

BEFORE THE UNITED STATES
OFFICE OF MANAGEMENT AND BUDGET
OFFICE OF INFORMATION AND REGULATORY AFFAIRS

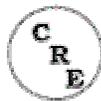
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Re: Reporting of Information and Documents)
About Potential Defects B Retention of Records)
49 CFR Part 579) OMB Number 2127-0616
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COMMENTS OF:

The Center for Regulatory Effectiveness

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November 6, 2002



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November 6, 2002

NHTSA Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, N.W.
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SUBJECT: Comments on the National Highway Traffic Safety Administration's Proposed Collection of Information, Reporting of Information and Documents About Potential Defects B Retention of Records 49 CFR Part 579; OMB Number 2127-0616

The Center for Regulatory Effectiveness (CRE), a regulatory watchdog, respectfully submits the following comments to the Office of Management and Budget (OMB) on the National Highway Traffic Safety Administration's proposed collection of information in the above captioned proceeding. In that the Early Warning ICR is one of the first major information collections to be presented to OMB after October 1st, CRE will be reporting on the Early Warning reporting system's compliance with the Data Quality Act on our website, www.TheCRE.com.

NHTSA's Planned Use of the Early Warning Information Must Comply with the Paperwork Reduction Act and the Federal Data Quality Act

The PRA Requires Agencies to Have a Plan for Using the Information they Propose to Collect

The Paperwork Reduction Act (PRA), Sec. 3506 (c)(1)(A)(vi), requires that agencies have A plan for the efficient and effective management and use of the information to be collected...@Furthermore, Sec. 3506 (c)(1)(B)(iii)(II) of the Act requires that the agency inform the persons responsible for providing the information, A the way such information is to be used.@ Thus, the PRA requires that NHTSA both have a plan for using the Early Warning Data and explain to companies providing that data how it is to be used.

The Data Quality Act Requires that Proposed Information Collections Adhere to OMB and Agency Data Quality Standards

In addition to the specific requirements of the PRA, the proposed collection of information must also comply with the requirements of the Federal Data Quality Act, which amends the PRA, and implementing guidelines. OIRA Administrator Dr. John Graham emphasized the need for agency ICR comply with the Federal Data Quality Act in his June 10th memorandum to the President's Management Council which stated, "OMB will approve only those information collections that are likely to obtain data that will comply with OMB and agency information quality guidelines."

In compliance with statutory and OMB requirements, DOT's own Data Quality guidelines similarly require that "With respect to information collection requirements covered by the PRA, the Department will ensure that these requirements are consistent with the guidelines and will state so in the PRA submission to OMB." Despite this clear requirement in DOT's Data Quality guidelines, NHTSA's October 9th *Federal Register* Notice notifying the public that the ICR has been transmitted to OMB makes no reference to the Department's Data Quality guidelines and does not provide the necessary certification that the proposed collection of information is consistent with the guidelines even though the ICR is being transmitted after the October 1st date on which the guidelines become effective. Although the Data Quality has just recently become effective, it is important for NHTSA and OMB to establish an early precedent of compliance with the Data Quality Act for Information Collection Requests. Therefore, CRE requests that OMB ensure that the proposed collection of information complies with OMB and DOT Data Quality guidelines in the following key respects:

1. NHTSA's plan for using the Early Warning data must adhere to Data Quality requirements for transparency, reproducibility and pre-dissemination review; and
2. Any contemplated release of Early Warning data must pass DOT's pre-dissemination review standards as well as DOT's Confidential Business Information rules for the data.

NHTSA's Plan for Using Early Warning Data Must Comply with Data Quality Requirements for Transparency, Reproducibility and Pre-Dissemination Review

Under the PRA, NHTSA must have a plan for efficiently and effectively using the Early Warning data they propose to collect. Under the Data Quality Act, such use must meet standards for transparency and reproducibility. Specifically, the DOT guidelines state, "With respect to analytic results, the Department's policies favor sufficient transparency about methods to allow independent reanalysis by qualified members of the public. In situations where public access will not occur (e.g., because of confidentiality requirements or the use of proprietary models), the Department's policy is to apply and document especially rigorous robustness checks. In any case, the Department's policy is to provide the maximum feasible transparency with respect to specific data sources, quantitative methods, and assumptions used."

Although, as discussed below, there are legal and regulatory factors sharply constraining release of the Early Warning data itself, NHTSA is required by the Data Quality Act and their own Data Quality guidelines to provide for public review the quantitative methods and assumptions the agency plans to use in analyzing the Early Warning data they would receive under the proposed ICR. Furthermore, DOT's Data Quality guidelines explicitly require the agency to develop a data analysis plan and have it reviewed. The guidelines also provide substantial instruction as to how the agency should develop their data analysis program. Specifically, Section 4.4, Data Analysis and Interpretation, of the detailed guidelines contained in Appendix A of the DOT Data Quality guidelines state that,

The planning of data analysis should begin with identifying the questions that need to be answered. For all but simplistic analyses, a project plan should be developed. Subject matter experts should review the plan to ensure that the analysis is relevant to the questions that need answering. Data analysis experts should review the plan (even if written by one) to ensure proper methods are used. Even exploratory analyses should be planned.

The DOT Data Quality guidelines also require that,

All statistical methods used should be justifiable by statistical derivation or reference to statistical literature. The analysis process should be accompanied by a diagnostic evaluation of the analysis assumptions. The analysis should also include an examination of the probability that statistical assumptions will be violated to various degrees, and the effects such violations would have on the conclusions. All methods, derivations or references, assumption diagnostics, and robustness checks should be documented in the plan and final report. [emphasis added]

Thus, DOT's Data Quality guidelines require NHTSA to have a detailed written plan for analyzing the Early Warning data and that the plan be reviewed. The guidelines also require that the agency provide a maximum feasible transparency about their planned analytic techniques and assumptions. In that OMB has publicly committed to not approving any ICR that is not in compliance with OMB and agency Data Quality guidelines, OMB cannot and should not approve the subject ICR until NHTSA provides for public comment an Early Warning data analysis plan which meets the requirements of the Department's and OMB's Data Quality guidelines.

It is also important to note that, like virtually all information disseminated by the agency, NHTSA's plan for using the data needs to undergo pre-dissemination review. DOT's Data Quality guidelines for such review, contained in the Pre-Dissemination Reviews section of Appendix A,

state that,

A subject matter specialist other than those directly involved in the data collection and analysis should review the plans, methodology documents, and reports prior to dissemination. They should also review publications and summaries resulting from the data for content and consistency.

The DOT guidelines for pre-dissemination review also require that,

A statistician or other data analysis specialist other than those directly involved in the data collection and analysis should review the plans, methodology documents, and reports prior to dissemination for compliance with these guidelines. They should also review publications and summaries resulting from the data for the wording and statistical interpretation.

Although NHTSA has not yet provided their planned quantitative methods and assumptions for use of the Early Warning data, the agency has provided significant information and engaged in a public dialog regarding their plans for managing the Early Warning data. The Public Meeting held by NHTSA on September 24th is a positive example of NHTSA providing transparency regarding their required plan for managing the data. The Public Meeting could also provide a practical model for NHTSA to build on in providing transparency regarding their analytic methods and in further development of those methods. Another federal precedent NHTSA may find useful in developing their data analysis plan is EPA's Council of Regulatory Environmental Modeling. Specifically, the Council's Model Evaluation Protocol could provide useful standards for ensuring the reliability and utility of the analytic techniques NHTSA intends to use in their plan for the Early Warning data.

Any Release of Early Warning Data Must Comply with DOT's Data Quality Guidelines and DOT's Confidential Business Information Rules

The OMB and DOT Data Quality guidelines require that disseminated information poses utility. As the DOT guidelines explain, data ~~A~~has to be *relevant* to users. ~~@~~emphasis included in original] The guidelines describe the various steps necessary to assure such relevance including principles related to data analysis and interpretation. One of the analysis principles is that analyses, ~~A~~should be designed to focus on answering the key questions rather than showing all data results from a collection. ~~@~~emphasis added] Thus, in addition to possible violations of the TREAD Act, routine release of Early Warning data would be contrary to DOT's Data Quality guidelines.

As noted earlier, a key element of OMB's and DOT's Data Quality guidelines is a pre-dissemination review process. Two of the requirements for the pre-dissemination review process discussed in Section VII of the Department's guidelines are:

- \$ Consulting with stakeholders that have a substantial interest in the proposed dissemination of the information.
- \$ Verifying compliance with the Department's Data Quality guidelines and other DOT organization specific guidance/procedures.

Thus, at the very minimum, any NHTSA disclosure of Early Warning data would require: 1) a proposal by the agency to disclose the information; 2) consulting with relevant stakeholders; and 3) following other relevant DOT guidance/procedures. With regard to the Early Warning data, the key DOT guidance/procedures, aside from the Data Quality guidelines themselves and the statutory restrictions on dissemination of Early Warning data contained in Section 3(b) of the TREAD Act, would be NHTSA's Confidential Business Information regulations specific to the data. NHTSA's Notice of Proposed Rulemaking (NPRM) for the Early Warning reporting system explicitly stated¹ that:

1. The proposed Early Warning rule did not establish rules governing the disclosure or confidentiality of information submitted pursuant to the early warning rule.
2. NHTSA has published a proposed rule which, in the course of that rulemaking will consider issues related to confidentiality and disclosure.

Thus, until NHTSA finalizes their CBI rule for Early Warning data, they will not be in a position to potentially disseminate any Early Warning data. Therefore, for NHTSA's ICR to comply with the Department's Data Quality guidelines, OMB's terms of clearance should prohibit any release of the Early Warning data prior to the agency issuing final CBI rules for the data.

Recommendations

1. OMB should make clear that Control Number 2127-0616 does not apply to Early Warning data unless and until they approve the subject ICR.

¹ 67 FR 45866, Footnote 6.

2. No Control Number for Early Warning data should be granted until NHTSA provides and seeks public comment on the NHTSA plan for analyzing the Early Warning data that is required by the Paperwork Reduction Act, Federal Data Quality Act and DOT Data Quality guidelines.
3. OMB should ensure that the NHTSA plan for using Early Warning data complies with pre-dissemination review requirements contained in the DOT Data Quality guidelines, including the requirement for consultation with the public and other stakeholders on the data use plan.
4. OMB should, as part of the terms of clearance, prohibit NHTSA from disseminating Early Warning data prior to finalizing their guidance/procedures for addressing the CBI issues associated with the data.
5. OMB should, as part of the terms of clearance, require that any information, reports or other analyses that may be eventually disseminated as a result of the Early Warning data comply with the pre-dissemination review requirements contained in the DOT Data Quality guidelines.

Sincerely

A handwritten signature in black ink, appearing to read "Jim Tozzi". The signature is stylized with a large, sweeping initial "J" and "T".

Jim Tozzi
Member, Board of Advisors