NBSIR 80-2123

Need for Economic Information on Standards Used in Regulatory Programs: Problems and Recommendations

Maureen Breitenberg

Office of Standards Information, Analysis
and Development
Office of Engineering Standards
National Bureau of Standards
U.S. Department of Commerce
Washington, D.C. 20234

September 1980

U.S DEPARTMENT OF COMMERCE
NATIONAL BUREAU OF STANDARDS

NBSIR 80-2123

NEED FOR ECONOMIC INFORMATION ON STANDARDS USED IN REGULATORY PROGRAMS: PROBLEMS AND RECOMMENDATIONS

Maureen Breitenberg

Office of Standards Information, Analysis
and Development
Office of Engineering Standards
National Bureau of Standards
U.S. Department of Commerce
WAshington, D.C. 20234

September 1980

U.S. DEPARTMENT OF COMMERCE, Philip M. Klutznick, *Secretary*

Luther H. Hodges, Jr., *Deputy Secretary*
Jordan J. Baruch, *Assistant Secretary for Productivity, Technology, and Innovation*

NATIONAL BUREAU OF STANDARDS, Ernest Ambler, *Director*

Foreword

This report is one of a series of reports published by the Office of Engineering Standards (OES) concerning the use of voluntary standards by government regulatory agencies.

The purpose of this series is to provide standards writers and government regulators with information necessary to allow voluntary standards to be used effectively by government. It is also hoped that this information will strengthen the voluntary standards development process.

This report provides information on the requirements and pressures placed on regulatory agencies in their regulatory process. It is intended to provide standards writers with guidelines on the type of information that they should try to collect on standards that may be used in a regulatory activity. It is not intended to be a hard and fast set of rules. It is hoped that this report will stimulate more dialogue and greater cooperation between regulators and standards writers.

Joan Koenig
Group Leader
Standards Management and
Impact Analysis Project

Acknowledgements

I would like to thank Joan Koenig, Robert Atkins, and JoAnne Debelius for their help in reviewing and in providing valuable comments on several drafts of this report.

I would also like to thank William Cullen, James French, Carol Chapman Rawie, George Sinnott, John Dise and Elio Passaglia who made many useful comments and provided different points of view on this issue.

Table of Contents

Executive Summary

It has been suggested that the government can save resources by making greater use of private sector standards in regulatory programs. However, agencies that adopt voluntary standards which do not include economic impact data run the risk of not being able to defend such standards in court or in other public and congressional forums. Federal executive branch agencies also need this type of data to comply with the requirement of Executive Order 12044 to conduct regulatory analyses of all major regulations. Pending regulatory reform legislation, may extended these requirements to independent agencies as well as increase the degree of analysis required.

One of the greatest deficiencies in the regulatory analyses appears to have resulted from weaknesses in the data on which the analysis were based. If regulators and standards writers work together, they can begin to eliminate some of these weaknesses in the data base. For example, in many cases, the standards-writing committee may have access to better impact data than a regulatory agency; and, if a diversity of interests is represented on the committee, may have a better understanding of all the impacts of the standard. The cost of obtaining data can, however, be high. If the data is required to aid a regulatory agency in using the standard as part of its regulatory program and the private standards-writing organization is unable or willing to undertake the entire expense, then government should be willing to bear a share of the costs. There is also a need for better communication between standards writers and the government to prevent unnecessary duplication of data that may already be available somewhere within the government but be unknown to the standards-writing committee. It is important for standards-writing committees to check with the agency or agencies that are likely to be using the standard to see if they have or can obtain needed information. Most agencies have a central source for standards committees to contact regarding what types of data an agency is likely to include in its analysis of the standard. The names and telephone numbers of the contact persons within each agency should be made available to the standards-writing committees. In addition to the costs involved, the standards writing committees and the Federal regulatory agencies are both likely to experience other serious problems in assessing the economic costs and benefits of standards. These problems include:

- the need to rely on forecasts and assumptions whose validity can only be tested by the passage of time.
- the willingness of corporations to release relevant data for public scrutiny.

- o the need to examine the effect of proposed standards on individual types of firms that comprise the industry affected by the standard -- both domestic and foreign -- because of potential differences in impacts.
- o the existence of a time lag between exposure to a product and the appearance of adverse effects, as well as the existence of intervening or interacting happenings that may affect the appearance of adverse effects.
- o the possible existence of a "learning curve" or accelerated technological progress occuring after the implementation of the standard.
- o the inadequacy of the current available methods for assigning dollar values to non-quantifiable costs and benefits.
- o the choice of an appropriate discount factor.
- o the choice between standards producing the greatest net economic benefit and those producing equitable cost charing.

While regulators and standards writers should be aware of these problems, many are not easily resolvable. Some will require the development of new methodologies by the government or researchers working in the area.

The following steps could increase the effective use of the standards-writing committees in improving the quality of the economic analyses: 1) Federal regulatory agencies should prepare lists of the specific costs/benefit categories that they are interested in and have the committee collect data primarily on these categories; 2) standards writing committees should begin the collection of economic data as soon as the development of a standard is begun; 3) the committees should concentrate their efforts on data collection and not on the application of cost/benefit/effectiveness techniques; 4) committees should not try to quantify the compliance costs incurred by agencies and the paperwork burdens imposed on industry but consider them only in general terms; and 5) the data collected should be disseminated as broadly as possible and the data records should include any objections to the accuracy or applicability of the data.

While economic analyses cannot and should not be used to predetermine the nature of the final standard because of the many potential data base and methodological problems noted above, they can provide the regulator and the standards writer with a mechanism for collecting and organizing available information, highlighting alternatives and uncertainties, and in making informed, rational decisions.

I. INTRODUCTION

Purpose and Scope

The purpose of this paper is to explore the trend towards more intensive analysis of the impacts of proposed Federal regulations, some of the causes for this trend, and the implications for standards writers and government regulatory agencies which use standards developed by the private sector. This paper also discusses some of the problems that may be encountered in conducting economic analyses and makes recommendations for both standards writers and regulators on their respective roles in conducting economic analyses of voluntary standards likely to be used in regulatory programs.

Background

Before reaching a decision, most individuals make some type of analysis to compare the costs and benefits of their actions. Business owners continually make such comparisons to survive in a competitive market. Government agencies have recently begun conducting such analyses in a far more rigorous manner as well as attempting to thoroughly document the process.

Costs and benefits assessment of regulation began with the passage of the National Environmental Protection Act, which requires agencies to prepare Environmental Impact Statements before taking any major actions. In his 1974 Executive Order (E.O.) 11821, (later amended by E.O. 11949), President Ford required that "impact statements" be prepared on the inflationary impact of proposed regulations. E.O. 12044[1/] signed by President Carter on March 23, 1978, requires that a "regulatory analysis" be made of all "significant" regulations issued by Executive Branch agencies. The requirements and resulting pressures imposed by E.O. 12044 will be explored in this paper.

President Carter also set up the Regulatory Analysis Review Group (RARG) to "improve the quality of analysis supporting proposed regulations, identify and attempt to resolve common analytic problems among agencies, and assure adequate consideration of less costly alternatives."[2/] RARG examines in detail a limited number of these "regulatory analyses". The U.S. Regulatory Council created by the President in October 1978 is designed not only to identify and resolve cross-cutting issues but also to review the cumulative impact of regulations on vulnerable industries or sectors of the public. The Council includes the heads of 35 Federal regulatory agencies and publishes the Calendar of Federal Regulations - a synopsis and brief analysis of regulations likely to have a substantial economic or public impact.

Additional regulatory reform efforts are also on the horizon. Senator Abe Ribicoff (D-Connecticut), Chairman of the Senate Governmental Affairs Committee, indicated that in May 1979 the Committee had no less than 15 regulatory reform proposals pending.[3] Many of the bills that have been introduced including S.2147 also known as the Culver-Laxalt bill (which will be discussed later in this paper); S.262 introduced by Ribicoff; and S.755, the President's regulatory reform proposal require more analysis of the economic and non-economic effects of major proposed rules. For example, S.262 covers independent regulatory agencies which are currently exempt from the requirements of E.O. 12044. Ribicoff also indicated that the momentum for reform is strong and that Congress is in a receptive mood - both indications that the future trend will be towards increased analysis of regulations.

Consequently, there is a growing need for economic and non-quantifiable impact data on standards that will be used by Federal agencies in their regulatory programs. Data is also needed on the risks, hazards, and problems that a standard is designed to correct. This is especially true for those standards that meet either the criteria set forth in E.O. 12044 or the criteria established by individual regulatory agencies to implement this Executive Order. Data is also needed for those standards likely to be debated in a courtroom or in public or congressional forums.

Standards writing committees can have an important role in improving the quality of these evaluations. As the National Bureau of Standards noted:

> After nearly 80 years of history and experience, the discipline of identifying and qualifying both technical and economic impacts of standardization is still in its infancy.

A General Accounting Office Report noted:

> The evaluation of regulatory activities comes down to answering two fundamental questions. What costs are imposed by the regulation? And, what benefits follow from the regulation?... However, answering the questions is more difficult than posing them.[4]

Standards-writing committees may have access to needed data not readily available to Federal regulatory agencies. They may also have a better appreciation for and recognition of the various effects of a standard because of the wide ranging interests that are frequently represented in a committee.

One of the major assumptions of this paper has been that a private standards writing organization can determine if a standard is likely to be used by a Federal regulatory agency. In some cases, this information is available. The Bureau of Medical Devices in the Food and Drug Administration (FDA), for example, has developed and prioritized a list of needed standards. This list was published on February 1, 1980, in the Federal Register.[5] The Bureau has also actively communicated these needs and priorities to standards organizations working in the medical device area. Other regulatory agencies have not effectively communicated their interests to private standards organizations and need to do so before an effective working relationship can occur.

II. ANALYSIS REQUIREMENTS IMPOSED BY EXECUTIVE ORDER 12044

As noted earlier, Executive Order 12044 requires Federal executive agencies to analyze and compare the impact of all alternatives to "significant" regulations.[6] While each agency has some discretion in defining its own criteria for "significant", the factors that it is to consider in developing these criteria include:

1. The type and number of individuals, businesses, organizations, State and local governments affected;
2. The compliance and supporting requirements likely to be involved;
3. Direct and indirect effects of the regulation including effect on competition; and
4. The relationship of the regulations to those of other programs and agencies.[7]

Those regulations that meet the agencies' criteria for "significant" and which may have a major economic effect on the general economy or on specific regions, industries, individuals, or the government itself require an analysis and comparison of the economic consequences of various regulatory alternatives. The Order provides that, at a minimum, such analyses will be performed for all regulations which result in:

1. An annual effect on the economy of $100 million or more; [8] or
2. A major increase in costs or prices for individual industries, levels of government or on geographic regions.[9]

As the result of analyzing the progress made on the implementation of E.O. 12044, the Office of Management and Budget (OMB) intends to:

> "...stress to the agencies that a regulatory analysis should be done for: 1) any sufficiently important or controversial rule that the agency head thinks deserves analysis; and 2) any rule with potentially major cost/price effects on a particular region, group, industry, or economic sector."[10]

The RARG, for example, reviewed the Environmental Protection Agency's proposed standard for toxic effluents by the leather-tanning industry. The standard was considered a precedent-setting rule despite an estimated impact of only $7 million -- far below the $100 million criteria for a "significant" regulation.

The Order also includes a requirement for reviewing existing regulations. This requirement may result in regulatory analyses of standards that were included in regulations issued prior to March 1978 - the date of the Order.

This Order is still new and its implementation is not complete. "The Order has been in existence since March 1978, but it has been operational in most agencies only since January 1979."[11] Agencies are still learning how to develop analyses that "contain a succinct statement of the problem; a description of the alternative ways of dealing with the problem; an analysis of the economic consequences of each of the alternatives; and a detailed explanation of the reasons for choosing one alternative over the others."[12]

OMB guidelines on conducting regulatory analyses require:

1. Each regulatory analysis will contain an analysis of the economic consequences -- direct as well as indirect effects, and their significance -- of each of these alternatives (including the no action alternative); such consequences should be presented in comparative form to sharpen the issues and provide a clear basis for choice among alternatives; these consequences include:

    a. specific burdens imposed by each alternative

        (i) what types of burdens (and how much) are placed on specific groups as a result of compliance?

            - capital outlays
            - other costs of compliance including operating and maintenance costs
            - administrative burden (reporting requirements, delays, uncertainty, etc.).

        (ii) who bears these burdens?

            - what burden falls on what types of enterprises, levels of government, major geographic regions, communities, and urban areas? (e.g., the impact on employment, fiscal conditions, availability of public services, etc.)

- how are consumers and various population groups burdened? (e.g., income distribution, housing availability, etc.)

(b) specific gains produced

(i) what type of specific gains (and how much) to society as a whole would each alternative produce?

(ii) who would be helped, how, and by how much, by each alternative?

(c) overall economic impacts of each alternative

(i) how would productivity and overall economic efficiency be affected?

(ii) how would prices and employment be affected?

(iii) how would the U.S. foreign trade position be affected (e.g., effect of increased costs for domestic companies on the price of goods that compete with imports, effect of increased costs for domestic companies on the price of U.S. exports, effect on the quality or utility of products and thus on the demand for U.S. exports, extent to which foreign competitors are subject to similar regulations, effect on competition between U.S. and foreign suppliers in third countries)?

(2) A detailed explanation of the reasons for choosing one alternative over the other; questions to be answered:

(a) will the selected alternative produce the intended results in the least burdensome manner possible? If not, why is this the preferred alternative?

(b) Why isn't the action more stringent? -- less stringent? What tradeoffs does the selected alternative reflect?13/

III. ECONOMIC ANALYSIS REQUIREMENTS OF S.2147

Of the many regulatory reform bills pending before Congress, the provisions of S.2147, will be discussed to indicate future trends in regulatory analysis requirements. This bill was chosen because it incorporates many of the reform measures contained in other bills.

S.2147, the Regulatory Flexibility and Administrative Reform Act of 1979, was sponsored by Senators John C. Culver (D-Iowa) and Paul Laxalt (R-Nevada). On May 7, 1980, the Senate Judiciary Committee reported out S.2147. Some of the bill's provisions which will have an effect on the need for analysis of regulations include:

- o A requirement that all agencies including independent regulatory commissions prepare regulatory analyses of proposed rules. These analyses are to include the need for the regulation, projected consequences and practical alternatives.

- o A requirement that agencies also develop regulatory flexibility analyses designed to encourage agencies to tailor their rules to fit the scale and resources of individuals, businesses, organizations, or Government jurisdictions that must comply with the rules.

- o A requirement for periodic review of regulations to determine if they need to be revised or dropped.

- o A procompetitive standard to encourage competition and innovation. This standard will require economic regulatory agencies in certain instances to choose the least anticompetitive alternative.

Other provisions of the bill include:

- o Establishment of a Regulatory Policy Board to consolidate the regulatory oversight functions in the Executive Branch.

- o A requirement that all major Federal regulatory agencies be re-evaluated by Congress and the President over a 10-year cycle - a form of "sunset" legislation.

- o Expedited formal hearing procedures as well as authorization to adopt "hybrid" rulemaking procedures that resemble legislative hearings.

Provisions such as these are included in other bills and indicate that the need for standards writers to work with regulators in conducting analyses of standards will be more critical in the future.

The provisions contained in this bill also show that a greater analysis will be required of standards used in regulatory programs, especially on (1) their impact on different types and sizes of organizations or firms; and (2) on innovation and competition.

IV. ECONOMIC ANALYSES -- IMPLICATIONS IN THE COURTROOM AND IN PUBLIC AND CONGRESSIONAL FORUMS

A. In the Courtroom

Economic analyses are needed not only to comply with E.O. 12044 or in anticipation of potential regulatory reform measures that are likely to be passed, but also because they are assuming greater implications in the courtroom. Regulated industries have consistently sought to bring about greater consideration of alleged economic and inflationary impacts arising from agency rule-making by urging agency adoption of c/b/a (cost/benefit/analysis) - primarily through litigation challenging agency actions not premised on c/b/a.[14] On October 5, 1978, a Federal appeals court in Louisianna struck down the Occupational Safety and Health Administration (OSHA) standard for benzene -- an industrial chemical suspected of causing leukemia and other fatal blood disorders even in low level concentrations such as the levels found around automotive service stations. The standard was struck down because "without an estimate of benefits supported by substantial evidence," the court argued, "OSHA is unable to justify a finding that the benefits to be realized from the standard bear a reasonable relationship to its one-half billion dollar price tag."[15] Since OSHA is not required by statute to conduct economic analyses, the court, in effect, has added to OSHA's statutory requirements. While this case was still pending before the Supreme Court for review as of June 1980, the implications are clear. The court is not immune to economic persuasions.

Judge David Bazelon, a well known figure in this area, indicated that the:

> ... important thing is that the agency generate a record in which the factual issues are fully developed. By articulating both their factual determinations and their value preferences, and by attempting to separate the one from the other administrators make possible effective professional peer review, as well as legislative and public oversight.[16]

Regulatory agencies which adopt voluntary standards which do not include economic impact data, stand the risk of not being able to defend such standards in court.

B. In the Public and Congressional Forums

While not all regulatory agencies' authorities, statutes and court decisions come as near as OSHA's in implying that economic considerations should be taken into account, public and congressional pressure can be brought to bear on all regulatory agencies making economic analysis of regulations almost as mandatory. In the case of the Food and Drug Administration (FDA), the criteria for the approval of drugs is safety and effectiveness, not economic considerations. However, when a study done by University of Chicago economist Sam Peltzman 17/ concluded that the 1962 Drug Amendments resulted in a net loss to consumers of $200-$250 million annually or the equivalent of a 5% - 10% tax on drugs, FDA invested considerable resources in refuting the results of this study. Controversial regulations and decisions are likely to be debated in public and congressional forums, if not in an actual courtroom setting. Regulatory agencies must have data available to explain and/or defend a standard in such arenas.

Congressional oversight hearings, one type of congressional forum, can be called to hear testimony on an agency's actions. The agency is under great pressure in such hearings to have adequate data to support its position. Questions raised during budget hearings, another type of forum, can be an extremely effective way to call attention to an agency's actions because appropriations can hinge on the adequacy of an agency's responses. "Sunset" reviews, such as those required under S.12147, could provide yet another reason for agencies to have adequate data available to justify their regulations and consequently their existence.

Congressional studies provide another check on the cost/benefit/ effectiveness of agency actions. For example, an extensive Study of Federal Regulation was sponsored by the Senate Committee on Governmental Affairs and was published in July 1977.18/ Recommendations of the study included guidelines for developing regulations and suggested a series of cost/benefit/ effectiveness-type questions which should be addressed prior to any regulation changes. The Committee also published a study on the Benefits of Environmental, Health, and Safety Regulation in March 1980.19/ That study reviewed existing private and public sector studies on the costs and benefits of certain regulatory areas. The Joint Economic Committee published the study, Government Regulation: Achieving Social and Economic Balance, in June 1980. This study recommends that such cost/benefit reviews be mandated by Congress20/

In addition, the Congress uses the General Accounting Office (GAO) to evaluate the cost/benefit/effectiveness of regulation. GAO has done numerous studies on the regulatory activities of specific agencies, the cost/benefit/effectiveness of specific regulations, as well as studies on regulatory activities in general. These studies provide Congress with information on the merits of agency regulations and pressure agencies to assure that the regulations studied are economically desirable.

Legislative veto provisions, another congressional check, appear in approximately 300 statutes delegating regulatory authority to the President, to the executive branch or to independent agencies.[21] They usually enable Congress to invalidate a rulemaking action upon passage of a resolution by one or both Houses of Congress within a 30 to 90 day period - an increased pressure on regulatory agencies to develop data to justify their regulations. In Nader v. Adams No. 78-1034, (D.C. Cir., filed January 13, 1978), consumer advocate Ralph Nader alleged that the Department of Transportation (DOT) delayed its airbag order because it feared a legislative veto, though no such veto occurred. The possibility of a legislative veto, however, appeared to have a significant impact on the DOT's rulemaking.

In the future, Federal agencies may also face a congressionally-imposed "regulatory budget" requirement. Such a requirement was recently called for in the June 1980 study on government regulation published by the Congressional Joint Economic Committee.[22] A regulatory budget would require a strict accounting of the costs of newly proposed regulations and consequently would require detailed cost data on any voluntary standards used in Federal regulations.

Regulatory activities are also frequently "news." The news media keeps the activities of regulatory agencies before the public, and such scrutiny can put tremendous pressure on agencies to publicly explain and justify their actions. The media also brings congressional reviews of regulatory activities before the public, serving as a second barrel of a double barreled shot gun - agencies thus have two chances of getting shot down if they cannot adequately explain their actions.

V. PROBLEMS IN ASSESSING ECONOMIC COSTS AND BENEFITS

A. Difficulties Experienced in Implementing E.O. 12044

In conducting economic analyses, standards writers and regulators can learn from the experience and results of Federal agencies in implementing E.O. 12044. OMB's analysis of the progress of government agencies in implementing E.O. 12044 pointed out that the Federal government has had considerable difficulty in conducting economic analyses of proposed regulations that have met the criteria established under E.O. 12044. For instance, according to OMB, deficiencies in the Department of Agriculture's analyses have included: "inadequate quantification of impacts, unimaginative development of alternative options, tardy preparation of the analysis, and unnecessary reluctance to reveal areas of uncertainty or the negative effects of options."[23/] Problems in the Department of Commerce's analyses have included: "limited data; lack of appropriate economic models to judge changes in costs, prices, productivity, employment, and other conditions..."[24/] In the case of the Department of Interior (DOI), one commentor in the OMB report noted: "Industry was having to make its own analysis only to find that industry numbers and agency numbers were not the same. Truth was, they (DOI) didn't have the data to make an analysis -- it was incomplete -- inconsistent."[25/] While most government agencies currently lack the necessary expertise and experience to do their own economic analyses, they are at least in the process of acquiring it. Deficiencies in the data used in the analyses appear to be the greatest problem. The problems resulting from and the causes for some of the deficiencies in the data as well as deficiencies in the techniques used to assess the data are discussed in more detail in the following sections.

B. Availability, Adequacy and Cost of the Data

When analysts develop economic data on the effects of any standard, they must make a series of forecasts and assumptions whose validity can only be tested by the passage of time. The rate or amount of the price increase of the product(s) covered by the standard, for example, cannot be predicted with certainty. The effect on product safety also must be estimated. Economic data is only as valid as the estimates on which it was based.

The cost of obtaining the necessary data can also be very high or even prohibitive. If the data is required to aid a regulatory agency in using the standard as part of its regulatory program and the private standards-writing

organization or industry is unable or unwilling to undertake the entire expense, then government must be willing to bear a share of the costs. Data that a standards-writing committee may need on the impact of a voluntary standard under development may be available within the government but be unknown to the committee. Communication problems between government and private standards-writing committees prevent the sharing of this information. If a Federal regulatory agency wants a standards-writing committee to undertake the collection and development of hazard, impact, and cost data, then good communication and equitable cost sharing are vital.

Another problem in data collection, already experienced by the government, is the unwillingness of corporations to release relevant data for public scrutiny. Companies are likely to be reluctant to release data particularly on the health, safety and environmental impact of the products they produce. For example the aluminum industry, by court order, stopped the Consumer Product Safety Commission from releasing information on hazardous aluminum wiring affecting a number of buildings and homes.[26] Other such incidents are:

- In the early 1970's the chemical industry estimated its compliance cost with the proposed vinyl chloride standard at 200 fold what it turned out to be ...

- The Securities and Exchange Commission found that the U.S. Steel Corporation kept two sets of data on compliance costs with environmental standards: one for investors and another higher one for the media and the public ...

- In a May 29, 1974, letter to the U.S. General Accounting Office, Volvo, the Swedish automaker, noted that most of the data released by U.S. automobile manufacturers on the cost of meeting federal regulations was based and "aimed purely at resisting regulation." ...

- In response to a query from Ralph Nader, a garment manufacturer estimated that flame-retardant pajamas would retail for $1.70 more than regular pajamas. When it later provided actual cost data, the manufacturer revealed that the differential was less than one-third of its initial estimate.[27]

As the cases above point out, resistance to the voluntary or mandatory standards, the desire to have less stringent requirements in a standard under development, and fear of adverse legal implications can cause industry to refuse to release data or to misstate the data it releases.

If erroneous data is supplied to the standards development committees and is included in the economic analysis of the voluntary standard, this data will be used by a regulatory agency to evaluate the voluntary standard. Not only is the validity of that voluntary standard likely to be questioned if the errors are discovered, but the future work of the committee and the data it supplies are also likely to be viewed as suspect. The credibility of a voluntary standards development group and the effective use of voluntary standards by the Federal government are intrinsically correlated.

Even if "producer" committee members are able to obtain cost data from their firms, because such members are more likely to be employed by the larger firms in the industry, the data may reflect such a bias. One example of this effect can be seen in the estimates that the auto companies have provided to the Department of Transportation on the fixed costs of complying with existing Federal emmissions, safety and fuel economy standards from 1978 through 1985 (see Table I.)

Table I

SALES, PROFITS, AND ESTIMATED
REGULATION-MANDATED COSTS FOR THE BIG THREE[28/]

	Chrysler	Ford	General Motors
Cost of regulation (millions)[a]	$800	$1,000	$2,000
Cost as percent of sales	7.0	4.2	4.6
Cost as percent of aftertax profits	496.9	112.7	68.5
Cost per car produced	$550	$340	$345
Net sales (millions)[b]	$11,390	$23,969	$43,430
Aftertax profits (millions)[b]	$161	$887	$2,918
Number of cars produced (thousands)[b]	1,451	2,933	5,782

[a]Average for 1978-85.

[b]Figures are for 1977 North American operations.

In the auto industry, Chrysler (while it is a large firm by absolute standards) is small relative to the size of Ford and General Motors. Chrysler's cost per car has been $550, while the cost per car for Ford and GM has ranged from $340 to $345.

Some standards, if they are adopted as part of a regulation, could alter the competitive structure of the industry in a similar manner by imposing a disproportional burden on smaller firms. This can occur in several ways.

> If the regulation imposes an ad valorem burden - that is, imposes costs directly proportional to the value of the company's output - it is equivalent to a uniform sales tax. If the regulation imposes a per unit burden, it is equivalent to a tax bearing most heavily on those units with the least value added. Finally, if the regulation imposes a fixed burden without regard to the quantity of output it is equivalent to a lump sum tax. Given generally similar unit values of output, such a uniform requirement for each firm in the industry will impair the performance of small firms relative to large firms.29/

Small firms are not able to pass on more of the costs of a standard or a regulation through product prices increases than the competitive process allows. Small firms cannot usually remain competitive with larger firms if the small firms must charge more for a comparable product. If the effect of the standard on different sized firms is not determined and only an average cost per firm is calculated, then consideration will not be given to the possible anticompetitive effects on the industry of some firms having to increase prices substantially more than other firms. It is necessary to examine the effects of any proposed standards on individual types of firms that comprise the industry affected by the standard - both domestic and foreign.

Data on the impact of a standard on firms producing different grades or types of products covered by the standard may also be needed. In a study done by the Consumer Product Safety Commission on the economic impacts of an upholstered furniture standard, they discovered:

> The larger firms in this industry tend to produce large runs of cheaper grade furniture, whereas many small makers are producing a limited line of more expensive custom-styled furniture. So on an item-by-item basis non-destructive testing would have a greater per-unit percentage cost impact on cheaper items produced by large manufacturers. However, CPSC is aware that there are

> within this industry small firms making a less expensive line who would be severely impacted. The Commission also points out that fabric supply shortages could result from flammability standards, which would be expecially damaging to smaller makers of finer furniture.30/

The relationship between the type and size of a specific firm and the impact of a standard can be very complex. If the relationships are not determined, however, and an anticompetitive effect results from the use of the standard in a regulation, then the regulation could be subject to challenge in the courts and possibly overturned. Likewise, it is possible that different groups, localities of consumers, or different categories of users may be affected differently by a standard.

C. The Problem of What Costs Should Be Measured

The net economic cost of regulatory standards ideally should include only those costs that are solely required by the standard plus all incremental benefits. It should not include costs that the industry would have incurred or benefits that would have been realized regardless of the existence of a standard. Estimating what an industry would have spent and what benefit would have been realized regardless of the existence of a standard is a very difficult process. Firms may have begun implementing a standard in anticipation of its passage, and these costs could end up being reflected as costs the firms would have incurred without such a standard. Estimating the incremental costs resulting from secondary effects such as loss of productivity, construction delays, and inflation are especially difficult.

D. Problems in Developing Data on Hazards/Risks

Risk identification and quantification are necessary to justify a standard or a regulation and to measure the potential benefits from risk reduction. Such identification, however, can be difficult if not impossible. As noted by Dr. Irving Selikoff of Mr. Sinai Medical School:

> We will not know for another twenty years whether the chemicals introduced in the 1960's are hazardous."31/

The adverse affects of the drug, diethylstilbestrol (DES), used to prevent miscarriage over a twenty-five year span are just now being realized.

The causes of these problems result from a number of factors including: (1) the existence of a time lag between exposure and the appearance of the effects as in the case with DES; (2) the existence of intervening or interacting events which may or may not affect the appearance of adverse results; and (3) poor or nonexistent data. Data problems can, for example, result from extrapolating animal data to humans which is a questionable practice at best. Yet using humans as guinea pigs in such testing would be unacceptable. In addition, a product may have minimal risks associated with its use -- provided it is not used with certain other products or chemicals or under certain circumstances. The possibility of additive or synergistic adverse effects among interacting agents is not only a difficult problem to identify, but it can also a difficult if not impossible task to include such interactions within the context of a cost/benefit or cost/effectiveness equation. For example, a given noise level may be below the threshold level at which hearing damage occurs; but nonetheless if the noise is in the workplace, it can reduce visual acuity to the point where there is an increased risk of industrial accident. Quantifying and including the potential effects resulting from all possible interactions in a cost/benefit equations, even if such effects are known, would be a difficult task. There have been numerous documented cases of adverse reactions resulting from mixing certain foods and beverages with particular drugs, as well as with the amount of and the time of day a drug is consumed. Techniques currently available to assess such risks are far from adequate; and as the National Academy of Sciences noted:

> Perhaps the most important problems are those for which there are no data -- the effect of today's radiation ten years hence, the probability of nuclear meltdown, (and) the future buildup of nuclear wastes ...32/

Other problems include lack of knowledge on how a hazard reacts with or is affected by its environment, such as: how hazardous pollutants react with other chemicals in the atmosphere; the potential for increased risk to population subgroups, such as the aged or pregnant women; and lack of knowledge regarding the physical expression of mutagenic effects in a biological system.

E. The Existence of a "Learning Curve"/Accelerated Technological Progress

Economists and other analysts have difficulty in assessing whether or not a "learning curve" or "the acceleration of technological progress" will occur upon implementation of a new standard or regulation. These terms refer to a situation where costs will go down as greater experience is gained or new

methods are developed in implementing the standard or regulation. Whole new industries may arise as the result of regulation and the desire to control or reduce the costs of complying with a regulation. For example, the government's pollution control regulations have lead to a flurry of innovative activity as well as the formation of a pollution control industry which manufactures devices and chemicals designed to deal with the problem of pollution. This has lead to the creation of new products, new jobs, and many other benefits.

A study on the cost of new bumper safety standards done by Dr. Murray Weidenbaum of the Center for the Study of American Business estimated the cost per car to be $340. The National Highway Traffic Safety Administration later found that the actual cost per car was closer to $250.[33/] One of the problems with Weidenbaum's estimate was that it failed to take into account a "learning curve" -- that experiments with different materials could and, in fact, did lead to the development of a less expensive bumper which could meet the standard.

F. Problems in Assigning Dollar Values to Some Costs and Benefits

Those seeking to quantify the value of costs and benefits for comparison purposes have considerable difficulty when confronted with impacts that have not traditionally been quantified and assigned economic values or with the mathematical idiosyncracies of available methodology. Methods of analysis currently available are, for the most part, unable to effectively deal with these types of problems. The two most widely used methods of analysis are the cost/effectiveness technique and the cost/benefit technique. While the cost/effectiveness technique supposedly overcomes the problems of assessing non-quantifiable benefits, it is rare that relative benefits do not have to be compared in some fashion. For example, suppose that the desired result of a standard is to reduce risk by 50 percent or more. One alternative may reduce risk by 65% at a cost of $1,000,000. The other technique may reduce risk by 55% at a cost of $800,000. The choice of alternatives approaches a quasi cost/benefit analysis exercise -- is the additional 10% decrease worth $200,000? In addition, placing a dollar value on intangible or noneconomic costs still poses the same problems as those experienced in cost/benefit analysis.

A mathematical quirk of cost/benefit and cost/effectiveness ratios is that they do not show which alternative produces the greatest benefits. For example, if one life can be saved for $100 and 100 lives can be saved for $100,000, the former alternative would be selected because it has the best cost/benefit ratio, although the benefits (lives saved) of the latter alternative are far greater - 100 to 1.

The problem of measuring and quantifying intangible or noneconomic costs and benefits with current analytical methods is also formidable, and none of the available techniques can effectively handle impacts that are non-quantifiable in monetary terms. Intangibles are products, services, or conditions not usually bought or sold at a price or a fee and whose value cannot be derived indirectly from the dollar value of any secondary products they might produce. They may only be measurable in monetary terms by arbitrarily attributing a dollar value to them. Such intangible or noneconomic benefits might include a better informed consumer; reduction in the hazards to human life; preservation of scenic beauty, wildlife, and the ecosystems; decrease in noise, smell, air pollution, water pollution, litter and food contamination; better national security; increased buyer confidence; reductions in the restrictions on trade, innovation, and competition; more efficient industrial process; better products; safer, healthier workplaces; and reduced production of unsafe products. Intangible costs could include the opposite of those mentioned above, as well as interuptions in production and employment resulting from the implementation of the standard, and increased discomfort or lack of ease in using the product(s) covered by the standard. These intangible costs and benefits can either be ignored in the equation making the final outcome questionable, or an attempt can be made by the analyst to assign a value to them. The methods currently available, however, to quantify intangibles have serious deficiencies. The National Academy of Sciences' Committee on the Principles of Decision Making for Regulating Chemicals in the Environment noted:

> Different individuals place different values on things such as human life, aesthetics, or national security. Thus an analysis that assigns a quantitative value to ... these factors is necessarily subjective and, to some degree arbitrary.34/

In addition, human lives are not homogeneous.

For example, while new approaches are being developed there are at least five approaches now being used to assign a value to a human life outside of pure judgement. One is the discounted future earnings (DFE) approach which places a value on a life based on the computation of the value to society of a person's labor. Future earnings are discounted to reflect the assumption that a dollar is worth more now than in the future. Other losses and costs may be added to the DFE base such as the costs of the person's living or dying to society, and the costs of medical care, lawyers, and funeral expenses.

Under this method, however, the value placed on the lives of those without much earning potential such as the handicapped, the aged, or the very poor is next to nothing -- an assumption that a person in one of those classes might question. The life of a baby boy would also be assigned a higher value than a baby girl's life since his earning potential would be greater. The discount factor, in addition to being difficult to determine, can also place higher values on those who are closer in age to their future earnings. A baby's life would, therefore, be valued less than an eighteen year old who might be starting his productive earning career.

Another method, "willingness to pay" (WTP), is equally flawed. WTP allows an individual to place a value on his own life, safety, or health. Problems arise because the value that an individual places on these factors is likely to increase as the risks increase. For example, an employee may accept $1,000 for a 1-in-1000 risk but may not accept $10,000 for a 1-in-100 risk. In addition, willingness-to-pay frequently correlates with the ability-to-pay -- a rich person is often able to and willing to pay more for his life than a poorer person. For these reasons, the applications of this method have not shown much consistency in the results obtained. Two surveys, for example, which discussed the disparity of the dollar values assigned to a human life, noted:

> Such outrageous range of values ($28,000 - $5,000,000), spanning two orders of magnitude, seems less a reflection on human intelligence than an indication of the primitive state of the survey (WTP) approach.35/

Dr. Edward I. Mishan, Professor of Economics, London School of Economics and American University, developed an approach which expands on the WTP method and accounts for not only the benefits and costs to those whose health and safety risks are directly affected, but also for costs and benefits to those indirectly affected. This includes the negative benefits (costs) to those that may wish to see the person harmed.

> For example, an analysis of a health program especially effective in reducing the risk of death for the elderly would add the WTP of the elderly, their friends, family, and the public at large -- but then subtract from this total the amount necessary to compensate any greedy heirs for the decrease in their welfare resulting from the possible lengthening of the lives of their eventual benefactors. 36/

While this approach may be theoretically sound, it is inconsistent with the American political and moral philosophies to recognize malevolent preferences.

Explicit valuations of the worth of a life in the form of jury awards for wrongful death is also a possible, though less frequently used, approach to placing a value on human life. The court determination is usually based primarily on the loss of the victim's net earnings, but may also include other losses such as loss of the victim's services.

Courts have faced serious difficulties when awarding compensation to parents for the loss of a child. Recent court awards have considered the parents' investment in raising the child and the loss of the child's companionship, though prior court awards only carried compensation in cases where the child's services exceeded the cost of his support.

Placing a value on a human life based on court awards results in discrimination against certain segments of society - those who are not wage earners or who are not contributing valuable services to other members of a family or society. The awards are also person-specific; that is, each award is identified with one specific individual and not a category of individuals. There is also considerable variation between the amounts awarded by the court in similar cases.

Yet another approach similar to the DFE approach involves estimating the worth of a person's life by the amount of foregone consumption. In this approach, the value of a life is also age-dependent. Because as the probability of death at any specific future time increases with age, the value of the foregone consumption decreases. Children, therefore, would have the highest value placed on their lives; and the aged the least. This again is a form of discrimination against certain segments of society.

A fifth way of placing a value on a life rests on using the number of dollars that the government has expended in order to reduce certain types of deaths. The problem with this method is that agencies are not consistent in the amounts that they

are willing to spend to save a human life. As noted below, there are not only differences between agencies, but there may also be differences between programs within a single agency. If the government has spent more to reduce the number of deaths for certain categories of individuals than for others, the lives of those former categories would be assigned a higher value - again a form of discrimination.

> The Nuclear Regulatory Commission has adopted a value of $1000 per man rem to use in its (cost/benefit analysis) application which, when multiplied by the number of rems capable of producing different types of deaths, provides dollar values for human life. The Environmental Protection Agency's Office of Radiation Programs, also dealing with the health effects of radiation ... has chosen a value of $500,000 per life ... The Consumer Product Safety Commission has used values ranging from $200,000 to $2 million per life in different analyses. Highway transportation officials have frequently used a value of $200,000 per life. The National Bureau of Standards (in several studies) used $300,000 per life ...37/

Similar problems arise in the application of the available methods for assigning a value to the other intangibles -- many of which directly or indirectly involve placing a value on life and health.

As a Senate Committee on Governmental Affairs study noted:

> ...(T)here is no appropriate way to put a dollar value on the costs of the pain and suffering endured throughout the lifetime of a child who is the victim of a sleepwear fire... Clearly it is not enough to total up... the reduced costs of medical treatment.38/

As noted in a Congressional Research Service Report, this lack of methodology has resulted in values being assigned to intangible costs and benefits which vary depending on who conducts the cost/benefit study:

> What has disturbed several observers of some cost (benefit) estimates particularly projected cost estimates for many individual regulations (standards) ... is that they tend to support the vested interest of the sponsor of the estimate or to fit the hypothesis of the individual making the estimate... The effectiveness of federally mandated safety standards in saving lives and limiting injuries is estimated to be greater by insurance companies than by automobile manufacturers.39/

One congressional subcommittee noted:

> The most significant factor in evaluating a benefit-cost study is the name of the sponsor.[40]

It is unlikely that the values assigned to intangibles by private standards-writing committees (even if they could be assigned in an acceptable manner) would the same as those assigned by a Federal regulatory agency. As the Commission on Law and the Economy of the American Bar Association noted regarding proposed governmental actions:

> When proposed actions and their consequences are viewed in a political balance, "value" is often in the eye of the beholder.[41]

G. The Discount Factor

Any person who tries to place a current value on future costs and benefits will run into the problem of choosing a discount factor to evaluate future impacts. While the Office of Management and Budget (OMB) indicated in a 1972 directive that the rate should be 10%, this directive has been largely ignored.[42] In the absence of a generally accepted discount rate, analysts are free to choose and often do choose discount factors that will support the action that they wish to be chosen.

The choice of the discount rate can be the deciding difference between two choices depending upon the rate that is chosen, because the lower the rate, the higher the value of future benefits and costs. For example, the present value of $100 which will be received in 10 years is $55.80 if a 6% discount rate is chosen; but only $16.20 if a 20% discount rate is used.

The problem of choosing a reasonable discount rate is compounded by unstable inflation rates, energy prices, and interest rates. Some government agencies base their choice of a discount factor partially or totally on the rate of interest that the government is paying on its long term obligations. However in recent months that rate has fluctuated between 8% and 14%.

Until the OMB or other appropriate Federal agency is able to publish and enforce the government-wide use of a uniform methodology to establish an appropriate discount rate, the choice of a discount factor like the assignment of values to intangibles should probably be left to the regulatory agency.

H. Greatest Net Economic Benefit Versus Equitable Cost/Benefit Sharing

Another problem for the standards writer and user results from the characteristics of the consensus process itself. The final standard is usually the one that is most nearly acceptable to all interests represented on the standards-writing committee.

Cost/benefit and cost/effectiveness techniques do not consider inequalities in the distribution of costs and benefit within or among generations. This characteristic is incompatible with the consensus process. The final version of the voluntary standard is not necessarily the one that generates the greatest net economic benefit. It is the result of compromises on the benefits and costs that will accrue to each interest group affected by the standard. In addition, the benefits and costs should be fairly shared with generations to come. A standards-writing committee will probably decide on a standard that, while it may not be the one that produces the greatest net economic benefit, at least allows the costs and benefits of the standard to be more equitably shared.

VI. RECOMMENDATIONS

The problems presented in this paper are not easily resolvable. There are, however, several steps that can be and should be taken to improve the effective use of standards by regulatory agencies. These include: (1) having Federal regulatory agencies prepare lists of the specific costs/benefit categories that they are interested in; (2) having standards writing committees begin collection of economic data as soon as the development of a standard is begun; (3) having the committee concentrate their efforts on data collection and not on the application of evaluation techniques; (4) not having committees try to quantify compliance costs incurred by agencies and paperwork burdens incurred by industry if standards are used in a regulatory program; and (5) disseminating the data collected as broadly as possible and including in the data records any objections to the accuracy or applicability of data. These recommendations and their rationale are discussed in more detail below.

A. RECOMMENDATION ONE: FEDERAL REGULATORY AGENCIES SHOULD PREPARE LISTS OF THEIR SPECIFIC COST/BENEFIT DATA NEEDS

Rationale:

As any economist knows, the direct and indirect costs and benefits that can be looked at in making economic evaluations are almost limitless. If a dog in one state bites a girl, then costs are incurred by the girl, the parents of the girl, the family and friends of the girl and her parents, the owners of the dog, relatives of the owner of the dog, etc. One can even carry the analysis to the point of trying to assess the benefits of that dog biting that girl in that state, because he was unable to bite children in another state at the same time. It is in neither the standards writing committee's nor in the government's interest to have standards committees spend time collecting data about all direct and indirect benefits and risks. Even in E.O. 12044, some guidelines, though inadequate, are given to agencies on where to direct their attention. Agencies need to develop specific guidance on what cost/benefit data are useful. How these guidelines are developed, along with their format and content, will depend on the interests and statutory authorities of the specific regulatory agency. The agency may wish to establish thresholds, i.e., include information on anticipated price impact when that impact is expected to affect the price of the article by X% or more. They may wish information to be obtained based on the type of product or type of standard regardless of any thresholds; i.e., the effects on competition of any design standard. Defining their interests as

specifically as possible will aid not only the standards group but also the agency itself when it comes time for them to make the actual analysis. It will help alleviate the need to do after-the-fact analyses which can and do delay implementation of standards. A list of intangible and tangible factors to be considered in calculating the economic impact of standards was developed and published in the National Aerospace Standard (NAS) 1524. The list (which is included in Appendix II) can be used by regulatory agencies to develop a basic list of factors and thresholds that a standards committee can use as a guideline for data collection.

For routine regulations or standards that will be used in regulatory programs, the Environmental Protection Agency (EPA) has indicated that it is interested in the following data:

- -the number of establishments that will be affected;
- -an estimate of the total costs that will be borne by each affected industry segment;
- -an estimate of the price impacts under an assumption that cost changes will be reflected in prices;
- -an estimate of revenue changes for each segment if costs are not reflected in price changes;
- -an estimate of job gains and losses;
- -an estimate of total energy impacts for each affected industry segment; and
- -an estimate of impacts on any particular regions and localities that will be more seriously affected than others.43/

For major regulations or standards that have significant economic impact, the EPA is interested in more detailed information. Their recommended approach for developing a data base for in-house analysis is as follows.

1. Prepare an economic profile of the affected sectors (producers and/or consumers), including the industry structure (e.g., degree of concentration, the way prices are determined), the type of competition in the affected sectors, and performance trends (e.g., financial rates, growth trends) of the affected sectors.

2. Segment the industry (or other affected groups) into categories of economic units that will be similarly-impacted (e.g., according to size distribution, polution control process, age).

3. Develop marginal (incremental) cost effectiveness curves for each process/strategy for each affected industry segment.

4. Analyze the economic impact of proposed standards and of alternatives including any economic benefits from regulation (standardization) such as the generation of new product markets and new employment opportunities. It may not be necessary to analyze all alternatives in the same level of detail. The following impacts are analyzed when feasible:

(a) price effects
(b) production effects
(c) industry growth, profitability, capital availability effects
(d) employment effects
(e) community effects, including disproportionate effects on particular regions or localities
(f) balance of trade effects
(g) energy effects[44] (See Appendix III for more detail)

In some cases, the agency may already have some or all of this data available. It is important for a standards committee to check with the agency or agencies that are likely to be using the standard to see if they have or can obtain this information from other government sources before the group attempts to "reinvent the wheel." It also benefits the group to check with the agency's organizational unit responsible for in-house economic analyses and/or the implementation of E.O. 12044 for additional guidance on how costs and benefits should be arrived at or estimated. EPA has an Economic Analysis Division which provides guidance in conducting economic analyses to EPA program offices. Most agencies have a central source for standards committees to contact regarding what types of data an agency includes in their economic analyses. The names of contacts should be made available by regulatory agencies to standards organizations for this purpose.

B. RECOMMENDATION TWO: STANDARDS WRITERS SHOULD CONDUCT AN INITIAL ANALYSIS OF THE STANDARD TO DETERMINE DATA NEEDS

Rationale:

An initial review of the potential impact is needed once a standards-writing committee agrees to work on a standard that is likely to be used by a Federal regulatory agency. This initial analysis by the standards-writing committee should determine: (1) what, if any, are likely to be the areas where the standard will have a significant economic impact; (2) what effects are likely to meet the criteria or guidelines set forth by the appropriate regulatory agency on its data needs; and (3) if the standard is likely to be controversial or have a more significant impact on one segment of the public sector.

As a matter of policy, several Federal agencies, such as the Departments of Agriculture and Transportation, undertake an economic evaluation of every proposed regulation. If the standard falls within their purview, at least some data will always be required. The initial analysis should look at alternatives to the standard and the costs and benefits of each alternative. This initial analysis should aid standards writers in assessing the potential economic consequences of their proposals as they proceed in the development process. The enumeration of costs and benefits may also help standards writers focus on objective rather than subjective considerations in the standards development process itself. The analysis may also show the types of data that a regulatory agency is likely to need, and give the committee time to contact the agency to see what data is available and what they need to collect. More time will be available to collect data not easily obtainable and to resolve any funding problems without slowing down the completion of the standard. Government has often discovered in "hindsight" the need to develop a regulatory analysis or to expand the analysis to include additional factors. In many cases, this delay could have been prevented if a careful initial analysis had been done. Standards writers should also periodically review their initial judgements to see if they have overlooked any impacts of significance as well as to assess the utility of the version of the standards proposal under consideration.

C. RECOMMENDATION THREE: STANDARDS-WRITING COMMITTEES SHOULD CONCENTRATE ON DATA COLLECTION

Rationale:

It is difficult for standards-writing committees to "second guess" a regulatory agency on what the values of intangible benefits and costs should be in cost/benefit and effectiveness equations. William D. Rowe, Director of the Institute of Risk Analysis at the American University, noted: "A risk (cost) is acceptable when those involved are no longer apprehensive about it.45/ When a regulatory agency uses a voluntary standard, the risks or costs of that standard are acceptable to the regulatory agency when the agency is no longer apprehensive about them. Haggai Cohen, Director of Reliability and Safety for Space Transportation Systems in NASA, noted: "An acceptable risk is one that we have looked at and determined that to attempt to eliminate it would cost so much in weight or dollars that we are determined to live with it."46/ It is difficult for standards writers to accurately gauge what a regulatory agency will "live with".

While better data can improve decisionmaking by standards writers and regulators, the benefits to be derived from placing a dollar value on all costs and benefits is subject to question.

Federal agencies are currently building expertise in making economic analyses in their efforts to implement E.O. 12044. As noted, a major weakness of government analyses of the impact of proposed regulations will likely lie in the continuing lack of accurate and adequate data -- an area where standards writers might be able to serve an extremely useful function.

If a standards-writing committee can tell how many lives can be saved per year by implementing a standard or the purchase/maintenance costs and useful life of a piece of equipment required for implementation, then the appropriate regulatory agency can, if it desires, assign its own value to a life or cost to the piece of equipment. For example, if a standards committee knows that the implementation of a standard will require a piece of equipment that has a cost of $500 and a useful life of 5 years and will replace a machine costing $300 with a useful life of 2 years, and that the machines will have salvage values of $100 and $200 respectively, then the regulatory agency can be left to deal with the issues of how to compare the costs and benefits of the two pieces of equipment to arrive at the cost/savings of the new piece of equipment. The agency can decide whether to use Present Worth analysis or Rate-of-Return comparisons, what the cost of capital should be, the inflation rate, etc. If a standards committee estimates that a standard will reduce pollutants given off by a manufacturing firm by 10% and that an alternative standard will reduce pollutants by only 5%, then the regulatory agencies can again, if it so desires, place a dollar value on the comparative benefits of the two standards.

The standards-writing organization, however, may incur a legal risk if their discussions of such data take on a price-fixing overtone or if the data they provide can be used in liability cases against the manufacturers on the committee. Care should be taken to avoid any appearance of price-fixing as well as to avoid identifying injury data on a specific manufacturer's products.

D. RECOMMENDATION FOUR: STANDARDS-WRITING COMMITTEES SHOULD NOT TRY TO QUANTIFY GOVERNMENT COMPLIANCE AND INDUSTRY PAPERWORK COSTS

Rationale:

One cost associated with the use of a voluntary, private sector standard as part of a regulatory program is the cost to the Federal agency of ensuring industry compliance with the adopted standard. These costs are usually readily ascertainable by the

agency itself. Their estimates are likely to be better than those developed by standards writers since they are likely to have had experience administering similar type of compliance programs and are better aware of what existing support functions can be modified to accommodate the new effort at a lesser cost than setting up new support functions. They are also usually more aware of what level of compliance they seek -- the higher the level, the greater the costs for most programs. Because of this, it is a waste of scarce resources for the standards writers to try to quantify these costs. The compliance issues should, however, be considered in general terms in developing the standard. If a standard cannot be easily enforced, it is not likely to be adopted. The cost of any paperwork burdens imposed on industry by a regulation mandating a standard developed by the private sector cannot be accurately assessed until the regulatory approach and requirements are known. Therefore, the standards-writing committees should not spend time on assessing specific paperwork costs.

E. RECOMMENDATION FIVE: FEDERAL AGENCIES SHOULD AID STANDARDS-WRITING COMMITTEES IN DISSEMINATING ECONOMIC DATA FOR COMMENT

Rationale:

While consensus by the committee on the accuracy of all of the data is probably not worth the cost in terms of lengthening an already long standards development process, recording any problems noted by standard writers in the data and in the assumptions on which the data was based is necessary. Some of the data problems can be resolved through wide dissemination. The difficulty lies in how to disseminate this information to those outside the committee for their review and comment. Government can aid the committee in an initial review by referring the data to outside advisory committees or similar groups. Dissemination of the data for review and comment through publication in the Federal Register as a proposed standard is another approach likely to uncover subtler problems in the assumptions on which the data was based, i.e., that large and small firms will not be equally affected and that all consumers or industrial users of the products covered by the standard will not uniformly receive the same benefits and incur the same costs. Special agency mailing lists can also be developed and used to disseminate data to those with a special interest in the area. Whether industry will be willing to release data that will be widely disseminated is not known.

What limitations will have to be placed on the dissemination of specific types of data such as the elimination of firm names, etc., as well as whether such restrictions are feasible in light of the Freedom of Information Act requirements placed on Federal agencies will have to be determined.

The best and most accurate data used to make regulatory decisions will result only when all who have relevant knowledge are given an opportunity for review and comment.

VII. CONCLUSIONS

Evaluating the economic impact of any action is a complex undertaking. Evaluating the economic impact of a standard is especially difficult because of the large number of factors that can be directly or indirectly affected by standardization, the difficulty and cost of obtaining data, and the difficulty in quantifying the intangible costs and benefits that result from standardization and in estimating such things as "learning curves" and accelerated technological progress.

Each of the recommendations in this report should be discussed within and between government and standards-writing committees to work out a mutually agreeable method for their implementation. The issue of funding these data collection activities also needs to be addressed by both parties to arrive at an equitable cost sharing. All the problems inherent in the process and in the techniques available for economic analysis are not currently resolvable; however, if regulators and standards writers work together, they can begin to eliminate some of the weaknesses in the data base used in regulatory analyses. This will work to both parties' benefit in assuring that government regulators will effectively utilize private sector standards, and that the standards developed will not only achieve their intended purpose but will do so in an economically desirable manner.

Economic analysis cannot and should not be used to predetermine the nature of the final standard. It can, however, provide both the regulator and the standards writer with a mechanism for collecting and organizing available information, highlighting alternatives and uncertainties, and in making informed, rationale decisions.

FOOTNOTES

1. See Appendix I for the complete order.

2. Office of Management and Budget (OMB), "Improving Government Regulations: A Progress Report," (Office of Management and Budget: September 1979) p. 6.

3. Abe Ribicoff, "For Effectiveness and Efficiency: S. 262," Regulation, May/June 1979, pg. 17-20.

4. General Accounting Office, Government Regulatory Activity: Justifications, Processes, Impacts, and Alternatives, (General Accounting Office: June 3, 1977), Report No. PAD-77-34, p. 28.

5. Food and Drug Administration, "Medical Devices: Procedures for Performance Standards Development; Requests for Data, Information and Comments on Voluntary Standards Development and Policy, and Request for Data and Information on in Vitro Diagnostic Devices," Federal Register, February 1, 1980, pp. 7493-7495.

6. Independent regulatory commissions are exempt from this Order.

7. Executive Order (E.O.) 12044, "Improving Government Regulations," Federal Register, March 24, 1978, p. 12662.

8. Some departments and agencies such as the Department of Commerce have lowered this dollar amount.

9. E.O. 12044, p. 12663.

10. OMB, p. 20.

11. OMB, p. 8.

12. OMB, p. 18.

13. Michael S. Baram, "Final Report to the Administrative Conference of the United States: Regulation of Health, Safety and Environmental Quality and the Use of Cost-Benefit Analysis," (Administrative Conference of the United States: 1979) p. 96-97. See also the OMB Memorandum to the Heads of Departments and Agencies entitled "Regulatory Analysis" (November 21, 1978).

14. Baram, p. 17.

15. "OSHA's Benzene Exposure Rules Set Aside by U.S. Court," The Washington Post, October 17, 1978, p. A3. See also American Petroleum Institute vs. OSHA, 581F. 2d 493 (5th Cir. 1978).

16. David Bazelon, "Coping with Technology Through the Legal Process." Paper presented at the Atomic Industrial Forum, Inc., Conference on United States Energy Policy, Washington, D.C. (January 10, 1977).

17. Sam Peltzman, "An Evaluation of Consumer Legislation: The 1962 Drug Amendments," Journal of Political Economy, September/October 1973, Vol. 81, No. 5.

18. Senate Committee on Governmental Affairs, Study on Federal Regulation, 95th Congress, 1st Session, July 1977.

19. _____, Benefits of Environmental, Health, and Safety Regulation, 96th Congress, 2nd Session, March 25, 1980.

20. Joint Economic Committee, Government Regulation: Achieving Social and Economic Balance, (united States Congress: June 1980).

21. Commission on Law and the Economy, Federal Regulations: Roads to Reform, American Bar Association, 1978, pp. 88-89.

22. Joint Economic Committee, p. iii.

23. OMB, p. A-7.

24. OMB, p. A-13.

25. OMB, p. A-47.

26. Mark Green and Norman Waitzman, "Business War on the Law: An Analysis of the Benefits of Federal Health/Safety, Enforcement," (Corporate Accountability Research Group, Ralph Nader: 1979) p. 16.

27. Ibid, pp. 24-26.

28. Clarkson, Kadlec, & Laffer, "Regulating Chrysler out of Business," Regulation, September/October 1979, p. 46.

29. Ibid, p. 45.

30. Charleswater Associates, Inc., "The Impact on Small Business Concerns of Government Regulations that Force Technological Change," (Small Business Administration and the National Bureau of Standards: September 1975) p. 73.

31. Business Week, October 30, 1978.

32. National Academy of Sciences, Assembly of Life Sciences, "Consideration of Health Benefit-Cost Analysis for Activities Involving Ionizing Radiation Exposure and Alternatives," (National Academy of Sciences: 1977) p. 5.

33. "The Contributions of Automobile Regulation," National Highway and Safety Administration, June 1978.

34. Baram, p. 26. See also National Academy of Sciences, Environmental Studies Board, "Decision Making for Regulating Chemicals in the Environment," (National Academy of Sciences: 1975).

35. Mark Green and Norman Waitzman, "Business War on the Law: An Analysis of the Benefits of Federal Health/Safety, Enforcement," (Corporate Accountability Research Group, Ralph Nader: 1979) p. 44.

36. Steven E. Rhoads and Max Singer, "What is Life Worth," The Public Interest, Spring 1978, p. 87.

37. Baram, p. 27-28.

38. Senate Committee on Governmental Affairs, Benefits of Environmental, Health and Safety Regulation, p. 7.

39. Julius W. Allen, "Estimating the Cost of Federal Regulation: Review of Problems and Accomplishments to Date," (Congressional Research Service: September 26, 1978) p. 22.

40. Ibid.

41. Commission on Law and the Economy, p. 85.

42. Barum, p. 32.

43. Environmental Protection Agency, "Improving Environmental Regulations; Final Regulations; Final Report Implementing Executive Order 12044," (EPA, Washington, D.C.: June 1979) p. 30995. Can also be found in the Federal Register, Vol. 44, No. 104, Tuesday, May 29, 1979, p. 30995.

44. Ibid, p. 30994.

45. Garrett Epps, "They Bet Your Life," Washington Post Magazine, November 18, 1979, p. 40.

46. Ibid., p. 44.

presidential documents

[3195-01] **Title 3—The President**

Executive Order 12044 • **March 23, 1978**

Improving Government Regulations

As President of the United States of America, I direct each Executive Agency to adopt procedures to improve existing and future regulations.

SECTION 1. *Policy.* Regulations shall be as simple and clear as possible. They shall achieve legislative goals effectively and efficiently. They shall not impose unnecessary burdens on the economy, on individuals, on public or private organizations, or on State and local governments.

To achieve these objectives, regulations shall be developed through a process which ensures that:

(a) the need for and purposes of the regulation are clearly established;

(b) heads of agencies and policy officials exercise effective oversight;

(c) opportunity exists for early participation and comment by other Federal agencies, State and local governments, businesses, organizations and individual members of the public;

(d) meaningful alternatives are considered and analyzed before the regulation is issued; and

(e) compliance costs, paperwork and other burdens on the public are minimized.

SEC. 2. *Reform of the Process for Developing Significant Regulations.* Agencies shall review and revise their procedures for developing regulations to be consistent with the policies of this Order and in a manner that minimizes paperwork.

Agencies' procedures should fit their own needs but, at a minimum, these procedures shall include the following:

(a) *Semiannual Agenda of Regulations.* To give the public adequate notice, agencies shall publish at least semiannually an agenda of significant regulations under development or review. On the first Monday in October, each agency shall publish in the FEDERAL REGISTER a schedule showing the times during the coming fiscal year when the agency's semiannual agenda will be published. Supplements to the agenda may be published at other times during the year if necessary, but the semiannual agendas shall be as complete as possible. The head of each agency shall approve the agenda before it is published.

At a minimum, each published agenda shall describe the regulations being considered by the agency, the need for and the legal basis for the action being taken, and the status of regulations previously listed on the agenda.

Each item on the agenda shall also include the name and telephone number of a knowledgeable agency official and, if possible, state

whether or not a regulatory analysis will be required. The agenda shall also include existing regulations scheduled to be reviewed in accordance with Section 4 of this Order.

(b) *Agency Head Oversight.* Before an agency proceeds to develop significant new regulations, the agency head shall have reviewed the issues to be considered, the alternative approaches to be explored, a tentative plan for obtaining public comment, and target dates for completion of steps in the development of the regulation.

(c) *Opportunity for Public Participation.* Agencies shall give the public an early and meaningful opportunity to participate in the development of agency regulations. They shall consider a variety of ways to provide this opportunity, including (1) publishing an advance notice of proposed rulemaking; (2) holding open conferences or public hearings; (3) sending notices of proposed regulations to publications likely to be read by those affected; and (4) notifying interested parties directly.

Agencies shall give the public at least 60 days to comment on proposed significant regulations. In the few instances where agencies determine this is not possible, the regulation shall be accompanied by a brief statement of the reasons for a shorter time period.

(d) *Approval of Significant Regulations.* The head of each agency, or the designated official with statutory responsibility, shall approve significant regulations before they are published for public comment in the FEDERAL REGISTER. At a minimum, this official should determine that:

(1) the proposed regulation is needed;

(2) the direct and indirect effects of the regulation have been adequately considered;

(3) alternative approaches have been considered and the least burdensome of the acceptable alternatives has been chosen;

(4) public comments have been considered and an adequate response has been prepared;

(5) the regulation is written in plain English and is understandable to those who must comply with it;

(6) an estimate has been made of the new reporting burdens or recordkeeping requirements necessary for compliance with the regulation;

(7) the name, address and telephone number of a knowledgeable agency official is included in the publication; and

(8) a plan for evaluating the regulation after its issuance has been developed.

(e) *Criteria for Determining Significant Regulations.* Agencies shall establish criteria for identifying which regulations are significant. Agencies shall consider among other things: (1) the type and number of individuals, businesses, organizations, State and local governments affected; (2) the compliance and reporting requirements likely to be involved; (3) direct and indirect effects of the regulation including the effect on competition; and (4) the relationship of the regulations to those of other programs and agencies. Regulations that do not meet an agency's criteria for determining significance shall be accompanied by a statement to that effect at the time the regulation is proposed.

SEC. 3. *Regulatory Analysis.* Some of the regulations identified as significant may have major economic consequences for the general economy, for individual industries, geographical regions or levels of government. For these regulations, agencies shall prepare a regulatory analysis. Such an analysis shall involve a careful examination of alternative approaches early in the decision-making process.

The following requirements shall govern the preparation of regulatory analyses:

(a) *Criteria.* Agency heads shall establish criteria for determining which regulations require regulatory analyses. The criteria established shall:

(1) ensure that regulatory analyses are performed for all regulations which will result in (a) an annual effect on the economy of $100 million or more; or (b) a major increase in costs or prices for individual industries, levels of government or geographic regions; and

(2) provide that in the agency head's discretion, regulatory analysis may be completed on any proposed regulation.

(b) *Procedures.* Agency heads shall establish procedures for developing the regulatory analysis and obtaining public comment.

(1) Each regulatory analysis shall contain a succinct statement of the problem; a description of the major alternative ways of dealing with the problem that were considered by the agency; an analysis of the economic consequences of each of these alternatives and a detailed explanation of the reasons for choosing one alternative over the others.

(2) Agencies shall include in their public notice of proposed rules an explanation of the regulatory approach that has been selected or is favored and a short description of the other alternatives considered. A statement of how the public may obtain a copy of the draft regulatory analysis shall also be included.

(3) Agencies shall prepare a final regulatory analysis to be made available when the final regulations are published.

Regulatory analyses shall not be required in rulemaking proceedings pending at the time this Order is issued if an Economic Impact Statement has already been prepared in accordance with Executive Orders 11821 and 11949.

SEC. 4. *Review of Existing Regulations.* Agencies shall periodically review their existing regulations to determine whether they are achieving the policy goals of this Order. This review will follow the same procedural steps outlined for the development of new regulations.

In selecting regulations to be reviewed, agencies shall consider such criteria as:

(a) the continued need for the regulation;

(b) the type and number of complaints or suggestions received;

(c) the burdens imposed on those directly or indirectly affected by the regulations;

(d) the need to simplify or clarify language;

(e) the need to eliminate overlapping and duplicative regulations; and

(f) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions or other factors have changed in the area affected by the regulation.

Agencies shall develop their selection criteria and a listing of possible regulations for initial review. The criteria and listing shall be published for comment as required in Section 5. Subsequently, regulations selected for review shall be included in the semiannual agency agendas.

SEC. 5. *Implementation.*

(a) Each agency shall review its existing process for developing regulations and revise it as needed to comply with this Order. Within 60 days after the issuance of the Order, each agency shall prepare a draft report outlining (1) a brief description of its process for developing regulations and the changes that have been made to comply with this Order; (2) its proposed criteria for defining significant agency regulations; (3) its proposed criteria for identifying which regulations require regulatory analysis; and (4) its proposed criteria for selecting existing regulations to be reviewed and a list of regulations that the agency will consider for its initial review. This report shall be published in the FEDERAL REGISTER for public comment. A copy of this report shall be sent to the Office of Management and Budget.

(b) After receiving public comment, agencies shall submit their revised report to the Office of Management and Budget for approval before final publication in the FEDERAL REGISTER.

(c) The Office of Management and Budget shall assure the effective implementation of this Order. OMB shall report at least semiannually to the President on the effectiveness of the Order and agency compliance with its provisions. By May 1, 1980, OMB shall recommend to the President whether or not there is a continued need for the Order and any further steps or actions necessary to achieve its purposes.

SEC. 6. *Coverage.*

(a) As used in this Order, the term regulation means both rules and regulations issued by agencies including those which establish conditions for financial assistance. Closely related sets of regulations shall be considered together.

(b) This Order does not apply to:

(1) regulations issued in accordance with the formal rulemaking provisions of the Administrative Procedure Act (5 U.S.C. 556, 557);

(2) regulations issued with respect to a military or foreign affairs function of the United States;

(3) matters related to agency management or personnel;

(4) regulations related to Federal Government procurement;

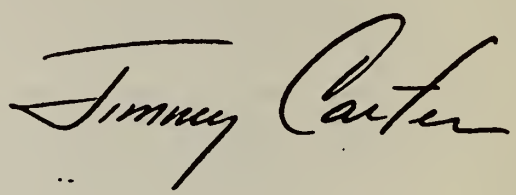
(5) regulations issued by the independent regulatory agencies; or

(6) regulations that are issued in response to an emergency or which are governed by short-term statutory or judicial deadlines. In these cases, the agency shall publish in the FEDERAL REGISTER a statement of the reasons why it is impracticable or contrary to the public interest for the agency to follow the procedures of this Order. Such a statement shall include the name of the policy official responsible for this determination.

SEC. 7. This Order is intended to improve the quality of Executive Agency regulatory practices. It is not intended to create delay in the process

or provide new grounds for judicial review. Nothing in this Order shall be considered to supersede existing statutory obligations governing rulemaking.

SEC. 8. Unless extended, this Executive Order expires on June 30, 1980.



THE WHITE HOUSE,
March 23, 1978.

[FR Doc. 78-8091 Filed 3-23-78; 12:58 pm]

APPENDIX II

Some Tangible and Intangible Factors to be Considered in Determining the Economic Impact of Standardization

(National Aerospace Standard (NAS) 1524)[1]

ENGINEERING

Reduce technical time in processing product design
Reuse of known items improves reliability and reduces "debugging"
Reduce hazard of technical error in judgment
Increase time available for work requiring special design or handling
Reduce need for special communication between engineers, draftsmen, production, etc.
Reduce need for minor supervisory decisions
Reduce need for waivers and nonstandard part testing and approval
Reduce redesign and redrafting effort
Improve interchangeability of parts, designs, packages, test fixtures, etc.
Promote use of improved methods and products
Help eliminate unsound practices based on prejudice, tradition, advertising, etc.
Develop cost estimates more economically

PROCUREMENT

Increase purchasing power through procurement of larger quantities of fewer items
Reduce number of purchase orders, receipts, payments
Reduce lead time
Provide a common language between buyer and seller reducing time required for negotiations
Put all suppliers on a fair competitive basis
Promote purchase by intrinsic value rather than by sales-talk

QUALITY CONTROL

Improve quality control based on accepted and explicit specifications
Decrease hazard of misunderstanding with suppliers
Provide better control of end product
Reduce and simplify inspection (sampling plan, etc.)

1/Taken from Tamas Foldesi, "Economic Effects of Standardization," ISO (Geneva, 1975) Annex 3.

INVENTORIES

Reduce capital requirement and amount tied-up
Reduce record keeping
Reduce storage area
Reduce material handling
Reduce obsolescence and spoilage hazards
Reduce stock-keeper's time
Reduce stock-keeper training required
Provide basis for data mechanization, handling, reduction in errors
More accurate and predictable planning and budgeting
Provide quicker service

PRODUCTION

More routine activity and familiarity in fabrication and assembly
Decrease rework
Improve mechanization
Derive economies through special-purpose machines performing standard operations, utilizing standard parts
Reduce the need for special tooling, training, layout and test
Reduce production methods and industrial engineering effort and manpower
Avoid production delays through stocked standard parts

MAINTENANCE

Reduce breakdowns and downtime
Reduce preventive maintenance time
Reduce repair time
Decrease critical expediting
Reduce the number of unfamiliar jobs encountered
Decrease number of service-spares
Decrease size and complexity of service manuals
Reduce operator training time

GENERAL

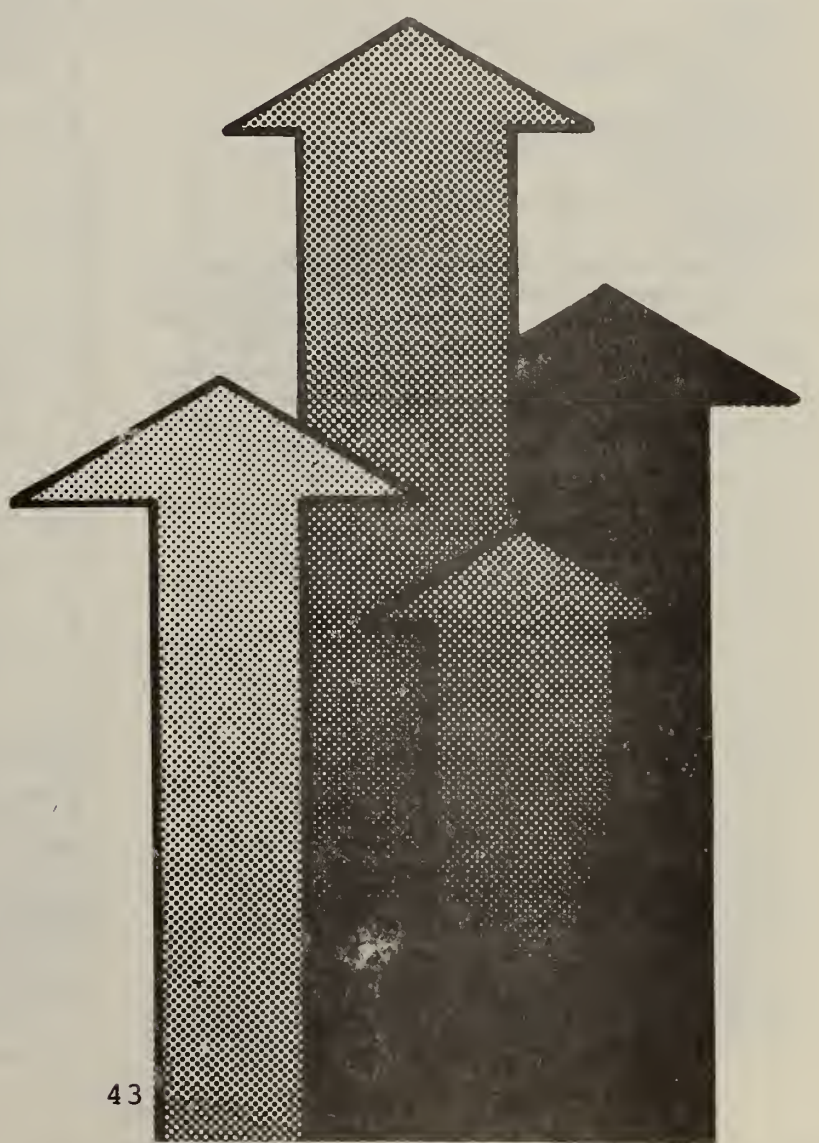
More routine work frees higher skilled people for unique aspects of project
Improve general communication
Ease selling design composed of customer approved or recognized devices
Improve user and customer confidence

United States
Environmental Protection
Agency

June, 1979

EPA

Improving Environmental Regulations; Final Report Implementing Executive Order 12044



ENVIRONMENTAL PROTECTION AGENCY

[FRL 990-8]

Improving Environmental Regulations

Agency: Environmental Protection Agency.
Action: Final report
Summary: The Environmental Protection Agency (EPA) presents its report on how it will implement Executive Order 12044, Improving Government Regulations. The report describes procedures to improve management oversight in the development of regulations, to involve the public and other governmental organizations in evaluating regulatory proposals, to analyze the effects of new and existing regulations, and to avoid unnecessary regulatory burdens on the public.

A request for public comments on EPA's plan appeared in the **Federal Register** on July 11, 1978 (Vol. 43, pp. 29891–29900), and the Agency held public meetings in San Francisco, Kansas City, and Washington, D.C. in August. A summary of EPA's response to major comments appears as Appendix B.

Dated: March 29, 1979

Douglas M. Costle,

Administrator.

Organization of this Report:

PREFACE

EPA is now using an efficient system for drafting and reviewing regulations, parts of which have served as models for the President's Order. This report presents ways in which we are modifying that system to comply with the Order. EPA's internal and external review procedures ensure that new EPA regulations meet the Order's standards for quality of analysis of regulatory impacts, openness to participation by outside parties, and avoidance of undue regulatory burdens.

Part A of this report describes EPA's internal procedures for writing regulations. Key features are the priority classification for all EPA regulations and the use of management controls that systematically focus attention on the most important regulations. Part B describes how EPA will involve interested citizens and outside groups (both private and public organizations and local, State and Federal agencies) in developing regulations, and presents EPA's plan to formulate a new Agency-wide policy for external participation in regulation development. Part C sets out guidelines for economic analysis of regulations in each priority class. It also describes a one-year project to screen all existing EPA regulations to identify those that require revision to eliminate unnecessary burdens or improve effectiveness. Part D describes how EPA will avoid unnecessary paperwork burdens on the public in the reporting and recordkeeping requirements of new and existing regulations.

The parts of this report describing EPA's mechanisms for public participation are printed in italics.

EPA has received and considered a large number of public comments on its proposed plan, including those submitted at public discussion meetings in three cities. Appendix B describes EPA's response to major comments and tells how to obtain a detailed analysis of all comments.

EPA is now implementing portions of this plan. Many other parts will be implemented through revision of the Agency's Manual for Regulation Development. The Manual will provide detailed instructions to those developing new regulations. *It will be publicly available in order to facilitate outside participation. To receive a copy when it is completed, write to Philip Schwartz, Standards and Regulations Evaluation Division (PM–223), EPA, Washington, D.C. 20460.*

The process described in this report meets all requirements of the Order. Table 1 lists sections of the Order and shows where to find a description of our plan to implement it. As indicated in Section 7 of the Order, failure to comply with procedures established in response to the Order is not grounds for judicial review of EPA regulations. Procedures described in this part will not apply when they conflict with statutory requirements.

TABLE 1—*Relationship of This Report to Executive Order Requirements*

Executive Order Section	*Corresponding Part(s) of This Report*
§ 2 Reform of the Process	
(a) Semiannual Agenda	B Agency Participation Policy
(b) Agency Head Oversight	A(2) Development Plan
(c) Public Participation	B Agency Participation Policy
(d) Approval of Significant Regulations	
(1) Necessity of the Regulation	A(2) Development Plan: A(3) Decision Package
(2) Consideration of Impacts	A(3) Decision Package; C(1) Analysis of New Regulations
(3) Evaluation of Alternatives	A(3) Decision Package; C(1) Analysis of New Regulations
(4) Response to Public Comment	A(3) Decision Package; B Agency Participation Policy
(5) Use of Plain English	A(3) Decision Package; A(4) Internal Review; B Agency Participation Policy
(6) Reporting Burden Assessment	A(3) Decision Package; D Reducing Burdens on the Public
(7) Name of Responsible Official	A(3) Decision Package; B Agency Participation Policy
(8) Evaluation Plan	A(3) Decision Package; C(2) Review of Existing Regulations
(e) Criteria for Significant Regulations	A(1) Initiation of Work; Chart 1
§ 3 Regulatory Analysis	
(a) Criteria	C(1) Analysis of New Regulations; Chart 4
(b) Procedures	C(1) Analysis of New Regulations
§ 4 Review of Existing Regulations	
(a) Selection Criteria	C(2) Review of Existing Regulations
(b) List of Possible Candidates	C(2) Review of Existing Regulations

PART A: AGENCY ADMINISTRATOR'S OVERSIGHT

This Part describes how EPA will strengthen top management oversight for the development of new regulations. It emphasizes EPA's internal processes and only touches on (see italicized sections) the way the Agency will involve outside parties in its decisions. Part B is entirely devoted to external participation in EPA regulation development.

In outlining the steps for EPA's process the following definitions may be useful:

—*Lead Office:* The Assistant Administrator for the relevant program (the Office of Air, Noise and Radiation, the Office of Enforcement, the Office of Toxic Substances, or the Office of Water and Waste Management) has the lead responsibility for initiating and writing most new regulations.

—*Work Group:* This is a group of specialists drawn from various offices within EPA to advise and assist the lead office in preparing each significant regulation and its support materials.

—*Steering Committee:* This is a continuing group representing the six Assistant Administrators, General Counsel, and appropriate Office Directors on the Administrator's staff. It oversees the mechanics of the process and conducts the first internal review of materials prepared by the lead office.

—*Red Border Review:* This is an internal review by all Assistant Administrators, General Counsel and chief Staff Office Directors. The heads of EPA's ten regional offices (Regional Administrators) also have an opportunity to submit comments. A full review takes three weeks.

—*Senior Management:* This group includes the Administrator, Deputy Administrator, Assistant Administrators, Regional Administrators, General Counsel, and appropriate Staff Office Directors.

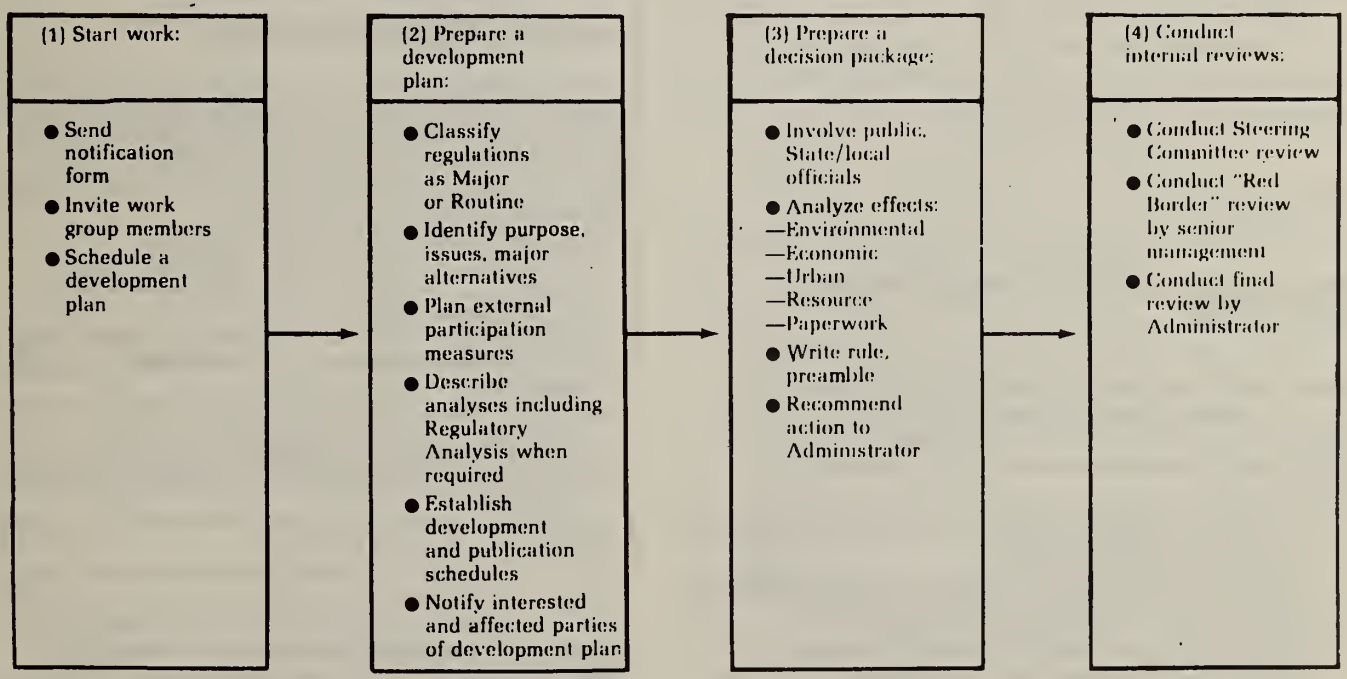
—*The Administrator:* As Agency head, the Administrator provides the final level of internal review.

—*Interagency Regulatory Liaison Group (IRLG):* This group includes EPA, the Consumer Product Safety Commission, the Food and Drug Administration, the Occupational Safety and Health Administration, and the Food Safety and Quality Service.

EPA produces regulations in a four stage process: (1) starting work on a regulation, (2) preparation of a development plan, (3) preparation of a decision package, and (4) conducting a three-part internal review prior to publication (see Figure 1). Each regulation goes through the third and fourth stages twice, first as a proposal and again in final form. The stages of regulation drafting are explained in detail below.

FIGURE 1

STAGES IN THE DEVELOPMENT OF SIGNIFICANT EPA REGULATIONS



EPA is changing this process in response to the President's Executive Order according to two general principles. First, EPA will establish priorities for all regulations and introduce management controls that reflect those priorities. Priorities and different degrees of attention are essential at EPA because of the large volume of regulations. More than 400 regulations are already in one stage or another of the drafting process.

EPA uses the label "Significant" (as recommended in the Executive Order) for about 200 of its regulations. These regulations are subject to the formal EPA procedures outlined in this report. Regulations that are not classified as Significant are not subject to the uniform procedures described in this report. They follow other specialized procedures that include provisions for public review and comment.

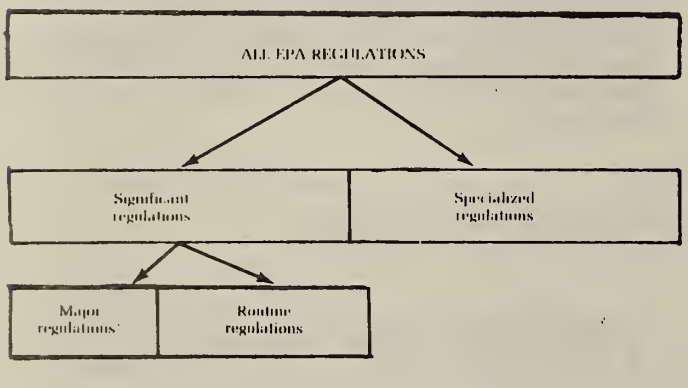
Significant regulations are subdivided as "Routine" and "Major". Routine regulations will include most of the Significant actions in the drafting process. The Major subclass of Significant regulations (about 50 at present) receive extra attention from senior management, allowing EPA and the public to focus their attention on the most important policy areas.

The criteria we use to classify regulations appear in Charts 1 and 2. Figure 2 shows how the classes are related.

Some of EPA's Major regulations require Regulatory Analyses as specified in Section 3 of the Executive Order. This requirement is the only factor distinguishing these regulations from other Major regulations for purposes of management oversight.

FIGURE 2

PRIORITY CLASSIFICATIONS FOR EPA REGULATIONS



*Some major regulations will meet economic criteria requiring preparation of a Regulatory Analysis. (See Part C.1.)

CHART 1

CRITERIA FOR SIGNIFICANT AND SPECIALIZED REGULATIONS

EPA presumes that all new regulations are Significant unless they fall into one of the specialized exclusion categories below. Significant regulations follow the uniform development process described in this report. Other regulations follow separate specialized procedures. Exclusions:

1. Regulations that are administrative or procedural in nature and do not affect stringency, compliance costs, or the environmental (health) benefits of EPA programs.
2. Minor amendments to existing regulations when the amendment does not affect the stringency, compliance costs, or the environmental (health) benefits of the regulation.
3. Regulatory actions resulting from detailed Congressional mandates (e.g., deadline changes) that leave EPA no discretion to evalua.e alternatives.
4. Regulations designated by a lead office Assistant Administrator in the notification form as not sufficiently important to require formal development procedures. Any senior manager may request a change in the classification to Significant.
5. EPA actions on regulations developed by State and local governments.* Some of these actions have large impacts; however, adding this report's procedures to State/local regulation development procedures would introduce unnecessary duplication of effort and excessive delay. Such actions include:

   a. Approval or disapproval of the following plans and their revisions: (a) State Implementation Plans (SIP) under section 110 of the Clean Air Act and (b) plans for designated pollutants from designated facilities under section 111(d) of the Clean Air Act. Although the approval of a SIP or a 111(d) plan with national policy implications is not subject to full regulation development procedures, additional EPA review is required. All SIPs, 111(d) plans, and their revisions are subject to specialized EPA review procedures that include public participation.

   b. Water Quality Standards set by States or by EPA in the event a State fails to set an acceptable standard. These local standards are subject to specialized EPA review procedures that include public participation.

6. Pesticide tolerances and regulations to exempt pesticides from the provisions of the pesticide statute (the Federal Insecticide, Fungicide, and Rodenticide Act—FIFRA) under its section 25(b) because of a determination that: (a) the pesticide is adequately regulated by another agency, or (b) it is of a character which need not be subject to FIFRA in order to carry out the purposes of FIFRA.* [Note: Many important decisions in EPA's pesticide program do not take the form of regulations and are not therefore subject to this report. These include pesticide registrations, cancellations, suspensions, "rebuttable presumptions against registration", experimental use permits and emergency exemptions. These actions follow specialized requirements for public notification and comment.]

* These actions do not require the notification form described in Part A(1).

CHART 2

CRITERIA FOR MAJOR REGULATIONS

For internal management purposes EPA will divide all Significant regulations into two classes, Major and Routine. Both types will follow the uniform regulation development process. However, Major regulations will receive extra attention from senior Agency management. We will classify a regulation as Major if it is likely to:

1. Address a major health or ecological problem.
2. Result in a major health, ecological, or economic impact.
3. Cause substantial urban impact, including constraints on transportation mobility.
4. Initiate a substantial regulatory program or change in policy.
5. Cause a substantial impact on another EPA program or another Federal agency program.
6. Cause a substantial change on a national scale in the scope of State-administered environmental programs or in the relationship between EPA and States or localities.
7. Cause a disproportionate impact on a particular region of the United States.
8. Implement a regulatory program central to the basic purpose of the statute under which it is adopted.

The second general principle of the internal process is extensive and continuous participation by various EPA offices. Participatory decisionmaking continues to be important at EPA because systematic review by other offices provides several types of valuable input. Scientists and economists check data and analyses; lawyers check procedures, clarity and consistency with the law; and other program managers will know how proposed regulations would affect their programs. This process starts when the lead office invites Assistant Administrators, the General Counsel, Regional Offices, and Staff Offices to send representatives to a work group to participate in writing a

Significant regulation. The lead office seeks to identify and resolve issues at each stage, in work groups, Steering Committee review, and senior management review. The lead office retains primary responsibility for new regulations. When consensus is not reached at a particular level, the disagreement is spelled out and the matter is taken to a higher level for review. When consensus is reached on major issues at lower management levels, the lead office identifies for senior management the nature of the issue and the consensus that has been reached. As a result, final decisions remain with publicly responsible appointed officials at the top of the Agency. The lead office may withdraw a particular regulation from parts of the formal process, or use some modification of the process, as long as it justifies the need and meets legal and Executive Order requirements. Before making such changes, the lead office Assistant Administrator must notify the other Assistant Administrators, the General Counsel, and Office Directors and consult with them if requested. The Administrator resolves any differences of opinion.

The four stages of regulation writing and review are as follows:

Stage 1: Starting Work on a Regulation

When the Assistant Administrator for a lead office determines that he or she is required by law or otherwise decides to start work on a new regulation, he or she sends a *notification form* to senior management. This brief standard form requires no analysis. The lead office submits this notification form as soon as possible, usually within 45 days of the time it learns (through passage of new legislation, a court order, etc.) that regulation may be necessary.

The notification form tells interested persons that a regulation is contemplated and allows them to plan accordingly.

The notification form indicates whether or not the new regulation is Significant based on the criteria in Chart 1. At the request of another office the Administrator may reclassify a regulation as Significant. *Submitting this form places Significant regulations on EPA's Regulatory Agenda, which is printed quarterly in the Federal Register and distributed to the public.*

NOTE: Regulations not classified as Significant are not subject to the requirements described below for a development plan and a decision package. These regulations do not pass through Steering Committee review. When published in the **Federal Register**, EPA will indicate that they do not meet the criteria for Significant EPA regulations and are subject to specialized development procedures.

Notification forms invite interested offices to assign appropriate personnel as work group members. (See Chart 3 for a list of EPA offices with formal responsibilities for regulation development. These offices receive a notification form.)

The notification forms set a date for submitting a development plan for Significant regulations to the Steering Committee.

CHART 3

WORK GROUP REPRESENTATION

EPA Regional Offices
Office of Air, Noise and Radiation*
Office of Enforcement
Office of General Counsel
Office of Legislation
Office of Planning and Management
Office of Research and Development
Office of Toxic Substances
Office of Water and Waste Management**

The Office of International Activities, Office of Civil Rights, Office of Environmental Review, and Office of Public Awareness will serve on appropriate work groups.

*Previously called the Office of Air and Waste Management.
**Previously called the Office of Water and Hazardous Materials.

Certain actions, such as revisions in State Implementation Plans, State water quality standards, and some pesticide actions, are initiated by other organizations and reviewed by EPA. They do not require a notification form.

Stage 2: Preparation of a Development Plan

The Assistant Administrator for the lead office (or someone, such as a Deputy Assistant Administrator, to whom such authority is delegated) appoints a chairperson for the work group assigned to work on a particular Significant regulation. In the event that special expertise exists in a Regional Office, the lead office Assistant Administrator considers asking the Regional Administrator to concur in the appointment of an expert in the Regional Office to serve as chairperson. The lead office puts together a development plan with the advice and assistance of the work group. An early step in this process is deciding whether the Significant regulation falls into the Routine or Major class (see Chart 2 for criteria). At the request of another office the Administrator may change this classification.

Development plans for Routine regulations are approved by the lead office and reviewed by the Steering Committee before substantial work begins. These development plans are sent to senior managers for their information.

Development plans for Major regulations are reviewed by the lead office and the Steering Committee but must pass through Red Border review and receive the Administrator's approval before substantial work begins.

The format for the development plan varies according to the type of regulation. Development plans include the following items when they are applicable.

- *Purpose:* This is a brief description of the possible need to regulate and the consequences of not regulating.
- *Schedule:* This is a timetable with target dates for: identifying and notifying interested outside parties, completion of required analyses of the impacts of the proposed actions (including a Regulatory Analysis when required [See Chart 4], an Environmental Impact Statement when required by Agency policy, and such other analyses as the lead office will include in the decision package), completion of the initial draft, internal and external review of drafts, award and completion of contract work, any required progress reports, Steering Committee review, publication of the proposed regulation, end of the public comment period, and promulgation of the final regulation.
- *Public Notice: This is the text of a Federal Register notice (usually an Advance Notice of Proposed Rulemaking) that describes the purpose of the proposed action, the development schedule, the issues that must be resolved, the alternatives to be considered, the special analyses that will be conducted, the plan to obtain external participation, and the name and location of an*

appropriate Agency contact person. It invites comments and solicits the submission of needed information.

- *Priority Classification:* This reports whether the Significant regulation is Routine or Major according to EPA criteria (Chart 2).
- *Issues:* This is a list of issues to be resolved.
- *Alternatives:* This is a summary of the major options (available under the authorizing statute) that will be evaluated, including a discussion of whether alternatives or supplements to direct regulation are feasible (such as economic incentives; see the discussion of alternatives in Part C.1).
- *Exclusions:* This is a list of any normally required materials that the work group expects to omit from the decision package, with a brief explanation.
- *Internal Participation:* This is a list of offices within EPA whose expertise and assistance will be needed, and a plan for coordination with EPA Regional Offices.
- *External Participation: This is a plan to involve those parties outside the Agency in the regulation development process. It indicates how persons interested in and affected by the regulation will be identified, notified, and brought into the process. It notes any interest by other Interagency Regulatory Liaison Group members or other Federal agencies and lists contact persons. It lists actions planned for coordination with State and local governments.*
- *Resources:* This is an estimate of EPA money and personnel needed to develop the regulation, with a specific estimate of resources coming from EPA offices outside the lead office.

Stage 3: Preparation of a Decision Package

After the development plan is completed, the lead office with the advice and assistance of the work group begins analyzing alternatives, assembling support materials and writing the preamble and regulation. These make up the decision package.

Members of the work group may, in some cases, write portions of the document. They review drafts as they are prepared and keep in close touch with their offices' senior management and Steering Committee representatives.

The work group chairperson has overall responsibility for regulation drafting and is accountable to lead office superiors (Division Director, Deputy Assistant Administrator, and Assistant Administrator), who provide guidance on the substance, procedures, and policy of the regulation.

The chairperson is responsible for resolving any issues or problems that may arise during the drafting process. This may be done through progress reports to senior management or by consultation with lead office superiors and other appropriate EPA managers. For Major regulations the lead office has an affirmative duty to keep EPA senior management periodically informed of issues that the work group has under consideration and to seek their policy guidance.

The lead office actively seeks the views of outside groups and consults with them both before and after formal publication of regulatory proposals. These groups include those persons directly affected by the regulation, environmental and other interested groups, industry representatives, other Federal agencies and State and local governments. This last group, State and local governments, often have a major role in the process because they implement and enforce many EPA regulations and have special knowledge of local conditions and available program resources. Whenever possible, the lead office provides an opportunity (and adequate time) for the outside parties to review regulatory proposals and support documents, including the Regulatory Analysis when one is prepared.

The decision package contains the following items:

- *Action Memorandum:* This is a brief summary of the regulation, and includes a description of alternatives considered, environmental, economic, and resource impacts, unresolved issues, anticipated reactions by the public, and recommended action. The alternatives described should include realistic options that the lead office and work group have considered seriously. Where feasible, a summary of incremental environmental and economic effects should accompany the discussion of each alternative. The action memorandum contains a summary of why the recommended alternative is the least burdensome way to accomplish environmental goals.
- *Federal Register Documents:* These include a preamble written in plain English that describes the facts and rationale for the decision to regulate and how the regulation fits into the larger regulatory program; it shows how the recommended action is the least burdensome way to accomplish environmental goals. *For final regulations the preamble summarizes public and inter-governmental comments and the Agency's response to each major point raised.* The regulation itself is written in a manner clearly understandable to those it affects and complies with the *Federal Register Document Drafting Handbook. The name and address of an EPA contact is included.*
- *Analyses:* These are support documents that lay out the major issues and show how alternatives were analyzed. The analyses identify and quantify (where possible) the regulation's environmental effects, economic (including incremental) impacts, energy impacts, technical feasibility, anticipated barriers to implementation, alternatives and supplements to direct regulation, and, for selected Major regulations, urban and community impacts. When any of these impacts cannot be determined exactly, the documents include the operating assumptions the Agency has made. The analyses show how unnecessary duplication with other EPA or Federal programs has been avoided. The Regulatory Analysis, when one is required, summarizes the results of several of these analyses. An Environmental Impact Statement is written when necessary to comply with Agency policy. *The support documents are available to the public or the reason for confidentiality is explained.*
- *Resource Requirements Summary:* This is a summary of money and personnel that EPA, State, and local governments will need to implement the regulation. *(Affected officials and the public have an opportunity to review a draft of this assessment.)* Where possible, this includes (or refers to) portions of Agency program guidance and zero base budgeting documents that show necessary short term and long term adjustments in EPA resources.
- *Reporting Impacts Statement:* This details the impacts of reporting and record-keeping on those subject to the regulation, including staffing projections and required expertise. New EPA reporting and record-keeping requirements have "sunset" expiration schedules. (See Part D.)
- *Public Participation Summary: This is a summary of comments, including comments from other Federal agencies and State and local governments received during the process, and the Agency's response to each major comment.*

•*Evaluation Plan:* This is a plan and schedule for subsequent evaluation of the effects of the regulation. (See Part C.2.)

Stage 4: Conducting Internal Reviews

After the lead office Assistant Administrator approves the decision package, he or she submits it for prepublication review. This process has three parts: Steering Committee review, Red Border review and final review by the Administrator.

The Steering Committee reviews all Significant regulations to help resolve any issues on which the work group does not reach consensus and to make sure the decision package meets standards of completeness, quality, and comprehensibility. When the Steering Committee resolves a major issue it identifies for senior management the nature of the issue and the resolution reached. The Steering Committee makes sure all components of the decision package are prepared and that material to be published is clear and understandable. It is the Steering Committee's responsibility to see that the regulation meets the eight specific requirements set forth in Section 2(d) of Executive Order 12044.

For Routine regulations, EPA's senior managers rely on the Steering Committee to see that decision packages are in order. They are notified when the Steering Committee reviews Routine regulations. Unless a senior manager requests a full Red Border review period, any Routine decision package that has received consensus approval from the Steering Committee is scheduled for an expedited Red Border review of eight working days. At the end of the eighth day it goes to the Administrator for signature. If the Steering Committee does not reach a consensus the package enters normal Red Border review.

During the Red Border process EPA senior management reviews all Major regulations regardless of concurrence at lower levels. For Major regulations, the Steering Committee checks the completeness of decision packages and makes sure any unresolved issues are clearly and fairly presented to senior management.

Red Border review of Major regulations does not exceed three weeks. The lead office Assistant Administrator may request a shorter review period. The lead office reports to the senior management on how formal objections or comments by senior managers have been resolved.

When all top-level reviews are complete or the review time has lapsed, the regulation goes to the Administrator. When the Administrator has signed it, it is published in the Federal Register.

PART B. EXTERNAL PARTICIPATION

EPA will continue to place a high priority on improved public awareness and public participation in its decision making processes.

The Administrator will continue to approve Regulatory Agendas and will see that they are published four times a year. Each Regulatory Agenda will list the title and status of all Significant regulations for which notification forms have been filed and that will be issued in the next year. It will cite the appropriate statutory authority, say whether a Regulatory Analysis is required, and give the name and telephone number of a person to contact at EPA. The Agenda will show the status of regulations removed from the list since the last Agenda was published. It will list existing regulations that are scheduled for review (see Part C.2) and reporting requirements that will reach their sunset date (see Part D). In addition to publishing the Agenda in the Federal Register, EPA will distribute it directly to interested and affected parties.

For each Significant regulation, EPA will:

(1) Draw up a plan for external participation (as part of the development plan) that shows in detail how interested and affected parties will be identified and notified.

(2) Provide early notice that regulation development is under way. This includes publishing a Federal Register notice (usually an Advance Notice of Proposed Rulemaking), which informs the public that work is beginning, provides the general approach and schedules, and identifies particular areas where additional information is needed. This notice describes the purpose, schedule, issues, available alternatives, analyses, external participation measures, and the name, address and telephone number of an EPA contact person for the regulation. EPA will mail this Notice directly to interested and affected groups and will use appropriate news articles and radio and television spots to provide timely notice that regulation development is beginning.

(3) Meet to discuss issues and alternatives during the development of the regulation with representatives of consumer, environmental and minority associations; trade, industrial, and labor organizations; public health, scientific and professional societies; educational associations and other appropriate individuals or groups of interested and affected parties from outside the Agency.

(4) Hold open conferences, workshops, hearings, meetings, and arrange direct mailings as appropriate to supplement other opportunities for public participation, and keep a mailing list of those interested in receiving draft regulations and background materials.

(5) Provide suitable background information prior to any meeting to those who will be attending. This information may include such material as a description of EPA's regulation development process; a summary of the draft regulation and key supporting materials; a list of major issues; and the name, address and telephone number of persons who can supply additional information.

(6) Consult with State and local governments. On the day that he signed Executive Order 12044, President Carter also signed a memorandum that terminated existing procedures for the review of Federal regulations by State and local governments. He asked that each Agency develop substitute measures. EPA is currently working with national organizations of State and local public officials to replace the former review procedures according to the President's memorandum. For particular regulations EPA also coordinates with particular States and localities and consults with groups of non-Federal environmental officials. A summary of intergovernmental consultation appears in the Federal Register preambles for new regulations that have major intergovernmental consequences.

(7) Track any Agency overlap or joint interest with other members of the Interagency Regulatory Liaison Group. For regulations of interest to other IRLG members, the preamble will describe coordination efforts and how they have affected the substance and procedure of the regulation.

(8) Communicate with other Federal agencies affected by a planned regulatory action. EPA's lead office contacts another Federal agency when the other agency (a) has a statutory mandate in the area to be regulated, (b) will require additional resources because of the EPA action, or (c) has important expertise relevant to the matter to be regulated. (Note: where possible, any interagency differences will be resolved at the staff level).

(9) Write the regulation and explanatory materials clearly. To help lead offices write regulations that people

can understand. EPA is developing a style book for regulation writers, selecting several regulations and developing them as models of good writing, and hiring editors to assist work groups write selected regulations.

(10) Make available a draft of the Regulatory Analysis (when one is required) by the time we publish a Notice of Proposed Rulemaking. The Federal Register preamble will have a summary of the Regulatory Analysis and information on how the public can obtain it. (Note: EPA will make public a final Regulatory Analysis when it publishes the final rule.)

(11) Provide at least 60 days for public comment, measured from the date the proposal is published, and refrain from requiring commenters to supply multiple copies of their comments. When a 60-day comment period is not possible the proposal will contain a brief statement of the reasons for using a shorter time period.

(12) Summarize outside comments, indicate EPA's response to major points and distribute both to interested and affected individuals and groups. (We summarize comments and our responses in preambles to our final regulations.)

As stated in the July 11, 1978 version of this report, EPA will adopt an Agency-wide public participation policy and write specific guidance to its employees for ensuring public participation in the regulation writing process. We intend to adopt the policy and corresponding guidance using a process that will fully and effectively involve interested and affected persons outside EPA. Although we don't now know the form the overall policy or the guidance will take, they will contain at a minimum the twelve elements listed above.

PART C. ANALYSIS

The Executive Order calls for careful analysis of available regulatory alternatives. In this Part we describe criteria and procedures for EPA analysis of (1) the economic effects of new Significant regulations and (2) regulations the Agency has already issued.

(1) Economic Analysis for New Significant Regulations

Other parts of this report (see Part A) describe the range of analyses that EPA will provide for all Significant regulations: EPA assesses health, ecological, economic, urban, energy, and program resource impacts. This subpart provides further detail on EPA's economic analysis requirements. In each economic analysis the lead office indicates by reference the other parts of the decision package that analyze the benefits the regulation will generate. This provides to the extent possible a clear identification of the regulation's costs and benefits. The economic analysis itself examines, in appropriate cases, positive as well as negative economic consequences.

The extent of analysis of the economic impact of new Significant regulations depends on whether the regulation is Routine, Major, or subject to the Regulatory Analysis requirements of the Executive Order. Guidelines based on our current internal requirements are presented for each of these categories. The guidelines in section (a) apply to those Major regulations that trigger a Regulatory Analysis (see Chart 4). Not all regulations requiring a Regulatory Analysis lend themselves to the analytic approach in the guidelines. In these cases, the lead office with the advice and assistance of the work group may amend the approach to suit the circumstances. For other Major regulations a less intensive analysis is sufficient, as described in section (b). For Routine regulations the basic guidelines in section (c) apply.

CHART 4

CRITERIA FOR CONDUCTING REGULATORY ANALYSES

The lead office prepares a Regulatory Analysis of potential economic impacts for any regulation that triggers one of the following criteria:

1. Additional annual costs of compliance, including capital charges (interest and depreciation), total $100 million (i) within any one of the first five years of implementation, or (ii), if applicable, within any calendar year up to the date by which the law requires attainment of the relevant pollution standard.
2. Total additional cost of production of any major industry product or service exceeds 5 percent of the selling price of the product.
3. The Administrator requests such an analysis (for example, when there appear to be major impacts on geographical regions or local governments).

(a) *Guidelines for Regulatory Analysis*

The lead office bases its Regulatory Analysis on the general approach described below. EPA has used this approach to determine the costs of such regulations as effluent guidelines and new source performance standards. Some types of regulations may require a modified approach. Sewage treatment plant regulations and some solid waste regulations that affect primarily other government agencies are examples that do not require industry segmentation as part of the analysis.

General Approach

1. Prepare an economic profile of the affected sectors (producers and/or consumers), including the industry structure (e.g., degree of concentration, the way prices are determined), the type of competition in the affected sectors, and performance trends (e.g., financial rates, growth trends) of the affected sectors.

2. Segment the industry (or other affected groups) into categories of economic units that will be similarly-impacted (e.g., according to size distribution, pollution control process, age).

3. Develop marginal (incremental) cost effectiveness curves for each process/strategy for each affected industry segment.

4. Analyze the economic impact of proposed standards and of alternatives including any economic benefits from regulation such as the generation of new product markets and new employment opportunities. It may not be necessary to analyze all alternatives in the same level of detail. The following impacts are analyzed when feasible:

(a) price effects
(b) production effects
(c) industry growth, profitability, capital availability effects
(d) employment effects
(e) community effects, including disproportionate effects on particular regions or localities
(f) balance of trade effects
(g) energy effects

When feasible, effects on productivity are described. For grant programs, some impact categories are not applicable, although user charges (as an analogue to price), effects on communities (affordability, employment, growth), and energy effects may be applicable.

EPA has developed more detailed internal working guidance to assist program offices in conducting their economic analyses. It is available upon request from Frans J.

Kok, Director, Economic Analysis Division, EPA, Washington, D.C. 20460.

Alternatives

Although the decision package for a regulation addresses alternatives available under the authorizing statute, the lead office and work group may, during their analysis, identify attractive regulatory alternatives that cannot be implemented under existing law. EPA will review such alternatives and, where appropriate, develop (apart from the regulation development process) legislative proposals that would permit their use.

The analysis covers the important alternatives that EPA has considered. Such alternatives may include:

1. Alternative types of regulations
—taking no additional regulatory action.
—relying on market forces (e.g., use of a marketable rights approach).
—using an informational requirement where applicable (e.g., product labeling).
—specifying performance levels (e.g., an allowable level of emissions) but allowing those regulated to achieve attainment by whatever means they prefer.
—using engineering design approaches that specify how a proposed outcome is to be achieved.
2. Alternative stringency levels
—making the standard or regulation either more or less stringent.
—tailoring the degree of stringency to stages of processing, particular industries or other pertinent groups.
3. Alternative timing
—using different effective dates.
—phasing in the requirement more or less rapidly.
4. Alternative methods of ensuring compliance
—using economic incentives.
—employing various enforcement options (e.g., on-site inspections vs. periodic reporting, sharing implementation responsibilities variously among the different levels of government).
—using different compliance methods for different industry segments or types of economic activity where costs of compliance vary sharply (e.g., treating small firms and large firms differently).

(b) *Other Major Regulations*

For Major regulations that do not require a Regulatory Analysis, the lead office conducts an analysis for EPA purposes. This analysis follows the same general approach as outlined above, but it need not provide the same level of detail as a formal Regulatory Analysis.

(c) *Routine Regulations*

EPA will continue to analyze all Routine regulations for insights into the potential effects on the economy and on those who are affected.

To minimize the burden on lead offices, this analysis is less sophisticated. It includes the following estimates:
—the number of establishments that will be affected
—an estimate of the total costs that will be borne by each affected industry segment
—an estimate of the price impacts under an assumption that cost changes will be reflected in prices
—an estimate of revenue changes for each segment if costs are not fully reflected in price changes
—an estimate of job gains and losses
—an estimate of total energy impacts for each affected industry segment
—an estimate of impacts on any particular regions and localities that will be more seriously affected than others.

This analysis covers both the proposed regulation and, if applicable, the alternatives considered, however some alternatives may be analyzed in less detail.

(2) Review of Existing Regulations

Section 4 of the Executive Order calls for the review of existing regulations. To comply, EPA has established criteria and processes to select regulations for immediate review, and to identify additional regulations for subsequent review. Section 2 of the Executive Order requires that each new Significant regulation include a plan for its future evaluation.

(a) *Selection Criteria and Process*

Many of EPA's most important regulations have recently been reviewed or scheduled for review in response to statutory or judicial direction:

Air Program
—Ambient Air Quality Standards
—New Source Performance Standards
—Approval of State Implementation Plans
Water Program
—Best Available Technology for Primary Industries
—Water Quality Management and Standards Regulations
—NPDES Permit Regulations
—Construction Grants Regulations

This set of reviews is either under-way or completed. To make the review of existing regulations a comprehensive program, EPA has begun to screen all of its existing regulations. The screening will conclude in November 1979. The EPA program office responsible for each part (or subpart) of Title 40 of the *Code of Federal Regulations* (which contains almost all of EPA's regulations) has formed work groups to conduct the screening.

The lead office, with the advice and assistance of the work group, is relying on currently available data for this initial screening. The selection criteria are:
—Estimated high actual costs to the public of the regulation;
—Estimated low actual benefits;
—Existence of overlap with other regulations (issued by EPA or other agencies);
—Need for integration with other programs;
—Existence of preferable alternatives;
—Low degree of compliance;
—Low enforceability;
—High reporting burden;
—Lack of clear language;
—Length of time since the regulation became effective or was last substantively amended; *
—Intensity of public sentiment in favor of changing the regulation;
—Availability of adequate data for analysis of the effectiveness and cost of the regulation.

During the screening the lead office will summarize its assessment of each regulation and designate appropriate regulations for formal review. It will prepare a plan to review all regulations so selected within five years. When possible the lead office will schedule related regulations for review at the same time.

The review plan will include an estimate of the necessary dollar resources and identify data needed for the review. Where there are not sufficient data for review, the plan will include provisions for obtaining them. The lead office should make any request for additional or reprogrammed resources

* EPA is now writing regulations that will be adopted during the screening project, including regulations to implement a hazardous waste control program, identify criteria for acceptable landfills, and set various new air quality and drinking water standards. Such new regulations are not subject to the screening or review requirements listed in this Part. They are subject to section (c) of this Part which asks that each new Significant regulation contain an evaluation plan.

to carry out its review plan through the zero base budget process.

The lead office will submit designated regulations and review plans to the Steering Committee for review and to senior management for approval.

EPA will publish its five-year review schedule in 1979 and will indicate upcoming reviews as a regular part of its quarterly Regulatory Agendas.

(b) *Nature of the Review*

Once it has selected a regulation for review, the lead office will conduct the review at the time scheduled in the five year plan with the advice and assistance of a work group.

The review of existing regulations will follow the procedures for the development of new regulations, including measures to assure public participation. The review will not duplicate any analyses made when the regulation was first issued if the analyses are still valid and meet current quality standards.

(c) *Development of Evaluation Plans*

Section 2(d)(8) of the Executive Order requires that each new Significant regulation have a plan for evaluating its effectiveness. In compliance with this requirement, the lead office for each Significant regulation develops a plan to evaluate the regulation within five years of implementation. Evaluation plans indicate the resource needs, data requirements, and a schedule for conducting the subsequent evaluation. One objective of the evaluation is to improve the relevance and adequacy of data collected over time to support the analysis of regulatory effectiveness. *In order to invite public involvement in these evaluations, a schedule of upcoming assessments will appear regularly in EPA's Regulatory Agenda.*

If an evaluation leads to modification of the regulation, the full procedures of this report (including provisions for external participation) will apply.

Part of each evaluation will be a plan and schedule for subsequent evaluation. In this way EPA regulations will receive continuing retrospective reviews.

PART D: REPORTING BURDENS REDUCTION

To carry out its statutory mandates, EPA must obtain data from the public, industry, and State and local governments. We often request data on environmental (health) effects, economic parameters, pollutant discharge and emission rates, and much more. EPA's permit and grant programs also require submission of applications that often contain detailed requests for information.

While this information remains essential, EPA has installed mechanisms to minimize paperwork, record-keeping and reporting burdens wherever possible. These devices comply with Section 2(d) of the Executive Order, which requires an analysis of new reporting or record-keeping burdens before Significant new regulations are adopted; and with Section 4 which requires a review of burdens imposed by existing regulations.

First, EPA has established a "sunset" policy on reporting and recordkeeping requirements contained in new regulations. This will terminate automatically those reports that cannot be justified after a set period, usually five years. If a lead office requests renewal of a reporting requirement, EPA will conduct an internal review (not to exceed six months) of its costs and its benefits. The reporting requirement will not expire during the time it is under review. *The review process will include an early opportunity for public comment.* Only after this review, and upon order of the Administrator, will a reporting requirement continue beyond its sunset date. (See Appendix A for details of this policy.)

Second, EPA requires a "reports impact analysis" for all new Significant regulations. This analysis is part of the decision package that moves through the review stages described in Part A. The analysis describes the reason for the reports, evaluates major alternatives (including the use of existing sources of information), outlines the information requested and the form of the report, and estimates the costs for the Agency and for those reporting to collect, prepare and analyze the data. The analysis describes any known overlapping data requirements imposed by other government agencies in order to prevent duplication of burdens. *EPA considers public comments on the analysis before it issues the regulation.*

Third, EPA continues to include a request for public comment on reporting burdens in the Federal Register preambles for proposed new regulations. In the past, EPA has sent these comments to the Office of Management and Budget when seeking OMB clearance for the report. *The lead office and work group consider these comments in drafting the final regulation.*

Fourth, as part of its screening and review of existing regulations (according to subpart C.2 of this report) EPA is re-examining reporting and record-keeping requirements. *These reviews follow the public participation measures used for new regulations.*

APPENDIX A—SUNSET POLICY FOR NEW REPORTING REQUIREMENTS

I. Coverage

New regulations that impose a reporting or record-keeping requirement contain a provision for repeal of that requirement on a specific date unless action is taken by EPA to renew or modify it.

This policy places a continuing burden of proving the report's desirability on those who advocate its retention. *The process will include participation by affected parties and the general public.*

The lead office proposing a new regulation that imposes a reporting requirement must include a sunset provision. The lead office has three options:

(1) To set as a termination date the semiannual sunset date (May 1 or November 1) that falls within 5 years after reporting begins (e.g., a reporting requirement taking effect on January 1, 1979 would expire no later than November 1, 1983).

(2) To set an earlier or later sunset date, depending on such factors as the life-span of the program for which the information is being sought; the time needed to evaluate the usefulness of the report; and the burden that frequent changes in the reporting requirement might impose.

(3) To exempt the reporting requirement from the sunset process if the resources that would be needed for a sunset review are greater than the burdens imposed by the report itself, or if the report is required by statute.

II. Review

The review process will begin six months before the scheduled sunset date. *At that time, EPA will publish in its Regulatory Agenda a list of reporting requirements due to expire on the next semiannual sunset date. This notice will invite public comment on the need to review, modify or terminate any of the requirements scheduled to expire.* The EPA lead office administering the requirement and any

outside party affected by the program may request renewal for an appropriate period.

After 60 days, another public notice will list those reporting requirements for which renewal has been requested. It will invite further public comment to be included in a public docket for each requirement.

The lead office that administers the requirement will evaluate it, inviting other interested EPA offices (including the office with responsibility for reports management) to participate on a work group. The evaluation will resemble the reports impact analysis for new regulations, but will reflect the actual costs, burdens, and usefulness of the reporting requirement. The program office and work group either must provide a justification for renewing the requirement or recommend that it be modified or terminated.

The Steering Committee will review the assessment along with public comment and Agency responses to those comments and recommend to the Administrator that he renew, modify, or terminate the reporting requirement. Upon his approval the Administrator will sign an order implementing the decision.

On the sunset date, a Federal Register notice will list those regulations repealed and those renewed. Reporting requirements will not lapse while they are under review. In the case of a regulation for which modification is proposed EPA will retain it until the Agency completes procedures to implement the modified regulation.

APPENDIX B—RESPONSE TO PUBLIC COMMENTS

I. Background

In the two months following publication of its draft report on improving the regulation writing process, EPA received 65 written comments from interested organizations and individuals. These suggestions and critiques came from private companies, trade associations, governmental agencies, public interest groups and citizens. They were carefully considered along with transcripts from public meetings in San Francisco, Kansas City and Washington, D.C., as the EPA staff prepared the final report on the regulatory process.

This summary of public comments cannot begin to catalog the depth and variety of thoughtful comments EPA received. All of the public comments, however, have been compiled for internal use, especially in drafting public participation provisions of the proposed "EPA Guidelines for Regulatory Development." For a detailed compilation of public comments please contact Chris Kirtz, EPA, (PM–223), Washington, D.C. 20460.

II. Analysis for New Regulations

One of the most important revisions had to do with the impact of EPA regulations on local communities. As a result of comments, a new criterion has been added to the list of items to be considered in the Regulatory Analysis conducted for new regulations. In the future each new regulation will be examined for any disproportionate effects it might have on particular regions or localities. Similarly, regulations that do not require a Regulatory Analysis will also be studied for an estimate of the impacts on particular regions or localities that are most severely affected.

In addition EPA has specified that economic analyses of new regulations consider the positive as well as any negative economic consequences of the regulation being proposed. This suggestion came from several commenters.

Because EPA has to regulate in situations where information is imperfect or incomplete, certain assumptions must be made. In the future, the analyses will state these assumptions explicitly and their rationale.

A number of commenters suggested that the quantitative criteria for preparing a formal Regulatory Analysis—$100 million in annual costs or 5% impact on product costs—are too high. We retained these criteria, which EPA has used for preparing Economic Impact Assessments in the past. EPA will subject all regulations to rigorous economic analysis, but feels it must marshal its analytic resources to provide the most thorough analysis on the regulations with greatest potential impact.

III. Review of Existing Regulations

The public's concern with procedures for reviewing existing regulations led to modifications in the final report. Those commenting on the review process agreed that EPA must take into account the cumulative effects of related regulations. In the future, lead offices will schedule existing related regulations for review at the same time when possible. Because the public expressed interest in which regulations will be reviewed and when the review will take place, EPA will publish a five year review plan that will list all the major existing regulations scheduled for scrutiny. Upcoming reviews of individual regulations will also be listed in EPA's quarterly Regulatory Agenda.

Several commenters recommended a "sunset" policy for all EPA regulations. EPA believes that the existence of expiration dates for its regulations could give those regulated an incentive to delay compliance. However, the final report clarifies the Agency's intent to conduct a fresh evaluation of regulations every 5 years.

IV. Paperwork Burdens

Some commenters expressed concern that EPA regulations might impose reporting or record-keeping burdens duplicating those of other government agencies. In response to this concern, EPA lead offices are now required to describe in their "reports impact analysis," known data requirements imposed by other agencies so that duplication can be avoided. This reports impact analysis will be presented for Administrator and senior management review in each decision package going to the Administrator for signature.

There was extremely broad support for EPA's proposed "sunset" provision that will set a five-year time limit for reporting and record-keeping requirements unless a need for their continuance is demonstrated. The final report clarifies that "sunset" covers both reporting and record-keeping and makes it clear that the burden of proof rests with those advocating retention of the requirements.

V. External Participation

Most commenters, particularly the participants in the public meetings, were interested in the public participation procedures for EPA regulation writing. Based on their suggestions, EPA has made several modifications for this final report. To make sure there is no delay in informing the public about a proposed regulation, a new requirement has been added. Whenever a lead office Assistant Administrator learns that a new regulation will be required—due to new legislation, a court order, etc.—the lead office will submit a notification form within 45 days. The next Regulatory Agenda will provide public notice that action is intended.

As another step to keep the public regularly informed of work in progress, EPA has expanded the publication of its Regulatory Agenda from twice a year to four times a year.

Comments on the importance of early and informed public participation generated additional procedural changes,

including requirements that (1) the lead office keep lists of interested and affected people outside the Agency for use as contact points for each regulation; (2) the Agency provide appropriate background information for public use prior to public meetings; and (3) the Agency distribute Advance Notices of Proposed Rulemaking as widely as possible.

There were several comments that a 60-day public comment period for proposed regulations is too short, that EPA should more frequently hold meetings and hearings in relevant field locations, and that State and local governments should be invited to consult on new regulations. The final report does not address these suggestions; the Agency will investigate these points more carefully as it develops its Agency-wide guidance on external participation and as it formulates its new intergovernmental consultation procedures in compliance with the President's March 1978 memorandum.

Opinion was divided on whether EPA should fund external participation in regulation development. The final report takes no position on this matter. EPA has undertaken a pilot funding program and will base its policy on the results of the test program.

NBS-114A (REV. 9-78)

U.S. DEPT. OF COMM. BIBLIOGRAPHIC DATA SHEET	1. PUBLICATION OR REPORT NO. NBSIR 80-2123	2. Gov't. Accession No.	3. Recipient's Accession No.

4. TITLE AND SUBTITLE
Need for Economic Information on Standards Used in Regulatory Programs: Problems and Recommendations

5. Publication Date
September 1980

6. Performing Organization Code

7. AUTHOR(S)
Maureen Breitenberg

8. Performing Organ. Report No.

9. PERFORMING ORGANIZATION NAME AND ADDRESS

NATIONAL BUREAU OF STANDARDS
DEPARTMENT OF COMMERCE
WASHINGTON, DC 20234

10. Project/Task/Work Unit No.

11. Contract/Grant No.

12. SPONSORING ORGANIZATION NAME AND COMPLETE ADDRESS *(Street, City, State, ZIP)*
Office of Engineering Standards
National Bureau of Standards
Department of Commerce
Washington, D.C. 20234

13. Type of Report & Period Covered
Final

14. Sponsoring Agency Code

15. SUPPLEMENTARY NOTES

☐ Document describes a computer program; SF-185, FIPS Software Summary, is attached.

16. ABSTRACT *(A 200-word or less factual summary of most significant information. If document includes a significant bibliography or literature survey, mention it here.)*

A number of government regulatory agencies are increasing their use of standards developed by the private sector. Federal regulators are, however, being required to provide increasing justification for their regulations, especially information on their economic desirability. If regulators are to effectively use voluntary standards in their regulations rather than develop standards in-house, they will need the same types of economic information on the voluntary standards as they would have on their in-house standards. This paper describes the types of requirements and pressures that regulatory agencies are faced with in justifying their actions, and provides standards writers with guidelines on the types of economic information that may allow regulators to make greater use of voluntary standards.

17. KEY WORDS *(six to twelve entries; alphabetical order; capitalize only the first letter of the first key word unless a proper name; separated by semicolons)*
Economic information on standards, Standardization, Procedural history, Rationale, Federal use of voluntary standards, Economic impact of standards, Economic impact of regulations.

18. AVAILABILITY ☒ Unlimited

☐ For Official Distribution. Do Not Release to NTIS

☐ Order From Sup. of Doc., U.S. Government Printing Office, Washington, DC 20402, SD Stock No. SN003-003-

☒ Order From National Technical Information Service (NTIS), Springfield, VA. 22161

19. SECURITY CLASS (THIS REPORT)
UNCLASSIFIED

21. NO. OF PRINTED PAGES
61

20. SECURITY CLASS (THIS PAGE)
UNCLASSIFIED

22. Price
$7.00

USCOMM-DC