I. Federal Agencies Compliance with DQA’s Pre-dissemination Review Requirements

The Office of Management and Budget’s (OMB) government-wide data quality guidelines, implementing the DQA, requires that agencies establish a pre-dissemination review process to “substantiate the quality of the information it [the agency] has disseminated....” In discussing the need for the pre-dissemination review process, OMB explains, “Agencies shall treat information quality as integral to every step of an agency’s development of information, including creation, collection, maintenance, and dissemination.” Thus, the pre-dissemination review process is far more than a simple tick-list of steps that are applied to existing data to determine if it is ready for release. The pre-dissemination review is an essential quality assurance process that takes place throughout the development and analysis of information disseminated by an agency.

Importantly, the SEC needs to only look to the precedence established by other agencies, specifically the Department of Transportation (DOT), the Environmental Protection Agency (EPA), National Oceanic and Atmospheric Agency (NOAA), US Fish and Wildlife Service, and the Department of Agriculture, for guidance on how it should conduct its pre-dissemination review of the data received through Form SD.

A. DOT’s Pre-dissemination Requirements

i. DOT’s 6 Main Components of its Pre-Dissemination Review Policy

DOT established the benchmark for pre-dissemination review by establishing six (6) essential steps for a comprehensive pre-dissemination review. The pre-dissemination review steps include:

1. Review and Consultation

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1 67 FR 8459
2 Id.
DOT’s pre-dissemination review process requires that agencies allow “adequate” time for review, consistent with the standards required for the type of information to be disseminated. Thus, agencies need to allow more review time for more significant information. This requirement is fully consistent with OMB’s government-wide data quality guidelines which state, “The more important the information, the higher the quality standards to which it should be held....”

In addition to requiring adequate time for review, the DOT guidelines impose a positive duty on agencies to consult with stakeholders including, but not limited to, the public, other DOT organizations and State governments. The consultation requirement is important because it enables the agency to comply with the “quality” and “transparency” goals of the DQA.

2. Compliance Verification

The pre-dissemination review process requires that agencies verify that covered information complies with the DOT guidelines as well as with the other guidance and procedures issued by DOT agencies. This compliance verification component is, in many respects, the heart of the pre-dissemination review process since it is an essential step for ensuring that only information that meets data quality requirements is disseminated.

An integral element of the DOT guidelines with which agencies must verify compliance are the detailed principles and guidelines for statistical data located in Appendix A of the document. The Appendix is, “a subset of the DOT Information Dissemination Quality Guidelines.” Appendix A, “incorporate[s] the statistical aspects of the OMB guidelines as a baseline and elaborate[s] on its recommendations to produce statistical guidelines adapted for the Department of Transportation.” The detailed data quality requirements in Appendix A, “apply to all statistical information that is disseminated on or after 1 October 2002 by agencies of the Department of Transportation...” The Appendix also explicitly states that the guidelines apply to third-party data disseminated by the Department, as part of a covered dissemination, with the

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4 DOT Guidelines, p. 1-3
5 Id at 1-2
6 Id.
exception of the data acquisition requirements if the data was acquired by a nonfederal source. The guidelines apply to “reporting systems, surveys, and special studies.”

As discussed in greater detail below, DOT also publishes comprehensive compliance reports for data used in relation to specific programs.

3. Influential Information

The DOT guidelines require that agencies maintain records of the additional standards are applies to information considered to be influential. Thus, there are two key issues with respect to influential information:

i. The Department’s definition of information considered to be influential; and

ii. The additional quality standards applied to the information.

DOT, in keeping with the OMB guidelines, sets specific attributes defining the term influential. The key requirement is that the information have a “clear and substantial impact” on important private sector decisions or public sector policies. DOT explains that this means, among other requirements, that the expected impact must be highly likely to occur rather than speculative. DOT also notes that, based on OMB’s definition, the term influential only applies to scientific, financial or statistical information. Thus, a policy decision, no matter how important, would not be considered as influential information although at least some of the information in the administrative record underlying that decision might potentially be classified as influential.

In regulatory contexts, the Department relies significantly on the Executive Order on regulatory review for assessing whether information is influential. Specifically, DOT states that influential information is “information that can reasonably be regarded as being one of the major factors in the resolution of one or more key issues in a significant rulemaking, as that term is defined in Executive Order 12866.” The Executive Order defines a “significant regulatory action” as one which is likely to have at least one of the four impacts.

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7 Id at 19.
8 Id. [emphasis in original]
9 Id.
10 58 FR 51738.
i. **Economic.** An annual impact on the economy of at least $100 million or a material adverse affect on the economy, a sector of the economy, productivity, jobs, competition, public health or safety, the environment or state, local or tribal governments or communities.

ii. **Interagency conflict.** A serious inconsistency or otherwise interfere with an action already taken or planned by another agency.

iii. **Budgetary Impact.** Materially altering the budget impact of entitlements, grants, user fees, or loan programs or affect the rights and obligations of the recipients of such programs.

iv. **Novel Issues.** Raise novel legal or policy issues rising out of legal mandates, the President’s priorities or the principles in Executive Order 12866.

In non-regulatory contexts, when considering whether information is influential, DOT considers two aspect of information--the breadth of the expected impact and the intensity of expected impact. Thus, information which affects a broad range of parties, such as an industry, is far more likely to be considered as influential than information affecting a narrow range of parties, such as a given company, even if the impact on that company is significant. With regard to the intensity of impact, DOT will be guided by the same types of factors that determine whether a rulemaking is significant. However, these factors are considered as guidance and actual decisions will be made on a case-by-case basis.

DOT explains that certain classes of information may be defined as influential. Decisions regarding other information will be made on a case-by-case basis. DOT agencies are encouraged to apply the influential label “only when clearly appropriate.”

**Standards for Influential Information.** DOT has adopted the quality principles standards set forth in the Safe Drinking Water Act (SDWA) amendments of 1996 for analyses of risks to human health, safety and the environment. This use of the SDWA standard is in addition to the specific principles and guidelines relevant to influential information, such as the requirements for “critical data systems” that are contained in the DOT’s detailed statistical guidelines. The SDWA requirements adopted by DOT include:

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11 *Id.* at 28.

12 *Id.* at 16
i. Use of the best available science and supporting studies; and
ii. Use of data collected by the accepted or best available methods;

Furthermore, when disseminating influential risk-related information, the SDWA language requires that the information include:

i. Each population addressed by any estimate of applicable effects;
ii. The expected or central estimate of risk for the specific affected populations;
iii. The upper and lower bounds of the risk estimate;
iv. Each significant uncertainty identified in the risk assessment and studies that would help reduce the uncertainty; and
v. A list of studies known to the agency which support, are directly relevant to or fail to support the findings of the assessment and the methodology used to reconcile inconsistencies in the scientific data

With regard to the reproducibility of information, the DOT guidelines state that they intend to follow a policy determining, in consultation with relevant scientific and technical communities, when reproducibility standards should be applied to original and supporting data. Furthermore, with regard to analytic results, DOT’s policy is to “favor sufficient transparency about methods to allow independent reanalysis by qualified members of the public.” When confidentiality requirements obviate such transparency, DOT’s policy is to “apply and document especially rigorous robustness checks.” Thus, DOT’s policies regarding reproducibility are fully consistent with OMB’s government-wide guidelines

4. Ensuring the Entire Information Product Fulfills The Agency’s Intentions

DOT’s pre-dissemination review process includes ensuring, “that the entire information product fulfills the intentions stated and that the conclusions are consistent with the evidence.” This component of the pre-dissemination review process can be considered as an opportunity for the agency to look at the “big picture.” DOT shows considerable foresight and common sense in understanding that it is possible to lack overall perspective when going through the minutia of a

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13 Id. at 15.
14 Id.
15 Id. at 15-16.
16 Id. at 19.
detailed process. Thus, even after the responsible agency has gone through the detailed compliance verification process, they still need to step back and take a big-picture perspective to ensure that an information product makes sense, i.e., conclusions are consistent with the evidence, and that the project’s goals were achieved. The detailed statistical guidelines provide important tools, including the extensive documentation and planning requirements, that can be used in ensuring that the final work product fulfills agency intentions. Although DOT does not provided specific guidance on how to ensure such a forest-not-trees perspective, that may be most appropriate for this purpose.

5. **Provide Origin of Data**

Knowing the origin of data is one of the basic requirements for transparency. Thus, one of the specific pre-dissemination review steps is to ensure that, when using data from an external source, the origin of the data is indicated. With regard to statistical information, compliance with the comprehensive documentation requirements discussed in the Compliance Verification section of this document should ensure the agency complies with the origin of data requirement. For non-statistical information, this component of the pre-dissemination review process provides the opportunity to ensure that the origin of all third-party data is clearly provided.

6. **Additional Data**

The final component in DOT’s pre-dissemination review process is ensuring that “each program office can provide additional data on the subject matter of any covered information it disseminates.” This step of the pre-dissemination process serves as a capstone of the overall data quality assurance process. By being able to provide additional data on all covered information disseminations, the Department is demonstrating its intention to be ready to respond to requests from the public and other stakeholders for clarification or additional insight into an information product. Thus, the DOT guidelines recognize that communications are a two-way process and that data quality is one element to assist in the ongoing dialog between the Department and the stakeholders it serves.

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17 *Id.* at 20.
18 *Id.*
Moreover, DOT has issued extensive dissemination reports for the data related to specific programs and policies. For instance, DOT published a 77-page report on the compliance of the Long Term Pavement Performance (LTPP) program titled, *Long-Term Pavement Performance Compliance with Department of Transportation Information Dissemination Quality Guidelines*. The report has extensive analysis of the data used as part of the LTPP program.

The report further details the requirements of the pre-dissemination reviews specific to the LTPP program. The report states:

> All formal data disseminated by the LTPP program undergo some type of review prior to release. The type and extent of the review depends on the subject matter being released. LTPP is developing an information category for dissemination that does not receive a "formal" review prior to dissemination.

The following types of formal predissemination reviews have been conducted by LTPP:

- The contents of the database are reviewed by experts and staff prior to release. These review staff members are not directly involved with data collection or analysis. Data collection is the responsibility of four regional data collection contractors who collect data, process data, and review data prior to each upload to the national database. At the national level, data from the four regions are combined into a single database. Prior to each release of the database, the TSSC staff members perform a predissemination review of the database contents, notify the regional data collection contractors on needed corrections, and review corrections received prior to the release. Known data problems not corrected prior to release are documented using the Data Analysis Operation Feedback Report process.
- Paper publications are subjected to a variety of predissemination reviews depending on subject content.
  - All published paper documents are reviewed by editors employed or contracted by the FHWA TFHRC publication staff. These

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editors are specialists trained in style and visual information content of FHWA publication standards.

- Program promotional material and status reports are reviewed by FHWA LTPP staff and contractors who did not actively participate in preparation of the draft document.
- Research reports containing engineering and statistical analyses receive an external and internal peer review in addition to the other predissemination reviews previously mentioned. The peer reviews are conducted by a diverse group including voluntary experts from the TRB ETG on data analysis, paid experts from the LTPP TSSC, and, most importantly, engineering staff from the regional data collection contractors. This rigorous peer review process includes knowledgeable individuals from outside the program who represent program stakeholders and academia; a paid staff of researchers not involved with the performance of the data analysis work, but who have unique knowledge of the LTPP program and have resources available to independently check reported results; and, most importantly, reviewers who collected the data and possess knowledge on its proper analytical interpretation.
- Report reviewers on the TRB ETGs are required to report prior DOT technical/policy positions on issues related to LTPP as part of their conflict-of-interest disclosures required by the National Academy of Sciences before being appointed.
- LTPP contractors are required by the Federal Acquisition Regulation (FAR) guidelines to report conflict-of-interest concerns in their proposals.
- The peer review process has resulted in nonpublication of program-funded analysis reports.

- After the passage of Section 508 of the Americans with Disabilities Act, all disseminations of information via electronic media have been reviewed by specialists who have received training on this legislation. All LTPP contractors responsible for managing Web pages containing LTPP program information have Section 508 compliance clauses included in their contracts. All LTPP-sponsored Web pages have been reviewed by LTPP staff for compliance conformance. As a long-term program, LTPP has been hampered by the lack of effective FHWA guidelines on implementation of this policy. To date, LTPP electronic documents have not been challenged by persons with disabilities for nonconformance with the Section 508 requirements.
• Data products were disseminated by LTPP prior to enactment of Section 508 of the Americans with Disabilities Act. Since these data products can no longer be controlled by the program, documentation has been published that these data products are no longer supported by the program, and concerned data users should use current data products or contact LTPP concerning accessibility accommodation for the disabled. To date, LTPP has not received such a request.

LTPP had developed plans for a system that allows dissemination of raw data that has not undergone a formal predissemination review. While the bulk of these data are contained in the database, the data included in this category are classified as objects in database terminology. Most of these electronic objects consist of electronic picture formats, but, on the advice of the external peer reviewers, many are the unedited electronic files from data collection devices. This allows a data user the opportunity to evaluate LTPP data processing and quality systems. At the heart of the process was the creation of a metadata database. The concept that was previously developed is that the metadata about an object contain adequate information to describe the format, content, quality review level, and nature of the data included in this module. The LTPP metadata database was planned as an electronic library based on the Dublin Core Standard and in concert with electronic library standards currently under development by the U.S. National Archives, Library of Congress, and internal FHWA publications staff. Due to budget cuts, development of the formal metadata database has been curtailed to documents indexed by the FHWA library staff.

Another example of DOT’s detailed analysis of its compliance with pre-dissemination review requirements is contained in the report, BTS Statistical Standards Manual.20 In the report, the Bureau of Transportation Statistics outlines its compliance with its “Formal Pre-Dissemination Review.” The report states:

All information products require pre-dissemination review to ensure compliance with OMB and DOT Information Quality Guidelines, and BTS standard procedures.

• Before sending an information product outside the originating office for review, the product manager should:
  o Verify compliance with all applicable BTS standards and guidelines (BTS 2002, 2003, 2004, 2005),

20 Bureau of Transportation Statistics, BTS Statistical Standards Manual
Double-check facts,
Proofread text, and
Clearly mark the product as a draft for review only, and not for attribution or further distribution.

- All information products require a confidentiality protection review (BTS 2004).
- Verify calculations through an independent recalculation of a random selection of statistics in the information product.
- Persons not directly involved in preparing the information product should proofread the text and verify that numbers in tables, graphs, maps, and text are consistent.
- All information products require a subject-matter review by someone, preferably from within BTS, who is familiar with the topic area and with the techniques used. The information product may require a separate review of the statistical methodology.
- If the topic may be of interest to another DOT organization, industry group, or others in general, ask formally for review by those deemed most interested.
- Publication specialists should edit text products to ensure consistency and readability.
- The appropriate office director should review and clear all information products before submitting the products to the Director or the Director’s designee. The Director or designee will review the product and determine whether the product needs further review within the Research and Innovative Technology Administration (RITA) prior to final dissemination approval.
- Information products to be posted on the web require review for compliance with BTS web guidelines. Each information product should be assigned to at least one of the program web pages.\textsuperscript{21}

B. \textit{EPA’s Pre-dissemination Review Requirements}

\textit{i. EPA’s Pre-Dissemination Review Guidelines}

The EPA also gives special attention to DQA pre-dissemination requirements. Specifically, in 2006, the EPA issued the \textit{Pre-dissemination Review Guidelines: Review

\textsuperscript{21} Id. at Guideline 6.1.3.
Guidelines to Ensure that Disseminated Information is Consistent Information Quality Guidelines.22 The Guidelines state:

[P]re-dissemination reviews are designed to provide additional assurance that information EPA disseminates to the public is consistent with the quality principles described in the [Data Quality Guidelines]. Agency Program Offices, Regions and Labs (“Agency Offices”) should develop pre-dissemination review procedures consistent with the Guidelines and their respective authorities and activities.

EPA’s Office of Environmental Information (OEI) is providing these pre-dissemination review guidelines to help Agency Offices in developing their own procedures, if they haven’t already done so, to allow for consistent cross-Agency pre-dissemination reviews while meeting each office’s particular needs. These pre-dissemination review guidelines provide non-binding internal policy and procedural guidance intended solely for EPA management and staff.

Systematic planning, typically part of a quality system, ensures that quality is built into information. The pre-dissemination review procedures outlined in this document are intended to provide assurance that quality has been built into the information we disseminate, rather than to add another review stage at the end of the information development process. Ultimately, such reviews reinforce good government and common sense.23

Notably the EPA Guidelines on pre-dissemination review also requires that the agency offices must “specify how the office retains pre-dissemination review records.”

ii. EPA Compliance with Pre-dissemination Requirements on Specific Programs

One example of EPA’s adherence to its Pre-Dissemination Guidance is with the Region 3 Quality Management Plan (QMP). In the Region 3 QMP, the EPA does an excellent job of centering the program on pre-dissemination review. The specific pre-dissemination review policies are as follows:

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23 Id. [emphasis added]
A Pre-Dissemination review as defined in section 7 of the [Data Quality Guidelines] is intended to insure that information EPA disseminates is of the highest quality possible and meets standards for objectivity, utility and integrity. Any disseminated information not meeting these standards can be subject to a "request for correction" (RFC) and its appeal, a "request for reconsideration" (RFR) by any person. OEI has a formal process in place for the administration of RFCs and RFRs. Past and current RFCs and RFRs can be viewed on the EPA website.

EPA issued its Pre-Dissemination Review Guidelines in 2006 to assist offices and regions in implementing their own pre-dissemination review procedures. This document therefore serves as a basis for Region 3's procedure for conducting pre-dissemination reviews. Region 3 offices may expand upon the review procedure presented here. Please note that EPA's pre-dissemination review guidelines provide non-binding internal policy and procedural guidance intended solely for EPA management and staff (EPA Final Pre-Dissemination Review Guidelines, September 2006).

**Pre-Dissemination Review**

One of the most important things to remember about conducting a pre-dissemination review is that it is not intended to consist solely of a final review in the development of a product. Rather, it should be conducted throughout a product's development life cycle. The Information Quality Guidelines Pre-Dissemination Review Checklist (PDF) (1 pg, 102K) can be used to document the results of pre-dissemination review during development.

**Determine Eligibility**

- Determine if you need to conduct a pre-dissemination review using the IQG definitions of "information" and "dissemination" (Steps 2 and 3 below and IQG Section 5.3). The Region 3 IQG officer can be consulted should you have questions about whether the IQG apply (and thus a review is needed). Examples of non-applicability of the IQG are given in IQG Section 5.4.
- Determine whether the product to be reviewed is information. "Information" generally includes any communication or representation of knowledge such as facts or data, in any medium or form.
- Determine whether the product will be disseminated by EPA. EPA disseminates information to the public when EPA initiates or sponsors the distribution of information to the public.
- If neither step 2 or 3 applies then no PDR is necessary at this time. Otherwise continue to step 5. Note that under certain circumstances a product may
become eligible for a review (e.g. EPA decides it would like to disseminate a report that had been only available within EPA).

**Determine whether quality is maximized and IQG quality criteria are met**
- Determine whether the product to be disseminated has maximized quality and has met the IQG criteria for utility, objectivity and integrity. "Utility" refers to the usefulness of the information to the intended users. "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. "Integrity" refers to security, such as the protection of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification. (See IQG, Sections 5.1 and 6.1).
- Determine whether the product is influential. "Influential," when used in the phrase "influential scientific, financial, or statistical information," means that the Agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact (i.e., potential change or effect) on important public policies or private sector decisions. If the product is influential then a higher degree of transparency for data and methods will be required. Consult IQG Section 6.3 on transparency requirements.

**Approval of information prior to dissemination**
- Obtain approval for the information to be disseminated from the appropriate program director. Approval can include other types of reviews such as legal reviews, peer reviews, programmatic reviews, scientific and technical review clearance processes, stakeholder reviews, and product review in accordance with the Office of Public Affairs guidelines.

**Records management**
- Pre-dissemination review records (such as the Information Quality Guidelines Pre-Dissemination Review Checklist (PDF) (1 pg, 102K)) should be retained with other product documents. Records should be retained using the appropriate records schedules.24

As mentioned above, the Region 3 QMP also integrates a Pre-dissemination Review Checklist25 to be retained evidencing the pre-dissemination review.

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In addition, the 2007 report *EPA’s 2007 Report on the Environment: Highlights of National Trends* also demonstrates the EPA’s commitment to complying with pre-dissemination requirements. In the report, the EPA states that the report was issued, “solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. This document has not been formally disseminated by EPA. It does not represent and should not be construed to represent any Agency policy or determination. EPA will consider any public comments submitted in accordance with this notice when revising the document.”

C. **NOAA Pre-Dissemination Review Requirements**

i. **NOAA’s Pre-Dissemination Guidelines**

NOAA is another example of agency with an exemplary record when it comes to pre-dissemination review, especially through the National Marine Fisheries Service (NMFS). NOAA established guidelines for its pre-dissemination review.26 The purpose of the guidelines are “To assist in Data Quality Act compliance, NOAA Fisheries has established a series of actions that should be completed for each new information product subject to the Data Quality Act.”27 The guidelines provide that “Before information is disseminated, it must be reviewed for compliance with the NOAA.”28 The guidelines further provides that a certification is required by an upper management official. Specifically, “The Pre-Dissemination Review should be conducted during the normal course of clearing the information product for release. The person conducting the PreDissemination Review will sign and date the Pre-Dissemination Review Documentation Form. The reviewing official must be at least one level above the person generating the information product.” Moreover, the guidelines provide “The Pre-Dissemination Review form and the supporting information quality documentation must accompany the information product through the clearance process and be maintained on file.”29

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27 *Id.* at 1.
28 *Id.* at 2.
29 *Id.* at 3.
The guidelines then provide extensive instructions on how a standard “Pre-dissemination Review & Documentation Form”\textsuperscript{30} is to be completed. This is described in the subsequent section.

\textit{ii. NOAA’s Pre-Dissemination Review and Documentation Form}

Similar to the EPA, but more extensive, NOAA has a standard Pre-dissemination Review & Documentation Form.\textsuperscript{31} The Pre-dissemination Review & Documentation Form contains several questions pertaining to the utility of the information, integrity of the information product, and objectivity of the information product. This is an excellent practice to have implemented the documentation form, because it ensures in a formal and standardized manner that all data disseminations are being vetted through a standard analysis.

Moreover, NOAA publishes several completed (in both draft and final form) Pre-Dissemination Review & Documentation Forms for specific programs. A completed Pre-Dissemination Review & Documentation Form on the Biological Conference Opinion on the Long-Term Operations of the Central Valley Project and State Water Project can be accessed here: \url{http://www.swr.noaa.gov/ocap/Information_Quality_Act-Pre-Dissemination_Review_&_Documentation_Form.pdf}. Likewise, a Pre-decisional draft of a Pre-Dissemination Review & Documentation Form pertaining to the dissemination of a research publication can be found here: \url{http://www.cio.noaa.gov/Policy_Programs/Form515_Section515_Pre-dissemination_Review_Documentation_Certification_EXAMPLE.pdf}.

DQA.\textsuperscript{32}

\begin{itemize}
\item \textsuperscript{30} Id. at 3-5
\item \textsuperscript{31} See \url{http://www.nmfs.noaa.gov/op/pds/documents/04/108/04-108-02.pdf}
\item \textsuperscript{32} Multinational Legal Services Memorandum on the Justiciability of the Data Quality Act, May 27, 2010, available at \url{http://thecre.com/pdf/20100527_DQA_Reviewability.pdf}
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