, offers the agency much more opportunity to experiment by offering new concerns, ideas, and approaches. Agency officials can proffer these ideas in speeches and at seminars, and see what type of reaction they receive. Procedure manuals and training materials can be issued with the direction of having agency personnel approach issues from a new perspective and see how the regulated community responds. Enforcement officials can offer these ideas as arguments in specific cases and see whether judges accept them as valid interpretations of the law and regulations.

The quotation above from the Appalachian Power case, as well as remarks by numerous commentators, suggests that agency guidance should be looked at with scepticism and suspicion. There is a fertile kernel of truth to that point of view. In order to develop strong compliance programs, regulated entities need consistency and predictability. Any situation where an agency can change its position and the obligations of the regulated community without warning or discussion should be subject to challenge. This concern is especially true when the change is ‘announced’ through enforcement proceedings.

However, the Appalachian Power case does warn us that reliance on reliance on guidance documents carries a number of risks. Rather than fixing problems with the underlying regulations, the agency may simply issue new documents attempting to clarify or explain the rules. All of these materials are subject to change virtually at the whim of the agency, with little or no notice. In addition, their application in specific situation depends on who is involved. Changes in agency management and personnel can result in a change in how the rules are applied even if the materials themselves have not been changed.

Consequently, use of guidance documents is only part of the process. Counsel needs to monitor agency activities on an ongoing basis, watching for changes in agency positions and personnel that may place the viability of the guidance in question.

6.0 Conclusion

Obtaining the knowledge necessary to establish a robust compliance program can be challenging at best. Agency guidance documents are one set of tools that can be used to develop this information. By using an array of materials, counsel can develop a clearer picture of how the agency intends to interpret and enforce the laws that create it and the regulations it has adopted to implement those laws. Guidance documents do suffer from a number of problems. These problems include their often unilateral development by the agency without public input and their potentially nonbinding nature. Nevertheless, the benefits they offer clearly outweigh these concerns.
7.0 References


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Jack Sorokin has had extensive experience as regulatory affairs counsel, most recently as Deputy General Counsel for Beckman Coulter, Inc., a leading international manufacturer and marketer of biomedical testing instrument systems. His practice covered the range of regulatory issues including medical device, environmental, occupational safety and health, hazardous materials, controlled substance and transportation. His practice also included corporate law and governance, SEC compliance, finance, risk management, supply chain, manufacturing, real estate, procurement and import/export law. He is currently teaching, writing and working as contract Counsel. He may be contacted by email at jesorokin@gmail.com.