June 10, 2002

OIRA REVIEW OF
AGENCY DRAFT INFORMATION QUALITY GUIDELINES

Additional Quotations of
Proposed Agency Provisions Organized by Topic

I. SCOPE OF AGENCY GUIDELINES.

Use of Statements of "Intent" to Delimit Scope. SSA and NSF use "intent" to indicate what is covered: e.g., "statistical or actuarial information *prepared for* public dissemination; reports, studies and summaries *prepared to inform* the public" (SSA, 2 of 2; NSF, 1).

Justice uses intent to exempt "procedural, operational, policy and internal manuals *prepared for* the management and operations of DOJ that are not primarily intended for public dissemination" (Justice, 3).

Exemption for Press Releases. FDA/HHS exempts press releases "unless they contain new substantive information not covered by previous information dissemination" (FDA/HHS, 3). EPA adds a different qualifier: "These guidelines do not apply to press releases, fact sheets, press conferences or similar communications in any medium that announce, support the announcement or give public notice of information EPA has disseminated elsewhere" (EPA, 15).

State also limits the scope of the press release exemption to apply to distributions of information or other materials that are "distributed to the press as a summary of a recent event or Department action" (State, 6).

Exemption for Public Filings.

> Distribution of information in public filings: Public filings include information submitted to EPA by any individual or person. ... *The guidelines do not apply where EPA distributes this information simply to provide the public with quicker and easier access to materials submitted to EPA that are publicly available.* This will generally be the case if EPA has not authored the filings, and is not distributing the information in a manner that suggests that EPA endorses or adopts the information, and EPA does not indicate in its distribution that it is using or proposing to use the information to formulate or support a regulation, guidance, or other Agency decision or position (EPA, 16).

Exclusion For Agency Employed Scientist, Grantee, or Contractor.

> A Component does not initiate the dissemination of information when a Component-employed scientist or Component grantee or contractor publishes and communicates his research findings in the same manner as his academic colleagues, even if the Component retains ownership or other intellectual property rights because the Component paid for the research. To avoid confusion regarding whether the Component agrees with the information, the researcher should include an appropriate disclaimer ... that the views expressed are his own and do not necessarily reflect the views of the Component. In contrast ..., if the Component has directed a third party to disseminate information or retains the authority to review and approve the information upon release, then the Component has sponsored the dissemination of the information (DOD, 4).

> Distribution of information by federal employees and recipients of grants, cooperative agreements, and contracts: These guidelines do not apply to information distributed by recipients of contracts, grants, or cooperative agreements, unless the information is disseminated on EPA's behalf, as when EPA specifically directs or approves the dissemination. These guidelines do not apply to distribution of any type of research by federal employees and recipients of EPA grants, cooperative agreements, or contracts, where the researcher (not EPA) decides whether and how to communicate and publish the research, does so in the same manner as his or her academic colleagues, and distributes the research in a manner that indicates that the research does not represent EPA's official position (for example, by including an appropriate disclaimer). Distribution of research in this manner is not subject to these guidelines even if EPA retains ownership or other intellectual property rights because the Federal government paid for the research (EPA, 15-16).

Exemption for Subpoenas or Adjudicative Processes.

FMC explains this exemption succinctly:

> Excluded categories include: ... Subpoenas or adjudicative processes, including Commission orders, opinions, amicus and other briefs. *Adjudicative processes also include factual allegations by the staff during the investigative and litigation phases of cases brought by the Commission's Bureau of Enforcement.* Because there are well-established procedural safeguards and rights to address the quality of factual allegations and adjudicatory decisions, and to provide persons with an opportunity to contest decisions, these guidelines do not impose any additional requirements on the Commission during adjudicative proceedings and do not provide parties to such adjudicative proceedings any additional rights of challenge or appeal (FMC, 7).

II. COVERAGE OF "THIRD-PARTY" INFORMATION UNDER THE GUIDELINES.

Agencies included "third-party" information under the guidelines in a variety of contexts:

> Component dissemination of information prepared by an outside party *in a matter that reasonably suggests* the Component agrees with the information, renders Component dissemination of the information subject to these guidelines (DOD, 4).

> Section III mentions an important concept that may not be immediately obvious to persons reading the OMB guidelines for the first time. As Dr. John Graham, Director [sic: Administrator] of the OMB Office of Information and Regulatory Affairs (OIRA) and others have pointed out in meetings about the information quality guidelines, the standards for data quality that apply directly to Federal agencies also apply, at least indirectly, to outside parties who supply information to the Department. If the Department is to rely on technical, scientific, or economic information submitted by, for example, a commenter to a proposed rule, that information would need to meet appropriate standards of objectivity and utility. Numbers submitted by a commenter as the basis for a regulatory decision – which the Department would necessarily disseminate as part of a rulemaking issuance – should meet data quality standards no less than in the case of information the Department itself generates (DOT, 3).

> The standards of these guidelines apply not only to information that DOT generates, but also to information that other parties provide to DOT, if the other parties seek to have the Department rely upon or disseminate this information or the Department decides to do so (DOT, 8).

> EPA disseminates information to the public for purposes of these guidelines when EPA initiates or sponsors the distribution of information to the public. EPA initiates a distribution of information if EPA prepares the information and distributes it to support or represent EPA's viewpoint, to formulate or support a regulation, guidance, or other Agency decision or position. EPA initiates a distribution of information if EPA distributes information prepared or submitted by an outside party in a manner that reasonably suggests that EPA endorses or agrees with it, if EPA indicates in its distribution that the information supports or represents EPA's viewpoint, or if EPA in its distribution proposes to use or uses the information to formulate or support a regulation, guidance, policy, or other Agency decision or position (EPA, 14).

> **What happens if information is initially not covered by these guidelines, but EPA subsequently disseminates it to the public?** If a particular distribution of information is not covered by these guidelines, the guidelines may still apply to a subsequent distribution of the information in which EPA adopts, endorses or uses the information to formulate or support a regulation, guidance, or other Agency decision or position. For example, if EPA simply makes a public filing (such as facility data required by regulation) available to the public, these guidelines would not apply to that distribution of information. However, if EPA later includes

the data in a background document in support of a rulemaking, these guidelines would apply to that later dissemination of the information in that document (EPA, 17).

III. AGENCY COMMITMENT TO INFORMATION QUALITY STANDARDS.

Performance Standards. Some agency guidelines adopted performance standards and a commitment to meeting them. For example, The Office of Special Counsel clearly states information quality standards as performance goals:

> Information *should adhere* to a basic standard of quality ... Information *should be* objective in substance and presentation ... Information *should be* responsive to its intended users ... The integrity of information *should be* protected (67 FR 21318, April 30, 2002).

Justice draft guidelines adopt the provision from the OMB guidelines relating to performance standards (III.1).

> Overall, agencies shall adopt a basic standard of quality (including objectivity, utility, and integrity) and will take appropriate steps to incorporate information quality criteria into agency information dissemination practices ... A basic standard of quality will be ensured and established for all information prior to its dissemination (Justice 1-2, 3).

Then the Justice draft sets forth a standard and commits the DOJ components to reaching it:

> DOJ components *will ensure* disseminated information [meets the standard of objectivity] ... DOJ components *will ensure* information [meets the standard of integrity] (Justice, 4).

The Small Business Administration combines the approach taken by Justice:

> It is SBA's policy to ensure and maximize the quality, objectivity, utility, and integrity of the information that it disseminates to the public. SBA will take appropriate steps to incorporate information quality criteria into SBA's information dissemination practices, and will ensure the quality of information the agency disseminates in accordance with the standards set forth in these Guidelines. SBA is committed to integrating the principle of information quality into every step of SBA's development of information, including creation, collection, maintenance, and dissemination. SBA will comply with all then-existing legal and policy rules, regulations, directives, and guidance at every step of the process (SBA, 4).

The Federal Energy Regulatory Commission similarly sets standards and commits to reach them:

> The Commission *strives to present* information to the public in an accurate, clear, complete,

and unbiased manner. ... The Commission also *aims to provide* information that is accurate, reliable and unbiased (FERC 5, 6).

Core Definition of "Objectivity". The following are concise, accurate summaries of the heart of the OMB definition of "objectivity":

> Objectivity involves two distinct elements; presentation and substance:
>
> (A) Presentation:
> Disseminate information in an accurate, clear, complete, and unbiased manner. This involves presenting information within a proper context.
>
> (B) Substance:
> Focus on ensuring accurate, reliable, and unbiased information.
> In a scientific, financial, or statistical context, generate the original and supporting data, and develop the analytic results, using sound statistical and research methods (Treasury, 3).

> Objectivity means ensuring that information is accurate, reliable and unbiased and that information is presented in an accurate, clear, complete and unbiased manner (ERS/USDA, 7).

> "Objectivity" focuses on whether the disseminated information is being presented in an accurate, clear, complete and unbiased manner and as a matter of substance, is accurate, reliable, and unbiased (DOD, 3).

"Influential" and "Reproducibility". DOT has a carefully considered discussion of influential. Some highlights are:

> DOT emphasizes that to be influential, information must have a clear and substantial impact. A clear and substantial impact, first of all, is one that the agency is firmly convinced has a high probability of occurring ... In rulemaking, influential information is scientific, financial, or statistical information that can reasonably be regarded outcome determinative with respect to one or more key issues in a significant rulemaking, as that term is defined in Executive Order 12886 ... In non-rulemaking contexts, DOT will consider two factors – breadth and intensity – in determining whether information is influential ... DOT organizations should consider whether the information affects a broad range of parties ... DOT organizations will also consider whether the information has an intense impact. Information that has a low cost or modest impact on affected parties is less likely to be influential than information that can have a very costly or crucial impact. In considering whether information has a high-intensity impact, DOT organizations will establish and use as a benchmark the $100 million figure used to determine whether a rule is economically significant (DOT, 20-21).

Justice also has a well-considered definition of influential:

When information is defined as influential there is an added level of scrutiny afforded this information, to include the need to ensure it is reproducible. At DOJ, influential information is that which is expected to have a genuinely clear and substantial impact at the national level, on major public and private policy decisions as they relate to federal justice issues. The accuracy of this information is significant due to the critical nature of these decisions. A clear and substantial impact, first of all, is one that the agency is firmly convinced has a high probability of occurring. If it is merely arguable that an impact will occur, or if it is a close judgment call, then the impact is probably not clear and substantial. To determine that there is a clear and substantial impact, the agency must have greater certainty than would be the case for many ordinary factual determinations. The impact must be on "important" public policy or private sector decisions that are expected to occur. Even if information has a clear and substantial impact, it is not influential if the impact is not on a public or private decision that is important to policy, economic, or other decisions ... The "influential" designation is intended to be applied to information sparingly. DOJ components should not designate information products or types of information as influential on a regular or routine basis. Nor should DOJ components actually place an "influential" label in the title page or text of an information product (Justice, 4).

Both State and DOT, in describing "influential", emphasize the causal link between the information itself, and the effect it may have on the policy position involved:

To be considered influential, information must be based on objective and quantifiable data that constitute a principal basis for substantive policy positions adopted by the Department (State, 6).

It should also be noted that the definition applies to "information" itself, not to decisions that the information may support. Even if a decision or action by DOT is itself very important, a particular piece of information supporting it may or may not be "influential" (DOT, 21).

Analysis of Risks to Human Health, Safety and the Environment. FDA adapts the SDWA standards carefully and practically to the kinds of Risk Assessments that FDA conducts.

Some of the influential information that we disseminate is based on an analysis of the risks to the public of certain actions or exposures to hazardous substances. For purposes of this guidance, we are defining risk as the likelihood that injury or damage is or can be caused by a substance, technology, or activity. We use risk analysis (the integration of risk assessment with risk management and risk communication) as a tool to enhance the scientific basis for all of our regulatory decisions.

The OMB Guidelines provide special considerations that must be taken into account in certain risk assessments, those that provide the basis for the dissemination of influential information. The Guidelines state that "With regard to analysis of risks to human health, safety, and the

environment maintained or disseminated by the agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (SDWA) (42 U.S.C. 300g-1(b)(3)(A) and (B))."

The SDWA risk assessment principles are as follows:

1. To the degree that the agency action is based on science, the agency shall use

   a. the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices;

   b. data collected by accepted methods (if reliability of the method and the nature of the decision justify use of the data).

2. In the dissemination of public information about risks, the agency shall ensure that the presentation of information about risk effects is comprehensive, informative, and understandable.

3. In a document made available to the public in support of a regulation, the agency shall specify, to the extent practicable

   a. Each population addressed by any estimate of applicable risk effects;
   b. The expected risk or central estimate of risk for the specific populations affected
   c. Each appropriate upper-bound or lower-bound estimate of risk;
   d. Each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty; and
   e. Peer-reviewed studies known to the agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile the inconsistencies in the scientific data.

Many of our actions are based on scientific experts' judgments using available data, are essentially qualitative, and are generally carried out for non-cancer-causing hazards. Such assessments provide useful answers in most instances that are sufficient for regulatory purposes, and much more elaborate, quantitative estimates extrapolating beyond the data are unnecessary. For example, we may issue regulations on submission requirements for product approval applications, electronic submission of product labeling, or periodic reporting by manufacturers of adverse events from drugs; devices; and biologics, including blood, vaccines, and tissues. Although we analyze the economic costs of the regulations and consider alternatives, regulations like these do not lend themselves to the types of quantitative risk assessments contemplated by the Safe Drinking Water Act principles.

Other actions are based on research and supporting data that are generated outside FDA. For example, most product approval actions are based on scientific studies conducted by sponsors seeking marketing approval in accordance with our regulations and guidance documents. Our regulations and guidance documents describe sound scientific practices for conducting human and animal studies of medical products and analyzing the resulting data. Most information in these studies is considered confidential commercial information and is closely held by the sponsors. As a result, formal peer-review of the data is rare. However, for certain drug approval applications, the safety and/or effectiveness information is presented to scientific advisory committees for recommendations. Evaluations of food safety and nutritional data are also presented to scientific advisory committees.

As a result, we have adapted the general principles for risk assessments from the SDWA to fit these situations. The principles we intend to apply to risk assessments involving the dissemination of influential information affecting product approval actions or regulations that do not lend themselves to quantitative risk assessment are as follows:

1. The Agency will use

   a. the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer reviewed studies when available; and
   b. data collected by accepted methods (if reliability of the method and the nature of the decision justify use of the data).

2. In the dissemination of public information about risks, the Agency will ensure that the presentation of information about risk effects is comprehensive, informative, and understandable.

In situations requiring a quantitative risk assessment, we generally follow basic risk assessment principles in the NAS paradigm of 1983. Our needs for quantitative risk assessments range over a wide variety of hazards including physical hazards encountered during use of a medical device, food chemical residues, and antimicrobial resistance genes in bacteria. Thus, we also ascribe to the statement from NAS when it revisited the risk assessment process in 1994 (*Science and Judgment in Risk Assessment*, NAS 1994): "Risk assessment is not a single process, but a systematic approach to organizing and analyzing scientific knowledge and information." In each of the areas we regulate, we apply risk assessment practices to the specific task that are widely accepted among relevant domestic and international public health agencies.

For quantitative risk assessments in support of the dissemination of influential information, FDA intends to apply the following principles:

1. The agency will use-

a. the best available science and supporting studies conducted in accordance with sound and objective scientific practices;

b. data collected by accepted methods (if reliability of the method and the nature of the decision justifies use of the data).

2. In the dissemination of public information about health risks, the agency shall ensure that the presentation of information is comprehensive, informative, and understandable, within the context of its intended purpose.

3. In a risk assessment document made available to the public, the agency shall specify, to the extent practicable-

a. Each population addressed by any estimate of applicable effects;
b. The expected or central estimate of risk for the specific populations affected;
c. Each appropriate upper-bound and/or lower-bound risk estimate;
d. Data gaps and other significant uncertainties identified in the process of the risk assessment and the studies that would assist in reducing the data gaps; and
e. Additional studies not used to produce the risk estimate that support or fail to support the findings of the assessment and the rationale of why they were not used (HHS/FDA, 18-20).

IV. QUALITY INTEGRAL TO CREATION AND COLLECTION OF INFORMATION.

Labor and USDA state the general principle extremely clearly:

> The quality assurance process should begin at the inception of the product development process (Labor, 5).
>
> USDA agencies and offices will review the quality (including the objectivity, utility, and integrity) of information before it is disseminated and treat information quality as integral to every step of their development of information, including creation, collection, maintenance, and dissemination (USDA, 3).

The Small Business Administration explicitly included "information development", "information acquisition", and "information maintenance" within the scope of its information quality guidelines:

> When SBA *develops information*, it will use its enterprise architecture as a guide in building

the groundwork for the information. This enterprise architecture will help define the goals for the information, information sharing requirements, original and supporting data needs, and all the applications for the information, among other things. SBA will determine and document all requirements for the information (SBA, 4).

At the *information acquisition stage*, SBA will remain cognizant of potential problems with information quality, including accuracy, currency, and completeness. Wherever possible during the information acquisition process, SBA will verify (assess completeness, accuracy, consistency, currency, timeliness) and validate (assess whether the data are appropriate for the measures it was collected to show) the data it collects, and scrub such data to correct problems. SBA will use lessons learned from this process to improve its information acquisition procedures. SBA also will document limitations on data and other information as a result of problems discovered during the information acquisition stage that SBA could not correct before it disseminates the information (SBA, 4).

SBA will make every effort, within SBA's available resources, to improve the *information it maintains*, including its data systems or processes. SBA will encourage feedback from both internal and external sources on the quality of SBA's information, and will consider making changes to its information development and acquisition procedures to correct errors and other problems. SBA will conduct information quality assessments, including reviews and inspections of data, comparisons with other sources of similar data, and verification and validation of information and data. SBA also will take steps to ensure that the information SBA maintains remains secure from unauthorized access, revision, falsification, or corruption (SBA, 5).

V. ADMINISTRATIVE MECHANISM TO ADDRESS PUBLIC COMPLAINTS.

Applicable Standards. It is important that the administrative mechanism to address public complaints point out that agency failure to comply with either the OMB or the agency information quality standards can serve as a basis for complaint. For example, "ERS has developed administrative mechanisms to allow affected persons to seek and obtain correction of information disseminated ... that does not comply with OMB, USDA, or ERS Information Quality Guidelines" (ERS/USDA, 14). By citing the OMB, department, and departmental component's guidelines, ERS assures compliance with all of the applicable guidelines and this provision in its guidelines is consistent with the OMB guidelines.

"Affected Persons". HHS and its components ask the complainant to "describe how the person submitting the complaint is affected by the information error" (HHS, 13). SEC invites the complainant to identify the perceived affect – "an explanation of how the requestor is an affected person with regard to those facts or data" (SEC, 7).

SSA and FERC prevent the word "affected" from having any limiting effect by not using it. SSA and

FERC make no mention of affected persons in their complaint procedures, and do not require the complainant to explain how he is affected (*see*, SSA, 1; FERC, 8).

Information Provided to the Agency. HHS encourages complainants to provide needed detail. "Requests for correction that are specific and provide evidence to support the need for correction will enable the agency to provide a satisfactory response" (HHS, 12).

DOT takes the same approach:

> DOT may be unable to process, in a timely fashion or at all, requests that omit one or more of the requested elements. DOT will attempt to contact and work with requesters to obtain additional information when warranted (DOT, 15).

Decision Criteria and Burden of Proof for Resolving Complaints. In the preamble to the OMB guidelines, OMB emphasized the discretion agencies had in deciding how to resolve complaints.

> Overall, OMB does not envision administrative mechanisms that would burden agencies with frivolous claims. Instead, the correction process should serve to address the genuine and valid needs of the agency and its constituents without disrupting agency processes. Agencies, in making their determination of whether or not to correct information, may reject claims made in bad faith or without justification, and are required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved, and explain such practices in their annual fiscal year reports to OMB (66 FR 49721, September 28, 2001).

Justice emphasizes the limits of its obligation:

> After it has completed its review, DOJ will determine whether a correction is warranted, and, if so, what corrective action it will take. Any corrective action will be determined by the nature and timeliness of the information involved and such factors as the significance of the error on the use of the information, the magnitude of the error, and the cost of undertaking a correction. DOJ is not required to change, or in any way alter, the content or status of information simply based on the receipt of a request for correction. The Department need not respond substantively to frivolous or repetitive requests for correction. Nor does the Department have to respond substantively to requests that concern information not covered by the guidelines or from a person whom the information does not affect (Justice, 6).

State articulates the many different ways in which it may respond:

> Subject to applicable law, rules and regulations, corrective measures may include, without limitation, personal contacts via letter or telephone, form letters, press releases or postings on

the Department website to correct a widely disseminated error or address a frequently raised request. Corrective measures, where appropriate, should be designed to provide reasonable notice to affected persons of any corrections made (State, 5).

Labor stresses practical constraints in correcting errors:

> Any structured process would not apply to an agency's archival information or to public filings. Agencies may choose not to respond to complaints about claimed defects that are frivolous or unlikely to have substantial future impact. It may not be in the public interest for agencies to devote significant resources to correcting information where the expenditure of such resources is not, in the agency's view, cost effective in light of the significance of the asserted error, the benefits that are likely to be derived from such a correction, the costs of the correction, and the agency's more pressing priorities and obligations (Labor, 7).

DOT includes economic concerns in its criteria for deciding what and how much to correct:

> The costs and benefits of using a higher quality standard or a more extensive review process will be considered in deciding the appropriate level of review and documentation (DOT,13). When the DOT organization determines that a correction of the information is warranted, revisions/corrections to the information in question will begin as quickly as practicable. However, the Department's budget, resources, and priorities, as well as the complexity of the correction task itself, may result in DOT actually taking this corrective action within a reasonable time after the Department has made the determination that a correction is appropriate (DOT, 18).

DOT plans to make both the complaint and subsequent DOT responses available on the web:

> In the administrative correction process, DOT will make extensive use of the internet accessible DMS. All requests for correction would come, in the first instance, to the DMS, whether electronically or in hard copy. By docketing requests for correction and subsequent DOT responses in the DMS, the Department will ensure the transparency of the request and response process. The DMS will also electronically notify DOT organizations of pending requests. In addition, filing requests with DMS will allow other interested parties to comment about or make requests with respect to an information issue. For example, suppose DOT publishes a study indicating that 75 percent of a certain kind of accident is caused by a component of a motor vehicle. Manufacturers of that component request correction of the study. Alerted to the request by the DMS posting, vehicle manufacturers could respond within 30 days. The Department seeks comment on this process (DOT, 3).

Time Periods for Resolving Complaints and Any Appeals and Notice to the Public.

EPA takes an indirect approach to setting time limits on the filing of any complaints. EPA exempts what it calls outdated or superseded information from being covered by the EPA guidelines:

> The guidelines do not apply to outdated or superseded EPA information that is provided as background information but no longer reflects EPA policy or influences EPA decisions, where EPA indicates (in a disclaimer or otherwise) that the materials are provided as background materials and do not represent EPA's current view (EPA, 15).

An Objective Appeals Mechanism. HHS requires that "the agency official who handles the original complaint will not have responsibility for resolving the appeal" (HHS, 13).

Labor requires that:

> The agency should generally provide that the official conducting the second level review is not the same official that responded to the initial request or from the same office that prepared the information in question. Designated agency officials may consult with other agency or Departmental offices, as the agency may deem appropriate to the resolution of the complaint (Labor, 6).

When Interior agrees with an appeal, it also takes steps to notify the public of its decision by withdrawing the information from the public domain.

> If at the end of the 45-day period, the bureau or office determines that the complaint is without merit, the complainant will be so notified. If at the end of the 45-day period, the bureau or office determines that the complaint has merit, it shall so notify the complainant, the appropriate program or office, and it shall take reasonable steps to withdraw the information from the public domain and from any decision making process in which it is being used. If the bureau or office determines that it will correct challenged information, it will notify the complainant of its intent and the corrective steps it proposes. The bureau or office may determine the schedule and procedure for correcting the challenged information, but may not disseminate the challenged information in any form until it has been corrected. Upon redisseminating corrected information, the bureau or office will provide the complainant with a copy of the corrected information (Interior, 2-3).

VI. MELDING THE STATUTORY REQUIREMENTS OF SECTION 515 INTO THE PROCEDURAL REQUIREMENTS OF OTHER STATUTES.

Treasury stated its position succinctly:

> Certain disseminations of information include a comprehensive public comment process (e.g.,

notices of proposed rulemaking (NPRM), regulatory analyses, and requests for comment on an information collection subject to the Paperwork Reduction Act). The administrative complaint mechanism described in these guidelines does not apply to such documents. Persons questioning information disseminated in such a document must submit comments as directed in that document. An additional complaint and appeal process for information that is already subject to a public comment process is inappropriate and unfair to other public commenters who submitted timely comments (Treasury, 6-7; Commerce took a similar approach, Commerce, 11).

DOT discusses this issue thoroughly:

> [T]here are some circumstances in which there is an existing process to respond to concerns expressed about the DOT's information. The OMB guidelines encourage agencies to make use of existing processes in a flexible way, tailored to their programs. *When there is a sound existing process, (such as a process that provides opportunities for public participation in making an agency decision), DOT organizations are asked not to duplicate that process with a separate request response mechanism.* For example, when an agency issues a notice of proposed rulemaking (NPRM), it typically describes in the preamble the basis for its proposed regulatory provisions, which may include technical or scientific studies and a regulatory evaluation. In so doing, it disseminates these studies or evaluations, within the meaning of these guidelines. The public comment process can, and often does, generate views from interested persons about the soundness of the underlying information. If someone submits a request for correction pertaining to a document cited in an NPRM, DOT would treat it procedurally like a comment to the rulemaking, responding to it in the preamble of the final rule or a subsequent document such as a Supplemental Notice of Proposed Rulemaking (SNPRM), rather than through the separate request response mechanism of these guidelines. The content of the response would address the issues of the document's compliance with the information quality principles of the OMB and DOT guidelines. (DOT could choose to make an earlier correction, if warranted, assuming so doing would not delay the issuance of the final rule.) This approach would also apply to other processes involving a structured opportunity for public participation on a proposed document before a final document is issued, such as a draft environmental impact statement (EIS), an air quality conformity determination, or a Section 4(f) determination under the Department of Transportation Act ...
>
> On the other hand, with respect to new information appearing for the first time in a final rule or EIS, DOT would consider a request for correction. The Department would not stay the final action involved. However, if it appeared that the information that was the subject of the request did not comply with the guidelines, and that, as a result, the final document was materially flawed, DOT would treat the matter as a request for reconsideration. In such cases, the Department would use any already existing mechanisms and procedures to reconsider corrections, such as the process to petition for a new rule or to request a Supplemental EIS.

The submission of a request for correction by itself does not in any way affect the finality of a decision of the Department.

We believe that this approach serves the purposes of the guidelines, affords an opportunity for correction of any material that does not comply with the guidelines, yet does not duplicate effort or interfere with the orderly progress of DOT's work. We seek comment on this approach (DOT, 4-5).

This section concerns requests for correction concerning information on which a DOT organization has sought public comment (e.g., a notice of proposed rulemaking (NPRM), studies cited in an NPRM, a regulatory evaluation or cost-benefit analysis pertaining to the NPRM; a draft environmental impact statement; a proposed policy notice or aviation order on which comment has been sought; a request for comments on an information collection subject to the Paperwork Reduction Act).

The DOT organization's response to the request for correction will normally be incorporated in the next document it issues in the matter concerning which it had sought comment (e.g., in the case of an NPRM, the preamble to the final rule), DOT may choose to provide an earlier response, if doing so is appropriate and will not delay the issuance of the final action in the matter. Once again, the DOT organization will place their response in the DMS. As stated above ... , a DOT organization may reject a request for correction with respect to information in a final document if there was an opportunity for public comment or participation and interested persons could have requested the correction of the information at the proposed stage (DOT, 18).

If there is an existing process for reconsidering a particular sort of information disseminated by DOT, the DOT organization will make use of that process. For example, if the information relates to a final rule a DOT organization has issued, and the DOT organization has an existing process for handling requests for the reconsideration of a final rule, the DOT organization would use that process. If the information relates to a final EIS, the DOT organization may handle the request as though it were a request for a Supplemental EIS (DOT, 19).

Labor included this discussion with its public notice of the complaint mechanism:

This process is not intended to substitute for other legally authorized processes, such as the Privacy Act or the rulemaking processes. Concerns regarding information in a rulemaking must be presented in the rulemaking in accordance with the rulemaking's procedures. ... In deciding how to handle complaints, agencies should be especially mindful of their legal obligations, program priorities, resource constraints, and their duty to use resources efficiently. For example, agencies have important responsibilities to issue rules and provide compliance guidance to the public. Agencies must administer the complaint and appeal process consistent

with these obligations and their responsibilities to carry them out in an expeditious manner (Labor, 6-7).

DOT will reject a request for correction of information that could have been raised at the proposed rule stage:

> With respect to information in a final rule, final environmental impact statement, or other final document on which there was an opportunity for public comment or participation, could interested persons have requested the correction of the information at the proposed stage? If the DOT organization determines that the answer to [this] Question ... is "yes," DOT will reject your request (DOT, 17).