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REGULATORY USE OF STANDARDS: THE IMPLICATIONS FOR STANDARDS WRITERS

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PREFACE

I have mixed feelings towards this report. The upside is that it has been a rewarding challenge to organize and extend the various thoughts that have been rattling in my head for several years. The downside is that the task proved so formidable. The regulatory use of standards touches many aspects of administrative law, and standards are used by so many different agencies in so many different contexts that a thorough analysis of the entire use by the government of standards would result in a study of encyclopedic length. The limitations of time and budget meant that I had to settle for more of a survey and abstract analysis. Disquiet arises for that reason.

I believe that virtually any topic addressed in the report could benefit from further study. I especially believe that more empirical analysis of standards is merited, such as the information used to develop the standard as contrasted with the information developed by government agencies in similar situations. Also, I think some economic analysis of the voluntary adherence to standards, especially under the threat of regulation, would be beneficial.

I first began thinking of the problems of the relationship of standards to regulation while at the National Bureau of Standards, when I worked with several regulatory agencies that used them in their regulatory programs. Some of the particular concerns were brought to focus through

conversation with Walter Cropper of the American Society for Testing and Materials. My thoughts were then brought to a head in a trial by fire when I undertook the co-chairmanship of the President's Task Force on the revision of the OSHA safety standards. Those views have since been honed down through hours of discussion with George Horvath of the National Fire Protection Association. I wish to thank Walt and George for our discussions, and in particular the members of the OSHA Task Force who did a terrific job. I also want to thank Larry Eicher, Joan Koenig, and Carol Chapman of the National Bureau of Standards for our discussions over the years and for their criticisms and suggestions on this report.

Finally I wish to thank Anna Gaskins who endured drafts, revisions, and the final typing of the report. Her ability to read my rough drafts and translate them into a magnificent finished product is very much appreciated.

Philip J. Harter

FOREWORD

How can private standards developers write standards that would be useful in government regulation . . . or that would even make regulation unnecessary? To help answer these questions, NBS's Office of Engineering Standards awarded a research to Philip Harter, an attorney with extensive background in Administrative Law and government regulation. The result is this report.

While this report was being circulated in draft form, several people asked us how it was related to another report, The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Relating to Safety and Health, which Robert Hamilton prepared in 1978 for the U.S. Administrative Conference. The Hamilton report (now published in the November, 1978, Texas Law Review), also deals with regulatory agency use of privately-developed standards. This is no coincidence; before joining a private law firm, Mr. Harter was on the staff of the Administrative Conference where he planned the research project carried out by Robert Hamilton.

The present research builds on the Hamilton report, rather than duplicating it. The two projects have somewhat different purposes. The aim of Hamilton's work was to suggest to agencies how they should use privately developed standards, and it was intended to be the basis for formal recommendations

by the Administrative Conference. On the other hand, the primary goal of Harter's work is to suggest to private standards writers how they might write standards that would be acceptable for use in regulatory programs.

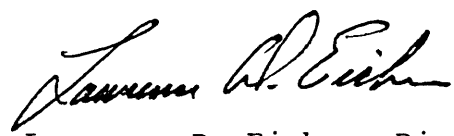
Harter also includes some suggestions to agencies, but these suggestions are not intended to be the basis for formal recommendations; rather, they represent the author's personal opinions. They do not necessarily represent the opinion of the National Bureau of Standards, and should not in any sense be construed as an NBS recommendation of other agencies.

The 1978 version of Harter's report to NBS has been included in the record of the hearings on the proposed Federal Trade Commission Trade Regulation Rule for Standards and Certification. Readers should be aware that several minor revisions have been made so that the present report is not identical to the one in the hearings record.

In addition to his work at the Administrative Conference, Mr. Harter has had other experience highly relevant to this report. It includes two years as Chief of Regulatory Programs at NBS's Experimental Technology Incentives Program (now Field Methods), which aims at helping agencies improve their regulation through studies and policy experiments, and a year as Co-Chairman of a Presidential Task Force aimed at

improving OSHA regulation. He is currently employed at a private law firm and is an Adjunct Professor of Administrative Law in the American University School of Government and Public Affairs.

We believe this report by Philip Harter represents some careful thinking by one who has been concerned for a long time about the relationship between privately-developed standards and regulation. It deserves the attention of both the standards community and regulatory agencies who would like to better tap the expertise represented by the private sector.



Lawrence D. Eicher, Director
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National Bureau of Standards

About OSIAD

The Office of Standards Information, Analysis, and Development (OSIAD) is part of the NBS National Engineering Laboratory's Office of Engineering Standards. OSIAD has established a standards Impact Analysis (SIA) project to provide NBS decision-makers with information that will help them better understand the national and international standards systems and the economic, social, and other impacts of standards. It is hoped that this information will increase the effectiveness of NBS's participation in voluntary standards work and will contribute to the development of more rational and cost effective standards.

Functions of the SIA program include:

*Identifying needs for research: 1. on the impacts of standards; and 2. on standards systems and how they operate, and making these known to the academic, economic, and standards communities;

*Conducting or contracting for needed research of specific interest to NBS programs; and

*Maintaining close liaison with NBS and outside groups involved in standards impact or system assessment and developing a collection of studies in this area.

Some areas in which SIA has sponsored research are:

Regulatory use of standards
Standardization in foreign countries
Economic principles applied to standard-writing
Economics of certification

For information on this report and other SIA studies, contact:

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EXECUTIVE SUMMARY

Purpose

The purposes of this report are: (1) to help standards developers prepare standards that are more acceptable to regulatory agencies, by providing a better understanding of the needs of agencies and how they go about their business; and (2) to suggest how regulatory agencies might improve their relationships with private sector standards organizations so they may better tap the expertise of the private sector.

The focus is on how lawyers look at the subject and, in particular, the implications of administrative law for the regulatory use of externally-developed standards -- i.e., standards developed outside the agency.

Legal Background

How Standards Are Used in Regulatory Programs.

Externally-developed standards are used in regulation in a variety of ways. An agency may use standards as mandatory requirements; it may use them as the starting point for writing a regulation; it may use them as purely advisory guidelines; or

it may even refrain from regulating in a given area because it believes that the voluntary standards are adequate.

The way a standard will be used in regulation, together with legal constraints on the agency, strongly influence how agencies review such standards and what rulemaking procedures they follow. However, law and practice concerning the regulatory use of standards are unsettled, so precisely what is expected of externally developed standards is unclear. Thus, standards-writing organizations need to learn about the particular agency they are concerned with as well as understanding the constraints imposed by administrative law on regulatory agencies in general.

Administrative Law

Regulatory agencies generally do not feel they can delegate regulatory power to private organizations. As a result, they will not agree to automatically adopt existing or future standards from private organizations. To use externally-developed standards in regulation, they must take positive action, following the normal regulatory processes.

Rulemaking Procedures

The informal rule-making required under the Administrative Procedure Act involves several steps (summarized in Table 1).

Before and during the rulemaking process, an agency will review an externally-developed standard to see if it meets the agency's needs. If not, the agency may modify the standard.

Except in a few cases, agencies must publish a Notice of Proposed Rulemaking. (Existing externally-developed standards may be published verbatim in this Notice or incorporated by reference.) The trend has been for courts to require agencies to explain the technical basis for their proposed regulations in this Notice.

The agency then allows the public to file written comments, which it must consider, and it may hold hearings as well. If an agency makes significant changes in the proposed rule in response to these comments, then it may have to go through another notice-and-comment cycle. When it publishes the final rule, the agency must include a preamble that explains the purpose and the factual and policy basis of the regulation.

Use Determines Procedures and Nature of Review

However, these steps do not have to be followed for all agency actions, only for rules that are binding and substantive -- including test methods which have an important effect on the substantive requirements of a regulation. Rulemaking requirements do not apply to general policy state-

ments and interpretative rules. In general, the more central the standard is in establishing mandatory obligations, the more likely the agency is to follow the normal rulemaking process described above.

Also, the more central the standard, the more rigor the agency will look for in the process of developing the original standard.

If an agency is considering whether to refrain from regulating because of an existing voluntary standard, it will probably apply a diluted version of the same review process it would apply in considering a standard for mandatory use. Also, it will have to determine whether industry is likely to follow the standard.

Because of these differences in the way agencies may review externally-developed standards, standard writers should be aware of how a standard is likely to be used in regulation. By anticipating agency and public review, those who prepare the standards can help ensure that relevant issues are fully debated and suitably resolved during the development process.

Recommendations for Standards Writers

Agency Regulatory Criteria. In preparing standards for potential regulatory use, standards committees should

consider an agency's regulatory criteria. If these criteria are kept in mind in writing a standard, the standard is more likely to give them the weight that is proper from the agency's viewpoint, and the agency is more likely to adopt the standard expeditiously and intact.

In reviewing standards, regulatory agencies will generally consider technological and administrative feasibility, cost of compliance, and how doubt concerning risk is resolved. But different agencies will make different trade-offs. For example, in some cases, technologies required by a regulation must be readily available, while in other cases, a regulation may require the development of new technologies. Some agencies will consider compliance cost to be an important factor, while others will consider it to be relatively unimportant. Agencies will also differ on whether to resolve uncertainty concerning the level of risk in favor of more or less stringent regulations.

Standards writers can determine an agency's regulatory criteria by looking at the statutes and their interpretations by courts and the agency's other regulations, and by asking the agency. But, at best, they remain vague.

Purpose and Scope of the Standard. To facilitate agency review, a standard prepared for regulatory use should include sections which explain the expected use of the standard,

its intended purpose, and its scope. For example, which parts of the standard were intended to be mandatory? Which parts are aimed at safety, as opposed to efficiency?

Resolution of Technical Issues. More and more, courts are requiring agencies to explain both the factual basis and the reasoning behind their regulations, but there is no fixed test to determine how much evidence is needed. Sometimes the problem and solution are so obvious that no evidence is needed, just a cogent explanation. But sometimes courts require enough information to resolve the technical questions. If the issue is on the frontier of human knowledge, and if there is great risk to the public, less evidence would be needed. If the cost of complying would be great, more evidence would be needed.

Because of judicial review, agencies will want to know what information standards developers used in developing a standard, and what tradeoffs (such as between safety and cost) were made in writing the standard. This means standards writers may have to compile and document more evidence to support a standard than they otherwise would, or even carry out more research.

Balance and Due Process. It may be difficult for an agency to determine whether an externally-developed standard meets its needs simply by reviewing the standard. Because of

this, the agency may look at the process of the standard's development for assurance that relevant issues and views -- including views of the agency's important constituents -- were fully considered during the standard's development.

Agencies may properly use standards written by narrowly-based groups, but there is concern about doing so. One response to these concerns has been the suggestion that standards developers follow "consensus" procedures. However, following consensus procedures does not automatically result in standards suitable for regulatory use, for several reasons.

One reason is that simply raising relevant issues does not mean that an agency's regulatory criteria have been met; a standards committee may also need to give special consideration to the regulatory criteria when it resolves issues, e.g., in ruling on negatives.

Furthermore, in actual practice, the full theory of consensus may not be met; for example, an important agency constituent may not participate, technically qualified representatives may be hard to find, or minority views may be overruled on "political" grounds. Hence, for standards to be acceptable for regulatory use, standards writers may need to address these potential shortcomings of the consensus process. Also, they should describe the procedural history of a stan-

dard, including the composition of the committee, in an accompanying commentary.

Commentary or "Legislative History". It would help an agency review a standard and explain itself to others if the standards writers prepare a brief history and explanation of the standard to accompany the standard. The commentary could describe the standard's procedural history, such as the issues raised, how they were resolved, and treatment of negatives. It could also describe the information underlying the standard and explain the reasons for particular provisions, including their relevance to the goal of the standard if this is not obvious. A checklist of what to include in a commentary document is shown in Table 2.

This explanation, together with the purpose and scope sections described earlier, will help an agency to determine whether the goals of the standard match its own regulatory whether all relevant factors were considered and goals, resolved according to the agency's regulatory criteria, and whether any impermissable considerations entered into writing the standard. By explaining how issues were resolved, to a degree, a legislative history may be a substitute for the consensus process.

Tests. The standard should include an adequate and feasible testing program as a means to determine compliance

with the standard. The tests should be consistent with the underlying requirements; otherwise there may be confusion as to which imposes the real legal obligation -- the test or the underlying requirement. If the test imposes separate substantive obligations, then the discussion of this report concerning substantive standards applies also to test methods.

Design Versus Performance. Performance standards are almost universally recommended over design standards, but they have drawbacks, and many agencies like to specify precisely what must be done. Standards writers should find out agencies' views about proper balance between performance and design standards and, if they disagree with the agency, explain why.

Antitrust. While antitrust is not their main concern, agencies may modify, or may not use, a standard which is overly restrictive. Thus, standards should be no more restrictive than necessary, and standards writers should carefully explain the need for any requirements that may appear anticompetitive.

Clarity. An agency may rewrite a basically sound standard which is not clear. Therefore, if necessary, standards writers should consult legal drafting or other writing manuals. When incorporating another standard by reference, a standard should specify the relevant sections and date of the standard referenced. Also, standards writers should avoid overly vague

phrases so that the person who is regulated can tell what is expected.

Consistency with other Standards. If a standard differs from a similar or closely related standard, the differences should be explained. This will help an agency decide which standard best suits its needs.

Agency Relationships with Standards Writers. Externally developed standards can help an agency establish a regulatory program quickly, tap the expertise of the private sector, and save the time and money that would otherwise be spent writing a regulation from scratch. Or an agency may not need to take any formal action if an adequate voluntary standard exists.

Thus, regulatory agencies can benefit from having a good relationship with standards writing organizations. But standards writers have complained about various agency practices, including the following:

*Pre-emption. An agency may appear unreceptive to externally-developed standards. This may cause a standards committee to conclude that it is no longer worthwhile developing standards in the area of concern.

*Failure to update standards. This may make

standards committees less willing to have their standards used in regulation, for fear the standards may eventually become a retarding force.

*Arbitrary revisions of the standard by the agency.

*Misuse of a standard.

*Excessive time to review the standard.

Agency Actions That Would Improve the Relationship. Agencies can take a number of actions that would improve their relationships with standards writers. In particular, they could:

1. Provide the following information: what standards are needed; hazards data and other technical information; the agency's regulatory criteria; procedures it would like standards writers to follow in writing standards; and the time by which it needs the standard.

2. Help pay any extra expenses of standards writing caused by the agency's particular requirements.

3. Participate in the development of the standard. There is controversy about whether the agency representative should actually vote; the author's opinion is that voting is an important part of participation.

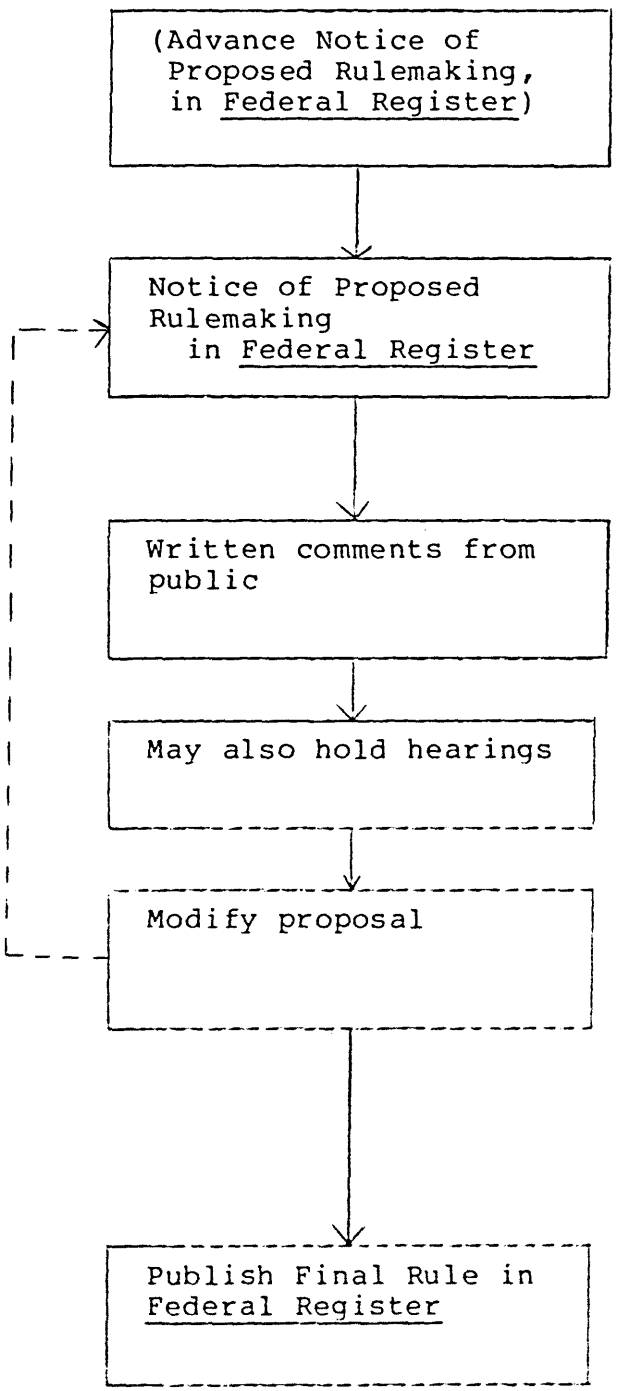
4. Agree to expeditiously review standards; and

5. Perhaps have a presumption in favor of using standards developed through full consensus procedures as a basis for rulemaking.

Federal Advisory Committee Act. If a working relationship develops between an agency and a standards organization, the Federal Advisory Committee Act may apply. An "Advisory Committee" is a committee which an agency uses to obtain advice which has at least one non-government employee. There are certain legal requirements governing Advisory Committees. While the law is by no means settled, an agency may feel it must impose these requirements before establishing an on-going relationship with committees developing standards for use in its regulatory program.

Table 1

STEPS IN INFORMAL RULEMAKING PROCESS



Optional

Must include:
-authority
-nature of RM
-substance of rule
-subject
-technical basis

Optional

If necessary to take into account public comments.

If changes are substantial, then agency issues another Notice of Proposed Rulemaking.

Must include preamble explaining purpose of Rule and factual and policy basis.

Table 2

CHECKLIST OF WHAT TO INCLUDE IN A COMMENTARY DOCUMENT

o Procedural History. Description of committee balance; technical qualifications of committee members (if not obvious); basis for negative votes; what negatives were overridden; other information to show that due process was followed.

o Purpose of the various provisions (for example, safety or cost-reduction?) and the relevance of the standard's purpose, if this information is not in the standard itself.

o Scope and Expected Use of the Standard. How it is expected to be used, including circumstances under which it is meant to apply, if this is not in the standard itself. For example, is it intended to be advisory only?

o Issues Raised. What issues were raised in writing various sections of the standard, and how were they settled?

o Technical Information. What technical information, including hazards data, was available and how was it used in developing the standard? How were technical uncertainties resolved?

o Design/Performance. If the standard strikes a design/performance balance different from what the agency thinks is appropriate, explain why.

o Competitive Effects. If the standard has potentially anticompetitive provisions, why was this necessary?

o Consistency with Other Standards. How does the standard differ from, or relate to, apparently similar or closely-related standards?

o Test Methods. To the extent that test methods set substantive requirements, an explanation of test methods included would also be needed.

PART I

INTRODUCTION: THE LEGAL SETTING

CHAPTER I

INTRODUCTION

During the past decade, there has been extraordinary growth in health, safety, environmental, and energy regulation. As a result, a number of Federal agencies are charged with issuing regulations that control, or at least substantially influence, the physical characteristics of products and processes.

There is a vast array of standards developed outside the government, prepared by numerous organizations. In two ways, these standards and their developers are potentially a significant resource for helping achieve the goals of regulatory programs: (1) they can aid the government in writing new regulations; and (2) they can induce voluntary action on the part of the private sector.

Purpose of the Report. The primary purpose of this report is to help standards developers prepare standards that are more acceptable to government agencies, by providing a better understanding of the needs of agencies and how they go about their business. A second purpose is to suggest how agencies might review standards for use in their regulatory programs. Ultimately, this report seeks to provide a basis for improving the relationship between the government and standards developers.

Many government regulations are based on standards developed by private standards organizations, and the standards organization have worked with various agencies in developing new regulations. But before the full potential of the regulatory use of standards can be realized, a harmonious relationship must be established between the government and standards organizations. Although this relationship appears to be developing, a considerable amount of skepticism and distrust still exists on both sides.

Concerns of Standards-Writers. Members of standards writing committees and organizations may believe that a standard they developed addresses a particular problem in a suitable manner so that the government agency should not issue any regulation at all but rather rely exclusively on the voluntary compliance with the standard. Or, they may believe the agency should adopt the standard immediately and inact as a regulation. Or, they believe the agency should turn to them to develop new regulations instead of writing them "in-house" because they may believe the insights and expertise available in the committee surpass that of the agency's staff. They may also believe that a wider variety of interests would be heard in the development of a standard than when a regulation is prepared solely within an agency. Or, they may believe that the agency will fail to revise a standard used in a

regulatory program in order to keep pace with changing technology or other requirements.

Concerns of Agencies. On the other side, government agencies may be suspicious of using privately-developed standards due to past criticisms of them. For example, the National Commission on Product Safety that was established by Congress in 1967 surveyed the existing standards applicable to consumer products and concluded:

> Unfortunately, these standards are chronically inadequate, both in scope and permissible levels of risk. They do not usually address themselves to all significant foreseeable hazards. They give insufficient consideration to human factors such as predictable risk-taking, juvenile behavior, illiteracy, or inexperience. The levels of allowed exposure to electrical, thermal, and mechanical and other energy exchanges are frequently too high. 1/

While Congress made a similar finding with respect to standards concerning occupational safety and health, it nonetheless required the newly formed Occupational Safety and Health Administration to adopt the very standards it found inadequate. 2/ The outcries that resulted from the imposition of these standards as mandatory

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1/ Final Report of the National Commission on Product Safety at p. 48 (1970).

2/ S. Rep. No. 91-1282, 91st. Cong. 2d Sess., reprinted in U.S. Code Cong. & Ad. News 5177 at p. 5182.

regulations would be enough to make any administrator hesitant to use privately developed standards for regulatory purposes if he believed anything remotely similar to the problem OSHA has had might develop.

Some of the criticism by government officials is more theoretical and argues that non-governmental standards are inherently unsuitable for regulatory purposes:

> Voluntary standards, both national and international, are agreed upon by a process of consensus. Viewed another way, this process may produce the lowest common denominator, the one least offensive to the various interests involved, and for that reason, the one that may represent the least progressive or advanced sector of the technology at hand.
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> Many government standards are being drafted not as a ratification of existing technology, but to set new goals for technologies that are deemed insufficiently advanced . . . . These two trends, consensus standards and goal standards, are divergent in purpose and method of formulation. 3/

This Congressional view was echoed by the Assistant Attorney General in charge of the Antitrust Division: "Where society has determined coercive sanctions are necessary to enforce a

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3/ "Voluntary Industrial Standards in the United States," Report to the Subcommittee on Science, Research and Development of the House Committee on Science and Astronautics, 93d Cong. 2d Sess. at 88-9 (1974).

standard, that standard should be established and enforced by a government agency."[4/]

But these excerpts tell only part of the story. Some criticism leveled at the standards may be unfair in that they are being measured against criteria they were never intended to fulfill, and the flat assertions that only the government can prepare mandatory, technical standards is unjustified.

In large part, both of these problems -- frustration of those who write standards with the lack of responsiveness on the part of government agencies, and the reluctance of agencies to use standards more widely in their regulatory programs -- undoubtedly stem from the lack of a clear understanding of the respective needs of each side. This report analyzes those needs.

In order to prepare a standard designed to address the regulatory needs of an agency, those who write standards must be aware of the constraints on the agency and what it will look for in a standard.

Approach. This study analyzes the requirements imposed on government agencies when they issue regulations, and the process agencies are likely to use when deciding

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4/ Address by John Shennefield, American National Standards Institute, 60th Anniversary Evaluation and Forecast (March 29, 1978) at 11.

whether and how to use standards in their regulatory programs. Because these obligations are mainly legal, and because lawyers will virtually always have a major role in the process by which regulations are issued, the focus is on how lawyers look at the regulatory use of standards. In particular, the report explores the implications of administrative law for the regulatory use of standards, and the process that agencies use in meeting their obligations under the law.[5/]

Scope of the Report. This report is limited solely to the regulatory use of standards that are developed under the auspices of a non-governmental organization. For convenience, when it is necessary to distinguish these standards from those developed by the government itself, they will be referred to as "externally developed standards" because our focus is on the government and the standards are developed outside of the agency itself. The term "voluntary" is not used because many of the standards that will be discussed, or to which this report applies, are developed with the specific intention that they will become part of a regulatory program and hence form the basis for a mandatory obligation. Or, even if that is not the intent of those who write the standard,

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5/ This report is not a legal treatise, and it does not purport to provide a definitive legal analysis of any issue. Rather, it is a survey of the salient points of administrative law as it applies to this topic. Therefore, if any specific question arises with respect to a legal issue touched upon in this report, advice should be sought from competent counsel as to that particular question.

there is a reasonable likelihood that it will find its way into some code or another. Thus, the term "voluntary" does not seem to fit because it connotes that the standard has little or no relation to the government but rather exists solely in the private sector. Although much of our concern will be with standards that are based on widespread participation in the development process, more narrowly based standards, such as those developed by a trade association or professional society, also have a potential role in government regulation. Thus, our concern is not limited solely to standards developed under some broadly-based "consensus" process in which a standard is promulgated only after substantial agreement is reached after a concerted effort to resolve objections.[6/]

Within the category of externally developed standards, the primary focus of the report will be on standards that are concerned with safety, health and the environment that are based on a scientific or technical appraisal of some product or physical system. The report is not concerned directly with other types of standards

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6/ This definition of "consensus" is from §4b, "Proposed OMB Circular on Federal Interaction with Voluntary Standards - Developing Bodies" that was published for comments by the Office of Management and Budget on December 22, 1977, 43 Fed. Reg. 49 (1978). This proposed circular is discussed below at p. 29. See p. 119 below for a more full discussion of "consensus" standards.

such as accounting principles, standards of ethical or professional conduct or price regulations.

This report covers only the regulatory use of standards; it excludes other uses of standards by the government, such as procurement. Many who participate in the development of standards are familiar with the government's use of standards for procurement purposes, in which the agency simply adopts the standard through a quick and simple process. These standards-writers are then confused when externally developed standards are not accorded similar treatment in regulatory settings. But there is a fundamental distinction between government regulation and procurement, and the distinction is central to the relationship between the government and external standards.

A regulation is imposed involuntarily and controls the actions of the person or firm to which it applies. In addition to those directly affected by the regulation, other people may be vitally concerned with the level of activity that is established. For example, an employee of a company may be concerned with the level of safety that is specified for the machines he uses, or someone who lives downstream from a plant may be interested in regulations that determine the permissible discharge from the plant. Because so many

interests are directly and involuntarily involved, various requirements have traditionally been imposed on the process by which the government establishes these duties and their correlative rights to ensure that the proper factors are taken into account and given proper weight in a manner that accords with our democratic views of government. It is these requirements that influence the process by which an agency reviews a standard in deciding whether and how to use externally developed standards in regulatory program.

On the other hand, in procurement the government is acting analogously to a private firm in that it is using standards to buy and sell products. (Even though, to be sure, some of those products may not resemble any that are bought or sold on the private market.) Theoretically at least, under normal circumstances no one is forced to sell to the government,[7/] so that if someone objects to a

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7/ The Fifth Amendment to the Constitution of the United States explicitly contemplates that occasions will arise when people will be forced to sell their property to the government. It says, "nor shall private property be taken for public use, without just compensation." The usual example of this power of eminent domain is the condemnation of real property for the construction of roads or other public works.

Of course, a firm may be forced to sell to the government by economic necessity, but that lacks the same protection that is accorded when personal rights and duties are determined, as in the regulatory context.

procurement specification they always have the alternative of not doing business with the government. Thus, in procurement, anyone who dissents from a standard may ignore it. To a very real extent, the procurement specifications are "voluntary" standards. As described by the Deputy Administrator of the General Services Administration, "The procurement process, unlike rulemaking by federal regulatory agencies, is a consensual relationship which has been found to adequately protect the interests of both the Government and the contractor."[8/]

The distinction between regulation and procurement blurs near their intersection, such as in those cases where government funds are used to induce conduct which is deemed socially desirable. An example of this would be the minimum property standards that houses must meet before a purchaser may obtain a Federal loan. However, the two have been distinct historically and the procedures used for each are different. Thus, procedural requirements that agencies must follow when issuing regulations do not apply to government

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8/ Letter from Robert T. Griffin, Deputy Administrator of the General Services Administration to Robert A. Anthony, Chairman of the Administrative Conference of the United States, dated May 23, 1977.

procurement.[9/] As a result, the process an agency uses in reviewing externally developed standards for procurement is quite different from the one it uses for regulatory purposes, and the experience of standards-writers with procurement is likely not to apply to the regulatory use of standards.

9/ Procurement law does, of course, have procedures for protecting against arbitrary or capricious behavior by government officials. In general, they are not the same as those that will be described in this report and the procedures permit a greater latitude of action by government officials in adopting and using standards.

CHAPTER 2

HOW STANDARDS ARE USED IN REGULATORY PROGRAMS

Government agencies use externally developed standards in a wide variety of ways that are outlined below. The way an agency uses a standard may have a large bearing on the criteria it will use in reviewing the standard, both as to actual content and the method by which it was initially developed. As a general rule, the more central the role played by a standard in prescribing mandatory conduct, the more rigor the agency will require in the process of developing the standard. Thus, the prospective use is important for those who prepare a standard, because it influences both the nature of the standard -- such as whether it emphasizes design or performance criteria -- and the procedures used in preparing it.

This description of the various uses provides a setting for describing how agencies review standards and what they look for in them.

Each of the uses is described in greater detail later in the appropriate part of this report.

Adoption Outright. An agency may adopt a standard, or a code of standards, outright and without

change. One example of this is when a statute specifies the very standards that an agency will impose, as in the case of the Social Security Administration where the statute specifically provides that "provisions of the Life Safety Code of the National Fire Protection Association (23rd edition, 1973)" apply to skilled nursing facilities.[10/]

Another version of adoption outright is where the agency adopts the standards as regulations. This may be under the explicit direction of Congress, as in the case of the Occupational Safety and Health Administration.[11/] Or, the agency itself may feel that the standards adequately fulfill their needs. This has been done by many agencies for many standards, including the regulations of the Department of Transportation concerning hazardous materials[12/] and

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10/ 42 U.S.C. §1395x(j)(13). The statute is amended from time to time to update the version of the Life Safety Code that is adopted.

11/ §6(a) of the Occupational Safety and Health Act of 1970, 29 U.S.C. §651(a), required OSHA to adopt all National Consensus safety standards and existing federal safety standards, without regard to the normal rulemaking requirements of the Administrative Procedure Act, unless OSHA determined that the adoption of a particular standard would not improve safety in the workplace.

12/ 49 CFR §§171-179.

those of the Department of Housing and Urban Development with respect to mobile homes.[13/]

This adoption outright may be done by incorporating the standard by reference in the agency's regulations simply by listing the title of the standard. For example, OSHA adopted the National Electric Code by incorporating it by reference into its regulations.[14/] Or the agency may reprint the standard in its entirety (or with only very minor changes) in the Federal Register and then codify it in the Code of Federal Regulations. The bulk of the standards adopted by OSHA were done in this manner.[15/]

Strong Deference. An agency might grant strong deference to the standards developed by a particular organization for a particular purpose, so that it will use the standards in its regulatory program unless someone

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13/ 24 CFR §280. HUD did not adopt all of the National Fire Protection Association (NFPA) standard, and some controversy has developed over their modification of parts of the standard. See, Robert W. Hamilton, The Role of Nongovernmental Standards In the Development of Mandatory Federal Standards Affecting Safety or Health, Texas Law Review, November, 1978, at p. 1421. (This report was prepared for the Committee on Licenses and Authorizations of the U.S. Adminstrative Conference.)

14/ 29 CFR §1910.309.

15/ See, e.g., 29 CFR §1910.212.

demonstrates to the agency why it should not do so. For example, the Securities and Exchange Commission has said:

> In meeting [its] statutory responsibility effectively, in recognition of the expertise, energy and resources of the accounting profession, and without abdicating its responsibilities, the Commission has historically looked to the standard-setting bodies designated by the profession to provide leadership in establishing and improving accounting principles. The determinations by these bodies have been regarded by the Commission, with minor exceptions, as being responsive to the needs of investors.16/

The Commission generally requires that the principles of the Financial Accounting Standards Board must be followed in financial statements. This type of deference, at least with respect to physical standards, is rare.

Basis for Rulemaking. The most common use of externally developed standards is the basis for rulemaking proceedings. In this case, the agency reviews the standard, makes the changes it thinks are appropriate, and publishes the revised standard in the Federal Register as a proposed regulation. Changes may be made in the standard in response to comments made by the public during the rulemaking proceeding. The Department of Housing and

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16/ Release No. AS-150, 38 Fed. Reg. 1260 (1973).

Urban Development modified parts of NFPA's Mobile Home Standard before they were published in the Federal Register as proposed regulations and further modifications were made after public comment.[17/]

Regulatory Guides. An agency may suggest that adhering to a particular standard is an acceptable, but not necessary, way of complying with a regulation. Used in this way, the standards are called regulatory guides after the term employed by the Nuclear Regulatory Commission in its generally successful program.[18/] Such an approach was recommended by the President's Task Force on the Revision of the OSHA Safety Regulations.[19/]

Guidelines. An agency may use standards as guidelines as to how to comply with general requirements in such a way that standards are, at least theoretically, neither necessary nor sufficient. Rather, they are provided for advice only, and even if a firm does comply with the applicable standards, the agency could still find a violation of

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17/ Hamilton, supra note 13 at p. 1422.

18/ Ibid. at 1417.

19/ Paul W. MacAvoy [Ed.], OSHA Safety Regulation, (Washington: American Enterprise Institute for Public Policy Research 1977); 42 Fed. Reg. 1742 (1977).

the general regulation. Nor can the agency cite someone simply for the failure to adhere to the standard guidelines. The American Society of Mechanical Engineers (ASME) has established a Gas Piping Committee that publishes a guide as to how to comply with Federal pipeline safety standards (which were largely built on ASME's Code for Pressure Piping).[20/]

Deference in Lieu of Developing Mandatory Standard. An agency may decide that it need not issue a mandatory regulation because voluntary compliance with either an existing standard or one developed for the purpose will be sufficient to meet the needs of the agency by reducing the problem addressed by the standard. The Consumer Product Safety Commission has done this for such products as home playground equipment[21/] and ladders.[22/] The Commission has been working with the Chain Saw Manufacturers Association in the development of a voluntary standard that addresses the risk of injury due to kickbacks from chain saws rather than issuing a mandatory safety rule.[23/]

20/ Hamilton, supra note 13, at p. 1430.

21/ Product Safety Letter, August 28, 1978.

22/ 41 Fed. Reg. 52,1000 (1976).

23/ CPSC News Release (March 30, 1978).

CHAPTER 3

ADMINISTRATIVE LAW AND THE REGULATORY USE OF STANDARDS

The rulemaking provisions of administrative law determine the procedures by which agencies develop and promulgate regulations, and thus, substantially influence how agencies use externally developed standards. This chapter outlines sources of administrative law and points out that law and practice concerning regulatory use of standards are unsettled.

What Administrative Law Is. Administrative law is the legal requirements and restrictions on how government agencies make decisions which affect members of the public. It controls what agencies must do and what agencies cannot do. Its concern is the process by which those decisions are made, as opposed to the substance of the decisions themselves. The final part of the definition -- the limitation to decisions affecting members of the public -- indicates that administrative law, at least as will be described here, is not concerned with the internal management of the government, but rather is concerned with the relationship of government agencies to the private sector.

Sources of Requirements on Agencies. There are basically four sources of administrative law.

o Administrative Procedure Act. The first is the Administrative Procedure Act (APA).[24/] Congress passed the APA in 1946 following several years of detailed study. The procedures that agencies should follow when making decisions affecting the public matured during the growth of the federal government in the thirties, and the APA largely codified these precepts. Although the Freedom of Information Act, the Privacy Act and the Sunshine Act have been added to the APA recently, its general principles remain unchanged. The Act provides the basic procedures that agencies must follow when issuing rules and in adjudicatory proceedings. It also provides the criteria courts use to review the decisions of an agency.

o Substantive Statutes. The second major source of administrative procedure that an agency must follow when issuing a rule or regulation[25/] is the particular statute that gives it the power to issue the rule in the first place. Many, if not most, of the statutes creating regulatory authority that have been passed within the past decade

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24/ 5 U.S.C. §§551-559, 701-706.

25/ The terms "rule" and "regulation" will be used interchangeably in this report. The term in the Administrative Procedure Act is "rule".

contain a specific section that sets out the procedures the agency must follow in implementing the statute. Generally, the procedures supplement those of the Administrative Procedure Act.[26/] Thus, for example, the Occupational Safety and Health Act, unlike the Administrative Procedure Act, requires OSHA to conduct an oral hearing if anyone requests it before issuing a regulation (or, as rules are called in the Occupational Safety and Health Act, a "standard").[27/] The Act also provides a different criteria for judicial review, so that one could argue that OSHA is obligated under its act to develop more specific factual information to support one of its rules than would be an agency operating under the Administrative Procedure Act alone.[28/] To take another example, the Consumer Product Safety Act(CPSA)contemplates an entirely different sort of rulemaking process than that envisaged by the APA: Under the CPSA, whenever the Consumer Product Safety Commission desires to issue a product safety standard,

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26/ Some statutes, however, permit a more streamlined procedure than that required by the APA. For example, for the first two years of its existence, OSHA was authorized to adopt existing consensus standards without subjecting them to the normal rulemaking process. See, supra note 11.

27/ §6(h), 29 U.S.C. §651(h).

28/ This point will be discussed at note 142.

it may solicit offers to develop the standard from groups in the private sector, instead of developing the standard inside the agency as is the normal process of the APA.[29/]

o Due Process Clause of the Constitution. The third source of requirements imposed on agencies is the Due Process Clause of the Fifth Amendment to the Constitution of the United States. It provides, "No person . . . shall be deprived of life, liberty, or property, without due process of law". This clause means that if the government does something that takes or destroys the property of an individual or firm, then it can only do so by adhering to at least minimally acceptable procedures. Usually, the due process clause is applied in non-commercial situations involving private individuals. But it does serve to constrain arbitrary conduct on the part of a government agency even when the issue is commercial.[30/]

29/ §7, 15 U.S.C. §2056.

30/ See, e.g., American Airlines v. CAB, 359 F.2d 624, 631 (D.C. Cir.), cert. denied 385 U.S. 843 (1966). The Due Process Clause is mentioned explicitly only when the government's actions affect only one or a few people or firms, as opposed to the development of a general policy or rule. However, the principles of fairness that the Due Process Clause embodies underlies the approach and analysis courts use when reviewing the procedures agencies use in developing and issuing rules.

o Courts. The final source of the requirements on agencies when they issue rules is the Federal Courts, led by the Court of Appeals for the District of Columbia Circuit. For the past decade, the courts have continually expanded the procedures agencies must follow. In part, these requirements have been based on the due process clause, although the courts have not explicitly relied on it, and on an expanded reading of the APA. But, in large part, they have simply been imposed by the courts on the agencies because the courts felt the agencies would do a better job more fairly if they followed the additional procedures.[31/] Very recently, however, the Supreme Court chastised the lower courts for imposing these additional requirements, saying that so long as the agencies follow the procedures established by Congress the courts are not free to require additional steps.[32/] The implications of this decision are not yet clear.

Thus an agency may be constrained by any of four sources as to how it must proceed when issuing a regulation.

Changing Emphasis. During its formative years, the focal point of administrative law was adjudication because that

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31/ Kenneth Culp Davis, Administrative Law Treatise, 2d Ed. (San Diego: K.C. Davis 1978) at p. 35.

32/ Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc., 98 S.Ct. 1197 (1978).

was how the government conducted its business. Thus, most of the early writing and judicial decisions concern the refinements of the trial type hearings that are modeled after court proceedings and are used in agency adjudication.

But in the late sixties administrative agencies entered the era of rulemaking[33/] with the creation of many new regulatory programs that were designed to issue highly complex technical rules. With the change in how the government conducts its business came an increased concentration of administrative law on rulemaking that has specifically focused on the information agencies develop to support their technical rules and the methodology they use to go from that information to the final rule.

Lack of Attention to Standards. While the number of government programs that issue highly technical regulations has grown, with a concomitant growth in the potential use of externally developed standards in regulatory programs, and while the focus of administrative law has switched to the process by which these regulations are developed and issued, until quite recently no serious attention had been

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33/ Davis, supra note 31, at pp. 33-35.

given to the relationship between standards and government regulation.

For example, the Panel on Engineering and Commodity Standards of the Department of Commerce's Technical Advisory Board set out with the mission

> to make recommendations as to activities important to meeting national requirements for standards, with particular emphasis on the role of the Federal Government and the Department of Commerce. It will be important to give special attention to the relationship between activities of the private standards groups and the Federal Government....34/

The report of the panel, generally known as the LaQue Report, was highly influential on the relationship of the government to externally developed standards and to the organizations that develop them. Interestingly, the report contains no discussion of the regulatory use of these standards, other than as building codes. The implication seems to be that as of 1965, when the report was issued, that relationship was not a major concern.

Nor is there any discussion of the regulatory use of standards in the legal literature, and only a scattering of judicial cases specifically address the issue.

34/ Report of the Panel on Engineering and Community Standards of the Department of Commerce Technical Advisory Board (1965) at p.1.

Lack of Coherent Policy. As a result of this lack of attention, the law and practice is unsettled. William T. Cavanaugh, Managing Director of the American Society for Testing and Materials (ASTM), has described the lack of anv coherent Federal policy on the use of externally developed standards.

> [O]ne of the objectives of the Administrative Procedure Act was to achieve consistency and fairness in the handling of administrative elements of public affairs. It would seem we need some sort of parallel and similar system for the handling of technical elements in public affairs, especially now since so many of these involve what we can characterize as high technologies. It seems, for example, that all concerned agree that Federal Register publication is a very poor way to elicit total response to complicated technical questions. They usually add, "but it's the only ball game we have." Perhaps we need a different ball game. At the very least, it deserves discussion at the highest levels in government -- but where?35/

Mr. Cavanaugh went on to say:

> Right now, ASTM has day-to-day working and thinking involvements with about 25 federal agencies -- bureaus, departments -- and who knows how many subsidiary groups of various hierarchical levels in these organizations. The attitude of every one of these agencies is different, both from a policy and operations point of view. Basic attitudes vary

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35/ "ASTM in the U.S. Measurement System", address at the National Bureau of Standards Conference in Standard Reference Materials and Meaningful Measurements, (1973) at p. 7.

> all the way from chilly detachment to all-enveloping warmth.36/

This contrast between the attitudes of the various agencies can be seen in the standoffish or even hostile attitudes of the Department of Transportation concerning the use of NFPA's standards for liquified natural gas37/ and of the Department of Housing and Urban Development concerning NFPA's standards for mobile homes,38/ as compared to the good working relationship between the Nuclear Regulatory Commission and the Nuclear Standards Management Board of the American National Standards Institute (ANSI).39/

Recent Interest. Quite recently, however, a considerable amount of thought and attention has been given to standards developed by non-governmental organizations, and part of this thinking bears on the regulatory use of the standards.

Several years ago, Congress investigated complaints about some standards excluding allegedly meritorious products

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36/ Ibid. at p. 8.

37/ Hamilton, supra note 13, at p. 1431.

38/ Ibid., at IV-41.

39/ Ibid., at IV-35.

from the market, and successive bills were introduced to require standards-writing organizations to adhere to certain procedures.[40/]

The Office of Management and Budget published a draft circular for comment in December, 1976[41/] that generally supported the use of externally developed standards and would require agencies to use them more widely. Following extensive comments on the original draft, another draft circular was issued for comment on December 22, 1977.[42/] This version is also generally in favor of the use of external standards, although it cautions that they should be used for regulatory purposes only "after a careful evaluation of such standards assures their adoption and use to be in full accordance with the agencies' statutory missions and responsibilities..."[43/] The 1977 version of the circular would

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40/ S.3555, 94th Cong., 2d Sess. (1976); S.825, 95th Cong. 1st Sess. (1977); extensive hearings were held on both bills before the Subcommittee in Antitrust and Monopoly of the Committee on the Judiciary. And, John Ray, Assistant Counsel, Senate Subcommittee in Antitrust and Monopoly, U.S. Congress, Congress Looks at the Voluntary Standards System and Reacts, ASTM, Standardization News, June, 1977.

41/ 41 Fed. Reg. 53, 723 (1976).

42/ 43 Fed. Reg. 49 (1978).

43/ §6a(3).

impose many of the procedural requirements from the Congressional bills before federal agencies could participate in the development of these standards.

The Administrative Conference of the United States [44/] commissioned a study by Professor Robert W. Hamilton of the University of Texas Law School on "The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Relating to Safety and Health." The Conference will likely issue formal recommendations to agencies on the regulatory use of standards some time within the next year. [45/]

The Federal Trade Commission has completed a study of standards-writing and instituted a rulemaking proceeding to the end that the Commission would issue a Trade Regulation Rule establishing procedures that standards-writing organization must follow. [46/]

44/ The Administrative Conference is a government agency comprised of government officials and private citizens (mostly lawyers) that makes formal recommendations to Congress, the President and the agencies on improving administrative procedure. 5 U.S.C. §§571-576.

45/ Hamilton submitted his report and draft recommendations to the Committee on Licenses and Authorizations of the Conference. The Committee modified the recommendations and circulated the report and revised recommendations to interested agencies and individuals for comment. Based on the comments submitted, the proposed recommendations were revised, debated, and passed by the membership of the full Conference in December, 1978. See 44 Fed. Reg. 1357 (1979).

46/ 43 Fed. Reg. 57,269 (1978).

Finally, an ad hoc group of individuals interested in the relationship of externally developed standards to the government convened under the title "The National Standards Policy Advisory Committee" to "prepare a recommended U.S. National Standards Policy that would, if implemented, go a long way towards creating a working environment within which the Nation's standards capability -- both public and private -- could be effectively, economically, and equitably used on behalf of the national interest."[47/] The Committee drafted a "Recommended National Standards Policy for the United States", and the Department of Commerce published it for comment in the Federal Register.[48/]

Law and Practice Unsettled. Not only is the law and practice concerning the relationship of externally developed standards to government regulation unsettled, but, also, the many inquiries currently in progress indicate a lack of a "consensus" over what that relationship should be. Thus, the procedures and criteria by which agencies review externally developed standards will remain in flux for at least several years while the thinking matures. Meanwhile, agencies will not approach the question of the regulatory use of standards anywhere near uniformly.

47/ 43 Fed. Reg. 6298 (1978).

48/ Ibid.

Implications for Standards Writers

Until the law and practices settle down, there can be no clear answers as to precisely what is expected of externally developed standards that are used for regulatory purposes. In the meantime, standards writing committees should take into account the constraints on and concerns of the particular agencies that may use the standards. A better understanding of the needs of individual agencies and how they go about their business can facilitate the preparation of standards that are acceptable for regulatory purposes.

CHAPTER 4

DELEGATION OF POWER

One constraint on an agency's use of externally developed standards comes from the limits which it believes exist on its ability to delegate power to private organizations. This chapter discusses congressional delegation of power to agencies and the limits on the abilities of agencies to redelegate that power to private organizations.

Delegation from Congress to the Agencies.

Before an agency can issue any regulation, it must have the authority to do so. The authority is granted by a statute passed by Congress. The nature of this transferral of power from Congress to an agency has important consequences for those who prepare standards that could be used by the agency because it defines what factors the agency must take into account in its regulatory program and the procedures it must follow in exercising its authority. To fully appreciate the current state of the law and the views of agencies towards externally developed standards, it is necessary to review some history.

The Constitution provides that "All legislative power herein granted shall be vested in a Congress of the United States ..." It does not define "legislative power", but does list a number of items that Congress has authority over, including the "Power ... to ... provide for the ...

general Welfare of the United States."[49] A practical notion of what constitutes "legislative power" is that it is the power to develop and impose policy of general applicability (i.e., it applies to everyone within a broadly defined category as opposed to only a specified few), and future effect (i.e., it applies to action taken after the policy is established rather than to conduct that occurred earlier).[50] Thus, in a real sense, "legislative power" is the ability to exercise discretion in choosing policies as contrasted with only implementing existing policies by applying them to specific circumstances.

A strict reading of the clause quoted above could lead to the view that Congress cannot delegate its legislative power to any other branch of government or to any private group, since the "legislative power" is "vested in"

49/ Article I, Section 8.

50/ Neither limitation is universally true. A law may apply to only a few as exemplified by private bills that are passed to exempt a person from a particular requirement of general law or there may be only one person within a category that is defined generally. And, the legislation may be phrased in terms of future effect but in fact apply to action that occurred in the past. That happens, for example, when Congress changes the income tax rate during the particular year to which it applies.

Congress, meaning that Congress alone has that power. And indeed any number of Supreme Court decisions have contained "categorical statements suggesting that Congress may not relinquish any of its power to enact legislation through grants of policy making power to administrators."[51/]

But from the very outset, it has been clear that Congress does not have the time and ability to grapple with all the details necessary to codify a fully functioning regulatory system, and even the very first Congress granted discretionary power to the Executive -- that is, it delegated some of its legislative authority. In order to accommodate the practical necessity for delegating some power to the Executive with the theoretical prohibition on it, a number of rationalizations developed. One of the most enduring is that the grant is permissible only if Congress establishes the "primary" or even an "intelligible" requirement that limits the discretion available to the administrative agency which fills in the details of the program.

For example, Section 3 of the Poison Prevention Packaging Act of 1970 provides:

51/ Jerry L. Mashaw and Richard A. Merrill, The American Public Law System (St. Paul: West Publishing Co., 1975) at p. 191.

> (a) The Secretary, ... may establish... standards for the special packaging of any household substance if he finds that --
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> (1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance; and
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> (2) the special packaging to be required by such standard is technically feasible, practicable, and appropriate for such substance.
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> (b) In establishing a standard under this section, the Secretary shall consider --
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> (1) the reasonableness of such standard;
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> (2) available scientific, medical, and engineering data concerning special packaging and concerning childhood accidentical ingestions, illness, and injury caused by household substances;
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> (3) the manufacturing practices of industries affected by this Act; and
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> (4) the nature and use of the household substance.52/

The theory is that a court can then review the agency's action to be sure it is consistent with the will of

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52/ 15 U.S.C. 147.

Congress as expressed in the requirements section of the legislation. In the example, a regulation issued under the statute can be reviewed by a court to determine if the criteria established in the legislation have been met. If they have not, the court will invalidate the regulation.[53/] In this way, the discretion of an agency is held within check by Congress and the courts.

Only two cases in the history of the United States have invalidated a grant of legislative power to the Executive Branch on the grounds that it was an excessive delegation of authority. In 1935, in Panama Refining Co.[54/] v. Ryan, the court struck down a statutory provision which authorized the President to ban the transportation of certain oil. The Court felt the act in question did not sufficiently establish the criteria that would govern the exercise of the discretion:

53/ For example, the statute authorizes the Secretary to issue a regulation only if required to protect children from serious injury. He is not authorized to issue regulations simply because he thinks some other form of packaging would be more convenient. If, to take an extreme case, the Secretary were to issue regulations ordering new tops to beer cans because he finds flip-tops difficult to use, a court would rule that the Secretary did not have the power to require such changes.

54/ 293 U.S. 388 (1935).

> "Congress has declared no policy, has established no standard, has laid down no rule. There is no requirement, no definition of circumstances and conditions in which the transportation is to be allowed or prohibited."55/

The second case, which followed four months later and concerned a different section of the same statute, is particularly interesting from the standpoint of the regulatory use of standards. The section in question empowered the President to adopt codes of "fair competition" that were developed by industry groups. Under the act, before a code could even be considered, the group submitting it must be "truly representative" of the industry to which the code would apply, and the group could not impose any "inequitable restrictions on admission to membership"; finally, the code could not be "designed to promote monopolies or to eliminate or oppress small enterprises [or] discriminate against them." The authority to adopt these codes was invalidated in Schecter Poultry Corp. v. United States56/ on the grounds that the authority was too broad, or to quote Justice Cardozo,

> "The delegated power of legislation which has found expression in this Code is not canalized

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55/ 293 U.S. at 430.

56/ 295 U.S. 495 (1935).

> within banks to keep it from overflowing. It is unconfined and vagrant ...."57/

The government had argued that other statutes granted broad power to agencies and had been upheld, but the court distinguished the other statutes by saying that each of them was exercised only by following established procedures -- such as notice, an opportunity for a hearing, the requirement that the agency base its decision on findings of fact, and judicial review -- while the present delegation was not confined to any particular procedure. Thus, the Court made clear that there is a certain trade off between the need for specific goals and limitation in grants of power to administrative agencies and the procedures by which delegations are exercised.

These two cases are generally regarded as aberrations and more explained by the struggle between President Roosevelt and the Supreme Court during the early days of the New Deal than by constitutional theory. Moreover, the grants of power considered in the two cases were at the time viewed as extreme, although the power discussed in Panama would undoubtedly be upheld today. But their very existence serves to prod Congress -- if only gently -- to establish

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57/ 295 U.S. at 551.

the criteria or other limits, such as specific procedures, an agency must adhere to when exercising the power granted it.

Currently, the general pattern is for Congress to determine that a particular problem exists and then to create an agency or new regulatory program to do something about it. The statute creating the new program establishes the criteria the agency must follow in implementing the regulatory program, either in issuing regulations or making specific, individual decisions. Some of these criteria are so exceedingly broad that they are practically meaningless, such as requiring that actions must be in the "public interest", or that the grant of a new license for transportation must serve the "public necessity and convenience." Thus, the doctrine that legislative power cannot be delegated to an agency in the Executive Branch has not served particularly well to limit the scope of the authority of the agencies.[58/]

Delegation to Private Organizations. If Congress, which at least theoretically possesses the exclusive power to establish legislation, can delegate substantial authority to administrative agencies, the question naturally arises as to

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58/ Kenneth Culp Davis, Administrative Law Text (St. Paul: West Publishing Co. 1972) at p. 34.

whether administrative agencies can redelegate some of their power to private organizations. That is the legal characterization of the question so often asked by standards writers, frequently in emotional terms: Why doesn't the agency simply adopt the standard we wrote?

On the Federal level, the law as to whether legislative power may be delegated to a private organization is remarkably sparse. Schecter invalidated a program which empowered the President to adopt codes developed by trade associations or other business groups as mandatory regulations. Interestingly, the statute required that the group submitting a proposed code must be "truly representative" of the industry in question. Thus, in modern standards parlance, the groups had to be "balanced," at least within the affected business community. And, the statute provided that the codes in question must not lead to monopolies or hurt small business, so that Congress developed some criteria to guide the development of the codes. Although the Court invalidated the program because it was an excessively broad delegation of power to the President, an important aspect of the Court's reasoning was that no procedural safeguards were provided for those who may be affected by the codes. The Court was concerned that the codes which were developed by

an outside organization -- even one that is balanced -- were adopted without being subjected to the normal administrative process that accompanies government decisions that inflict mandatory obligations.

A year after it decided Schecter, the Supreme Court considered a statutory provision that authorized representatives of coal producers and coal miners to set maximum hours of labor and minimum wages. The Court's analysis of the legality of the delegation of power to the private group is brief:

> The power conferred upon the majority is, in effect, the power to regulate the affairs of an unwilling minority. This is legislative delegation in its most obnoxious form; for it is not even delegation to an official or an official body, presumptively disinterested, but to private persons whose interests may be and often are adverse to the interests of others in the same business. The record shows that the conditions of competition differ among the various localities. In some, coal dealers compete with the mechanical production of electrical energy and of natural gas. Some coal producers favor the code; others oppose it; and the record clearly indicates that this diversity of view arises from their conflicting and even antagonistic interests. The difference between producing coal and regulating its production is, of course, fundamental. The former is a private activity; the latter is necessarily a governmental function, since, in the very nature of things, one person may not be entrusted with the power to regulate the business of another, and especially of a competitor. And a statute which attempts to confer such power undertakes

> an intolerable and unconstitutional interference with personal liberty and private property. The delegation is so clearly arbitrary, and so clearly a denial of rights safeguarded by the due process clause of the Fifth Amendment, that it is unnecessary to do more than refer to decisions of this court which foreclose the question.59/

Thus, the Court held that the power to regulate an industry cannot be delegated to a private group, because the power of regulation "is necessarily a governmental function." This passage by itself constitutes most of the law with respect to the delegation of power to private groups.

Again, the total rejection of the concept of delegation to private groups in Carter can be explained in large part by the times, especially since the Court invalidated other parts of the same statute that plainly would be upheld today. But both Schecter and Carter reflect a basic distrust of turning over government authority to private organizations, if by that we mean that the government simply adopts and enforces a code developed by the private organization without subjecting it to the normal administrative procedures by which regulations are developed.

Perhaps surprisingly, these two cases stand virtually alone in directly addressing the question of

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59/ Carter v. Carter Coal Co., 298 U.S. 238 (1936) at p. 311.

delegation of power to a private group.[60] From time to time, an individual judge will raise a related issue, but no case since has considered the question directly. However, similar skepticism over the relative roles of the government and private sector was expressed by a court when it considered the evidence underlying a standard issued by the Consumer Product Safety Commission:

> [T]he experts who provided the opinions were private consultants. While courts traditionally defer to the expertise of government regulatory agencies, the case for deference is not as strong where the opinions of private individuals are concerned. An expert in water safety is not necessarily an expert in government regulation of private individuals, and may lack proper sensitivity to [the amount of evidence required for] government intrusion into the daily lives of the citizenry. Determining the best way to run your own swimming pool is not the same as deciding how the government should force your neighbor to run his.[61]

In the same opinion, the court mentions that it has a "bias in favor of information exposed to [public] comment".[62] While in that case the court was not confronted with a standard

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60/ One recent case briefly mentions that a group was considering challenging the wage/price controls of the early seventies on similar grounds but nothing ever came of it. Amalgamated Meat Cutters & Butcher Workers v. Connally, 337 F. Supp. 737, 763 (D.D.C. 1971).

61/ Aqua Slide 'N' Dive v. Consumer Product Safety Com., 569 F.2d 831, 843-844 (5th Cir. 1978).

62/ Ibid. at 838.

that was adopted intact by an agency without permitting public comment on it, the two quoted passages lead to a conclusion that the court would not look favorably on such a scheme. Thus, the reasoning of the court could be regarded as bolstering the two decisions of the thirties that government power cannot be delegated to private groups in the sense that a standard developed by the private group is adopted by the agency without any further administrative procedures.

But, the authority to make some regulatory-type decisions is in fact occasionally delegated to private organizations. For example, regional groups of physicians review medical services provided under Medicare and Medicaid to determine if they are reasonably necessary and of acceptable quality. These groups make final and binding determinations of a quasi - adjudicatory nature as to whether the services are qualified for Federal reimbursement.[63] And, at least one commentator believes that a limited delegation of power to private organizations to develop regulations is appropriate in some situations.[64]

63/ See, Public Citizen Health Research Organization v. HEW, 449 F. Supp. 937 (D.D.C. 1978).

64/ Liebmann, Delegation to Private Parties in American Constitutional Law, 50 Ind. L. J. 650 (1975).

Moreover, examples of delegation of rulemaking powers to private groups can readily be found on the state level, such as professional licensing organizations. While, this delegation is from the legislature rather than from an administrative agency, it shows that the notion that power cannot be delegated to private organizations is inaccurate as a general principle of government.[65/]

Agency Views on Delegation. Even if the law is not entirely clear on the matter -- largely because there is so little of recent vintage and the two cases of the thirties are of questionable authority -- the common belief remains that an agency may not delegate its power to a private organization. Agencies frequently assert they lack the authority to do so when they undertake a review of a standard or when they respond to an inquiry as to the relationship between government regulation and externally developed standards.

For example, when the Department of Housing and Urban Development was urged to adopt NFPA's standard concerning mobile homes, the Department responded that adoption by reference of the standard would be inappropriate because it

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65/ See, Jaffe, Law Making by Private Groups, 51 Harv. L. Rev. 201 (1937).

would imply

> that future amendments to the ... standard will automatically be adopted as the Federal standards or will be given special consideration by HUD. Adoption of the NFPA mobile home standard thus commits HUD to a de facto delegation of its authority to develop standards for promulgation. Such a course of action is neither envisioned nor authorized by the Act.66/

While the logic of the Department that adoption of an existing standard implies a commitment to adopt future revisions is unclear, their concern was expressed in terms of delegation of power.

The Department of Transportation responded similarly when it said that it is for the government to determine the appropriate level of safety by developing a mandatory standard, but that private organizations can help this process by recommending methods of complying with the mandatory obligations.67/ Again, the concern is over the proper roles of the government and private organizations.

The Environmental Protection Agency commented that using externally developed standards in a regulatory program would be inappropriate, particularly when "those organizations which are to be regulated by the same standard"

66/ 40 Fed. Reg. 40,261 (1975).

67/ 42 Fed. Reg. 20,777 (1977).

participate in its development either directly or as part of a process of reaching consensus.[68/]

Thus, either because they believe the law does not permit government power to be delegated to private groups or because they believe it would be inappropriate to do so, administrative agencies generally refuse to delegate their power to a private organization.

Implications for Standards Writers. The fact that agencies cannot or will not delegate the power to issue regulations to private organizations means, at a very minimum, that an agency will not authorize a private organization to set maximum or minimum levels of performance in a specified activity that all members of an affected industry must meet at the pain of some sanction. The power to impose virtually any act of discretion or policy choice would be a grant of regulatory authority, and hence forbidden under the notion that only the government may exercise that power. Three other consequences for the regulatory use of standards flow from the prohibition on delegation of regulatory authority.

68/ Letter from Richard Redinius, Assistant Administrator for Planning and Management, to Hugh Witt, Administrator, Office of Federal Procurement Policy, OMB in response to the 1976 proposed OMB circular; quoted in Hamilton, supra note 13, at p. V-5.

The first is that an agency will not agree to adopt an existing standard as its own mandatory regulation simply because the standards-writing organization developed the standard, even if the organization adheres to "good" procedures in doing so. In such case, the agency would be delegating power to the private organization to exercise discretion with respect to the various competing factors that go into making any regulatory decision. Rather, the agency must exercise its own discretion in deciding upon the regulatory requirements, and even if it agrees explicitly with the standard, it must follow procedures of the APA and other relevant statutes to use the standard in its regulatory program.

The second consequence is that for exactly the same reasons an agency cannot (or will not) agree to be bound by a standard that is developed in the future.

Finally, the agency cannot agree to be bound by future revisions of a standard that it has already adopted.

Consequences of Non-Delegation. In practice, non-delegation often leads to problems. The organization which developed the standard initially may revise the standard to keep abreast of changing technology or to reflect the experience with the existing standard, but the agency may not keep

pace by adopting the revision.[69]

To meet this problem, Francis LaQue, who served as Deputy Assistant Secretary of the Department of Commerce for Product Standards and who chaired the influential committee on standards in 1965, proposed that a "regulation could stipulate specifically that references to an identified standard will carry over to any revision of it that may be made from time to time by its source in the private sector."[70] He noted, however, that regulatory authorities may be "reluctant" to commit themselves in advance to the revisions. Indeed, such a committal would be a delegation of power to the standards-writing organization.

69/ The starkest example of this has been OSHA. Congress made clear when establishing the agency that many of the existing standards were out of date and in need of revision. Many of the standards that were adopted by OSHA soon after its creation have been revised, some more than once, by the organizations that developed them, but OSHA has not made any revisions. Thus, those standards that were out of date to begin with are more so now. Generally, an employer can meet both the OSHA regulation and the revised external standard, but in those instances where the old standard is inconsistent with the new, OSHA requires the antiquated technology.

70/ "Notes Re Reference to Standards in Codes or Other Regulations", February, 1977, presented to Technical Board of the Society of Automotive Engineers; a copy was forwarded by Walter V. Cropper, Director, Developmental Operations Division, ASTM.

Moreover, the regulations of the Administrative Committee of the Federal Register, which is responsible for printing all the regulations issued by the government agencies, provide that an agency's incorporation by reference of an externally developed standard

> is limited to the material as it exists on the effective date on the document. Future amendments or revisions of material incorporated by reference are not included. They may be added as they become available, or at any later time, by the issuance of an amendatory document.71/

Thus, when an agency refers to a standard in its regulation, it refers to a specific standard, which will generally be the latest version of the standard as it exists on the date the reference is made.72/ In particular, the reference does not mean the standard as revised in the future, unless the agency takes specific action to adopt the revision.

What Must be Done to Avoid Non-delegation. The requirement that an agency cannot delegate its power to a

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71/ 1 CFR §51.8(c).

72/ When incorporating by reference a number of standards, an agency provided "The latest issue of the following publications dated prior to this Bulletin, form a part of this Bulletin [listing the standards]". "Fire Safety Requirement for Plastic Plumbing Fixtures," Department of Housing and Urban Development, 43 Fed. Reg. 18034, 18038 (1978).

private organization does not mean that an agency cannot use an externally developed standard at all or even that it cannot adopt the entire standard intact. It means simply that the promulgation of the standard as a regulation must be through the action of the agency itself rather than resulting automatically from the action of a private organization. Thus, the agency will have to reserve the right to review a standard before using it in its regulatory program.

The Future. The notion that governmental power cannot be delegated to private organizations is undoubtedly more of a policy decision by agencies than a hard and fast legal requirement. It is based on a fear that externally developed standards are suspect and are less likely to fulfill the legitimate regulatory goals of an agency than those written by the agency itself. If a process can be developed by which a government agency can determine whether or not confidence in a standard is merited, the agency may be more willing to use the standard in its regulatory program. That in turn is likely to lead to a limited form of delegation. But, before such a delegation can occur, two requirements must be met: The agency must have confidence that the standard addresses the appropriate issues and resolves them suitably. And, procedures must be followed by the private organization so that interested members of the public can comment on a proposed standard in such a way

that legitimate concerns are taken into account when developing the final standard. The former is necessary to meet the obligations imposed on the agency by Congress, and the latter is required to meet the concerns of the courts as expressed in the passages quoted previously and of Congress as embodied in the Administrative Procedure Act.

This process will likely take a long time to mature. But, there is progress. The many inquiries currently in progress will spark thought on the appropriate roles in regulation for standards developed in the private sector. The mutual understanding that results will enable both the government and those who write standards to accommodate to the legitimate needs of the other. Indeed, the Consumer Product Safety Commission recently found that externally developed standards have improved since the negative comments were made by the National Commission on Product Safety.[73/] The CPSC now believes the standards better address risks of injury associated with consumer products.[74/]

73/ Commission Involvement in Voluntary Standards Activities, 43 Fed. Reg. 19216, 19222 (1978); CFR §1032.1(a). Hereafter referred to as CPSC Policy Statement.

74/ Ibid.

PART II

AGENCY REVIEW OF STANDARDS

CHAPTER 5

NATURE OF USE DETERMINES PROCEDURES

This chapter outlines rulemaking procedures required under the Administrative Procedure Act (APA) and explains which types of agency regulatory actions must follow these procedures.

If an agency cannot or will not delegate its regulatory power to a private organization, it must exercise its own discretion in deciding whether and how to use an externally developed standard. Exercise of that discretion is controlled by the general principles of administrative law, although the requirements imposed on individual agencies and in particular circumstances vary. As a general proposition, the procedural rigor the agency must follow when issuing a rule or using a standard depends on the nature of the use. Frequently the agency is not free to simply review a standard informally and publish it as a regulation even if the agency thinks the standard fulfills its requirements. Rather, it must follow the prescriptions of the APA.

Outline of Rulemaking Procedures. The APA requires that when issuing a rule, an agency must publish a Notice of Proposed Rulemaking in the Federal Register with the following information: the agency's authority to issue the proposed rule; the time, place and nature of the rulemaking

proceedings; the terms or substance of the proposed rule, or a description of the subject and issues that will be covered by the proposed rule.[75/] Whereas the explanations that must accompany proposed rules used to be brief,

> [t]here is a growing demand (including a number of not so subtle nudges from the judiciary) for regulatory documents to include adequate background information because, without it, the Federal Register makes little sense to an increasingly interested public. Recognizing this need, the regulations of the Federal Register now require every proposal and every rulemaking document to begin with a clear preamble statement that describes the contents of the document in a manner sufficient to apprise a reader, who is not an expert in the subject area, of the general subject matter of the rulemaking document.[76/]

As the quote indicates, the courts have required agencies to explain the technical basis for their proposed regulations, by including in the notice a review of the studies

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75/ 5 U.S.C. §553.

76/ Document Drafting Handbook, (Washington: Federal Register, 1975) at p. 1; indeed, the Federal Register has recently expanded its requirements for regulatory documents to provide even more information, including the name and telephone number of someone in the agency who can speak knowledgeably about the document. 1 CFR §18.12 (1977).

and factual data on which the agency relies and by permitting the public to review the materials.[77] At minimum, under the APA, the agency must then permit members of the public to file written comments on the proposed rule -- including both the technical validity and the overall wisdom of the rule -- and frequently agencies hold oral hearings as well. (If the issues are particularly complicated or the agency feels it needs the insights and advice of the public on how it should approach a particular regulatory issue, it may issue an Advance Notice of Proposed Rulemaking before publishing the notice of proposed rulemaking. Indeed, the current theory is that agencies should involve the public earlier in the regulatory process, when the agency is beginning the development of a significant regulation).[78] The agency must then take into account the substantive comments it receives, and change its proposal in response to those that are meritorious.[79] If the changes it proposes to make vary too much from

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77/ See, e.g., International Harvester Co. v. Ruckelshaus, 478 F.2d 615 (D.C. Cir. 1973); Ethyl Corp. v. EPA, 541 F.2d 1 (D.C. Cir.) (En Banc), cert. denied 426 U.S. 942 (1976).

78/ See, §2(c), Executive Order 12044, 43 Fed. Reg. 12661 (1978); Recommendation 76-3 of the Administrative Conference of the United States, 1 CFR §305.76-3.

79/ Portland Cement Association v. Ruckelshaus, 486 F.2d 375 (D.C. Cir. 1973) cert. denied 417 U.S. 921 (1974).

the initial notice, then the agency is required to provide another notice and receive additional comments on the revision.[80/] When the final rule is published, the agency must include in the Federal Register a preamble to the rule that explains its factual and policy basis as well as its purpose.[81/] This process is known as "notice and comment" or "informal" rulemaking.[82/]

When the General Principles Apply. Except in unusual, isolated programs[83/] these provisions apply whenever the agency issues substantive rules that have a direct, legal effect in that they are binding on members of the

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80/ Wagner Electric Corp. v. Volpe, 466 F.2d 1013 (3rd Cir. 1972).

81/ Automotive Parts & Accessories Ass'n v. Boyd, 407 F.2d 330 (D.C. Cir. 1968).

82/ The APA also provides for "formal" or "trial-type" rulemaking proceedings in which the rule is developed after an oral hearing that resembles a trial. These proceedings are required by some statutes and some agencies use them voluntarily to develop specific factual material. However, the Supreme Court narrowly interpreted the requirement to use these proceedings, with the result being that now very few statutes require agencies to conduct the more complex and expensive proceedings. United States v. Florida East Coast Ry. Co., 410 U.S. 224 (1973).

83/ An example is the authority granted OSHA for two years after its creation to adopt existing standards without subjecting them to the normal rulemaking process. See, note 11, supra.

public, on a court, and on the agency itself. These rules are the fulfillment of a delegation of power to an agency: Congress has authorized the agency to "make law" by issuing rules. For example, Congress explicitly authorized the Secretary of Labor to "promulgate, modify, or revoke any occupational safety or health standard",[84/] and the Consumer Product Safety Commission is empowered to issue rules that are "reasonably necessary to prevent or reduce an unreasonable risk of injury associated with [a] product."[85/] Once these substantive rules are issued, they are the law and are controlling, not the statute which delegated the power to the agency.

When the Principles Do Not Apply. Some rules issued by agencies are not binding, but rather set out the agency's views or interpretations as to what is required by the statute that it administers. In this case, the statute and not the rule is controlling and specifies the activity that must be followed. The rulemaking requirements of the Administrative Procedure Act do not apply to interpretative

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84/ §6(b) Occupational Safety and Health Act of 1970, 29 U.S.C. § 655(h).

85/ §7(a)(1) Consumer Product Safety Act, 16 U.S.C. §2056 (a)(1).

rules,[86] so that an agency may issue them without adhering to the procedures outlined above.[87] Nor do they apply to policy statements which are designed to describe the general views and directions of the agency but which do not impose mandatory requirements. Finally, the rulemaking requirements do not apply when the agency has good reason to believe that they would be "impracticable, unnecessary, or contrary to the public interest."[88]

At the fringes, the distinction as to whether a rule is substantive, interpretative, or something else is unclear, so that it is similarly unclear as to whether the agency must follow the requirements of the APA.[89]

86/ 5 U.S.C. §553(b)(A).

87/ However, if an interpretative rule in fact has a "substantial impact" on determining individual rights or duties, the courts may require an agency to adhere to the rulemaking procedures of the APA. See, Mezines, Stein & Gruff, Administrative Law (New York: Matthew Bender & Company 1977) §18.02[3].

88/ 5 U.S.C. §553(b)(13).

89/ One potentially significant difference between substantive and interpretative rules is that substantive rules can specify conduct more precisely. Thus, for example, a substantive rule could require that a product cannot contain more than x% of a particular chemical. However, it would be difficult to envision statutory language which could be

[Footnote cont'd. on p. 59]

Indeed, a statute may even be unclear as to whether it grants an agency the power to issue mandatory rules or whether the agency may only issue interpretations of the statutory requirements. However, the statutes that create regulatory programs concerned with technical standards will almost always make clear that the agency has the authority to issue substantive rules, so the question as to whether the agency must adhere to the APA will depend on the nature of its action. Thus, an agency may be able to adopt a particular standard directly and without following the procedures of the APA or, in order to adopt precisely the same standard, it may have to meet those procedures rigorously, depending on the use.

[Footnote 89 cont'd. from p. 58]

"interpreted" as requiring the product to have less than x% of the chemical; most statutes are phrased in terms of "reasonable," "unreasonable," "danger" or the like, and an interpretation of these general terms would not be as precise as a specified level of activity. The agency could set out its policy that the product should have less than that amount, but it would then be up to the court to make the determination as to what is required by the statute, and the agency's views would not be binding on the court although the court will take the views of the agency into consideration. As was said in one famous case, "The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control". Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944).

Interpretative Use. An agency may wish to issue guidelines which are used to enforce the mandatory, general requirements that are imposed either by a statute or by the agency's own regulations. In this case, the standards would be promulgated as advice on how to comply with the mandatory obligations or as an interpretation of what the agency expects in the way of meeting those obligations. Whether or not the guidelines are met carries no legal weight whatever, at least theoretically. Even though a company adheres to the guidelines, the agency may believe that it did not meet the duties imposed by the general regulation and issue a citation for failing to comply with the regulation, although outrage would likely result over the fickle view of the agency unless it suitably explains why it is not following its own advice. But, nor may an agency cite a company for failing to meet the guideline.

However, compliance officers may believe that a firm should follow the standard (in part because it may be easier to measure compliance with the guideline than to make a subjective judgment as to whether a general, performance - oriented requirement is met), so that if a company does not meet a particular guideline the officer will issue a

citation. The citation would have to allege a violation of the regulation or statute and not the guideline. The company can then defend the assertion by showing it meets the regulatory duty even if it did not comply with the guideline.

In this case, the standard that is used as a guideline does not establish the acceptable level of activity in question -- usually safety or health -- so that it is not a substantive rule that must be promulgated through the procedures of the Administrative Procedure Act. As a result, these guidelines may be issued informally by the agency without being subjected to the notice and comment requirements of the APA. On the other hand, if the agency adopted precisely the same standard as a regulation that companies must follow, the agency would be required to use the rulemaking procedure.

This illustration shows how uncomfortable the distinction is between interpretative and substantive rules. The guideline in fact has a substantial effect in determining the upper limit of benefits provided by the general regulation because in essence it says that if the regulated company meets it, no citation will be issued; contrariwise, it also has a large effect in determining the duties of the

employer and may be overly stringent. The rulemaking procedures are designed to enable the affected members of the public to participate in the development of the rule by expressing their views on the appropriateness of a regulation in such a way that the agency must consider their views. Simply publishing guidelines by-passes this normal, protective procedure. As a result, recommendations have been made that interpretative rules having significant effects on the rights and duties of members of the public should be issued only after being subjected to notice and comment rulemaking procedure.[90/]

A variant of the guideline approach is used by the Nuclear Regulatory Commission. "Regulatory guides" are issued to describe what is acceptable to the staff of the Commission in meeting the regulatory obligations. Thus in a sense, the guides are sufficient but not necessary ways of complying with the mandatory duties of the regulations and the statute: If a company complies with the applicable guides, the staff will be satisfied that the duties are met; but if the company can determine another way of meeting those duties without complying with the guides -- for example a cheaper way or using

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90/ Recommendation 76-5 of the Administrative Conference, 1 CFR §305.76-5.

a new technology -- it is free to do so. Under the regulatory guide approach, the Commission itself may disagree with its staff and take the view that adherence to a guide is not sufficient to meet the regulatory duties so that more is needed. If, however, the system is to work well, that should not happen very often.

When issuing the regulatory guides, the NRC publishes a notice in the Federal Register describing the subject area. While the full text is not printed, the notice tells the public where they can obtain a copy of the proposed guide. Members of the public may then comment on the proposal, and the staff of the Commission takes the comments into account when issuing the final regulatory guide. The NRC has endorsed or referenced many externally developed standards in regulatory guides and over the years has had a good working relationship with the standards-writing community.[91/]

Yet another variant on this approach was recommended by a task force created by President Ford to develop a new approach to OSHA safety regulations. The task force proposed a general performance standard for machine guarding that would have to be met by all employers. A series of

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91/ See, Hamilton, supra note 13, at p. IV-35.

standards that applied to various specific types of machines would be included in an appendix to the regulation, and compliance with the applicable standards would be deemed compliance with the general requirement (as opposed to simply acceptable to the staff) absent some unusual situation.[92/] Like the regulatory guides, however, an employer need not follow the specific standards so long as the general duty is met. The task force contemplated that many of these specific standards would be based on externally developed standards. Because the standards in the appendix would determine the level of safety provided by the respective machines, the Task Force believed they would have to be subjected to the procedures of the Administrative Procedure Act.[93/]

Definitions and Test Methods. All of the standards discussed above are concerned with the substantive characteristics of the activity that the regulatory program is addressing, such as the safety of a machine, the pressure a pipe must withstand, or the amount of a particular effluent that is permissible. However, many standards

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92/ OSHA Task Force Report, supra note 19.

93/ OSHA published the Task Force recommendations as a "Request for Information", 42 Fed. Reg. 1742 (1977), and held hearings in it. No further action has been taken on the specific recommendations. However, OSHA has adopted the general approach with respect to fire safety.

that are used in the regulatory program are not directly related to determining the appropriate level of activity, but rather provide definitions or test methods.

An agency may use an externally developed standard to define a particular term that is essential to the regulation. For example, OSHA used a Chemical Abstract listing to define benzene when issuing its regulation with respect to occupational exposure to benzene.[94/] An even more common use of these types of standards is when the agency relies on an externally developed standard as a test that will be used to determine compliance with a mandatory regulation issued by the agency. For example, the Environmental Protection Agency has used externally developed standards as test methods for determining compliance with the effluent limitations issued under the Federal Water Pollution Control Act.[95/]

The tests or definitions may be wholly non-controversial and more or less descriptive, in that the level of activity is specified in the regulation and the standard does not affect that level, although it may be used to describe duty or determine whether or not it is met. On the other hand, a particular test may be intertwined with

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94/ 43 Fed. Reg. 5964 (1978).

95/ 40 CFR §136.3.

the legal obligations that are imposed in the regulation so that the test itself significantly affects the minimum level of activity that is permitted. For example, the controversey over the flammability of cellulose insulation was in large part an example of this phenomenon: A regulation could provide a general standard for the nonflammability of insulation, but the various conditions under which it is tested have a substantial bearing on the practical effect of the performance criteria of the general regulation. Or, a test may itself be controversial in that some may argue that it does not accurately measure the desired performance because it does not adequately simulate the actual circumstances that are addressed by the regulation so that it would not predict performance. For example, a test which purported to determine the risk presented by toy mouthpieces was held invalid because it was not shown to reflect the actual risk to children.[96/] And a test for air brakes that was supposed to simulate skids was set aside because it did not adequately take into account the natural differences in road surfaces.[97/]

96/ Clever Idea Company v. CPSC, 385 F. Supp. 688 (E.D. N.Y. 1974).

97/ Paccar, Inc. v. NHTSA, 573 F.2d 632 (9th Cir. 1978), cert. denied, 439 U.S. 862 (1978).

The regulatory use of test standards will be discussed more fully later, but for the immediate purposes, the question is whether the agency must follow the APA when using an externally developed test standard. Like the substantive standards, the rule of thumb is that the more effect the test has on the substantive requirements, the greater the need to adhere to the rulemaking procedures. Thus if a test has a significant effect in determining the actual substantive duties specified in the regulation, the agency will have to follow the notice and comment rulemaking procedures.[98/] Or, if a test is controversial because someone challenges whether it measures the appropriate variables, or whether it adequately simulates the actual conditions in which the regulated activity will take place, then the appropriate way to resolve that controversy is by means of the rulemaking proceeding.

Implications for Standards Writers. In sum, the greater the extent a standard is used to impose a minimum acceptable level of activity, the more likely the agency will have to adhere to the rulemaking process imposed by the APA or a variant of it. That fact has potentially strong

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98/ Wagner Electric Corp. v. Volpe, 466 F.2d 1013 (3rd Cir. 1972).

consequences for those who prepare standards. The APA will certainly influence the procedures by which an agency reviews and possibly adopts a standard for regulatory use. But also if an agency is to use a standard in its regulatory program and meet the obligations imposed by administrative law, then it will look for various characteristics in the standard that may differ from characteristics of standards that were never intended to be mandatory. To the extent the standard does not have those characteristics, the agency will either reject it altogether or will have to supply them by changing the standard. Thus, if those who prepare standards take into account the legitimate needs of agencies, there is a greater likelihood that the standards can be directly used in regulation. To be sure, there is no precise set of requirements such that if a standard meets them an agency will automatically adopt it immediately and intact. Regulatory judgments are too subjective for that. But, an awareness of the regulatory process will help in the preparation of standards that can be used more easily in regulatory settings.

What follows is a description of the process an agency will likely use to review standards when deciding whether and how to use them in its regulatory program.

The emphasis is on converting externally developed standards into mandatory regulations, and hence on how agencies meet their obligations. But, to a very real extent, agencies will follow a similar process even when reviewing standards for uses that do not require rigorous adherence to the rulemaking procedures.

CHAPTER 6

STANDARD MUST CONFORM TO STATUTORY AND POLICY REQUIREMENTS

Before an agency will use a standard in its regulatory program, it must first decide that it is both permissible and in its interest to do so. Thus, it will review the standard to be sure that it meets the minimum criteria that all of the agency's regulations must meet, those imposed by Congress and the courts. And, the agency will only want to use those standards which further its own policies, so it will review the standard to determine if it is consistant with them. This chapter describes statutory and policy requirements of regulatory agencies.

Legislative Criteria. Whether required by a vestige of Panama and Schecter or for some other reason, when establishing new regulatory programs Congress generally establishes broad, abstract criteria that agencies must take into account when issuing regulations. If a regulation issued by an agency does not meet the general requirements in the statute giving it the authority to issue regulations, then a court will invalidate it.[99/] For example, the Consumer Product Safety Act provides that consumer product safety standards issued by

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99/ 5 U.S.C. §706(2).

the Consumer Product Safety Commission must be "reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product."[100/] Recently, two different standards were overturned by courts because the Commission had not demonstrated that they met these criteria. In D.D. Bean & Sons Co. v. Consumer Product Safety Commission[101/] parts of the Commission's standard on matchbooks were invalidated because the court was not convinced they were "reasonably necessary" to cure a particular problem. And in Aqua Slide 'N' Dive Corporation v. Consumer Product Safety Commission[102/] parts of the Commission's standard on swimming pool slides were invalidated because the Commission failed to show they would prevent or reduce an unreasonable risk of injury.

Administrative Criteria. From time to time, various commentators urge a resurrection of the non-delegation doctrine[103/] largely on the grounds that many of the decisions

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100/ §7(a)(1), 16 U.S.C. 2056.

101/ 574 F.2d 643 (1st Cir. 1978).

102/ 569 F.2d 831 (5th Cir. 1978).

103/ J. Skelly Wright, Beyond Discretinary Justice, 81 Yale L.J. 575 (1972); R.A. Schotland, We Come To Praise APA and Not to Bury It, 24 Ad. L. Rev. 261 (1972). Theodore J. Lowi, The End of Liberalism (New York: W. W. Norton & Co., Inc., 1969) at pp. 297-299.

that are left to administrative agencies are in fact political decisions of the highest order, such as striking the balance between increased cost and increased safety or an increased standard of living at the expense of the environment or the other way around. The commentators urge that Congress -- the branch of the government designed to make these kinds of political judgments -- should make these trade-offs and hence develop more specific criteria to guide regulatory decisions.

But, on the other hand, the elaborate array of problems that have been addressed by even recent legislation means Congress as a body cannot develop the specific, technical information to make detailed decisions, nor can it anticipate the wide variety of possible circumstances to which a fairly detailed statute would apply. Thus, it is widely believed that agencies need broad discretion in order to fulfill their functions in meeting the general societal goals Congress establishes, which means it would not be practical to write stringent limitations in legislation.

At the same time, there has also been a feeling that the "malady" of the administrative agencies -- an inability to make decisions, the development of badly based

policy, and long delays in reaching decisions -- stems from the lack of well defined criteria which guide the individual decisions of the agencies. As a result, the agency must limp along on a case by case basis, making the same political judgments over and over again in each case.[104/] This has led to the theory that administrative agencies should develop their own internal guidelines that will control and contain future agency decisions such as issuing regulations, by deciding the general, recurring questions once as a matter of policy that will then be applied in individual decisions as they arise in the future.[105/] In that way, the public is protected from arbitrary action because the agency must adhere to its established policies[106/] and yet flexibility is preserved because the agency can change the criteria as the need arises without the necessity of time consuming legislation.

104/ See, e.g., Philip J. Harter, In Search of OSHA, Regulation (Sept./Oct. 1977) at p. 33.

105/ Amalgamated Meat Cutters v. Connally, 337 F.Supp. 737 (D.D.C. 1971); Kent v. Dulles 357 U.S. 116 (1958); K.C. Davis, A New Approach to Delegation, 36 U. Chicago L. Rev. 713 (1969); Henry J. Friendly, The Federal Administrative Agencies: The Need for Better Definition of Standards (1962).

106/ Service v. Dulles, 354 U.S. 363 (1957).

Nature of the Regulatory Criteria. Whether the agency develops its own internal criteria that will be used to implement its regulatory program or makes its decisions on a case-by-case, decision-by-decision basis, the agency must still determine what factors it will consider in issuing regulations and what weight it will give each one. As seen above, sometimes these factors are spelled out in the legislation that establishes the regulatory program. Sometimes they are derived from the history and intent of the legislation, as determined by the hearings and debates on the bill that leads to the statute as well as the nature of the problem that the legislation addresses. But, in other instances, the agency must simply establish some sort of policy as to how it is going to execute its obligations. Thus, in issuing technical regulations, the agency will have to develop views -- either explicitly by means of establishing policy, or implicitly by reaching particular decisions -- on a variety of questions. Some of the factors an agency will need to consider include:

o Technological Feasibility. Many of the newer regulatory programs call upon the agency to assess the state of technology before imposing regulations. At the lowest end

of technological sophistication, the regulatory program may only require that readily available, existing technology be used to achieve a minimally acceptable level of performance. For example, before OSHA may charge a company with failing to guard a machine to protect an employee who is exposed to a hazard, it must demonstrate that a guard is technologically feasible -- i.e., readily available.[107/] The Consumer Product Safety Commission noted that "necessary changes to lights can be made within the limits of existing manufacturing practices and technology" when discussing its proposed standard on miniature Christmas Tree lights.[108/] And, as a statutory example, the National Traffic and Motor Vehicle Safety Act of 1966 requires that "Federal motor vehicle safety standard[s] shall be practicable".[109/] A court has pointed out that the term "practicable" means that all relevant factors must be considered by the agency, "including technological ability to achieve the goal of a particular standard as well as consideration of economic factors."[110/]

107/ OSHA Task Force Report, supra note 19 at p. 23.

108/ 43 Fed. Reg. 19 126 (1978).

109/ §103(a), 15 U.S.C. §

110/ H & H Tire Co. v. Department of Transportation, 471 F.2d 350 (7th Cir. 1972).

At the other end of the spectrum lie statutes that are designed to force the development of new technology -- providing a "technological push". As one regulatory agency recently said of its statute that requires its standards to be "feasible":

> [C]onsiderations of technological feasibility are not limited to devices already developed and in use. Standards may require improvements in existing technologies or require the development of new technology.111/

The National Emission Standards Act requires the Environmental Protection Agency to issue standards to control the emissions of automobiles, and it specifically contemplates that technology may have to be developed to meet the regulations issued under the Act: It provides that:

> [a]ny regulation ... shall take effect after such period as the Administrator finds necessary to permit the development and application of the requisite technology, giving appropriate consideration to the cost of compliance within such period.112/

As the discussion makes clear, when issuing regulations in a technical area, the agency must frequently make

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111/ Preamble of OSHA's standard on Occupational Exposure to Arsenic, 43 Fed. Reg. 19,585 (1978).

112/ §202, 42 U.S.C. § 7521(a)(2).

an appraisal of the state of the technology that may potentially be used to meet the overall goals of the agency. In some cases, the agency must be satisfied with existing technology, and can only act to ensure that the appropriate technology is employed to meet its goals. But, in other situations, the agency is called upon to make a prediction of whether or not a new technology can be developed and to take action to force the development and use of a new technology that can reasonably be developed within a specified time. In these circumstances, the agency must review the current state of technology and make a prediction of what can be developed in the future.

o Simplicity and administrative feasibility. A regulation may be theoretically "perfect" in that it precisely addresses each and every aspect of a particular problem and yet as a practical matter it may be a total failure because it is so complicated and convoluted that neither the agency itself nor those who are subjected to it can understand it well enough to implement it. And, if the regulation is that detailed, it may have to be revised frequently to keep pace with changing needs and technology, increasing agency administrative cost. For example, many of the complaints about the OSHA regulations are that they are overly detailed, that neither the companies nor OSHA can fully understand them, that the detail is much greater than is necessary to accomplish

the general goals of the regulations, and that OSHA has been unable to (or willing) to keep them current so that they prescribe antiquated technology.[113/]

The materials an OSHA compliance officer must master occupy approximately four feet of shelf space, according to the OSHA Task Force Report. As an example of the difficulties this amount of detail can create, the task force describes one of its own experiences while it was drafting recommended requirements for machine guarding. After one compliance officer had raised the question as to whether OSHA regulations contained a general requirement to reset a machine after power failure, it took consultation with three additional compliance officers to determine that there was such a requirement. The requirement was buried deep in the National Electric Code, which is only incorporated by reference by OSHA and is not published by it.[114/]

Thus, when writing regulations, an agency must consider what level of detail will best fulfill its regulatory goals, and that requires taking into account how it will be enforced and whether the level of detail specified will prevent those who are affected by it from meeting legitimate concerns in other ways which are equally effective. The effects of specificity are discussed further in the discussion of design and performance standards, beginning on page 171.

113/ OSHA Task Force Report, supra note 19.

114/ OSHA Task Force Report, supra note 19, at 16.

115/ Omitted.

116/ Omitted

o Cost. The role of compliance cost in determining what will be required is a question that arises virtually every time a technical regulation is issued. For example, should a regulation not impose a readily available technology because to do so would be too expensive?

Some regulators -- such as the past two directors of OSHA -- take a bold view and say that cost is irrelevant to their operations, because they are only concerned with achieving the particular goal of their substantive statute which, they argue, does not have an economic component.[116/] But at other times, even OSHA agrees that cost is factor:

> While the precise meaning of feasibility is not clear from the Act, it is OSHA's view that the term may include the economic ramifications of requirements imposed by standards. The determination that OSHA has the authority to consider economic feasibility factors in developing standards has been endorsed by the courts.
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> * * *
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> Congress did not intend the Secretary to promulgate standards which drive entire industries or large numbers of employers out of business. On the other hand, standards may be economically feasible even though, from the standpoint of employers, they are financially burdensome and affect profit margins adversely; further, the

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116/ See, The Wall Street Journal, August 3, 1978, p. 34; former Assistant Secretary of Labor for Occupational Safety and Health Morton Corn took a similar position in a paper reviewing the status of OSHA shortly before he left office.

> Court said, the concept of economic feasibility does not necessarily guarantee the continued existence of individual employers.117/

Thus, OSHA seems to take the position that cost is to be considered only in the extreme.

Contrariwise, some regulatory programs make explicit that cost is to be an important factor, and any benefits that may be derived from a regulation must be considered against its cost. For example, a consumer product safety standard must address only "unreasonable" risks, and

> the determination of unreasonable hazard will involve the Commission in balancing the probability that risk will result against the effect on the product's utility, cost and availability to the consumer.... Of course, no standard would be expected to impose added costs or inconvenience on the consumer unless there is reasonable assurance that the frequency or severity of injuries or illnesses will be reduced.118/

These requirements were imposed in an interesting way in D.D. Bean & Sons Co. v. Consumer Product Safety Commission.119/ In the case, the court invalidated CPSC's requirement (based on standard developed by ASTM under CPSC's offeror process) that matchheads meet a specified level of performance with respect to fragmentation because the "substantial added cost of testing to insure compliance with the performance standards requirements cannot be justified"

117/ Occupational Exposure to Benzene, Occupational Safety and Health Adminsitration, 43 Fed. Reg. 5918, 5934 (1978).

118/ H.Rep. No. 1153, 92d Cong., 2d Sess. (1972) at 33.

119/ 574 F.2d 643 (1st Cir. 1978).

because of a lack of evidence that the test would reduce the risk.[120/]

Thus, in preparing a regulation, and hence in reviewing a standard, an agency must determine what weight it is going to give the potential cost of complying with its requirements. Sometimes strong weight will be accorded, so that only relatively small costs can be imposed. In other situations, cost is virtually irrelevant.

o Resolution of Doubt Concerning Risk. The general purpose of a regulatory program that issues technical rules is to establish an acceptable level of performance with respect to whatever the goal is of the regulation in question. Setting that minimally acceptable level must be based on a determination of the risk involved -- the number and severity of any potential injuries and the likelihood of their occurrence. But, both the nature of the hazard and the chance of its occurring may be uncertain. Thus, doubt will arise as to what minimum performance the regulation should require. The question then is how to resolve the doubt: towards a more stringent level of protection or towards a more lenient one. That resolution depends on the underlying theory of the statute and the regulatory policy of the agency.

120/ Ibid. at 653.

Because the Consumer Product Safety Act requires that consumer product safety standards must be "reasonably necessary", the Commission is obligated to resolve doubt as to the existence of a hazard against issuing a standard. The Commission has expressed this one way by saying, "mandatory standards generally can only address unreasonable risks of injury associated with a product but ... voluntary standards can address any level of risk of injury."[121/] That statement follows the decision in Forrester v. Consumer Product Safety Commission[122/] where the court noted that parts of the CPSC's bicycle standard coincided with an existing externally developed standard, and said "While such private standards may tend to show the reasonableness of similar Commission standards, they do not prove the need for such provisions."[123/] The court then invalidated that part of the standard because CPSC had not shown that it addressed an "unreasonable hazard."

Other statutes are more prophylactic and do not require as strong a determination of actual, current risk. In these cases, the agency may simply make a judgment as to whether a particular requirement would be "reasonable" under the circumstances, after taking into account the goals and purposes of the statute in question. These statutes address those situations where the risk presented is uncertain.

121/ CPSC Policy Statement supra note 73 at p. 19,222.

122/ 559 F.2d 774 (D.C. Cir. 1977).

123/ Ibid. at 793; emphasis in original.

Sometimes, indeed many times when the issue involves the relationship of chemicals to human health, the full extent of the risk cannot be accurately determined because the issue is, to use a phrase that commonly appears in judicial decisions, "on the frontiers of scientific knowledge."[124/] In that case, agencies must "[n]ecessarily ... deal with predictions and uncertainty, with developing evidence, with conflicting evidence and, sometimes, with little or no evidence at all."[125/] For example, the company that appealed EPA's regulation concerning lead in gasoline contended that the agency must show "proof of actual harm" before it could take action under a statute that only permits regulation of gasoline additives that "will endanger the public health and welfare." The court noted that some statutory terms require a rigorous showing of risk of harm, such as "substantial likelihood" of the hazard occurring or that "potentially great dangers" are involved. But, it concluded the term "will endanger" is precautionary and does not require proof of actual harm before regulation is appropriate:

> Danger ... is set not by a fixed probability of harm but rather is composed of reciprocal elements of risk and harm, or probability and severity. *** That is to say, the public health may properly be found endangered both by a

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124/ Industrial Union Department, AFL-C10 v. Hodgson, 499 F.2d 467, 474 (D.C. Cir. 1974).

125/ Ethyl Corp. v. EPA, 541 F.2d 1, 6 (D.C. Cir.) (En Banc) cert. denied 426 U.S. 941 (1976).

> lesser risk of greater harm and by a greater risk of a lesser harm. Danger depends upon the relation between risk and harm presented by each case, and cannot be pegged to "probable" harm, regardless of whether that harm be great or small.126/

And, when the assessment of the risks are on the frontiers of human knowledge,

> Decision making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual analysis.127/

However, as discussed below, that policy judgment must still be rationally justified by an examination of whatever technical evidence is appropriate.

To summarize, before issuing a technical regulation designed to protect the public against the risk of injury from a hazard, the agency must determine the level of the risk involved. The level of risk sufficient to justify agency action varies according to the statute in question and the regulatory policy of the agency. Once the threshold showing of risk is made, the agency must then decide what is an acceptable level of risk -- how safe is safe, bearing in

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126/ Ethyl Corp. v. Environmental Protection Agency, 541 F.2d 1, 18 (D.C. Cir.) (En Banc), cert. denied 426 U.S. 941 (1976).

127/ Industrial Union Department, AFL-C10 v. Hodgson, 499 F.2d 467, 474 (D.C. Cir. 1974).

mind that zero risk, or absolute safety, can never exist and that many factors must be balanced together in reaching the determination. Only then can the agency decide what regulatory action to take in an effort to achieve the desired level or risk.

The Implications. These legislative and administrative regulatory criteria form the general principles by which an agency will judge a regulation and, consequently, any standard that it may consider using in its regulatory program. For example, if either the statute or the agency's policy requires that the cost of compliance be given very little weight in determining what is an appropriate regulation, the agency would not look favorably on a standard that resulted from a process that placed significant importance on cost. Contrariwise, in another regulatory program, the costs of compliance may be very important, and the agency would want to know whether those who developed the standard carefully assessed the costs involved when writing it. Following the specific examples above, OSHA is less likely to pay significant attention to the costs of complying with a standard than is the Consumer Product Safety Commission. Similarly, an agency will review a standard to see if it applies the proper degree of technological

assessment, or whether it meets the agency's need for administrative feasibility.

Thus, if a standard is being prepared for use in a regulatory program, those who develop it should explicitly address the governing criteria the agency will use to review it. Unless these criteria are kept in mind, the standard may not give the various factors their proper weight -- which is only to say the weight the agency is likely to ascribe to them -- or they may not be addressed at all. At minimum, this means becoming familiar with the statutory requirements that are imposed on the agency by Congress. Those who write the standard should be aware of them, because if the standard does not meet them, the agency cannot use the product of their work. In addition, it would be helpful to know how the courts have interpreted the statutory terms and what administrative criteria the agency has developed as its regulatory policy.

It would be nice if these criteria could be determined simply by looking them up in a book, but that will only rarely be the case. Instead, other regulations and their accompanying explanations will have to be reviewed to determine what factors the agency regards as important and how they apply those factors. For example, a review

of OSHA's health standards indicates how OSHA determines the relationship between engineering controls and personal protective equipment and how in practice they assess the role of cost; judicial interpretations will shed some light on what the vague term "feasible" means with respect to OSHA health standards. It may also be appropriate to ask the agency for guidance as to what it is looking for in a standard and how it should work.

Another important aspect of assessing the regulatory criteria before beginning to develop the standard is that the committee will then be able to explain why they believe the standard meets the appropriate criteria. As will be described more fully later, such an explanation will aid the agency in reviewing the standard.

Conclusion. The criteria discussed here are broad, general, and abstract principles that guide an agency's regulatory policy. Applying them requires subjective judgment, and the exercise of a considerable amount of discretion. Thus even if a standard-writing committee rigorously adheres to what it understands to be the agency's criteria, the agency may still disagree with the standard because it believes the discretion should be exercised differently. And, of course, it may be very difficult or

even impossible to predict precisely what criteria the agency will use in reviewing the standard because the agency itself has yet to develop them and will only do so on an ad hoc basis. Nonetheless, it will increase the likelihood that a standard will be adopted expeditiously and intact if those who prepare the standard are aware of the criteria the agency will use in reviewing it and taken them into account when they develop the standard.

CHAPTER 7

PURPOSE AND SCOPE OF THE STANDARD

If a standard is prepared specifically for a particular regulatory use, it may be relatively straight forward for an agency to determine if its criteria are met. But, in other cases, an agency must review an existing standard prepared for other uses to determine if it would be appropriate for its regulatory program. This review will be facilitated if standards writers make clear in the standard, or in a companion document, the expected use, purpose and scope of the standard and the issues that were raised during its development.

Expected Use. One of the problems with the OSHA safety standards is that when they were developed they were never intended to be followed completely by all firms, let alone to be regulatory requirements.[128/] Instead, some were only recommended practices. Often they did not have the concurrence of senior management of the firms, but rather were the work of people with narrower interests in the company. As a result, some may have reflected an ideal

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128/ R.E. Stevens, "A Place for Voluntary Standards," Fire Standards and Safety (Philadelphia: America Society for Testing and Materials & The National Bureau of Standards 1976) 222, 226.

rather than something to be practically achieved. Some were manufacturing and procurement specifications so they were overly specific as to how to build something. Some included requirements irrelevant to safety. And, some did not provide the requisite level of safety that would be expected of regulation that determines minimum obligations. When the standards were only "voluntary" firms could ignore those with which they disagreed or those that had become obsolete. But when they became mandatory as OSHA regulations, they resulted in many complaints that they are inappropriate for regulatory use, generally, because they are too detailed and complex.[129/]

Thus, in reviewing a standard for possible regulatory use, an agency will want to know whether the standard was originally intended to be used as a mandatory regulation. If the standard was not, the agency will then have to be more careful in determining whether the standard meets the regulatory criteria, since it is more likely that a standard that was intended to be mandatory in the first instance would employ similar criteria than would a standard that was not expected to establish minimum requirements.

129/ OSHA Task Force Report, supra note 19; Harter supra note 104.

It is not uncommon for externally developed standards to have essentially three parts: one that is intended to be followed by all firms; a second in the form of recommended practices; and a third that suggests ways of meeting the first two. Sometimes the three parts are specifically distinguished in the standard itself, but in other instances the three parts are jumbled together so that it is difficult to determine precisely what those who wrote the standard regarded as the core of the requirement. In that case, the agency will have to determine what part of the standard is appropriate for regulatory use. That choice is not always clear,[130/] and it would be very helpful to agencies if those who write standards clearly indicate the three different parts.

Purpose. In determining whether its regulatory criteria are met, the agency needs to determine the specific goal of the standard: Even though the standard may appear to address the technical issue the agency is concerned with, in fact it may be aimed at achieving a different goal. In that case, those who wrote the standard would not have focused directly on the problem of concern to the agency, so

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130/ See, Analysis of existing standards by the OSHA Task Force, 42 Fed. Reg. 1806 (1977).

that they may not have given the various factors that entered into developing a standard the weight the agency thinks is appropriate. In effect, the standard would be "optimizing" a different substantive issue than the one of interest to the agency, so that the agency's concern was subjugated to another one of lesser importance to it.

For example, consider a standard concerning the chemical composition of gasoline. The purpose of the standard may have been to make engines run better so that the engines last longer and need fewer repairs; it may have been concerned with reducing auto emissions; it may have been to reduce the toxicity of the fumes; or, it may have been to increase the mileage of automobiles. The first example could be regarded as a consumer-oriented standard; the second might be considered an environmental standard; the concern of the third might be to protect workers in filling stations; and the goal of the fourth might be to conserve energy. If the goal of the standard was to improve mileage, those who prepared it may not have given appropriate concern for either the environment or the safety and health of workers so that it would be inappropriate to use the standard as either an environmental or occupational safety or health regulation. The example

points out an agency's need to know the specific purpose of the standard because it will generally give a clearer indication of the concern of those who wrote the standard and whether they followed criteria similar to those of the agency.[131/]

Scope. Once an agency determines the purpose of a standard, the next question is what is the scope of the standard. In order to get a clear picture of precisely what was intended by the standard, and how it might be used in a regulatory setting, the agency will want to know what assumptions underlay the development of the standard as to what exact circumstances -- both inclusive and exclusive -- it was intended to apply. Following the earlier example, if the gasoline standard was designed to protect workers from the adverse effects of the fumes, the underlying assumption may have been that it was designed to protect only those who

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131/ The example also points out the potential difficulty that might result if four separate agencies sought to regulate the same product, with each attempting to control its composition so as to enhance the particular goal of the agency. In that case, those who wrote the standard should be aware of all the competing requirements and know that they are potentially making trade offs. It is then an overall political decision as to the relative priorities of the competing programatic concerns, and which criteria should take precedence. Ideally, the decisions as to which competing factors should be favored should be made by Congress.

are exposed to very high concentrations of the vapors. In that case, it may be more appropriate to use a different standard in the routine filling station setting, and to take special action to meet the special case. Or, of course, the reverse could be the case, in which the standard was designed only for low-level exposure, so that more would be needed for the special setting.

As an actual example, some controversy developed over whether the OSHA standard with respect to woodworking saws should also apply to saws that cut plastic or plywood. The question is whether there are peculiar characteristics of either or both of those materials that would make the standard inappropriate, or whether they are sufficiently similar to wood that the theory of the standard would apply to them.[132/] Without knowing the underlying assumptions and the specific factors that were taken into account, the agency must either make an independent determination or guess as to whether the standard would apply to the situation it confronts.

Perhaps the most famous OSHA "horror story" stems from the lack of a suitable scope section. Most who have

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132/ Philip J. Harter, A View from the OSHA Task Force: Voluntary Standards Usde in Regulation, ASTM Standardization News (May, 1977) at p. 8.

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even the most cursory familiarity with OSHA's difficulties have heard that in its first batch of standards OSHA solemnly prohibited workers from using ice in drinking water. On its face, the standard as issued is absurd and suitable for ridicule. But, it is not if that ice had been made from contaminated water, and that was precisely the concern of the original standard -- its focus was ice cut from ponds that might be polluted. If only the scope section had been included, a laughable standard would have been reasonable.

Representatives of the National Institute of Occupational Safety and Health complained that an externally developed standard concerning protective eyeglasses specified requirements that are irrelevant to new technology lenses, but the standard does not indicate that it is so limited. A scope section would clarify the circumstances to which the standard applies and would thereby not inhibit the development of new technology glasses.[133/]

The question of scope also arises in enforcement contexts, where it is important to know whether a particular situation is covered -- both by the letter and

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133/ Testimony of Dr. John F. Finklea in Hearings before the Subcommittee and Antitrust and Monopoly of the S. Com. on the Judiciary , S.825, 95th Cong., 1st Sess. (1977) at p. 355.

the spirit -- of the regulation. For example, a regulation or standard may be broadly written, but in fact the concerns of those who wrote it were narrower so that it should have only qualified application to a particular circumstance that is covered by its language. The ice cube standard is such an example.

Thus, it will be helpful to an agency's review process if a standard has a scope section that clearly defines the circumstances to which it is intended to apply. That also means that if the standard should not apply to a particular situation, the scope section should indicate that fact. Such a section will not only make the work of the agency easier in reviewing the standard, it will also mean that any regulation which results from it will be better because those who use it will know more accurately when it applies.[134/]

Issues Raised. In reviewing a standard, one of the things an agency is likely to want to know is what issues or hazards were considered by the committee in developing the standard. The question is closely related to the purpose and scope discussion clause, but there are two

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134/ See, Final Report of the National Commission on Product Safety, 1970, at p. 126.

distinctions: (1) The purpose and scope of the standard are more abstract, in that they define the general problems and assumptions addressed by the standard; by contrast, the "issues raised" concern what individual factors the committee considered within the overall setting encompassed by the purpose and scope. (2) As a practical matter while a standard can fairly readily include purpose and scope sections, it will only rarely contain a section defining the exact issues that were considered in developing the standard; indeed, including such a section in the body of the standard itself would make the standard confusing and difficult to use.

An agency will want to know what issues were considered in the development of a standard so that it can be confident that all those that are relevant to the subject matter were addressed and resolved according to the agency's regulatory criteria. For example, the Consumer Product Safety Commission modified the standard proposed by its offeror with respect to miniature Christmas Tree lights because the Commission felt the original standard did not take into consideration some potential misuses that Christmas tree lights might be subjected to. 135/

135/ 43 Fed. Reg. 19136, 19142 (1978).

Additionally, and of equal concern, the agency will want to know whether any irrelevant, or even impermissible, considerations entered into the determination of the standard. As an extreme example, it would be highly inappropriate if one of the factors entering into a standard was an attempt by a company to gain a dominant market position. While the intention of market domination would not likely appear on any list of issues considered, the standard should be designed so that the agency can feel more comfortable that the relevant issues and hazards were addressed and that an irrelevant factor did not enter into the determination. Thus if the relevancy to the purpose of a particular section of a standard is not clear in its face, an explanation may be helpful.

For example, the Voluntary Product Standard concerning Carbonated Soft Drink Bottles[136/] published by the National Bureau of Standards specifies the height and diameter tolerances for soft drink bottles. It is not immediately clear that these are directly related to the safety of the bottles. It would be helpful if the section were accompanied by an explanation as to why the requirements

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136/ PS 73-77.

are directly related to safety, as opposed to, say, facilitating efficient filling. If the requirement pertains to the latter, then it would be inappropriate for an agency concerned with safety to impose the requirement.

In reviewing a standard, an agency will have to determine whether the standard addresses the hazards and other issues of concern to the agency, and then make the judgment as to whether it resolves them according to the relevant criteria. This can be a time consuming, expensive operation for the agency if it does a conscientious job, so that anything that is done to facilitate the review will make the standard more attractive to the agency.

Implications for Standards Writers. To provide the information discussed in this chapter, standards writers should (1) clearly indicate which portions of the standards were intended to be followed by all firms, which sections are recommended practices, and which merely suggest ways of complying with the first two types of provisions; (2) include sections describing expected use, purpose, and scope; and (3) describe issues raised during the standard's development and why requirements were set as they were. The latter information may be included in a commentary document, described in the next chapter, rather than being published in the standard itself.

CHAPTER 8

RESOLUTION OF TECHNICAL ISSUES

Because the technical judgment is the heart of a regulation, for an agency to use an externally developed standard it must know whether the judgment that is reflected by the standard was based on sufficient information. Indeed, as the discussion above concerning legislative criteria indicates, the courts will carefully review agency action to be sure it is supported by adequate evidence. Thus the courts have a considerable influence on how agencies review standards. This chapter examines (1) how a court will review the issuance of a regulation by an agency and (2) the agency's need to know what technical information underlies a standard it is reviewing for possible regulatory use.

Judicial Review. The Administrative Procedure Act provides that a court will "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law...."[137/] Formerly, that provision was interpreted to mean that an agency's rule would be upheld by the courts if there were any plausible factual situation

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137/ 5 U.S.C. §706(2)(A).

that would make the rule reasonable under the circumstances. That is, all a regulation needed to survive judicial review was a "rational basis".[138/] But starting a decade ago, which also coincides with the advent of the new technical regulation, the courts began requiring more. They shifted from a perfunctory review which gave a strong presumption of validity to any regulation issued by an agency[139/] to a method of review which requires an agency to explain in rather full detail what it is doing and why when it makes decisions based on technical questions.[140/] The courts also began a "searching and careful" inquiry as to whether the agency's decision was "based on a consideration of the relevant factors and whether there has been a clear error of judgment."[141/]

Under the new standard of review,[142/] a court will conduct a detailed review of a regulation to determine

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138/ See, e.g., Associated Industries of New York v. Dept. of Labor, 487 F.2d 342 (2d Cir. 1973).

139/ Mashaw and Merill, supra note 51, at p. 263.

140/ Automotive Parts & Accessories Assn'n v. Boyd, 407 F.2d 330 (D.C. Cir. 1968).

141/ Citizens to Preserve Overton Park v. Volpe, 401, U.S. 402, 416 (1971).

142/ Some of the newer regulatory statutes provide that the agency's regulations must be supported by "substantial evidence" --- the usual standard for reviewing evidence in a

[Footnote cont'd. on p. 102]

if the agency acted within the scope of its authority in issuing it, and this in turn may be based on whether there is sufficient technical evidence to support the agency's judgment, given the criteria it must meet. For example, part of the Consumer Product Safety Commission's standard on matchbooks was reversed by a court because of a lack of empirical evidence that there was in fact a problem.[143/] Similarly, the court made an extensive review of the technical information developed by the Environmental Protection Agency with respect to whether the lead in gasoline may have an adverse effect on people's health.[144/]

[Footnote 142 cont'd from pg. 101]

trial type hearing instead of the normal rulemaking proceedings of notice and comment. This change from the usual provision caused some difficulty at first, Associated Industries of New York v. Dept. of Labor, 487 F.2d 342 (2d Cir. 1973) but with the increased stringency of review under normal rulemaking provisions, there is now little, if any, difference between the two. Mashaw and Merril, supra note 51, at p. 274. However, recently a court said that because the agency's regulations must be supported by substantial evidence the court would require more specific evidence to support a rule. Aqua Slide 'N' Dive Corporation v. CPSC, 569 F.2d 831, 837 (5th Cir. 1978).

143/ D. D. Bean & Sons v. CPSC, 574 F.2d 643 (5th Cir. 1978).

144/ Ethyl Corp. v. EPA, 541 F.2ds 1 (D.C. Cir. 1976) (En Banc) cert. denied, 426 U.S. 941 (1976); see, also, Reserve Mining Co. v. EPA, 514 F.2d 492 (8th Cir. 1975) En Banc).

The court will also require the agency to explain both the factual data that supports its regulation, and the methodology it used in reasoning from that data to the proposed standard.[145/] And, if the data does not support the regulation, then a court will find that the action is "arbitrary and capricious," and it will invalidate the regulation. For example, the CPSC's standard with respect to swimming pool slides was in part set aside because of a failure to provide evidence that it would be effective.[146/]

No set, fixed test determines how much evidence a court will require to support a particular regulation. But a few rules of thumb do emerge.

Sometimes the problem and its solution are intuitively obvious, so that no supporting evidence is required, rather only a cogent explanation. For example, the court thought it is intuitively clear that matchbooks with the friction strip attached to the back are safer than those with it on the front, so that no empirical data was required to support the proposition.[147/]

145/ Portland Cement Association v. Ruckelshaus, 486 F.2d 375 (D.C. Cir. 1973) cert. denied 417 U.S. 921 (1974).

146/ Aqua Slide 'N' Dive Corporation v. CPSC, 569 F.2d 831 (5th Cir. 1978).

147/ D.D. Bean & Sons v. CPSC, 574 F.2d 643, 649 (5th Cir. 1978).

An issue that is not intuitively clear but that can be determined with a fair degree of accuracy by empirical research will require sufficient information to resolve the technical question and support the judgment contained in the regulation. Thus, the same court that supported the requirement that striking surfaces be mounted on the back of matchbooks invalidated another portion of the rule because of the lack of empirical research.[148/]

But many issues faced by regulatory agencies are not readily determinable but rather are on the frontiers of human knowledge so that no definitive answer can be developed. In such a case, a sliding scale is used in reviewing the evidence that supports an agency's regulations: If the issue

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148/ Ibid. at p. 650-651. In finding that the Commission did not have adequate evidence to support various requirements of the standard, the court said:

> While 'common sense' may so indicate, that is not evidence that the reappearance of a visable flame is a condition that exists with respect to any appreciable number of matches thus requiring correction. Nor is the occurrence of afterglow, delayed ignition or split splints adequately established. The statutory term "unreasonable risk" presupposes that a real, and not a speculative, risk be found to exist and that the Commission hear the burden of demonstrating the existence of such a risk before proceeding to regulate.

addressed is one which involves a great risk to the public, then the agency will not have to "prove" that the feared danger will materialize, but only that there is a reasonable possibility that it will, based on the scientific and technical evidence of that risk. The greater the risk and uncertainty, the less conclusive evidence is required. As one court pointed out, decisions of that nature "depend to a greater extent upon policy judgments and less upon purely factual analysis."[149/] Similarly, the greater the cost of complying with the regulation, the more evidence that is required to show it is necessary.[150/]

The Review of Standards. Because an agency may have to explain itself to a court, it will likely want to review any standard it relies on for the basis of a regulation to be sure that it meets the statutory criteria that the agency itself must meet. Indeed, the agency would undoubtedly want to make a similar review at any rate to be sure that its regulatory criteria are met. Thus, the agency

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149/ Ethyl Corp. v. EPA, 541 F.2d 1 (D.C. Cir. 1974) (En Banc) cert. denied, 424 U.S. 941 (1976) at p. 18.

150/ International Harvester v. Ruckelshaus, 478 F.2d 615 (D.C. Cir. 1973). See the excellent discussion of such a sliding scale test in, Note, Judicial Review of Facts In Informal Rulemaking: A Proposed Standard, 84 Yale L. J. 1750 (1975).

will want to know what information was brought to bear in developing the standard.

There are two possible implications for standards developers. One, they may need to compile more evidence or carry out more research to support a standard in a regulatory area than they would for some other type of standard; and two, they need to document -- in the standard itself or in a companion document -- the information supporting the standard.[151/]

If the technical question presented can be determined empirically, the agency will want to know whether the judgment that was made in arriving at the standard is supported by research or whether it was based simply on common knowledge, intuition, or an educated guess. In some absolutely clear situations, rough judgments without detailed data may suffice. Increasingly, however, more sophisticated evidence, such as laboratory testing and empirical field work, would be required to determine the extent of risk. Thus, if the standard deals with a hazard that can be fairly well quantified, research will be needed to show the nature of the risk and the effect of the standard in meeting that risk.

151/ This companion document will be discussed later, in Chapter 10, p. 141.

On the other hand, if the question addressed by the standard involves technical uncertainty as to whether hazard even exists -- such as the question raised in Ethyl Lead where no one really knows the risk posed by gasoline additives -- then the nature of the information required may be somewhat different. In that case, the agency may want to know whether those who prepared the standard compiled what evidence there was and then made an informed and reasonable policy choice based on that evidence.

In either event, the agency will want to know if the standard is supported by as much technical evidence as is necessary to make an informed judgment -- either in the form of pulling together existing research or by conducting new laboratory work to resolve questions that arose in the course of the development of the standard.[152/] Several who are active in standards development have commented on the growth of research that is used to resolve questions with respect to the preparation of standards,[153/]

152/ See, Proposed Procedures for the Development of Standards for Medical Devices, §861.24(a)(3), 43 Fed. Reg. 32264, 32768 (1978).

153/ See Stevens, supra note 128.

and that may well be in part due to the increased needs of the agencies that use the standards in their regulatory programs.

The technical evidence will almost never be so specific and precise that there is no room for judgment. Were it otherwise, standards could be developed in laboratories since the research conducted there would lead to the one and only acceptable standard.[154/] But clearly that is not the case: Many factors go into making up a regulatory standard, only some of which are technical questions. Those factors, as well as any technical uncertainty, must then be resolved into a standard, and that requires subjective judgment which in turn is a policy choice. This leads to another part of the agency review process. In large part, this review is nothing more than the agency's satisfying itself that its regulatory criteria are met. To satisfy judicial review, the agency will need to explain the methodology that is used in progressing from the technical information and other considerations to the standard itself. Thus, the agency will want to know, whether, after

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154/ Robert G. Dixon, Jr., Standard Developed in the Private Sector: Thoughts on Interest Representation and Procedural Fairness, (Boston: National Fire Protection Association 1978) at p. 23.

the technical research has been conducted so that the nature of the risk and the effects of the standard in meeting the risk is predictable, the standard is reasonable within the contours of the duties of the agency. In deciding that question the agency will apply its regulatory criteria to determine if the appropriate trade-offs were made. For example, those who wrote the standards for CPSC concerning both matchbooks and swimming pool slides included provisions they thought would meet a perceived risk, but parts of both standards were reversed by the courts because the wrong criteria were applied.

If the standard was written several years before the agency is considering using it for regulatory purposes, the agency is likely to want to know whether the technical information on which the standard was built is still current, or whether there is more recent information which would indicate that the standard should be reconsidered. In such a case, the best way to determine if the standard successfully meets the problem for which it was designed is to look to the experience with it: Has it reduced the hazard in those instances where it was adopted? If it has not been followed, then the agency will want to know

why, because that may reflect difficulties with the standard such as the determination by others that it will not fulfill its purpose, that it is hard to use, that it imposes excessive cost, or even that some other standard is better in some way. Or, of course, it may only be that firms lack the incentive to follow it short of having it imposed as regulation, and that it is perfectly suited for that use.

Caveat. The nature of the judicial review of administrative regulations is now fairly clear, although it has been in flux for nearly a decade. It is also fairly clear that an agency will likely use a similar, if less rigorous, process in reviewing the information that supports a standard it is considering using in its regulatory program. What is unclear is whether a court will require an agency to meet the same requirements that are normally imposed on it when issuing a regulation when the basis of the regulation is an externally developed standard. The recent cases involving the CPSC seem to indicate that the courts will require agencies to fulfill their normal obligations even if a regulation is based on an externally developed standard.

CHAPTER 9

BALANCE AND DUE PROCESS

This chapter discusses ways in which development of a standard through a consensus process may help a regulatory agency review a standard for possible regulatory use. In some cases, modifications in the standards-writing process may be needed for agencies to feel confident about using such standards. The need for such changes is discussed later in this chapter.

Importance of the Standards Development Process. It may be difficult for an agency to determine whether a standard meets its need simply by reviewing the standard. Even if an agency has well defined regulatory criteria, applying them does not lead to a fixed result because they are general principles that only guide how the competing factors such as safety and cost considerations are resolved. Moreover, the criteria are difficult to define precisely. And, finally, it is always hard to know how much research is enough to determine the technical issues. Thus, it must be hard for the agency to determine if its needs are met simply by reviewing a standard.

One way to address this difficulty is to provide a commentary document, discussed in the next chapter. Another is to follow standards-writing procedures that are likely to result in standards which are adequate from the agency's viewpoint. These procedures, when followed, will facilitate the agency's review. And, if the process of review by an agency is expeditious and inexpensive so that it can use standards easily

and with confidence, the agency is more likely to use standards in its regulatory program than if it must conduct time-consuming and expensive reviews that result in substantial changes in standards in order to meet the criteria.

Now we turn to the question: What kinds of standards development procedures are likely to result in a standard which is adequate for use in a regulatory program?

The Concerns. The discussion in the preceeding chapter concerns the regulatory use of all externally developed standards, regardless of who prepared the standard or the procedures followed in developing it. The principles established are equally applicable to standards that are written by a single company, a trade association, or a narrowly based "public interest" group that advocates a particular policy, as it is to standards that are prepared by committees that reflect a wide variety of interests under procedures ensuring the fair consideration of the views of all interests. That is because if a standard meets the needs of an agency, it is perfectly proper for the agency to use the standard in its regulatory program regardless of by whom or how it was

written.[155/] However, there are substantial concerns with using such standards in regulatory settings.

155/ The Federal Energy Administration Authorization Act of 1977 amended the Federal Energy Administration Act of 1977 to provide that if a rule proposed by FEA, now part of the Department of Energy, contains any "commercial standard", then the notice of proposed rulemaking must identify the name of the organization that developed the standard and whether or not the standard was developed in accordance with the procedures that are specified in the Act (which resemble the consenus procedures discussed below). 91 Stat. 278. However, the legislative history of the provision makes clear that "the FEA Administrator has the latitude to utilize a standard that does not comply with these regulations where he determines that such standard is the best available." H. Rept. No 95-323, reprinted in U.S. Code, Cong. & Admin. News (1977) at p. 480, 497.

One commentor urged the CPSC not to consider standards that were not developed under a consensus process in deciding whether an adequate voluntary standard exists so that the Commission need not develop a mandatory standard. The Commission responded that whereas it will take the procedural history of the standard into account, it "does not believe, however, ... that these [procedures] should necessarily be controlling factors in determining the acceptability of existing voluntary standards. If this were not the case, a voluntary standard that in fact eliminates or reduces an identified risk of injury but that was developed without widespread public participation, could not be considered to be adequate by the Commission. In view of the foregoing, the requested change is not deemed appropriate." 43 Fed. Reg. 19,220 (1978).

Nor under proposed rules would the use of an existing standard for medical devices depend on whether it is a consensus standard, as described below, although the procedures by which the standard was developed would be taken into account. 43 Fed. Reg. 32,268 (1978).

[Footnote cont'd. on p. 114)

The apprehension centers on the notion that businesses with vested interest dominate the standards-writing process, and the discretion that is inherent in writing a standard will be exercised to serve the parochial interests of those businesses. Thus, allegations are made that standards are set at a level that is acceptable to the industry and that they meet only the "least common denominator".[156/] Other complaints are that

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[Footnote 155 cont'd from p. 113]

The proposed OMB Circular advocates the use of "consensus" standards, but under its definition consensus means only that the decision of the group that wrote the standard was based on the views of more than a majority; in particular, it does not mean "due process," as described below, and the group writing the standard may be a narrowly based trade organization. "Questions and Answers to Clarify the Intent of the Provisions of the OMB Circular on Federal Interaction with Voluntary Consumer Standards-Developing Bodies," (2/24/78) Response of OMB to Question 1 of ANSI.

> There are no restrictions, whatsoever, on agency use of voluntary consensus standards (or, for that matter, on the use of any private or public sector standard including company standards and foreign standards) except that the agency must, of course, satisfy itself that the standard is adequate and appropriate for the agency's purpose. (Response to Question 3.)

156/ The legislative history of OSHA indicates that the Senate Committee found many existing standards "represent merely the lowest common denominator of acceptance by interested private groups." S. Rep. No. 91-1282, supra note 2. And, material quoted at note 3.

legitimate views of people who are concerned with a standard are suppressed so that the standard does not reflect their interests.[157/] Some argue that participating in the development of a standard is expensive so that the main incentive to participate in the process is to protect an economic interest, with the result being that those who do not have a direct and substantial economic interest in a particular standard will not participate and their views are not heard at all.[158/] Some argue that the standards are unresponsive to changing technology when the changes would threaten the position of a dominant member of the organization that wrote the standards or even the entire organization itself.[159/] The recent flurry of activity on the Federal level concerning standards is responsive to these allegations and the various "horror stories" that are used as examples.

157/ See Dissenting views of Monte Florman and George Papritz of Consumers Union to "A Recommended National Standards Policy for the United States". 43 Fed. Reg. 6,302 (1978).

158/ U.S. Dept. of Commerce, Voluntary Standards and Testing Laboratory Accreditation (1977) at p. 1.

159/ Ibid, Appendix B.

Even if these indictments are unfair in the great majority of cases,[160/] it may look like a "sell out" to base a regulation on a standard that was developed in large part by the very industry to be regulated by it.[161/] The concern of the agency simply is that the standard will not meet its regulatory criteria because those who wrote it would be overly concerned with protecting their own welfare so that the competing issues were either not raised at all or were not resolved according to the guiding principles.

Meeting the Concerns. One response to these concerns has been the suggestion that standards should be written by a group in which a "balance" of interests is

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160/ Dixon's analysis of the 28 frequently mentioned horror stories "turned up only one highly questionable standard, and one highly questionable practice." Supra note 154, at p. 9. Another observer pointed out that most of the complaints involve building standards. Letter from Carol Chapman, National Bureau of Standards, to Robert Hamilton, cited in Hamilton, supra note 13, at p. II-54. And another disinterested, indeed somewhat skeptical, observer found that the actions taken in several meetings he attended where standards were developed were frequently not directly consistent with the economic interests of the companies represented. Hamilton, supra note 13, at p. II-17. Finally, many of the criticisms of standards are the result of attempts to measure a standard against a use it was never intended to fulfill. For example, if a standard was never intended to be mandatory, it may be unfair to say it is not stringent enough for regulatory use. If it were more stringent, some manufacturers might not adhere to it so that their product would be cheaper and hence divert sales from those who do meet the standard.

161/ See comments of EPA in text at note 68.

represented under procedures which ensure that the views of each interest are fairly considered.[162/] The argument is that the standards which result from this process will be more attractive for regulatory purposes, as well as ensuring that they do not have a deleterious effect on the economy when they are used as the basis of industry self regulation. The theory is that they will be more attractive for regulatory use because an agency can be more confident that its regulatory criteria are met, and in addition, their use may be more acceptable to the important constituents of the agency than a more narrowly based standard.

For want of a better term, these standards are commonly referred to as "consensus" standards.[163/]

Nature of the Emerging Requirements. There is virtual agreement on the general principles of what

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162/ As Dixon says, "Like hex signs on Amish barns, changed procedures in private standards-making are advocated by some critics in the hope of warding off various assumed dangers which have gained some currency by frequency of mention." Supra note 154, at p. 8-9.

163/ The difficulty with the term "consensus" is that it begs the issue of the breadth of the consensus: among whom was the consensus reached. A standard written by a trade association also reflects a "consensus" -- the members of the association. As used here, the term will mean a standard that is written under the procedures described in the next subsection. See note 166 below for a further explanation of the term.

constitutes the "consensus" process, although the details of how those principles are implemented vary widely.[164/] Commonly, this set of principles is collectively referred to as "due process".[165/] They are:

-- Reasonable notice that a standard is being considered is provided to those who may be interested in its subject matter.

-- Representatives of those interested in a standard are able to participate effectively in its development through membership on the committee that is responsible for preparing a draft standard, and no one interest dominates the membership of the committee (this is

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164/ CPSC Policy Statement, supra note 73; Federal Energy Administration Authorization Act of 1977, 91 Stat. 278 amending the Federal Energy Administration Act of 1974; Draft OMB Circular, 43 Fed. Reg. 48 (1978); A Recommended National Standards Policy for the United States, 43 Fed. Reg. 6298 (1978). Procedures for Development of Voluntary Product Standards, 15 CFR §10. And see, procedural rules of the American National Standards Institute, American Society for Testing and Materials, and the National Fire Protection Association. Hamilton, supra note 13, at pp. II-11, II-12.

165/ ASTM, The Voluntary Standards System of the United States of America (Philadelphia: ASTM, 1975) at p. 7.

known as a requirement that the committee be balanced).[166/]

-- A method is provided for receiving and fairly considering the views of those who are interested in and affected by the standard during its development process.[167/]

-- The standard reflects substantial agreement of all interests concerned following a concerted effort to resolve objections; this consensus implies more than a simple majority of those voting, but less than unanimity.

166/ This a is limited or narrow view of consensus, in that it requires the various representatives to be able to participate in the development of a standard through membership on the committee that is responsible for the writing of the standard. Some definitions of the consensus process only require that a standard which has been drafted by a more narrowly based committee be circulated for comment among a broader group that includes representatives of the various interests, and that their comments are then fairly considered by the committee that drafted the standard. This is known as the "canvass" method of securing consensus. The narrow definition is used here because it ensures that concerns of diverse interests are directly considered in the development of a proposal whereas the canvass method only provides the opportunity for comments, which may or may not be made.

167/ This means that an objection or negative vote accompanied by an explanation must be considered by the committee responsible for the standard. The committee can then agree with the negative vote, decide it is unpersuasive, decide that it is not relevant to the subject matter, or decide that it raises a sufficient issue that the draft standard needs further study.

-- Written records of the discussion and decisions that were made concerning the standard are kept and are available for public inspection.

-- A right of appeal to higher authority is afforded those who feel aggrieved by action taken during the standards development process, such as an allegation that a committee is not adequately balanced or that a valid substantive objection was not adequately considered.

The Benefits Derived. The balance and notice requirements are designed to ensure that the concerns of those who will be affected by a standard are taken into account when developing it. They contemplate that a variety of interests will be represented during the development of a standard, such as producers, users, consumers, small businesses, environmentalists, labor, and government officials. The particular composition of the committee will depend on the subject matter of the standard in question because that will necessarily affect which interests are concerned. The requirement for structured decision making -- the process by which comments are resolved -- then ensures that the legitimate views of the affected interests are fairly considered. The requirements for an appeal and open records help ensure that the preceding principles are followed.

Under the consensus process, at least theoretically, no group or single interest can dominate the process so that the standard reflects its own parochial views. Thus, immediately, some of the concerns regulatory agencies may have with externally developed standards are met. But the consensus process may have further, positive benefits for the regulatory use of standards.

A balanced committee will help ensure that all relevant issues are raised during the consideration of the standard. For example, consider a standard which is designed to reduce the air pollution resulting from a particular industrial process. A balanced committee to consider such a standard might consist of representatives of both large and small companies in the industry involved, environmentalists, and representatives of some communities in which the plants affected by standard are located. The latter category may break down into several groups, one of which favors strict control and one of which is concerned with economic development. If the costs from pollution control would be great, it may be appropriate to have a consumer representative because the price of the end product of the industry might be raised significantly. Additionally, government representatives may also be appropriate since they may well be

concerned with the results of the standard. In the discussion that results, each participant could be expected to raise the issues of particular concern to the interest he or she represents. Thus, the technical issues involved with air pollution would be set out; the desirability of a clean environment and the adverse effects of pollution would also; the costs involved in terms of dollars to the company and hence ultimately to consumers, and in terms of local jobs would also be raised; the government officials could express their needs and views.

The structured decision making then means that these issues should be resolved fairly and the views of the various participants, as well as the views of others who file comments, should be fully considered.

The resulting standard should then reflect a reasonable resolution of the competing interests. No relevant technical issue should be left unresolved, at least not one that would adversely affect one of the interests represented because if it did, the representative of that interest would file a substantive objection that would have to be sustained as valid. Similarly, a reasonable accommodation would have to be reached on the stringency of the standard in terms of

resolving the competing desires for a clean environment, jobs, and money.[168/]

Thus, under the consensus process, an agency may have much greater confidence that the relevant issues were raised and resolved than is the case in a non-censensus standard. Indeed, one of the ways an agency may review a standard to determine if the issues that must be considered for the regulatory use of a standard were in fact is to determine whether a suitable consensus process was followed. If it was, the agency may feel it need not subject the standard to as close scrutiny and hence give it more deference.

Regulatory Criteria. Simply because the relevant issues were raised during its development does not mean the standard is suitable for adoption as a regulation, because the general regulatory criteria still may not have been met. In the above example, the statute under which the agency operates may provide that the economic cost of the pollution control devices should be considered only in the extreme. In that case, the agency would still have to know

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168/ Under this process it is likely that no one interest is totally happy with the outcome since it envisions compromise and negotiation. But the process is designed to provide a structure for making these trades-offs.

what weight was given to the role of costs -- was it simply one factor that was thrown into the pot with all the others, or were those who wrote the standard aware that it required a lot of money in the form of consequential costs to overcome increased protection from air pollution, and did they adhere to the requirement. As a result, an agency may still fear that a standard is too "weak" because it does not take into account the particular mandate of the agency. But if the agency is directed to reach only "reasonable" results, without further specification, then the consensus process is one way of providing that the result is reasonable, in that it is acceptable to the interests involved. Otherwise, if the agency has particular criteria it requires regulations to meet, it will help the agency's review process if those criteria are specifically taken into account when the standard is written. In that way, any adverse comments can be resolved in light of the regulatory criteria. In the example, a comment by the environmentalist that costs were given undue weight might be determined unpersuasive under normal circumstances and yet be held valid if the committee knows the role of costs in the regulatory criteria.

Participation of Important Constituents. People may not be sympathetic to a regulation that is imposed from

on high, even though they may accept the same requirement if they were able to participate in its development or are confident that their interests were taken into account in the negotiations leading up to it. It is simply human nature to have more trust in a process that you understand and can participate in.[169/] Thus, those who may be benefited by the regulation will want to point out any shortcomings in a proposed regulation, and those against whom the regulation will be enforced will similarly want to demonstrate any inappropriate obligations. Certainly part of the theory of the government's rulemaking procedures is to make the result more palatable to those it affects, as well as provide a method for increasing the amount and accuracy of the information on which the government operates.

These same concerns lap over into the regulatory use of standards. A government agency may feel inhibited

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169/ A protestation not infrequently heard among consumer groups is not necessarily a distrust of the substance of a decision. Rather, it is simply frustration over ignorance about what went into it and how it was made. There is, in brief, a severe problem of credibility and challenge to reconcile orderly administration with the desires of participatory democracy

Edward J. Burger, Protecting the Nation's Health, (Lexington, Mass.: Lexington Books, 1976) at p. 7.

from publishing as a proposed regulation what it may regard as an "ideal" standard in a technical sense if an important constituent did not participate at least passively in its development. The fact that the interests of the constituent were not represented in the development of the standard may mean that that constituent would oppose the use of the standard precisely because it did not participate. Thus, the agency may feel it is a political necessity for it to propose only those standards that are developed under a process which assures that the interests of its major constituents are represented.

The lack of participation may also raise important substantive concerns. A group will be a major constituent of a regulatory program only if its interests are significantly affected by the activities of that program. Thus, the interests of the constituent are the very ones the agency must consider when developing a regulation. Therefore, if the constituent did not participate in the development of the standard, the agency will logically be concerned that its interests were not adequately represented and that leads to a concern that the agency's regulatory criteria were not met.[170/]

170/ For example, the Consumer Product Safety Commission recently expressed concern over the effective participation

[Footnote cont'd on p. 127]

Thus, the agency may feel it is essential to use only standards that have been developed with the participation of its constituencies. The use of consensus standards, in which the appropriate interests were represented, is a vehicle for ensuring that. For even if the representatives of a specific interest do not predominate, either in numbers on the committee or on the resolution of all issues, under the "due process" requirements their views would be given a full and fair consideration. As one observer of the standards process has said:

> "Procedural fairness may also be the most feasible means of ensuring that the resultant standards -- whatever the formal make-up of the technical committees -- could claim 'legitimacy' as being in the 'public interest' as any standards directly made by government could claim to be."171/

Limitations on the Theory. There are several limitations on the theory that balance and due process will

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[Footnote 170 cont'd. from p. 126]

of consumer representatives on the committee that is developing a standard for use in the Commission's regulatory program. While the standard concerning chain saws is not to be imposed as a regulation, the Commission is going to determine if it sufficiently reduces the hazards of kickback and so it is holding off the development of a mandatory standard. Product Safety Letter, August 17, 1978.

171/ Dixon, supra note 154, at p. 4.

result in standards suitable for regulatory use. Considering the immediately preceding discussion, a major limitation on the theory would be if an important constituent refused to participate in the consensus process. If that happened, the agency may feel reluctant to use any standard that resulted. The constituent may feel the process is dominated by others and refuse to participate in a process in which its views may be outvoted.[172/] Some may feel that even though the consensus process is followed, it is still dominated by interests antagonistic to their own, so they refuse to participate because participation would add a "legitimacy" to the process that the constituent feels it does not have. Some may believe they can achieve similar goals through other means, such as the political process. Finally, the constituent interest may wish to devote its energies and resources to other issues. For example, some labor unions feel this way about safety standards.[173/]

172/ In the consensus process the interests of one group cannot be allowed to predominate, so that before the views of the constituent would prevail, it would have to convince others that they are legitimate.

173/ See, testimony of Sheldon W. Samuels on S. 825, supra note 133. It is interesting to note in this regard that

[Footnote cont'd. on p. 129]

A logical response to this ostrich-like attitude might be that the agency should feel free to use the resulting standard because the opportunity to participate was provided. But, the agency may still feel reluctant to do so either because the constituent is powerful and could resist the use of the standard, or because it would be concerned that the standard would not reflect the proper resolution of the appropriate issues. The Consumer Product Safety Commission has taken the latter view: "The Commission believes that merely providing an 'opportunity' for consumers and small business to be represented is not sufficient ..." for externally developed standards that are to be supported by the Commission by means of its participation in their development.[174/]

Identifying Relevant Interests. Another difficulty with the overall theory is the difficulty in identifying precisely those "interests" that should be represented. The term "consumer" does not describe a monolith: Some

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[Footnote 173 cont'd. from p. 128]

even though Hamilton believes the ANS B-11 committee which writes standards for machine tools is dominated by commercial interests, supra note 13, at p. 1363, OSHA weakened the B-11 standard concerning power presses. See, OSHA Task Force Report, supra note 19, at p. 26.

174/ CPSC Policy Statement, supra note 73, at p. 19,219.

people want products so safe as to be nearly foolproof; others would choose less safety if it means cheaper products; some want a diversity of products, while others do not care about uniformity. Since not all products are "consumer products," representation of "consumer" interests in all committees for all standards is clearly inappropriate; the difficulty arises in deciding just how much influence a standard must have on a consumer product before consumer representation is appropriate. And assessing the interests of those who are neither manufacturer nor purchaser, nor one directly affected by a product is sometimes difficult. For example, what interests does a consulting firm or an insurance company represent, and does a professor always represent "the public interest" because he/she has no direct ties to an obvious interest group. Interestingly, in these days of extremely high product liability awards, a producer may have the strongest incentive of all in producing safe machinery so that the traditional view of the producer working for lax standards may simply not withstand analysis. Thus the categorization

of the particular interests is difficult unless done on a case-by-case basis.[175/]

Dixon's analysis for the National Fire Protection Association concluded that "representation formulae keyed to committee membership and voting power is ... a chimera." He concluded instead that "[a]chieving the relevant input for wise standards-making is essentially a question of touching base with a sufficient number of informed and effected people."[176/] In Dixon's view, it is impossible to select all the interests that may be interested and affected by a standard to participate in its development. What is needed

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175/ The procedural rules for the Voluntary Product Standards of the National Bureau of Standards classify interests as "producer", "distributor" and "user and consumer". 15 CFR §10.5(f)(2)(ii). This very classification points out the difficulty of rigid, broad, and abstract categories. For example, why are "users and consumers" lumped together. With respect to picnic coolers, PS 49-71, a user is probably the same thing as a consumer. But with respect to Carbonated Soft Drink Bottles, ANSI/VPS PS 73-77, is the "user" the bottling plant -- the one which "uses" the bottles covered by the standard? If so, its interest may actually be antagonistic to that of the ultimate "consumer" -- the one who purchases the carbonated soft drink in the bottle. Or does user mean the ultimate consumer? In fact, the committee which wrote the Voluntary Product Standard in question was balanced among consumer organizations, bottlers, and bottle manufacturers. And, for picnic coolers, the degree of interest of the distributors hardly seems comparable to that of manufacturers or consumers. These examples show that interest analysis tailored to the situation may sometimes be necessary.

176/ Supra note 154, at p. 53.

instead is for the standards development process to reflect a diversity of viewpoints and concerns. Thus, as a practical matter, in determining whether a standard was developed by a "consensus," as the term is defined above, the agency will want to know whether the committee that prepared the standard represented a diversity of interests and whether a process was afforded in which all interests could have their comments on the draft standard considered.

Finding Representatives. A third difficulty with the theory is that some allege it is sometimes difficult to locate people who are willing and able to represent certain interests. It may be very expensive to participate fully in the development of a standard, because to do so would require attendance at meetings held in various locations across the country. As a result, someone may be reluctant to participate unless they or their employer have a direct and immediate interest in the standard.[177/] It may be

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177/ By the nature of the interest, a "consumer" representative is not as likely as other representatives to have an employer directly interested in the standard. There are, of course, organizations which represent consumers, but surely they cannot participate on all the committees that develop standards that affect consumers. Nor would it be appropriate for such an organization, or even a few of them, to always speak for such a diverse group as "consumers".

difficult to get consumers to participate on a voluntary, unpaid basis, since the benefit to any one consumer is likely to be low even though the collective effect on all consumers might be high.[178/] Or small businesses may feel the potential economic return is simply not worth the cost involved. If the participation of these interests is essential for an agency, it may be appropriate and indeed necessary for the agency of the standards organization to provide a subsidy. For example, the Consumer Product Safety Commission recently funded the participation of consumer representatives in the development of a standard.[179/] For another example, in 1978 ASTM set aside $40,000 to pay for consumer participation in four ASTM committees as part of a demonstration project.[179a/]

Technically Qualified Participants. Even though various interests are represented on the committee, that may only mean that someone whose interest in a standard coincides with that of a broader group is sitting at the

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178/ See, CPSC Policy Statement, supra note 73, at p. 19219.

179/ Article V of the contract between CPSC and the Chain Saw Manufacturers Association provides in part: "The CPSC shall directly fund eight (8) consumer representatives. . . ."

179a/ See, Report on Consumer Representation in Voluntary Standard Setting, Presented by the National Consumers League to ASTM, 1979.

table during the discussions. Simple physical presence is not really enough to ensure that that interest is accorded full respect. In order to participate fully in the decisions, the representatives of the various interests must have a high degree of informational parity. That is, they must be able to discuss the technical details of the standard as it is developed, because otherwise they cannot help resolve the competing issues and would have to rely on the views of others as to the consequences of a particular decision. Thus, for the system to work as planned, the representatives need to be technically qualified to participate.

Balance on Subcommittee. Although the consensus process contemplates balanced committees that are responsible for a standard, in fact the committees themselves may end up being large groups with many sub-groups that actually develop the standard. Since a technical standard cannot be drafted in a large organization, but rather must be done by a smallish group, it may be difficult to ensure that that group is balanced, even if its parent committee is. In that case, the committee itself may be converted into more of a ratifying organization than one which substantially

influences the standard initially.[180/] This can be a difficulty, since it is often the give and take of writing the initial draft that influences the ultimate shape of the standard. Thus, for example, the Office of Management and Budget explained the position it took in its draft circular as requiring "sincere, reasonable efforts to obtain balance at all levels".[181/] Nonetheless, the larger committee, or subjecting the draft standard to a consensus process by receiving widespread comments on it, will still serve as a form of check or safeguard to ensure that the relevant issues are suitably considered.[182/] The very fact of subjecting the

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180/ To certain extent, the Voluntary Product Standards of the National Bureau of Standards fall within this category. Although a VPS need not be written by a balanced committee, it is reviewed, modified, and approved by a balanced Standard Review Committee before being subjected to public comment. In this regard, the Standard Review Committee is in a similar position as the parent committee as described in the text.

181/ "Questions and Answers" supra note 155. The response is in terms of whether Federal employees would be permitted to participate on standards development committees; it is not directly related to the regulatory use of standards.

182/ In order to gain the insights from more interests than can be represented on a drafting committee, or even its parent if there is one, some organizations circulate draft standards for comment. The resulting comments are then taken into account in reaching the final draft that is then subjected to the consensus process. For example, the ANS B-11 Committee, Safety Standards for Machine Tools, does so, as does the National Bureau of Standards under its Voluntary Product Standards program. See 15 CFR §10.5(b).

standard to this form of review can provide an inducement to the drafting committee to be careful in meeting the relevant concerns. However, a legitimate concern may exist that the standard does not reflect the various interests in the same way as if they participated directly in the drafting.

Minority Views Overruled. Another aspect of the decision process that can lead to difficulty is the method of resolving disagreement within the committee. Under the consensus process, an objection that is supported by an explanation as to why the proposal is technically insufficient or the process by which it was developed is procedurally improper must be considered. But some interests may fear being overridden by the other interests in the committee in the form of having their objections ruled unpersuasive simply because they represent a minority, or unpopular, view. Such fear is sometimes given as the reason some groups believe it is futile to participate in the process. Thus, it is particularly important for the integrity of the system to be careful in resolving negatives so as to not ride roughshod over any particular interest.

Several procedural ways exist to counter this potential problem. The first is, of course, to provide a

full and fair appeals mechanism so that anyone who feels that a valid negative was inappropriately overridden can seek review. The committee will then be required to demonstrate why it believed the objection was without merit. Again, this potential review can serve as a valuable check.

Another way is to provide that the method of voting on a standard ensures that a particular interest will not be overridden on "political" grounds. That can be done in one of two ways. In one, the views of the particular interest in question -- usually the group which will be the "beneficiary" of the standard -- is accorded more weight than others, in that it will take more votes to override a negative vote of this interest. The committee will then have a higher burden of showing why their views are being overridden. The second way is to provide that the consensus must be reached both with the committee as a whole and within each particular interest group. For example, the regulations of the National Bureau of Standards for Voluntary Product Standards require that a standard must be approved both by an overall percentage and by a slightly lower percentage of the "producer segment, the distributor segment, and the user and consumer segment, each segment

being considered separately."[183/] Under these procedures, each of the interests that votes separately cannot be overridden as a whole, because the concurrence of a fairly high percentage of the representatives of that interest is required to approve the standard. This helps to ensure that the decision to reject an objection is based on merit and not on more philosophical grounds, because were it otherwise those sharing the general philosophy of the person objecting would not vote to overrule his dissent.

Yet another way to protect a particular interest that may be vulnerable is to have a specific review of the standards by someone other than the committee to ensure that any relevant negatives are treated fairly and that the issues relevant to that issue are considered by the committee.[184/]

Dixon has pointed out the difficulty of giving particular interests increased procedural protection: It may be hard to decide which interests merit special attention, and the more special treatment that is accorded, the more difficult it will be to reach consensus.[185/] But, it may

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183/ 15 CFR §10.5(f)(2)(ii).

184/ For example, ANSI has appointed a "Consumer Council" to review standards directly affecting consumers. (although it does not review negatives). See, Hamilton, supra note 13, at III-11.

185/ Dixon, supra note 154, at p. 30.

be worth the price if we can enhance the feeling that these views will be legitimately considered, if indeed there is a feeling otherwise. Also, the procedures may encourage participation by those who have refused to do so because of a fear of being outvoted.

Conclusion. A well functioning consensus process can be a potent vehicle for resolving the clash of competing interests into a workable standard. Thus, a standard which reflects a broadly based consensus should be more attractive for regulatory use, since the agency may feel more comfortable that the relevant issues were raised and resolved because each interest group would act to protect its interest. The resulting standard may well then be a "reasonable" accommodation of the competing interests. However, when considering that ideal state, several things must be borne in mind. Sometimes agencies have particular mandates that require them to impose regulations that are not just "reasonable", but rather extend or further a particular interest. In that case, the agency will legitimately want to know if that interest was given its proportional weight. And, there is always the question of whether the full theory of the consensus process was met: was the committee fully balanced, even assuming the interests could be identified; were negatives resolved appropriately;

was widespread comment received or was any broader approval only tacit.

Implications for Standards Writers. There is no question that great strides have been taken to meet these concerns in recent years. As the discussion above indicates, more may be necessary in some particularly sensitive instances to ensure that the theory becomes fact.

In particular, standards writers may need to: (1) take the agency's regulatory criteria into account in writing the standard, for example, by resolving adverse comments in light of regulatory criteria; (2) use procedures (such as those described in this chapter) that will assure that minority views are not overridden on "political" grounds; and (3) seek ways to alleviate other potential problems such as failure to have an important interest represented, lack of technically qualified representatives, and lack of balance in the actual drafting of the standard.

CHAPTER 10

THE NEED FOR A PROCEDURAL HISTORY AND RATIONALE

Some standards are published with explanatory notes that briefly review the history of the standard[186/] or suggested methods of meeting the standard.[187/] But, by and large, most standards[188/] are starkly presented without elaboration or explanation so that only their provisions are set out.

If someone wants to determine more about the history of the standard, they generally have to turn to the notes of the committee if indeed even those exist and are available. The records will generally show the membership of the committee, but they are frequently sketchy as to the issues raised, the information available to the committee, and the resolution of the various issues. To know more about the standard requires asking a committee member what went on, and that has all the risks of faulty memory and

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186/ Contrast Carbonated Soft Drink Bottles, PS 73-77, which includes a brief history with the same standard published as ANSI/VPS PS 73-77 which does not.

187/ See, e.g., the recent ANS B-11 Standards.

188/ No citation is given for the legitimacy of the quantification "most". The assertion is based on two things: What the lawyers call "information and belief", and a casual sampling of standards in the Standards Information Service library of the National Bureau of Standards.

learning only one person's view of a decision that was reached by a group. Thus, it may remain difficult to determine why a particular provision of a standard was set as it was.

Need to Know. The preceding chapters have described instances in which an agency will want to know something about a standard before it can determine whether it is appropriate for use in its regulatory program. One way is for the agency to make an independent assessment of the standard. Unless the agency participates in the standard's development, the agency will then either have to conduct tests de novo which amount to starting over on the standard, or it will have to guess at what issues were considered in writing the standard, what information was brought to bear on those issues, and how the issues were resolved. Clearly this is unsatisfactory and often will lead to the agency's simply writing its own regulations.

In order to avoid having to conduct its own extensive review of the standard, the agency will need to know something about it -- the agency must have some reason to have faith in the standard. This may be supplied in part by the mere fact that the standard was

subjected to a putative consensus process. But, as the preceding chapter indicates, even then the agency may legitimately want to know more. To meet these needs, it may be necessary to briefly describe the history of the standard, including an explanation as to its various provisions, in a report that accompanies the standard, or is at least readily obtainable. This commentary document, analogous to the "legislative history" of the law, can answer many of the questions which arise about a standard.

Composition of Committee. The agency may be concerned as to the composition of the committee that drafted the standard. A review of the committee membership, and the interests represented by the respective members by identifying their affiliation or qualification, can do much to indicate what broad issues (e.g. environmental impact, safety, liability, manufacturing costs, etc.) may have been raised during the discussion and some of the values that probably entered into their resolution. The National Electric Code includes such a list; NBS Voluntary Product Standards do not.[189/]

189/ Some, but not other, VPS standards list the members of the Standing Committee that is responsible for keeping the standard up to date, and the organizations and individuals who have filed written acceptances of the standards. Both lists include affiliations, but not positions, except as consumers and "general interest" representation; this general description of consumers is not informative as to whether they are qualified to make sophisticated technical

[Footnote cont'd. on p. 144]

For example, a description of the composition of the committee that prepared the VPS bottle standard could indicate what concerns were addressed: Was someone involved, such as a retailer or consumer, who might be concerned with breakage after the bottles left the bottling plant; were both large and small bottlers represented; were manufacturers of bottles represented; was a representative of a government agency which may have access to important data present? As it stands on its face, the source of the standard is an unknown, other than that it was initiated by the National Soft Drink Association and the Glass Packaging Institute. The fact that it was initiated by those organizations may cause some fear that retailers and consumers were not represented other than during the comment process. And that leads to a concern that the

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[Footnote 189 cont'd. from p. 143]

judgments. An indication of what position someone holds in a company or organization can help indicate what particular concerns that person may have. For example, someone from the marketing department of a company may have different views, and abilities, than someone from the engineering section. A government representative may come from a part of the agency that is sympathetic to industry or he/she may be from a part set up for a consumer protection of some sort.

review process may not have sparked a focused attention on the standard in which important issues were raised and resolved.[190/] A brief description of the history of the standard could answer these questions.

Provisions of the Standard. The agency may also want to know why particular provisions are included or set as they are. Without an explanation, the agency will have to guess whether its criteria are met, or whether a particular provision is appropriate.[191/] For example, the bottle standard provides "Returnable bottles shall withstand a minimum internal pressure of 225 psi and nonreturnable bottle shall withstand a minimum internal pressure of 200 psi." It then provides the method of testing to determine if the bottles comply with the requirement. A history of

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190/ The history of the standard that accompanies the VPS publication of the standard, but not its publication as an ANSI standard, indicates that it was sent to consumers and producers (of what is not specified) and that comments were received and taken into account in a subsequent draft.

191/ The procedural history of the VPS bottle standard indicates that the two sponsoring groups were initially unable to resolve differences, and that it took a considerable period and much effort to bring them to agreement. Immediately, the question arises as to what was in controversy. If an agency concerned with safety is interested in using the standard, it would logically want to know whether the dispute was over some technical detail that is irrelevant to safety, or whether there was a fundamental disagreement over the stringency of the standard.

the standard would explain why 225 psi and 200 psi were choosen: Were they determined after conducting research on the strength of the bottles; are the figures reasonable when considering the hazards that may arise, such as shaking bottles or having them sit in high heat; what internal pressures are generated in common situations. If bottles meet those figures, what level of risk remains; will those figures cure all explosions, or will it reduce the number to an "acceptable" level, and if the latter, was that figure based on a comparison with present experience. Do some bottles meet the standard now, or would new designs be required; if so, how expensive would that be? 192/

And, as discussed above, the bottle standard contains a provision concerning the physical dimensions of the bottle. Without an explanation, an agency that is interested in safety might not know whether that section is safety related, and hence proper for a regulation, or

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192/ Even if a representative of the relevant agency was a member of the drafting committee, preparing a history of the standard that addresses these issues is still worthwhile: The standard represents the consensus of the committee and the history will describe that process whereas an individual's report suffers from the frailty of memory concerning complex events and the inevitable bias of a personal perspective. The history explains these issues to neutral observers.

whether there is some other, non-safety related reason for its inclusion, in which case it would be improper for the agency to impose it as a requirement.

Implications for Standards Writers. It would help an agency or anyone else who is interested in that standard if the standards committee writes a short history which includes a description of the composition of the committee, the basic premises of the standard, the issues that were raised during the discussion, a short narrative discussion concerning each section of the standard (including both its rationale and why it is set as it is, which may only be a judgment that the figure is "reasonable" in light of the circumstances), the data and other information considered by the committee, and a procedural history of the standard. (A checklist of information to include is given in Table 1.) At minimum, an agency should be able to determine what negatives were overridden, or even the basis for all negative votes. While someone whose only interest is in meeting the standard may not care about the history of the standard, an agency is likely to be vitally interested in it because it helps provide the basis for confidence in the standard. Moreover, the history can help those who use the standard determine whether it is entirely applicable to their operations, or whether the theory of some section of the standard does not apply to them.

Agency Must Explain Itself. There is another reason an agency is likely to want to know what went into a standard. The agency is obligated to provide a relatively detailed description and explanation of a regulation both when it first proposes it and when it issues it in final form. The reason for the requirements is to enable someone else -- a court -- to review the regulation to be sure it is a rational exercise of the agency's jurisdication and that the proper factors entered into its consideration. In the preamble of a regulation, the agency discusses the general background of the standard and the various factors that underlie it; it then describes each section in more general terms. An agency will have to have similar information about a standard if it is to use it directly in its regulatory program. Otherwise, the agency will have to supply that information itself to meet its obligations.

A Substitute for Balance. This is not to say that a legislative history is essential for the regulatory use of externally developed standards, but only that such a history will help the agency ascertain whether its regulatory criteria are met. Similarly, the agency is likely to have some degree of confidence that its criteria are met under the consensus process, especially where the criteria do not

require a significantly skewed weighting of factors but rather only a "reasonable" accommodation of the competing interests.

To a degree, both the legislative history and the consensus process fulfill the same need -- aiding the agency in determining what was at stake. Thus, a good, thorough legislative history of a standard can be a substitute for a balanced standards-writing committee and other aspects of the consensus process. To do so, the history must show the issues addressed by the standard and how the questions were resolved, both in terms of the information underlying the resolution and why the particular resolution was made.

For example, one of the famous "horror stories" concerns a standard that describes the level of illumination for school rooms. The allegation is made that it is far higher than would be required for good vision because those who wrote it profit from the excessive illumination.[193/] If such a standard were presented to an agency for incorporation into its regulatory program, the agency could do several things to determine if it is appropriate:

193/ Ralph Nader and Peter Maier, The Case for Reforming Our Standards - Setting System, New Engineer (Jan. 1978) at pp. 28, 29.

If the committee that wrote the standard was balanced in that consumers, eye experts, educators and the like were represented as well as light bulb manufacturers, and if the committee followed rigorous procedures to ensure due process, then the agency would have a reasonable belief that the standard is proper. Or, even if the committee was not balanced, a legislative history could explain the technical reason for the particular standard. For example, it might marshall the scientific and medical data to show that a high level of illumination reduces eye fatigue or helps in some other way. That too could persuade the agency that the standard is proper. Barring either of these, the agency may have cause to believe the critics of the standard are right -- that illegitimate factors entered into its determination so that it would be inappropriate to use the standard in its regulatory program. Of course, the agency could set out and do its own research to determine appropriateness, which would be tantamount to drafting a regulation from scratch with the standard itself only helping the drafting process. That is hardly the basis for a good relationship between externally developed standards and regulatory programs.

CHAPTER 11

TESTS

A regulation imposing physical requirements must be enforceable, so that a testing program to determine compliance must be part of any regulation, although it may be implicit or obvious. As a result, standards that are used in regulatory programs also need tests for compliance. Such tests may be straight forward and non-controversial, so that they can simply be adopted by an agency without a formal proceeding as a means of enforcing requirements imposed in a regulation. But, a test may be intertwined with the actual obligations that are imposed so that it significantly affects the duties of those regulated, in which case it is subjected to the same administrative processes as is a substantive regulation. Whether the test for compliance is simple and well-established or highly complex and developed especially to enforce the regulation in question, tests can and do have a substantial influence on the substantive effect of a regulation. The following discussion highlights some aspects of testing programs that

need to be considered when developing tests for regulatory purposes.[194/]

Can Compliance with Each Requirement of the Regulation or Standard Be Determined? A regulation may impose multiple duties on those subjected to it, and both those affected by the regulation and the agency that is charged with enforcing it must be able to determine whether the various requirements are met. Thus, unless the method of measuring compliance is obvious, a standard that is to be used in a regulatory program must include some way of measuring compliance with each separate obligation. These measures may be qualitative and subjective,[195/] or quite specific and quantitative.[196/] The nature of the test will, of course, depend on the nature of the obligation imposed. But without a test for compliance both those affected and the agency itself may not know what is required and a person who is subjected to the regulation must be able to

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194/ A cautionary note is in order. This discussion is based on the general regulatory literature, but not on the considerable literature concerning tests that exists in the standards community. Thus, it should not be treated as a comprehensive discussion.

195/ See, Harter, supra note 132.

196/ §1910.23(e) of the OSHA regulations requires a barrier exactly 42 inches high to protect employees from falling off vertical drops.

determine with some degree of accuracy what his duties are. A complete standard will include a testing program for each obligation it imposes.

What Does the Test Measure? A test may simply determine compliance with a relatively specific obligation that is imposed independently in the regulation. For example, OSHA's regulation on vinyl chloride requires that "[n]o employee may be exposed to vinyl chloride at concentrations greater than 1 ppm averaged over any 8-hour period."[197/] The regulation continues to provide:

> The method of monitoring and measurement shall have an accuracy (with a confidence level of 95 percent) of not less than plus or minus 50 percent from 0.25 through 0.5 ppm, plus or minus 35 percent from over 0.5 ppm through 1.0 ppm, and plus or minus 25 percent over 1.0 ppm. (Methods of meeting these accuracy requirements are available in the "NIOSH Manual of Analytical Methods").[198/]

The duty imposed by the regulation is relatively specific, and the test is used solely to determine whether the prescribed level is achieved.

If the test is to measure compliance with a specific underlying requirement, the question is whether it

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197/ 29 CFR §1910.1017(a).

198/ 29 CFR §1910.1017(d)(4).

adequately does so.[199] If the test fails to accurately measure compliance with the general requirement, confusion would result as to whether the obligation that is imposed is the one contained in the substantive part of the regulation, or whether the test is determinative so that it de facto modifies the requirement imposed.[200] Thus, in the preparation of a regulatory standard, care must be taken to be sure that all tests that are included accurately measure compliance with the duties imposed.

On the other hand, a "test" may in fact determine the nature of the obligations imposed, if the underlying requirement is stated in less specific terms. For example, the offeror that developed a standard for CPSC on Minature Christmas Tree Lights charged that the Commission converted the standard from a performance standard to a design requirement by the addition of a couple of tests.[201] Tests of this

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199/ See e.g., 43 Fed. Reg. 18034 (1978) in which HUD discusses the appropriateness of various tests to determine the fire safety for plastic plumbing fixtures.

200/ For example, the NBS Bottle Standard provides that returnable bottles shall withstand a minimum internal pressure of 225 psi, and it provides a sampling plan to determine compliance. If the standard were adopted as a regulation precisely what it requires is unclear: Must each bottle withstand 225 psi, or only those that are selected in the sample? If the latter, then the test dilutes the requirements of the obligation as initially stated.

201/ Product Safety Letter, June 12, 1978.

nature are similar in effect to standards or regulations that impose substantive obligations, and the discussion above concerning substantive standards apply with equal rigor to them.[202/]

A test may be designed to simulate the actual conditions that a product or system will be subjected to in use. If the test omits a significant variable, the test may fail to provide an adequate measure as to whether the product or system should be used or meets a general regulatory requirement. For example, the Federal Trade Commission alleged that labeling certain plastics as "nonburning" and "self-extinguishing" was misleading because the "test standards permitting these false descriptions are invalid for determining how the products will behave in actual fires."[203/] A court reversed a test imposed by the Department of Transportation for air brakes because it did not take the natural variation of road surfaces into account.[204/] And, the Consumer Product Safety Commission was reversed for finding

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202/ Supra, p. 59.

203/ Society of the Plastics Industry, Inc., Trade Regulation Reports, ¶20,342 (1973).

204/ Paccar Inc. v. NHSTA 573 F.2d 632 (9th Cir. 1978), cert. denied 439 U.S. 862 (1978).

that a particular pacifier posed a danger to infants because the court felt the test did not adequately simulate the circumstances in which the pacifier would be used, so that it did not accurately measure any hazards that were posed.[205/] Thus, if the purpose of a test is to simulate actual use, it is important that the relevant variables are taken into consideration and that means that the test standard also needs a scope and purpose section, just like a substantive standard, which describes what the test tests and what factors it takes into account.

How Complex and Difficult Is the Test? Like substantive regulations, a test can be "perfect" in that it precisely measures whatever needs measuring, but as a practical matter it may not be suitable for regulatory use because it is too complicated for widespread use. Thus, as in other aspects of regulation, there is a trade-off between technical completeness and the need for administrative feasibility. This concern is particularly relevant when the test must be administered in the field, as opposed to a laboratory. For example, one of the concerns of the OSHA Task Force was that the OSHA regulations may require a

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205/ Clever Idea Company v. CPSC, 385 F. Supp. 688 (E.D.N.Y. 1974).

compliance officer to engage in sophisticated and difficult testing when he enters a plant to inspect it; the fear was that the officer may lack both the training and equipment to conduct these on-the-spot tests in any accurate manner.[206] On the other hand, tests that are conducted in laboratories by trained personnel may be more complex and require more specialized equipment. For example, in enforcing environmental regulations, samples obtained in the field may be tested in a laboratory rather than on location. Thus, in designing tests to enforce regulatory requirements it is important to keep in mind just how the test will be conducted, and if it is to be in the field, a relatively simple one may be required.

In addition, there must be a balance between the costs of administering the test and the benefits derived from the duty which the test measures. If the test is too expensive when compared to the benefits derived from the duty the test measures, the agency or a court may feel it is inappropriate to inflict the cost because there is no correlative benefit.[207]

206/ See, OSHA Task Force Report, supra note 19, at p. 18.

207/ See, e.g., D.D. Bean & Sons v. CPSC, 574 F.2d 643 (1st Cir. 1978). Of course, a court would likely be troubled if a less costly test were able to provide very nearly as good a measure as the one imposed by an agency.

If a test must necessarily be complicated, it may be appropriate to provide non-mandatory advice in the standard as to how to execute the tests.[208/]

How Is the Test Imposed? Another aspect of testing for regulatory purposes concerns just what must be tested and when. If the regulation applies to a product, must every single unit of that product comply? Must the product or system comply with the requirement when in use or just when manufactured? For example, must a consumer product continue to comply with a standard even after years of use and abuse? Many regulatory programs require that any unit tested must meet the requirement, so that each unit must comply all the time. But, other regulatory programs require only that a sample must meet the test, so that the question then is over the nature of the sample tested and the proportion of the sample that must pass the test; quality control systems are also a part of such programs. For example, a regulation of the Department of Transportation for automobile turn signals specified both sampling techniques and permissible failure rates. When the Department proposed changing the regulation to require all turn

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208/ See, G. McDowell, Recommendations on the Format of CPSC Regulations, National Bureau of Standards, 7/78.

signals to meet the performance requirements of the regulation, the industry argued that it could not meet that level of performance without the leeway permitted in the existing tests.[209/]

This is particularly a problem when the regulation requires destructive testing to determine if the product complies: A company cannot test each unit of production to determine compliance, and it must rely on some sort of sampling plan and quality control. Generally such matters may be left to the company itself to determine, but in certain instances it may be worthwhile for the standard itself to specify a sampling plan and permissible tolerances. It may be that there is no plan that can be followed on an industry wide basis, so that the agency may have to require each affected company to develop its own testing program so that it may then certify compliance with the regulation on the basis of that program.[210/]

209/ Wagner Electric Corp. v. Volpe, 466 F.2d 1013 (3d Cir. 1972).

210/ See, e.g. D.D. Bean & Sons v. CPSC, 574 F.2d 643 (1st Cir. 1978), where the court says that the Consumer Product Safety Commission decided to leave for "later rule-making the establishment of regulations for manufacturers' individually devised testing and certification programs." At p. 646.

Can the Test Be Applied Consistently? Another important aspect of tests, especially when a manufacturer certifies a product as meeting the requirements of a regulation, is whether the tests may be replicated: Will different people applying the test at different times achieve similar results? The Consumer Product Safety Commission rejected a test because it was "not described in sufficient detail to be considered adequately repeatable and reproducible for an enforcable mandatory standard." 211/ A reliable sampling plan and quality assurance program in the standard may be required. The tests themselves must also be tested for accuracy. For example, the recent OSHA health standards specify the tolerances for the accuracy of tests that determine the concentration of the chemical in question. 212/ If tests do not reach similar results when applied by companies, or to different production lots, or at different times, then the underlying obligation varies and the agency will legitimately be concerned that its objectives are not being met or that some are subject to more stringent requirements than were meant to be imposed.

211/ 42 Fed. Reg. 17,155 (1977).

212/ See, supra at p. 157. See, also, testimony of John B. Moran of the National Institute for Occupational Safety and Health on S. 825; Hearings before the Subcommittee on Antitrust and Monopoly of the Committee of the Judiciary, U.S. Senate, 95th Cong., 1st Sess. at pp. 344-345.

Conclusion. Tests translate abstractions into enforcible obligations. Therefore care must be given in clearly establishing the tests that are required to administer a regulatory program.

CHAPTER 12

CLARITY, SPECIFICITY AND CONSISTENCY

As an agency reviews a standard to be used in a regulatory program, its primary focus will be on the substance of the standard, but the agency will also review the standard to determine whether it has other, non-substantive characteristics. Some of these characteristics are precisely those of "good" voluntary standards, but others arise only because the standards are used in a regulatory program. These characteristics are described in this chapter.

Clarity. A standard may be "perfect" substantively -- it takes into account all relevant factors, applies thorough research to resolve existing uncertainties, and strikes an appropriate balance of the competing interests -- but it may still not be suitable for regulatory use because no one can understand it, or at least many people who would be affected by its use as a regulation. Any agency is more likely to use a standard that is easy to understand than one that is convoluted, turgid, or otherwise difficult to use. Indeed, the agency is more likely to have

confidence that a high degree of thought and concern entered into the determination of the substantive aspects of the standard; it will be easier for the agency to use the standard since it will not have to expend resources in re-writing it; and the agency will feel better publishing something it can be proud of.

An agency which believes the substance of a standard is basically sound will feel the need to rewrite the standard if it believes its points should be clarified. For example, when the OSHA Task Force reviewed standards concerning machine guarding for potential use in a proposed regulatory program it found that some of the standards needed to be more specific and detailed if they were to be used.[213/] The Department of Transportation revised and rewrote parts of ASME's pipeline standard.[214/] Recently, the Consumer Product Safety Commission rewrote the standard for miniature Christmas Tree Lights proposed by its offeror "to provide additional technical clarity for the requirements and to put the standard in a form suitable for publication in the Code of Federal Regulations."[215/]

213/ See, 42 Fed. Reg. 1742 (1977).

214/ Hamilton, supra note 13, at p. 1429.

215/ 43 Fed. Reg. 19136, 19137 (1978).

While clarity of expression has always been important, it is even more so currently. For the past several years there has been a strong emphasis on writing regulations clearly and straightforwardly,[216/] and if an agency is under pressure to write regulations clearly, it will review standards even more closely to determine if they meet the same requirements imposed on it. To be sure, highly technical issues can never be explained so that a person without any technical background will be able to understand their every detail. But, they can be written so that the audience to which they are addressed can follow them with a minimum of difficulty.

It is therefore important that standards be written clearly, which in turn is largely a matter of writing style.

As a first step towards writing standards in a suitable style, those who prepare them should continually ask themselves whether someone who is generally familiar with the technical subject under consideration, but who is not an expert in the exact topic of the standard and who is not directly familiar with the standard itself,

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216/ Executive Order 12044 requires that regulations be "as simple and clear as possible." §1, supra note 78.

would understand it with a minimum of effort. The question should continually be asked whether the standard can be made clearer and easier to follow.

Standards-writers should have several source books readily available. One should be a general style manual for the particular type of standard that is being written, so that the standard will use terms, abbreviations, and be organized in a manner consistent with other standards in the same field.[217/] Beyond these specialized publications, it is important to have manuals that provide guidance for writing in general -- even highly technical ideas are expressed in the same language we all use everyday, and the general rules of construction have evolved in order to make that language clear. If there is the least doubt about whether a particular usage is unclear or improper, then such a manual should be consulted. Indeed, it is a good idea to review some of the general rules before beginning to draft so that they can be taken into account during the process.

217/ See, e.g., ASTM, Form and Style For ASTM Standards (1976); ANSI, Guide For Consumer Product Standards; ANSI, Manual of Style.

Many handbooks can be of help. Certainly one that has been popular for a long time and is easy to use is Strunk and White, The Elements of Style.[218/] The Federal Register has published two books that can be useful, especially if the standard is specifically being prepared for use in a regulatory program. One is the Document Drafting Handbook[219/] that describes the requirements for documents that are published in the Federal Register, which would include most standards that are used in regulatory programs. The second is entitled Legal Drafting Style Manual;[220/] it provides helpful guidance on drafting in general, and it includes a bibliography. The National Bureau of Standards has published an analysis of building specifications which, although difficult to read in itself, provides a helpful orientation into the structure of standards and a mini-manual on writing style for standards.[221/]

218/ New York: MacMillan Publishing Co., 2d Ed. 1976.

219/ Washington: Office of the Federal Register, 1975.

220/ Washington: Office of the Federal Register; Interim Edition, 1977.

221/ S. Fenves, K. Rankin, and H. Tejuja, The Structure of Building Specifications, NBS Building Science Series 90, 1976.

A highly incomplete and abbreviated list of points to consider when writing a standard is provided below. To this observer, they seem to be the highlights of the structural suggestions of the sources cited above.

o Write short paragraphs and sentences, and use short, non-stilted words.

o Do not include distinct topics or requirements in a single paragraph.

o Avoid ambiguity in the form of misplaced modifiers, indefinite pronouns, and juxtaposed prepositional phrases (in which case it is frequently difficult to determine which noun the second phrase modifies).

o State conditions and exceptions clearly

-- if only one or two simple conditions must be met before a standard applies, state the conditions first, and then the standard, but if two or more must be met, then state the standard first, and then list the conditions;

-- a qualification or limitation on the applicabilty of a standard is introduced by "but";

-- an exception to the standard is introduced by "except that";

-- a condition is introduced by "if" or "when";

-- obligations and conditions are not set off with commas as if they were only parenthetical expressions.

- o Avoid long itemizations in a sentence but rather break into outline form so that each item is set out, and the overall structure of the requirement is clear.
- o Use present, not future, tense.
- o Use singular rather than plural nouns.
- o Use active rather than passive voice.

Clarity when Incorporating by Reference. A final, important point concerns incorporation by reference. Those who write standards must pay particular care when incorporating other standards and regulations into the standard in question so that the reader will know precisely what part is referenced. For example, if only one part of a test standard is applicable to the particular topic of the standard, it is more helpful to the reader to specify that section rather than refer to the entire test standard. It is also important to specify the date of the referenced standard rather than referring to a standard only by title, because the referenced standard may be revised and the reader would not know whether to follow the revised version

or the one which was current at the time the reference was made. Indeed, the non-delegation doctrine means that only the version in existence at the time the standard is adopted as a regulation could be followed, so it is important to know just what that version is.

Specificity. The person who is regulated must be able to determine with reasonable assurance just what is expected of him. As a result, subjective words that are not capable of measurement should be avoided in standards that are to be used in regulatory programs. It may be perfectly adequate in a voluntary standard to say that something should be "within easy reach" or that "ample room" should be provided,[222/] but how can anyone know with reasonable assurance that these criteria have been met. If someone who is regulated by an unquantified, general requirement such as these believes he meets the intent of the regulation, but the enforcing agency disagrees, the only way to resolve the ambiguity is through costly litigation. Or, if a regulation does not provide suitable guidance as to how to comply with its general requirements, a court may find it would be unfair to subject a company to liability

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222/ Hamilton, supra note 13, at p. 1393.

for violating the regulation because the company cannot reasonably determine what is required of it. In such a case, the court may simply set aside the rule.[223/]

Another example of insufficient specificity is when a standard provides open-ended phrases. For example, the OSHA regulation for machine guarding provides that the employer must guard the machine "from such hazards as. . . ."[224/] The term "such as" implies the existence of many more hazards than are listed without specifying what they might be.[225/]

As a result, it is generally better if standards that are to be used in regulatory programs make explicit and quantify within reasonable bounds each requirement that is imposed. In doing so, however, care must be taken to permit necessary flexibility.[226/] The standard should be as general as possible to achieve the desired goal but

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223/ Paccar, Inc. v. NHTSA, 573 F.2d 632 (9th Cir. 1978), cert. denied U.S. (10/78).

224/ 29 CFR §1910.212(a)(1).

225/ OSHA Task Force Report, supra note 19, at p. 11.

226/ Of course, many of the complaints about the OSHA standards are that they are far too specific. There is a difference between a regulation's providing someone with enough information so that he can determine the contours of his duty and its attempting to direct specifically how that duty must be fulfilled.

sufficient to describe what is required to a person reasonably conversant with the subject matter.

Design versus Performance Standards. Closely related to the need for specificity is the question of whether the standard should be performance or design based. A performance standard is stated in terms of the problem to be solved or the goal to be reached, whereas a design standard details how something must be built. Recently a great deal of discussion has focused on the distinction, and performance standards are almost uniformly recommended.[227/] The general concern with design standards is that they may be unduly restrictive and thereby inhibit both competition and technological growth, since there is no incentive for

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227/ See. e.g., S. 825 which states that "performance standards [are] preferred over design or construction standards and that standards [should] contain a clear description of the intent and purpose of design and construction specifications, in terms of performance and safety requirements. ..." §102(b)(2)(C) and (D). And, the proposed OMB Circular: "[P]reference is given to the use of performance criteria in standards development when such criteria may be used in lieu of design, materials, or construction criteria." §6(c)(11). The Federal Trade Commission said in an advisory letter, "Construction or specification standards should not be used except in exceptional circumstances and never when performance standards can be developed." Letter of March 8, 1971 to Mr. Rockwell, Director of Certification, American National Standards Institute, and published in 16 CFR §15.96, 15.152, 15.4. U.S. Department of Commerce, supra note 158, at p. 10.

anyone to develop a better and cheaper way to achieve the goal in question because the new approach would not be permitted by the specified design.[228/]

While this uniformity of opinion would seem to indicate that all standards that are used in regulatory programs must be performance based, such is not the case. For example, the proposed regulations of the Food and Drug Administration concerning Medical Devices provide that "performance standards ... shall include ... where necessary to provide reasonable assurance of safety provisions .. . concerning the design, construction, components, ingredients, and properties of the device."[229/] The offeror that developed the standard for Miniature Christmas Tree Lights accused the CPSC of converting its performance

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228/ This is reflected in the "Recommended National Standards Policy for the United States," supra note 47. "Because of concerns about the effects of standards on innovation and competition, preference should be given to the development and use of national standards which tend towards specifying performance rather than detailed design requirements. Design standards should be limited to those circumstances where the needs of interchangeability, the clarity of objective, and the nature of the attributes requiring measurement cannot be expressed in terms of performance without extensive delays for technological development or at obvious increased costs." Part IV, Section 8.

229/ 43 Fed. Reg. 32267 (1978).

standard into a design requirement by the imposition of tests that could only be met by lights made of particular materials.[230/] The industry contends that CPSC's proposed lawnmower standard is so design oriented that it will ban some lawnmowers which already meet the goals of the standard, but not its design requirements. And, of course much of the complaint with the existing OSHA safety regulations is that many are far too specific and detailed.[231/]

When developing an approach to safety standards that it would recommend, the OSHA Task Force reviewed the benefits and drawbacks of both design and performance standards. The following summary is taken from the report of the Task Force.[232/] Although expressed in terms relevant to OSHA, the various factors are equally relevant to other regulatory programs.

230/ Product Safety Letter, 6/12/78.

231/ See, Harter, supra note 104.

232/ Supra note 19, at pp. 18-19.

The benefits of design standards are:

- They set forth precisely what employers must do to meet the OSHA requirements, so that an employer will know what is expected of him.
- They limit the discretion available to the employer and to the compliance officer, so that employees can be certain the level of safety imposed by the standards is being followed if the standards are fully enforced.
- They provide the means for incorporating new technological developments in the standards and for requiring their implementation in the workplace.

The disadvantages of design standards are:

- They eliminate flexibility. An employer may not use an alternative approach which provides more protection or provides equivalent protection less expensively without going through a burdensome variance procedure.
- They often contain requirements which are not directly related to worker safety.
- They must be revised every time a technological change takes place. If they are revised, "grandfathering" problems result. If they are not, they retard technological progress and lead to inconsistencies between requirements and industrial practices.
- They may be difficult for compliance officers to enforce, since they require mastering a large amount of technical material and may require sophisticated testing.
- They are frequently so technical that neither employer nor employee can understand and follow them.
- Because of the wide variety of machines, the various models of a particular type of machine, and the extraordinarily wide variety of environments in which machines are used, it is impossible to devise specification standards for each machine in each workplace, let alone keep such standards up to date.

Advantages of Performance Standards

- o They are specifically and directly addressed to the problems to be solved.
- o They permit flexibility in devising the solution, thereby reducing costs and inducing innovation.
- o They apply equally to all machine groups.
- o If properly phrased, employees can readily determine whether the employer is complying without mastering difficult technical material.

Disadvantages of Performance Standards

- o The employer must translate the performance criteria into an engineering design suitable for implementation, and he may lack the resources and expertise to do so.
- o The employer may desire assurance as to what will be deemed an acceptable undertaking on his part.
- o They may require a compliance officer to make subjective judgments.

Reviewing the above list, an agency may be concerned with a performance standard because it may be abstract and complex so that it will require considerable subjective judgment to determine whether its obligations are met. That in turn can lead to controversy between the agency and the person regulated, which leads to litigation to resolve the dispute. Moreover, a performance standard must be translated into practice through engineering design which also may be difficult and expensive. Some regulators also express apprehension that companies will not meet performance standards, so that they will not meet the level of protection that is

desired.[233] And, for whatever reason, agencies seem to like to specify precisely what must be done.

The OSHA Task Force believed it was essential that the general requirement for machine guarding must be performance oriented in order to spur innovation and permit alternative approaches to solving complex problems.[234] But it believed that compliance with the standard must basically be objectively determinable so that the agency, the beneficiaries of the regulation,

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233/ "As for how companies meet standards OSHA officials say they would rather order employers to use specified, proven techniques. . . . If the employer, in an effort to save money, uses some technique that doesn't work, no amount of fines the government could levy on the employer will benefit workers who have been exposed to health hazards, OSHA officials argue." The Wall Street Journal, 8/3/78 at p. 34.

234/ The central requirement recommended by the Task Force provided:

> Each employer shall ensure that all machinery subject to this subpart is installed, safeguarded, operated and maintained at all times in a manner which protects all employees from traumatic injury or death resulting from the hazards enumerated [in the next section]. In order to protect against the hazards enumerated, . . . one or more of the methods of safeguarding described in [another section] shall be utilized as applicable.
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> 42 Fed. Reg. 1742 (1977).

and the regulated could determine whether the obligations imposed by the regulation were met. The Task Force also believed that specific guidance should be provided to those who desired it, so it proposed an appendix of non-mandatory design standards that an employer could use to meet its duties.[235/]

Because an agency will review a standard to determine if it reflects a "proper" balance between performance and design characteristics, people who prepare standards for regulatory use should determine the views of the agency as to just where the balance should be struck. It may be that those who are writing the standard disagree with the agency, and if that is the case, they should be prepared to explain why.

Antitrust. Much of the concern over and the writing about standards developed in the private sector centers on their potential for having a substantial anti-competitive effect. Indeed, a great deal of the recent criticism of voluntary standards stems from precisely

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235/ See p. 67, above. See also, Harter, supra note 132. Indeed the Task Force believed that design standards could not be written for all machines, so that only a performance standard could be used to provide adequate coverage.

such fears.[236] Many of the horror stories used to describe alleged shortcomings of the entire standards-development process charge that standards were used to exclude new, meritorious products.[237] Whether or not these allegations withstand scrutiny,[238] there is very real concern over the antitrust aspects of standards.[239] This is not the place for a general analysis of the antitrust implications of standards, except to the extent that it influences their use in regulatory programs.

Antitrust matters will generally not be of paramount concern to a regulatory agency, but rather its primary interest will be in achieving its overall regulatory goal, such as reducing accidents, protecting the public's health, or reducing pollution. But an agency will not totally ignore antitrust difficulties in the form of

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236/ See e.g. Hearings on S.825, supra note 40; FTC Staff Report on "Standards and Certification", September 20, 1978.

237/ See e.g., U.S. Dept. of Commerce, Voluntary Standards and Testing Laboratory Accreditation, July, 1977, Appendix B.

238/ See discussion above at note 161.

239/ Remarks of Calvin J. Collier, Chairman of the Federal Trade Commission presented at "An Evaluation Update of America's Voluntary Standards System" conducted by ANSI, December 7, 1976.

increasing concentration in a market, favoring some suppliers over others, or restricting competition in the form of inhibiting technological innovation.[240/] Thus, a standard that is to be used in a regulatory program should be no more restrictive than is necessary to achieve the regulatory goal in question. If the standard is overly restrictive, the agency either will not use it at all or weed out its anticompetitive aspects before proposing it for the agency's regulatory program.

Thus, standards writers should attempt to avoid anticompetitive provisions, and, if the standards-writing group feels that requirements which might be considered anticompetitive are essential to achieve a legitimate goal, it should explain the reasoning process in detail. A standard that is technically well grounded and developed by the consensus process will generally go a long way towards satisfying an agency that it will not have anticompetitive difficulties.[241/]

240/ See, e.g. CPSC Policy Statement supra note 73, §1033.5(h).

241/ As the Deputy Assistant Attorney General for Antitrust has said, "[A] safety standard which is technically well grounded, is not unreasonably restrictive, and which has not been established for anticompetitive purposes does not provide a sound antitrust cause of action on behalf of those who would market dangerous products to the public." Testimony before the Subcommittee on Energy and Power Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 95th Cong. 1st Sess. (4/3/77) at pp. 9-10.

Consistency. A standard that is proposed for use in a regulatory program may deal with a topic that is already the subject of an existing regulation that was issued either by the agency in question or some other agency, or of some other standard. To the extent that the standard being proposed varies from the existing regulation or standard, the differences and the reason for them should be explained. Agencies have different concerns and interests so that non-identical regulations dealing with similar topics are not bad on their face, unless of course they impose inconsistent duties on some people or firms. But an agency may still wonder just why the proposed standard varies from a related one, so that the differences should be explained. The discussion above concerning the composition of gasoline is just such an example.[242/] If, in that example, the standard were designed to protect workers against large concentrations of gasoline, a different safety measure may be appropriate for workers who are outside the scope of the initial standard. But, if either standard did not have suitable scope and purpose sections, the agency may not know they were addressing different topics since on their face they may look like they are directed to the same subject matter.

242/ At p. 92

Chapter 13

MODIFICATION AND PUBLICATION BY THE AGENCY

After carefully analyzing a standard, an agency may decide the standard does not precisely meet its need -- for various reasons outlined in this chapter -- and may modify it before using it in a regulatory program. Next, the proposed regulation containing the standard is published in the Federal Register for public comment. This notice-and-comment process is briefly discussed in this chapter, together with some implications for standards writers.

Modification. The agency may believe that insufficient research was conducted to support the technical judgments that were made in the standard, so that it must perform that research itself. For example, the Consumer Product Safety Commission found it "necessary to conduct additional tests to determine the feasibility and effectiveness of some of the recommended requirements to address the electric shock and fire hazards associated with miniature Christmas tree lights."[243/]

The agency may modify a standard which does not comport with its regulatory criteria. For example, the agency may believe that the standard is too strict, so that it would impose excessive costs as compared to the benefits derived. For example, OSHA relaxed the ANSI standard which required that mechanical power presses must be able to be operated

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243/ 43 Fed. Reg. 19136, 19137 (1978).

without the operator placing his hands in the point of operation during any portion of the operating cycle.[244/]

The agency may believe that parts of the standard are not technologically feasible -- at least within reasonable cost -- so that the standard must be modified accordingly. The agency may believe the standard is not strict enough, so that it should be modified to afford more protection or whatever else the goal of the standard is. For example, the Department of Housing and Urban Development changed NFPA's standard on mobile homes following an extensive study, and "[i]n instances where the study indicated the NFPA standard was imprecise or overly lenient, HUD simply revised the voluntary standard based on the NBS data."[245/]

The agency may believe the standard does not adequately cover all related topics, so that it should be supplemented. For example, the CPSC modified the proposed

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244/ OSHA Task Force Report, supra note 19, at p. 26.

245/ Hamilton, supra note 13, at p. 1423.

standard on Minature Christmas Tree Lights to cover possible misuse situations that it felt were not addressed in the original but which might reasonably arise.[246/] Contrariwise, the agency may believe that parts of a standard are not appropriate for its regulatory use, and hence it will delete those parts.[247/] The agency may also feel the standard needs to be re-written to make it clearer or more specific.[248/]

Thus, for a variety of reasons an agency may feel it should modify a standard before using it in a regulatory program. In part, the agency may simply be second-guessing those who prepared the standard in what is inherently a subjective judgment. Or it may be the agency's method of demonstrating dominion over the situation. But the changes may also be based on legitimate concerns in an effort to improve the standard.

Once an agency is satisfied with a standard, either as is or as modified, it will then proceed through

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246/ 43 Fed. Reg. 19136, 19142 (1978).

247/ See, e.g. the Department of Energy proposal to use elements of externally developed standards in its Energy Conservation Program for Appliances, 43 Fed. Reg. 65576 (1977).

248/ See, Miniature Christmas Tree Lights, supra at p. 166.

the rulemaking process, assuming that the standard is to be used in a manner that requires rulemaking procedures.

Incorporation by Reference. If the agency decides that the standard is acceptable without modification, it may simply incorporate it by reference in a Federal Register Notice instead of publishing it verbatim in the Federal Register, in which case the agency identifies the standard and states the manner in which it is to be used in the regulatory program.

Although the rule-making sections of the Administrative Procedure Act do not mention anything with respect to incorporation by reference, it has been widely done for years. In 1967 the Freedom of Information Act was added to the APA and gave explicit recognition to incorporation by reference: "[M]atter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register."[249/] Before the Director of the Federal Register will permit something to be incorporated by reference, the incorporation must substantially reduce the volume of the Federal

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249/ 5 U.S.C. §552(a)(1).

Register and the material incorporated must in fact be available "to the extent necessary to afford fairness and uniformity in the administrative process."[250/] When incorporating by reference, a brief description of the subject matter must be provided, as must a description of the material which is sufficient to identify it precisely, and the public must be informed as to where and how copies may be obtained.[251/] Finally, the material must be submitted to the Director of the Federal Register at least 10 working days prior to the time of its publication so that he may review it before granting his approval.[252/]

Publication in the Federal Register. In the normal rulemaking proceeding, the agency is required to publish a notice of proposed rulemaking in the Federal Register. This may take the form of simply incorporating an existing standard in a proposed rule by reference, but there may be difficulties with this because it does not provide direct notice to those who may be affected by the proposed use of the standard but rather it imposed the

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250/ 1 CFR §51.4.

251/ 1 CFR §§51.7, 51.8.

252/ 1 CFR §51.10.

additional step of having to obtain the material that is incorporated.[253/]

There are at least two reasons why an agency may choose not to incorporate a standard by reference. One is that an agency may modify a standard before using it (as frequently happens) so that it cannot incorporate the underlying standard. The second is that when a standard is incorporated by reference its substance does not appear in the Code of Federal Regulations which is the repository of government regulations; the notion is that the requirements the government imposes should be available in one central source, so that those affected are not forced to take the time, effort and expense of obtaining the details of the requirements from diverse sources. Thus, even if it does not make any changes in the standard, the agency may still want to publish it verbatim in the Federal Register.[254/]

253/ NRC often incorporates standards by reference in its regulatory guides. (Regulatory guides are acceptable, but not mandatory, ways of complying with NRC regulations. See page 17, Supra.)

254/ One of the reasons the incorporation by reference issue arises is that the organization which is responsible for the standard may have copyrighted it and opposes its publication by the government because doing so would deprive the organization of revenue from the sale of the standard. It is unclear whether the owner of a copyright on a standard could prohibit the government from using that standard as a regulation.

If the agency modifies the standard, it will have to publish it as modified, since it cannot simply refer to the original standard.

Publication for Comments. Even though a standard was subjected to widespread comment during its development process or as part of a subsequent consensus process, notice

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[Footnote continued from page 186]

The courts developed an exception to the copyright laws that permits the "fair use" of copyrighted material for limited purposes, such as in a reviews of the work, in a scholarly paper, or in brief quotes. This doctrine was codified in the recent revision of the copyright law. 17 U.S.C. §107. The extent to which the publication by the government of copyrighted material constitutes "fair use" and hence may be done without the permission of the holder of the copyright without infringing the copyright is not settled. See, Hamilton, supra note 13, at pp. VI-21. Whether or not the direct use of a standard by a government agency would constitute an infringement of a copyright or would be regarded as "fair use", normally when the government expropriates to its own use something developed by someone else it compensates the owner. Perhaps the same approach should be followed when the government uses standards: The agency should pay the owner of the copyright a royalty for the privilege of publishing the standard in the Federal Register in those cases where the publication will diminish the market for the standard.

must still be published in the Federal Register.[255/] No analysis is made as to whether publication during its development process was "adequate" or "sufficient" or whether a wider or different audience is reached by means of the Federal Register. Rather it is purely a legal requirement that is part of the rulemaking process.

Implications for Standards Writers. The publication in the Federal Register is a valuable political check on the system that helps ensure that the standard meets the agency's regulatory criteria: The work of the committee that prepares the standard will then necessarily be subjected to critical comment by those who are directly affected by the standard's proposed use -- some who will be regulated by it, others who will benefit by it. While the public comment on such proposals is generally "reactionary" in that they challenge what is proposed as opposed to offering creative solutions, shortcomings in the standard will be pointed out. If those who prepare the standard are aware that the standard will have that form of review, it will help ensure that the relevant issues

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255/ In a very few instances publication by a Federal agency is disposed of as "unnecessary" because the proposal affects only a particular state and that state subjected the proposal to a hearing similar to the one the Federal agency would use. See, Appalachian Power Co. v. EPA, 477 F.2d 495 (4th Cir. 1973).

are raised, fully debated, and suitably resolved during the development process.

If standards writers assure that the consensus process works as it is supposed to, so that the viewpoints of all interests are in fact adequately considered, and there is no undue domination by one interest, then the comments raised during the consensus process should be representative of those received in response to the Federal Register notice; comments received from the public should contain few surprises. 256/ If that is the case, the agency would then not have to change the proposal in response to the comments that are received. That, in turn, means that the agency will be able to complete its rulemaking proceeding more expeditiously than it could if it had to make substantial revisions.

256/. There has been a relatively recent increase in the visibility of standards of direct interest to consumers, or to lawyers and others who are involved in consumer-oriented matters. Several general publications, e.g. Product Safety & Liability Reporter, Consumer News, publish lists of standards that are being considered so that comments may be filed. This should help broaden the consumer participation and expose the draft standards to diverse views. Such a standard should anticipate the comments that would be received in response to a Federal Register notice. Notice of changes in the Fire Code published by NFPA has been published in the Federal Register. The notice solicits comments from the public that will then be considered by the standards-writing committee. These codes are used by a variety of Federal agencies. 43 Fed. Reg. 46582 (1978).

PART III

THE ORGANIZATIONAL RELATIONSHIP BETWEEN REGULATORY AGENCIES AND EXTERNALLY DEVELOPED STANDARDS

Chapter 14

STANDARDS AS A RESOURCE

Externally developed standards, and the organizations that develop them, can be important resources for regulatory agencies that can, for reasons discussed in this chapter, help an agency execute its duties responsibly.

Core of a Regulatory Program. An agency faced with the formidable task of implementing a new regulatory program may find it very helpful to use an existing code of externally developed standards as the foundation on which it will build. Indeed, Congress sometimes directs agencies to do so.

The agency may wish "to establish as rapidly as possible"[257/] the new regulatory program. It may believe that this new program can be implemented more rapidly if existing standards with which those affected are familiar are imposed instead of developing new requirements from scratch.[258/] In the case of adopting existing standards as the basis of a regulatory program the theory may be that the standards

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257/ Sen. Rept. 91-1282 describing the directive that OSHA adopt "all national consensus standards and ... established Federal standards unless [it] determines that a standard would not result in improved safety or health...."

258/ Ibid.

are basically adequate but they are not followed sufficiently; the agency will then enforce them as mandatory regulations. For example, the Natural Gas Pipeline Safety Act of 1968 was passed in part because testimony indicated that existing standards were not suitably enforced.[259/] The agency may wish to adopt the existing standards on an interim basis while it develops its own regulatory criteria[260/] and determines what particular areas it should concentrate on.[261/] Finally, the agency

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259/ Hamilton, supra note 13, at p. 1428. Part of the pressure for establishing OSHA came from the belief of the unions that existing safety standards were insufficiently followed.

260/ One of OSHA's major problems is that it was required to adopt all existing standards, and as a result they did not fit any pattern -- some were performance oriented while others specified exact details; some were stringent and others were not. As a result of these inconsistencies, OSHA did not develop regulatory criteria which it could then use to develop new safety standards and revise the old ones. In retrospect, the requirement that OSHA adopt all standards without change was a clear mistake. See, Harter, supra note 104.

261/ The Department of Transportation adopted the Code for Pressure Piping developed by the America Society of Mechanical Engineers as interim regulations under the Natural Gas Pipeline Safety Act of 1968. Hamilton, supra, note 13, at p. 1428. DOT also adopted NFPA's standard for liquified natural gas as interim regulations. Ibid. at p. 1431.

or Congress may decide that on the whole external standards provide a solid basis for regulatory use.[262/]

In each of these ways the existing code of standards will help the agency develop its regulatory program, and the agency may take advantage of the evolution of a complex set of standards that addresses an extraordinary range of problems. It may then set out to build on this foundation.

Expertise. Generally, most of the "experts" in a particular subject matter will be in the private sector. As the proposed findings of fact in S. 825 found: "The expertise to develop sound technical standards lies more in the private sector than in Government."[263/] The committees that write the technical standards can and do

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262/ See the discussion of Social Security above at p.13, and of the SEC, above at p. 16. The Coast Guard recently published an Advance Notice of Proposed Rulemaking concerning Waterfront Facilities. The notice says, "Numerous potential sources of information are being tapped in order to make these proposed regulations as realistic and responsive as possible." "National consensus standards" are among the sources listed; indeed, the notice says, "The Coast Guard has made a tentative decision to incorporate by reference consensus standards throughout the waterfront facility regulations when those standards are sufficient to provide appropriate safety or environmental protection." 43 Fed. Reg. 15108, 15109 (1978).

263/ Sec. 3(3).

tap a breadth and depth of practical expertise by assembling individuals who are highly knowledgeable about the subject under consideration. A regulatory agency can rarely accumulate similar expertise on its own staff. More commonly, the agency will have only a handful of people who are technically qualified in each of the relevant disciplines within its jurisdiction. As a result, it would help the agency if it could take advantage of the assembled expertise of the standards-writing committee. For example, the agency may ask the standards writing organization to develop a particular standard for it.[264] Or, it may be helpful to the agency if the committee reviews the agency's strategies and ideas so that it can gain the benefit of the committee's expertise.[265]

Time and Money. The development of a technical regulation is both expensive and time consuming. If an

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264/ NRC and FDA have prepared lists of standards they would like developed. See ASTM, Standardization News June, 1976 at p. 40, with respect to FDA.

265/ I do not know of any instances in which an agency actually asked a standards-writing organization to review its policies. However, the OSHA Task Force found the insights and advice of the ANS B-11 committee and the safety standards committee of NEMA quite helpful.

agency does it entirely in-house, it may require a substantial amount of staff time, and the agency may have to spend funds on the research necessary to support the regulation. It may be far cheaper for the agency to review and then use an existing external standard, or to ask that a particular standard be developed. Many of the people participating on the committee may volunteer their time, and they may have access to existing data so that new research need not be conducted. Moreover, those who participate in the committees may bring to bear a considerable practical insight into the problem the agency seeks to address, so that the Committee can write a standard with a smaller expenditure of resources than could the agency, because the agency would have to first educate itself in the practical aspects of the problem.[266/]

266/ The proposed OMB Circular, supra note 42, recognizes the potential savings when it says: "Federal use of voluntary consensus standards, whenever practicable and appropriate, will reduce the cost of developing and using regulatory ... standards and will, thereby, serve the public interest." §2, Background.

The Consumer Product Safety Commission recently estimated that to develop a regulation for chain saws would take 2 1/2-4 years and cost more than $1,000,000 if it was done by the Commission itself, as opposed to 18-19 months and a cost to the Commission of $330,000 when developed as an external standard. Product Safety Letter, April 3, 1978.

No Need for Mandatory Standard. It may be that an agency will feel that a particular problem can be adequately addressed by a standard that is voluntarily adopted by the industry affected, so that no mandatory standard is necessary.[267] For example, the Consumer Product Safety Commission has denied a number of petitions that request the development of a mandatory regulation on the ground that an existing voluntary standard is adequate. And the Commission has argued that one measure of its effectiveness is its encouragement of the development of a number of standards that are voluntarily followed and that reduce the hazards presented by consumer products.[268] The Commission recently codified the policy of these decisions by saying that when determining whether or not to institute proceedings for the development of a mandatory standard, the Commission will consider "whether there is an existing voluntary standard that adequately addresses the problem and the extent to which that voluntary standard is conformed to by the affected industry."[269] If the externally developed standard

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267/ See discussion in Chapter 18.

268/ Product Safety Letter, February 20, 1978.

269/ Policy Statement, supra note 73.

addresses the problem adequately so that the agency need not take any formal action, again the agency is able to conserve its resources and focus its attention on other topics.

Conclusion. This brief review of some of the benefits that an agency can derive from the use of externally developed standards has been included to show that it is frequently in the agency's interest to use them: The agency can tap a great expertise; it can save substantial amounts of time and money; and it can gain needed practical insight into the everyday affairs of the world. These potentials can be realized to a far greater extent than is currently the case if both agencies and standards-writers appreciate each other's needs.

Chapter 15

COMPLAINTS OF STANDARDS WRITERS ABOUT AGENCIES

Part II of this report describes what regulatory agencies look for in externally developed standards and it reviews the complaints that have been made about the regulatory use of these standards.

But, the complaints are not all on one side. Those who write standards also argue that the actions of the regulatory agencies inhibit a wholesome relationship between the government and the standards community and even that the agencies do not do an adequate job in promulgating technical regulations. This chapter reviews these allegations and the next chapter describes actions that might improve the relationship between agencies and standards writers that can help lead to the realization of the full potential for the regulatory use of externally developed standards.

Pre-emption. Standards are expensive and time consuming to develop, with the result being that they are only developed if they serve a significant purpose. If those who prepare the standards believe their work will not

have a substantial effect, then they may feel that it is simply not worth the effort and the committee will disband. This problem can arise when an agency issues regulations in a subject area in which a standards organization has been active and the agency does not give as much deference to the existing standards as those who prepared them think is appropriate. The agency may make it quite clear that it alone will make the regulatory decisions in the future so that the standards organization will not have a significant role to play in developing future regulations or in keeping the existing ones up to date. In that case, even if the standards organization continues to develop standards in the future, there is a significant chance that the agency would not use them even as a basis for rulemaking. As a result, standards organization may feel it is no longer making a substantive contribution, and that it will no longer have an effect, so that it stops writing standards. 270/

270/ A closely related problem is that of pre-empting the development and enforcement of standards by state and local governments. Once a standard becomes mandatory at the federal level, the states may stop developing and enforcing innovative regulations, even if they are not pre-empted as a matter of law. For example, some have asserted that states stopped developing new standards with respect to architectural glass once the CPSC adopted a mandatory standard. (Product Safety & Liability Reporter at p. 248). One jurisdiction reported that it had been enforcing its own standard for architectural glass, but stopped when the CPSC

This happened when the Department of Transportation assumed the duties of regulating natural gas pipelines. The committee which prepared the standards on which the Department built its regulatory program disbanded shortly after DOT took over because it no longer would serve a useful function.[271/] However, it later started

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[Footnote continued from page 199]

adopted its standard. As a result, no standard is rigorously enforced because the CPSC cannot devote the manpower to enforcing the standard on the local level. Another person active in standards development pointed out that the states are required to develop standards under a couple of recent statutes, and that concern has been expressed about possible pre-emption by federal agencies so that their work would be in vain. (Conversation with Joe Berke of the National Bureau of Standards.) On the other hand, federal agencies may worry about the effect of a multiplicity of state and local standards on the ability to mass produce products, and hence believe strongly that there should be a uniform national standard that varies only to reflect peculiar, local needs. However, the adverse effect on the development of future standards should continually be borne in mind by an agency.

271/ Hamilton, supra note 13, at p. 1430.

up again, in different form, to prepare a manual which explains the federal requirements and provides advice on how to comply with them.[272/] When the Department of Housing and Urban Development began issuing standards for mobile homes, it based them in large measure on an existing code developed by the National Fire Protection Association. HUD did make clear -- as DOT had also done -- that it welcomed NFPA's advice in the future, just as it welcomed advice from other organizations on the refinement of the regulations.[273/] But, the NFPA committee also decided that it no longer had a substantive role to play -- its work product had been adopted, after modification, and there was no reason to believe that future changes in the code would have a substantial effect on HUD. The committee members felt they could not justify the expense for developing purely advisory materials. As a result, the committee has not met since HUD adopted the regulations.[274/]

On the other hand, the committee that prepared the standards used as the basis for OSHA's machine guarding

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272/ Ibid.

273/ Ibid. at p. IV-45.

274/ Ibid. at p. IV-46.

regulations has remained active. It has revised each of the original standards at least once, and it has written more than twenty additional standards.

The distinction between whether an organization feels pre-empted and hence that it is not worth continuing and whether the committee continues to function may depend on how the group characterizes its own role. If it feels that it is writing the code, then it will likely feel frustrated by having to deal with an administrative agency that now says it cannot delegate to the standards organization the very power that that organization had before Congress directed the agency to occupy the area. The standards that were being written were never intended to be "voluntary" but rather they were always of a regulatory nature. On the other hand, if the committee views itself as preparing standards that are used as advice on how to do something, then the organization will not be threatened by the agency since its standards will serve the same role for the agency that they previously did for private companies and individuals.

So long as agencies cannot, or will not, delegate their authority, the problem of pre-emption will remain. However, agencies should be aware of the potential for undercutting the standards-writing organization to such a

degree that it loses its reason for existence. If the agency makes the conscious decision that it will write all future standards, and has the financial and technical resources to do so, then insisting that the standards organization play at most an advisory role is precisely appropriate. But, the agency should make those judgments with care, especially when it is in the process of adopting a regulatory scheme that is substantially based on the work of the standards organization. The long run interest of the agency may be to develop a close relationship with the standards organization so that it can tap the expertise of the committee on an on-going basis in order to keep abreast of changing technology and to react to any new data that demonstrates a particular need. And, the agency itself may not have the resources to keep the standards, as adopted, current. If the standards organization feels that it will continue to have an important substantive contribution to make to the regulatory program, then it may well continue to develop the needed standards that can form the basis of future rulemaking proceedings.

Failure to Keep Current. All technical standards must be periodically reviewed in light of changing needs and technologies: Time and experience may demonstrate that an

underlying premise was not entirely accurate, or that the expected results did not materialize, or that the technology has developed sufficiently that the standard should be re-written to encompass it, or that the standard was having some undesirable effect such as retarding development without a correlative benefit. Once an agency uses a standard in its regulatory program, it becomes the responsiblity of the agency to make that periodic review.

One of the most frequent complaints of those who prepare standards that are ultimately used in regulation is that government agencies too often fail in that responsibility. For example, Congress was worried in 1970 that the safety standards it directed OSHA to adopt were out of date, and it expected OSHA to revise them at an early time. While OSHA has had several false starts at it, those standards remain unchanged.[275/] In response to the recent Executive Order that requires each agency to make an agenda of regulations that it is going to revise, several agencies proposed

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275/ Harter, supra note 104. Despite much fanfare over putting an end to "nit-picking" after more than a year OSHA has not even completed its rulemaking proceeding with respect to ridding the standards of their undesirable aspects, let alone promulgating revised and updated standards.

revisions of regulatory programs that were built on externally developed standards.[276/] In each case, the agency has failed to keep the standards up-to-date.

This lag may occur for several reasons. One is that after the agency goes through the initial effort of adopting the standards, it then redirects its attention to another problem and no longer focuses on maintaining the regulations it has already issued until a major difficulty arises. A second reason, closely coupled to the first, is that the agency may simply lack the resources. Only a few members of its staff may be trained in the relevant discipline, and they may be busy with developing entirely new regulations and the renovation of an entire code of standards can consume a vast amount of staff time and funds; further, because an agency lacks the practical, day-to-day experience with the use of the standards, it may not be aware of the need to up-date the obsolete standards. A third reason is that sometimes an agency may find it politically difficult to change the existing standards -- at

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276/ OSHA, 43 Fed. Reg. 22920 (1978); Bureau of Materials Handling of the Department of Transportation, 43 Fed. Reg. 23922 (1978); the Federal Railroad Administration, 43 Fed. Reg. 2390 (1978).

least OSHA has.[277/] The problem is that someone may feel benefitted by the existing standard as compared to a newer version, and hence they will oppose the change. In effect, they take the position that they are entitled to the same level of benefit. If those who oppose the change are politically strong enough, the agency will feel hesitant about making the change. For example, the agency may believe that experience has demonstrated that a regulation did not provide a sufficiently high level of protection, and hence it may desire to increase the requirements; but, those who incur the added costs may strongly oppose the revision.

For whatever reason, the failure to keep current is a frequent complaint of those who write standards. They point out adverse effects of obsolete standards in terms of retarding technological growth or not achieving a societal goal as well as might be done by a more modern standard. But, in addition, they argue that the fact that agencies fail to keep standards current also impedes the willingness of those who prepare standards to co-operate with the

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277/ Secretary of Labor Marshall explained that one reason OSHA has not yet completed its "end of nit-picking" campaign is that it is more difficult to revise existing regulations than to promulgate new ones. Washington Post (8/12/78) at p. 2. See, Harter, supra note 104.

government for fear that the standard they write will not be kept current, and that it too will eventually be a retarding force. Several standards writers have mentioned this as the basis for their view that they much prefer to have the standard they write not be adopted by an agency but rather serve as a non-mandatory, truly voluntary standard.

Arbitrary Revisions. An agency may decide to modify a standard before publishing it for comment as part of a rulemaking proceeding. Some standards organizations seem to view this as a natural adjunct of the agency's responsibilities.[278/] For example, the "Recommended National Standards Policy for the United States" prepared by the National Standards Policy Advisory Committee,[279/] provides that "Standards ... may ... be base-line instruments by which government may assert its regulatory authority...."[280/] But those who write the standard are likely to object if they regard the changes that are made in their work product as arbitrary.

278/ Conversations with William Atkison, Secretary of ANS B-11 Committee and Walter Cropper of ASTM.

279/ Supra note 47.

280/ Part I, Introduction.

On the other hand, the National Fire Protection Association has strongly objected to the modification of its standards by a regulatory agency. In part, the objection may simply reflect an inflexibility and a refusal to acknowledge the practical aspects of the non-delegation of regulatory authority. NFPA has always written code-like standards, but the contention has more to it than pride of authorship and these underlying reasons need to be borne in mind when assessing the regulatory use of standards.

NFPA's analysis and resulting position begins by distinguishing between two rough categories of standards. The first type is based on empirical observation. These standards are more or less codifications of something that is directly and objectively determinable. For example, a standard that specifies an anti-slip design for a bathtub can be tested to determine whether or not it substantially reduces the slipperiness of the tubs or guards on machines can be tested to determine if they protect workers from hazards. Thus, these standards can be tested to determine if they fulfill their purpose. The second category of standards are those that are based more on judgment than on any technical information. NFPA argues that "the purpose of safety standardization is to achieve REASONABLE levels of

safety. Not maximum, not minimum, but something in between. Reasonable should be considered as an optimum point on a scale of many possibilities."[281/] It continues that no objective formula exists to determine what is reasonable, but rather that must be a highly subjective judgment. Furthermore, the information and experience on which to base that judgment is diffused throughout several groups of interests. These interests are unavoidably in conflict and no one person, or even a few, can choose a "right" position from among the competing viewpoints. The way to resolve these factors is through broad participation in the subjective judgment. Thus, the argument runs, the consensus process is better designed to reach a reasonable result than is the government rulemaking process in which the technical decisions are made by one or only a few individuals. It follows that in NFPA's view, "a regulation independently developed by [a government agency] may be unduly biased in one way or another."[282/]

281/ Letter from George K. Horvath, Director of Government Relations; capitalization in original.

282/ Statement of the National Fire Protection Association before the Subcommittee on Energy and Power, House Committee on Interstate and Foreign Commerce, hearings on Pipeline Safety, Liquified Natural Gas, and Fuels Transportation Safety, April 13, 1978, at p. 13.

This position has two corollaries: First, the only way to determine the "quality" of a standard is by the process by which it was developed and by nonsubstantive features such as clarity of language and scope. Second, agencies should participate in the consensus process and then adopt -- without change -- the standard that results from it.[283/] On a less theoretical plane, NFPA takes the position that its standards reflect the policy of the organization, and it is bound to support the policy before an agency that is considering using one of its standards.

Moreover, NPFA takes the position that if the agency wishes to make changes in an NFPA standard, then the agency should specifically note the changes that are being made instead of publishing a notice of proposed rulemaking which is largely built on an NFPA standard but with changes sprinkled through the proposal. Thus, NFPA requests that the agency make clear what was developed by NFPA and what was done by the agency itself.[284/]

283/ Ibid. at p. 10.

284/ The licensing provision that is included in NFPA standards provides, "Public authorities and others are urged to reference this document in laws, ordinances, regulations and administrative orders or similar instruments. Any deletions, additions, and changes desired by the adopting authority must be noted separately."

NFPA's position that an agency should participate in the development of a consensus standard and then be bound by the result is unquestionably an extreme view.[285/] But it is built on a concern that is widely shared in the standards

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285/ In our many conversations and debates on the subject, George Horvath and I have jokingly come to call this the "Hard to Swallow George Horvath Doctrine." While I believe the doctrine is very helpful in analyzing the potential relationship between regulation and standards, I do not fully agree with it. First, I believe it does not take appropriate cognizance of the difficulties an agency would have in delegating its authority to a private group which would in fact occur if an agency were to adopt, without change, the standards written under the auspices of NFPA. Nor can it be reconciled with the Administrative Procedure Act which requires the agency to take into consideration the comments received in response to a Notice of Proposed Rulemaking and to make substantive revisions based on meritorious comments. The NFPA doctrine would deprive the public of the opportunity to participate in the rule-making process (although this could be accommodated under the doctrine by submitting the comments to the committee for action). Further, while the regulatory criteria are not easily discernible so that a standard can be rigorously judged against them, they do exist and act as guiding principles for the development of a standard or regulation. Thus, "reasonable" does not exist in the abstract but rather must be judged against the goals of the agency and the particular problem to be solved. Finally, I am not as cynical about the inability of government agencies to reach reasonable results, however reasonableness is determined. The APA and the courts serve to require the agency to develop a sound rationale for its actions, and that in large measure protects against arbitrary action or the feared political decisions, although of course both do exist to a degree. It seems to me that the problems of pre-emption and not revising standards as they become outmoded are larger than the fear that an agency will reach arbitrary decisions in the first instance.

writing community: The consensus process is a better way to develop a technical standard than is the government's rulemaking procedure because the standard can be built from the ground up to reflect a reasonable accommodation of competing interests (including the regulatory criteria) as opposed to only permitting the interested parties to comment on, and react to, a draft prepared by the government; the fear continues that the decisions of the government will not be based on valid technical grounds but rather will reflect back room politics.[286/]

Misuse of Standards. Another complaint that standards-writers sometimes make about agencies is that occasionally a standard will be used inappropriately. Many of the OSHA standards that are now so reviled were never intended to be mandatory, and as a result they contain vague terms or are more design-oriented than they would be if they had been intended to be mandatory. Or, a valid test may be applied in the wrong situation so that it looks as if it is the test itself that is in appropriate.[287/] The fear

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286/ See, Testimony of the Chamber of Commerce of the United States in H.R. 10819, Amendments to the Consumer Product Safety Act, before the Subcommitte Consumer Protection & Finance H. Con. Interstate and Foreign Commerce, 95th Cong., 2d Sess. (2/24/78).

287/ Conversation with Walter V. Cropper, ASTM.

is that this mismatch will then be blamed on the standard, which may be perfectly good for its intended use, and not on the particular use to which it is put.[288/] This is another reason why agencies should be careful to use standards only for their intended purpose, or at least be sure that the standard is appropriate for the use intended by the agency.

Length of Time to Review. An organization which devotes time and resources to developing a standard for regulatory use whether under some understanding with an agency, or simply anticipating that the standard would be used in a regulatory program, may find it disconcerting if the agency takes a long time to review it.[289/] It is only natural to want early comment on the workproduct, and it may

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288/ One of the reasons NFPA gives for copyrighting its standards is to protect against the possible misuse of its standards, since an agency must ask permission to use the standard and NFPA can then determine whether the proposed use is appropriate.

289/ This is the flip side of the complaint agencies sometimes express over the slowness of the standards-development process. CPSC complained that it took longer to develop standards under its offeror process than the 150 day limit (with 60 days for the agency to review the submission) that is permitted in its statute. Bills to remove the time limit have been introduced in Congress. But complex and controversial technical rules also take a long time for the government itself to develop. It would be interesting to compare the length of time it takes under the government's rulemaking process and the consensus process to develop similar standards; my guess is that they would take about the same length of time -- 2-3 years for a final result.

be substantively important so that any resulting criticisms can be taken into account while the memories of the development process are still fresh and the committee assembled. Delay can sometimes be explained by lack of resources on the part of the agency in that it simply does not have the wherewithal to conduct the review. It may also mean that the agency desires to conduct a thorough, from the ground up review of the standard, including such things as the information base and the technical decisions that were made, which of course would consume more resources. This in turn may lead to the objection that the agency is simply second-guessing the committee and that the work should be judged on its own merits, or that the agency is not really reviewing a standard as such but rather is writing its own regulation using the standard only as draft. This, in turn, leads to the problems of preemption.

Conclusion. These sections describe some of the problems of the regulatory use of standards from the point of view of those who write standards. They need to be considered if a harmonious relationship is to be developed and the resources available in the private sector in the

form of externally developed standards are to be fully realized. Ways of meeting these concerns while preserving the duties of the agency are described in the next chapter.

Chapter 16

AGENCY ACTIONS THAT WOULD IMPROVE THE RELATIONSHIP

An agency may take a number of actions that will improve the relationship between externally developed standards and government regulation. By taking these actions, an agency may better harness the resources provided by the standards-development process so that: The standards will be better suited for regulatory use, the agency will be able to use them more easily, and standards will continue to be developed that can be used in the regulatory program or that address a problem sufficiently that no mandatory regulation is needed. Most of the points that follow have been mentioned, at least briefly, earlier. As a result, many are only outlined below. They are collected here in order to provide in one place a discussion of the actions that an agency might take.

Information. A variety of different types of information can help the development of standards that meet a regulatory need, whether they are to be used directly in a regulatory program or whether they will remain voluntary but address an issue otherwise within the cognizance of an agency. An agency can facilitate the development of informed standards by providing this information to those

who develop the standards. This is true whether the group is on-going or was formed solely for the purpose of writing the standard in question, and whether the standard is being developed at the request of the agency or because those who are writing it believe it is appropriate.

o Information As to Which Standards Are Needed. Undoubtedly, the most solid indication of a good working relationship between an agency and externally developed standards occurs when the agency requests a standards-writing group to prepare a standard for use by the agency in its regulatory program or as a nonmandatory standard that will serve as an adjunct to the regulatory program. At least two statutes specifically call for an agency to use externally developed standards in its regulatory program -- the Consumer Product Safety Act and the Medical Devices Amendments of 1976 290/ -- and another recognizes that the agency may wish to make such use. 291/

Over the longer run, if the agency is able to determine an agenda for the next several years that sets

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290/ See, supra p. 22. CPSC and FDA may either solicit offers by outside organizations to develop standards or use existing standards. See 15 USC 82056 and 90 Stat. 550.

291/ See, supra note 155.

out a priority of subject matters the agency wants addressed, standards-writing groups can begin to develop standards in the area of their respective expertise. For example, the Nuclear Regulatory Commission works closely with ANSI's Nuclear Standards Management Board and with the key technical committees actively developing nuclear standards. In this way, the NRC makes known the standards that it feels are most needed and in some cases identifies proposed projects that can be deleted or carried out on a lower priority basis.

A Memorandum of Understanding between OSHA and ANSI calls for the "two organizations [to] develop and implement a mechanism for consultation in the planning of occupational safety and health standards development activities in the areas of mutual concern to the extent consistent with OSHA policy and section 6(g) of the Act."[292/] Private standards organizations have responded to a list of needed standards for medical devices published by the Food and Drug Administration.[293/]

If the agency makes known the standards it needs, then relevant committees can determine whether they are in a position to develop the standards required. Otherwise,

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292/ Donald Peyton, "The ANSI-OSHA Memorandum of Understanding: Culmination or Beginning?" ASTM, Standardization News, May, 1977 at p. 12.

293/ ASTM, Standardization News, June, 1976 at p. 40.

those who write standards will develop standards on the basis of their own determination of need, uninfluenced by the views of the government.

o Technical Information. The agency may either have or be in a position to obtain technical information that would help a committee develop a standard. For example, the agency may be in a unique position to gather accident statistics through some sort of reporting requirement 294/ or the agency may conduct investigations of accidents or specific hazards. 295/ The information may help those who

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294/ The Consumer Product Safety Commission collects accident statistics from selected hospital emergency rooms and tabulates them by category of product causing the injury in its National Electronic Injury Surveillance System. CPSC also conducts in depth investigations of selected accidents. This information can highlight the areas that potentially need attention.

OSHA also collects accidents information, although "OSHA does not have detailed information about which machines cause injuries or about the severity of the injuries which are inflicted. This lack means that OSHA is unable to determine where to concentrate its standards-writing . . . activities." OSHA Task Force Report, supra note 19, at p. 34.

295/ For example, the Department of Housing and Urban Development conducted extensive analyses of hundreds of mobile homes that were part of a disaster relief effort. This information was then used as a basis for determining what problems actually occur in mobile homes. See, Hamilton, supra note 13, at p. IV-42.

write the standard know what the particular problems are that should be addressed in a standard.

The agency may have scientific or engineering information that would help the committee resolve some of the questions presented. For example, the Consumer Product Safety Commission has co-operated with ANSI in the development of three voluntary standards for ladders. CPSC furnished accident information and sponsored research on the engineering aspects of ladders and a study "to assess ladder user behavior."[296/]

The agency may also have laboratory facilities that may be helpful in determining some of the technical issues. Depending on the resources required to provide the information, the agency may have to allocate its efforts to provide the information to those who are developing standards of particular interest to the agency. Existing statistics should be readily available to all, but as the cost goes up -- such as for sponsoring research or using laboratory facilities -- the agency will have to pick and choose in deciding what new research to fund.[297/]

296/ CPSC Mid-year Review of History of Voluntary Ladder Standard, June 8, 1978.

297/ The CPSC Policy statement reflects the necessity from this choice. It provides that "the level of support

[Footnote cont'd. on p. 221]

o Regulatory Criteria. Throughout this report, the need for standards to meet the regulatory criteria of an agency has been emphasized. But the criteria may not be clear from either the underlying statute or prior agency action of a similar nature. In that case, those who prepare standards may not be able to determine how the agency will judge the resulting standard. One of the major complaints about the CPSC's offeror process has been the lack of guidance from the agency as to what it expected. The complaint has been voiced by a traditional standards-writing organization, 298/ and an established consumer

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[Footnote 297 cont'd. from p. 220]

[provided for the development of standard] will be dependent on the degree of Commission involvement. . . ." Three levels of involvement are specified: Liaison in which the Commission responds to requests for existing information; monitoring, in which the Commission maintains an awareness of the development of a standard by conducting inquiries and attending meetings; participation, in which Commission representatives regularly attend meetings and, "under certain circumstances, the Commission will contribute to the deliberations of the committee by expending resources to provide technical assistance including research engineering support, and information and education programs. . . ." 16 CFR §1032.2, as provided in the Policy Statement, supra note 73.

298/ ASTM has complained about CPSC's actions with respect to the standard for book matches. See, Hamilton, supra note 13, at p. 1414.

organization.[299] A former chairman of the Commission acknowledged that it had been a major problem.[300] To meet this difficulty, CPSC provided specific directions for its offeror with respect to miniature Christmas Tree Lights.[301]

In general, it would be helpful if the agency were to outline the major factors it will take into consideration when reviewing the standard. The standards-writing committee can then take them into account when developing the standard, and it can prepare a legislative history that explains why those who wrote the standard believe it meets the criteria of the agency. This may help streamline the agency's review of the resulting standard, and it may reduce the temptation of an agency to simply second-guess those who prepared the standard by imposing ad hoc criteria. As such, it may help the agency

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299/ Consumer's Union with respect to the lawn mower standard. Ibid.

300/ Testimony of John Byington, Consumer Product Safety Commission - Oversight, Hearings before Subcommittee on Oversight and Investigation and Subcommittee in Consumer Product and Finance H. Committee on Interstate and Foreign Commerce, 95th Cong., 1st Sess. (1977) at 358.

301/ One member of the Commission criticizes the offeror process in general and argues that it would be less time consuming for the Commission itself to develop the standard as it is to provide information and guidance for the development of a standard by an offeror. Statement of Commissioner Pittle, Ibid. at p. 248, 252.

in its own regulatory program by forcing it to sort out the factors it will take into account and how it will resolve the various competing issues.

o Procedures. If the agency has strong feelings about the process by which standards that are used in its regulatory program are developed, then it should make that fact known so they can be taken into account during the development process. For example, the agency may logically give far stronger deference to standards that are developed under a rigorous consensus process than to those that are written under a process that does not take adequate account of a diversity of viewpoints. Or, the agency may have particular views on the composition of the committee that drafts the standard.

o Time Limits. If the agency has a need, or desire, for a standard by a particular time, then it should inform the standards-writing committee of that need and the reasons for it. It may be that the time requirement is simply too short for the committee to do a responsible job, since standards are generally developed on a less than full time basis by people who are otherwise busy with other duties, and the committee may have to decline to write the standard. Or, in the more likely case, the committee can

then determine its schedule in order to meet the requirement.[302/]

Funds. Many who participate in the development of standards for regulatory use do so for several reasons: It may benefit their own organization by ensuring that its views are represented during the development process; it may help the individual professionally by meeting with others to solve a problem; and it is worthwhile to contribute their time and expertise to the public good. However, a standards organization or an ad hoc committee will understandably be hesitant to prepare standards directly for regulatory use if to do so requires it to expend a significant amount of its own resources in meeting the particular requirements of the agency. For example, ASTM estimates it spent more than $100,000 of its own funds in developing the proposed matchbook standard under CPSC's offeror process; Consumers' Union also incurred significant expense as an offeror in developing a proposed standard for lawnmowers;[303/] and an offeror that had been selected by CPSC backed out when

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302/ An elaborate flow chart was developed by Underwriters Laboratories to meet the time limits imposed on CPSC offerors; it is published in ASTM, Standardization News, May, 1977 at pp. 26-27.

303/ Hamilton, supra note 13, at p. 1414.

financing could not be arranged.[304/] Thus, if an agency imposes particular requirements on the committee that drafts the standard, so that additional costs will be incurred, or if the standard would not otherwise be developed, it is appropriate for the government agency to help defray the extra costs it imposes in writing the standard. For example, CPSC is contributing funds for the development of the chain saw standard to provide for consumer involvement.

The recent discussion draft of the proposed OMB circular provides:

> The granting of Federal support to a voluntary standards activity shall be limited to that which is clearly in furtherance of an agency's mission and responsibility. Normally, the total amount of Federal support given shall be no greater than that of all non-Federal participants in that activity except where it is in the direct and predominant interest of the Federal Government to develop a needed standard or revision thereto and such development appears unlikely to occur in the absence of such Federal support.[305/]

304/ Ibid. at IV-32.

305/ §6B(8). In the draft that was published for comment, this paragraph read:

[Footnote cont'd. on p. 226]

This draft recognizes that standards development activities may be of direct benefit to the government, and that it is appropriate for the government to pay for those aspects of the process that would not otherwise occur but for the government's need. Even then, it is unlikely that the government will be paying the full costs of the development of the standard, so that in a sense the government will continue to receive a subsidy in the form of the participation by private sector experts. Agencies should therefore be willing, if resources permit, to defray the out-of-pocket expenses incurred because the standard is prepared for regulatory use. These expenses may take the form of paying for the participation of consumers and representatives of small businesses who could not otherwise afford to attend

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[Footnote 305 cont'd. from p. 225]

> The granting of Federal support to a voluntary consensus standards-writing committee shall be limited to that which is clearly in futherance of an agency's missions and responsibilities. The amount of Federal support given shall be no greater than that of all non-Federal participants in that committee. (§b(6), Draft Circular, supra note 42.)

The two drafts differ considerably, in that the draft that was published for comment limits the Federal contribution to no more than half of the total cost of the standard, whereas the more recent discussion draft is not so limited.

several meetings at diverse locations; it may be for the research necessary[306/] to resolve an important technical question; or, in order to save time, it may be to finance staff work such as the preparation of an issue paper, a working draft of a standard that can then be reviewed by the entire committee, or to hire someone to serve part time as a committee consultant.

Monitor the Development of the Standard. An agency may be apprehensive of a standard that is presented to it as a fait accompli -- it may be skeptical about whether the relevant issues were raised and adequately resolved. If that is the case, then the agency may feel more comfortable in using the standard if it monitors its development so that it can be aware of what is happening: who is participating on the standards-writing committee, what issues are being discussed, what technical information is being developed to resolve the issues, whether any significant disagreements have taken place and how they have been resolved. Thus, the agency may wish to send a representative to meetings or to periodically receive narrative reports, copies of minutes of meetings and copies of draft standards considered by the committee.

306/ See e.g., CPSC Policy Statement, §1032.4(b)(4) supra note 73.

If the agency monitors the development of the standard as it evolves, it can then point out any concerns it may have, so that they can be taken into account as the standard is developed, as opposed to having the agency object after the standard is completed.

Participation. Certainly the best way for an agency to keep abreast of the development of a standard and to influence its evolution is to have a representative participate on the committee that writes the standard. Indeed, if the agency plans to use the standard in its regulatory program, then clearly it is an "interested" party as the term is used to define who should participate in the development of a consensus standard. Thus, if the consensus process is rigorously adhered to so that representatives of all interested parties actually participate, it is essential that the agency do so.

The agency representative who participates in the development of a standard can be the vehicle for exchanging the information between the agency and the standards developer. But participation means more than simply acting as a conduit: As a participant in the process, the agency representative can express his views or those of the agency as to why some action is not appropriate, or why some issue should have been considered, or that some

additional action should be taken. These views will then be fully considered by the committee, and if the committee believes they are mistaken, then it can explain why.

Whereas these same benefits can in part be derived simply by monitoring the standards-development process and making comments to those who are preparing the standard, for two reasons it is not the same as actually engaging in the give and take that leads to the ultimate standard. One is that the views may not be taken as seriously as if the representative participates. The other is that, if the agency simply sits back and issues edicts as to what is and what is not satisfactory, the benefits of the standards development process may be inhibited since it is built on a theory of reasoned and structured discussion that is destroyed by bullying. Thus, if an agency is interested in using a standard in its regulatory program, it is highly beneficial if it has a representative participate in the development of the standard so that the views of the agency will be presented and considered.

However, participation carries with it a variety of difficulties. The main problem is whether it is appropriate for the agency representative to vote. Some argue

that voting is not appropriate because the vote of a staff member could be misconstrued as an official agency imprimatur of the standard, when in fact the agency as such has not approved it. And, the argument runs, since the agency is bound to review the standard before publishing it for comment, it may be regarded as a conflict of interest if its representative voted on the standard since its official representative has already indicated approval or disapproval of the standard by means of his vote.[307/]

The counter argument runs that the agency employee, while representing the agency in the process, is speaking only from a staff level and hence in no way commits the

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307/ Hamilton recommended that agency representatives be non-voting. Hamilton, supra note 13, at p. 1473.

CPSC regulations provide, "In no case shall a Commission employee vote or otherwise formally indicate approval of a voluntary standard." CPSC Employee Membership and Participation in Voluntary Standards Organizations, 43 Fed. Reg. 30795 (1978), amending 16 CFR §1031.5(f). They also provide that any lists of committee members that includes a Commission employee must be listed as "advisory, non-voting member" and also carry a disclaimer that "involvement by a Commission employee does not constitute approval or endorsement of the standard." 16 CFR §1032.5(j).

OSHA also prohibits employees from voting, while NRC expects its employees to vote; EPA employees are urged to vote their technical opinions but to point out that the opinions are personal and not necessarily official policy.

agency to anything by voting.[308/] The argument continues, stating that voting is important for two reasons. One is that if a person cannot vote, he is less likely to engage fully in the debates that lead up to a vote. The other is that in the consensus process, negative votes must be resolved, whereas comments only need to be taken into account. Thus, votes carry more clout, and voting will mean the agencies views are better represented and must be given more respect.[309/]

My own view is that the second is substantially the better argument, since even if an agency representative

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308/ The draft OMB circular says that, "Federal agency participation in voluntary standards bodies will not of itself connote agency endorsement of standards approved by voluntary standards bodies." §6b(1), supra note 42.

309/ Don MacKay, an employee of CPSC who read the draft paper, disagreed with the author about the need for voting. He said that views of representatives of a regulatory agency must be perceived as counting even if the representative has no vote, and that an objection by a Federal agency representative would carry all of the respect of a negative ballot.

The OMB Circular provides that, "Federal agency representatives may vote in standards-developing groups unless specifically prohibited from doing so by the head of the agency or his designee." §6b(4) of the published draft. Ibid.

does not vote, the mere fact of the participation can be regarded as engendering the same imprimatur and conflict as voting unless a specific objection is made and publically noted. Thus, not voting carries with it the downside of participation but not the full extent of the benefits.

The concern people have that by voting in the standards development process the agency may generate a conflict of interest may have some merit if the agency representative has a fairly high level position within the agency since then he might be called upon to determine the agency's final position on the standard.[310/] In that case, his vote would likely signify the position of the agency, as opposed to simply the views of staff. Senior management should be in a position to review the final standard in a detached, unbiased manner to determine if the various criteria are met, and that may be difficult if it participated in the nitty-gritty of the development process. Thus, the agency representative should be from the staff and not senior management. Moreover, for similar reasons, the person who represented the agency should, if possible, not participate in the agency's review of the standard. But,

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310/ See, the regulations of CPSC, at 16 CFR 1031.5(c).

because an agency may have only one person with technical expertise in a given field, it may be essential that the person who represented the agency in the development process also prepare the briefing package for the agency. In that case, the staff member should make clear his own positions in the development process and the extent to which they were agreed to, so that the agency management can factor those views into account when reviewing the ultimate standard.[311/]

Length of Time to Review Standard. It can be terribly disheartening to expend a considerable amount of time, effort, and money in the development of a standard for regulatory use only to have the agency take an exceedingly long time to review it. Thus, an essential ingredient of a good working relationship between an agency and externally developed standards is some sort of commitment by the agency to expeditiously review the standards presented to it. For example, within ninety days after an ANSI nuclear standard has been issued, NRC either initiates its implementation--by referencing or endorsing it in whole or in part in a regulatory guide or proposing a revision of a regulation--or advises ANSI of its reasons for being unable to do so.[312/]

311/ See, e.g., CPSC's requirement at 16 CFR §1031.5(i).

312/ Hamilton, supra note 13, at p. 1418.

Contrariwise, OSHA has taken no action whatever to update its standards, even though petitioned to do so by ANSI.

If the agency feels it lacks the resources to conduct an early review, then it should make that fact known to the developer of the standard so that at least the participants will know the reason for the delay. But, the decision that the agency lacks resources may also be based on a preliminary substantive decision that specific aspects of the standard should be checked. In that case, those who prepared the standard may be able to explain in more detail what was done and why so that the concern of the agency may be reduced. It may be possible for the agency to satisfy itself that the standard is acceptable simply by looking at the process by which it was developed -- relying on the consensus process coupled with a good explanation to ensure the development of a standard that can be published as a notice of proposed rulemaking. This could take the form of a presumption in favor of using the standard in the regulatory program once the agency determines the full consensus procedures were followed. In this case, the agency would agree to publish the standard as a proposed regulation (or whatever use the agency was going to make of it) unless these is some reason why it should not do

so. This attitude on the part of the agency would be particularly appropriate in the case of revisions of standards that it has already adopted, which would curtail the difficulty of the agency's permitting standards to become stale even after they have been revised by the committee that developed the standard initially. Since the agency has already determined that the initial standard was satisfactory for its regulatory use, it should be a fairly straight forward matter for it to review the revision and point out any difficulties it may have.

Chapter 17

FEDERAL ADVISORY COMMITTEE ACT

The Federal Advisory Committee Act may, in some instances, apply to standards-writing committees that prepare standards for regulatory use.

The Act defines an advisory committee as

> any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof ... which is ... established or utilized by one or more agencies in the interest of obtaining advice or recommendations ... except that such term excludes ... any committee which is composed wholly of full-time officers or employees of the Federal Government.313/

Thus, if an agency "utilizes" a committee that has at least one non-government employee on it in order to obtain advice or recommendations, then that committee is an advisory committee within the meaning of the Act.

The courts have interpreted this passage in a number of different settings so that the contours of the definition have become more clear. When an agency held meetings with members of the affected industry to discuss proposed regulations, the court held that the group

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313/ 5 App. U.S.C. §3(2).

constituted an advisory committee.[314/] And, when the Department of Transportation consulted with an organization consisting of representatives of state highway officials about some pending regulations, those discussions were also held to be covered by the Act.[315/] But when an agency which had no regulatory authority over a particular subject matter met with an industry group to discuss a voluntary standard developed by the industry, the court held it was not an advisory committee since it was the industry group and not the government that was seeking the advice.[316] And, similarly, informal and unstructured meetings at the White House with major business organizations were not advisory committees because they were not conducted for the purpose of obtaining advice on specific subjects.[317/]

314/ Food Chemical News, Inc. v. Davis, 378 F. Supp. 1048 (D.D.C. 1974).

315/ Center for Auto Safety v. Tiemann, 414 F. Supp. 215 (D.D.C. 1976)].

316/ Consumers Union of the United States, Inc. v. Department of Health, Education and Welfare, 409 F. Supp. 473 (D.D.C. 1976), aff'd without opinion, 551 F.2d 466 (D.C. Cir. 1977).

317/ Nader v. Baroody, 396 F. Supp. 1231 (D.D.C. 1975).

These decisions define the nature of the relationship between the agency and the private sector groups that give rise to their being subject to the Act and indicate that some aspects of developing standards for regulatory use may mean that the standards writing organization could be regarded as an advisory committee. Thus, if a relationship is established in which the agency says it will use, or even seriously consider, the standard developed by the committee, then that committee may be regarded as an advisory committee because it is providing advice to the agency in the form of a recommended regulation. However, if the standards writing committee turns to the agency for advice -- such as technical information -- and there is no understanding whatever that the agency will use the standard in its regulatory program, then a court may apply the reasoning of the second group of cases and hold that the committee is not covered by the Act. Although this problem is not frequently discussed, the Department of Transportation raised the issue in a comment to NFPA as a reason why it would not participate on NFPA committees.[318/]

If the Act does apply, then the advisory committee can be established only with the permission of

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318/ Letter from Alan Butchman, DOT Materials Transportation Bureau to George Horvath, NFPA (July 11, 1977).

the head of the agency and the Director of the Office of Management and Budget.[319] A charter must be drawn up which describes the committee's responsibility, the estimated operating cost, the number of meetings, and the committee's termination date if less than two years.[320] The Act also specifies a number of procedures that must be followed by advisory committees:[321]

-- meetings must be open to the public and announced in the Federal Register;

-- all papers used by the committee, such as working documents and studies, must be available for public inspection and copying;

-- detailed minutes of meetings must be kept that include a list of people who attended, a complete and accurate description of matters discussed and

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319/ 5 App. U.S.C. §8(a). One would suppose that since OMB is urging the use of externally developed standards by government agencies that the Director should not object to further improving that relationship by means of establishing a committee to develop a new standard.

320/ §9(c).

321/ §10.

the conclusions reached, and copies of all reports received, issued or approved by the committee;

-- an officer of the Federal Government must attend each meeting, and he must be able to adjourn the meeting if he determines it to be in the public interest;

-- an officer of the Federal Government must approve the agenda of each meeting.

If the standards-writing committee adheres to the normal consensus process, then these requirements should not cause any great inconvenience, except for having to obtain permission to establish the committee and the prohibition of meeting without a representative of the Government present. However, FACA implies a degree of government control over the committee's activities that is somewhat inconsistent with the theory of the consensus process, and some may object to participating on these grounds.322/

322/ Professor Hamilton and the committee of the Administrative Conference that considered his report recommend that the Act be amended to exclude standards development activities from its coverage.

While the law is by no means settled in this area, those who prepare standards should be aware that an agency may feel it is bound by the act so that it will have to impose its requirements as a condition to establishing an on-going relationship for the development of standards for use in its regulatory program.

Chapter 18

VOLUNTARY STANDARD IN LIEU OF A MANDATORY REGULATION

A standard which is not adopted or otherwise used directly by an agency in its regulatory program may still play an important role in achieving the overall goal the regulatory program was designed to accomplish, and as such the standard can be regarded as an adjunct to the program. It may address an issue that is within the cognizance of the agency, and the industry to which it applies may adhere to it sufficiently to reduce the problem to a level that is not of sufficient magnitude to necessitate the development of a mandatory regulation. Indeed, it is not uncommon to hear that a voluntary standard is a preferred to mandatory regulation. For example, the draft OMB Circular says, "For regulatory applications, participation by Federal agency representatives [in "voluntary consensus standards--developing bodies"] should be aimed at contributing to the development of voluntary standards which will minimize the need for development of mandatory Federal standards."323/ The Consumer Product Safety Commission has said that even though voluntary

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323/ Supra note 42, at §6b(2).

standards cannot usually substitute for mandatory regulations, "a proper combination of voluntary and mandatory standards can have a higher 'payoff' in increased product safety than either mandatory or voluntary activities alone will have."[324/] And, the Commission has defended its failure to issue many mandatory standards by saying that its contribution to the development of voluntary standards is an important aspect of achieving increased product safety.[325/]

Even though as a whole an industry expects to comply fully with the voluntary standard, it may still vastly prefer that the standard remain voluntary as opposed to being adopted and enforced by the agency. This preference may simply stem from a desire to do something voluntarily, as opposed to being told what it must do. Or, of course, the industry may believe that it can shape the standard so that it will be less stringent than if the agency were to develop the requirement. On the other hand, those affected by the standard may feel strongly

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324/ Policy Statment, supra note 73, at 16 CFR §1032.1(b).

325/ See, e.g. Product Safety Letter, August 28, 1978.

that their views and insights are legitimate and the information they possess is better than that available to the agency but that the agency would not pay attention when developing a mandatory regulation. Thus, for them, participation is the key, and they feel the consensus process affords better participation than the government's rule-making process. The industry may also be concerned that if the government writes the standard it will not keep pace with changing technology and it will permit the standard to become obsolete whereas if it remains voluntary it can be updated by those affected.

In these cases, an important part of the motivation to develop a voluntary standard would be to ward off an agency's issuing a mandatory regulation -- even though the purely voluntary standard may be as stringent as the regulation it prevents.

An agency may also prefer the development of a voluntary standard in lieu of a mandatory regulation because it will save the agency important resources that it can then devote to other pressing needs. The agency may believe that it need not scrutinize a voluntary standard as carefully as it would a standard that it would use in its regulatory program so that the resources of reviewing the

standard would also be reduced. And, the agency may feel that the rulemaking process alone would consume more resources than the agency would prefer to spend on the problem. Thus, it may encourage the development of a voluntary standard:

> [T]he Commission believes that by encouraging the development and use of voluntary safety standards, the level of product safety in the marketplace can be increased with a relatively small expenditure of Commission resources, particularly when compared to the resources necessary to issue mandatory safety standards for consumer products. 326/

Before a voluntary standard can be used in lieu of a mandatory obligation, the agency must have some confidence that it will mitigate the problem it addresses sufficiently so that the agency itself will not have to issue a regulation. This in turn requires that the standard must adequately address that problem and that it will be followed by the relevant industry.

Technical Adequacy. If an agency uses standards in its regulatory program, then it must be sure the standards meet its regulatory criteria. However, there is no legal requirement that a voluntary standard which will not be enforced by an agency must meet the full rigor that a

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326/ CPSC Policy Statment, supra note 73, at 16 CFR §1032.1(b).

mandatory standard addressing a similar issue would have to follow.[327/] Therefore, at least theoretically, a voluntary standard will not have to take into account all the various factors that it would if it were to be used as a mandatory standard nor must it be based on as complete information. Rather, purely voluntary standards can be based on almost anything -- "arbitrary and capricious" or not.[328/]

If the issue is such that an agency would seriously consider issuing a regulation to control it, before the agency is likely to defer to a voluntary standard in lieu of issuing a mandatory regulation, it will likely want to know many of the same things about the standard that it would if the standard were to be used directly in the regulatory program. Moreover, it will want to know whether the standard, if followed, is reasonably likely to reduce the problem at hand. Thus, in reviewing the standard, the agency will probably apply a diluted version of the same

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327/ The CPSC policy statement says, "mandatory standards generally can only address unreasonable risks of injury associated with a product but ... voluntary standards can address any level of risk of injury." 16 CFR §1032.1(b). Thus, a voluntary standard could be more stringent, as well as less stringent, than a mandatory standard.

328/ Of course, the antitrust laws will mean that a standard cannot be used for anticompetitive purposes, at least not without a corresponding social benefit.

review process it would apply when considering using the standard directly. The regulatory criteria may not apply with full force, but they were developed as a political response to the problem of concern to the agency so that they should be more or less applied in any standard the agency defers to;[329/] the issues that were considered in writing the standards are still important because they will help the agency decide if the standard will reduce the

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329/ For example, if the aim of the regulatory agency is to stimulate technological development, the agency would not likely defer to a standard that accepts existing technology, although it still might defer to a standard that pushed technology a little but not quite as much as the agency itself would.

The notion is sometimes expressed that externally developed standards do not "push technology" but rather only codify and slightly extend existing technologies. To the extent this is true (no judgment on it is given), it may only result from the inability of "voluntary" standards to force anything, including technology, beyond what the relatively short-term market will support. Thus, purely voluntary standards would be unable to compel a company to develop a new technology to meet a long term need. But that is not an indictment of the process: The technical knowledge that is in the private sector and the method of structured decision making that is used to resolve competing viewpoints can be tapped for purposes of creating new technologies for regulatory purposes. If the resulting standard is used as part of a regulatory program, or as a voluntary standard but with the threat of mandatory regulation looming large, it will gain its "force" from its relationship with the coercive power of the government.

problem; the information that was considered in resolving the questions presented remains important.[330/]

Applying less rigor in reviewing a voluntary standard than one which is to be used in a regulatory program may be appropriate even if the desire is to reduce the problem addressed by the standard to acceptable proportions. But, the agency should be aware that by deferring to a voluntary standard that will in fact be followed by a industry, it may as a practical matter have a significant effect on both the affected industry and the potential beneficiaries of the standard because it will determine the performance of those affected by it. Thus, an agency should actually defer the development of a regulation only if it is fairly satisfied that the voluntary standard comes close to meeting the same requirements it

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330/ The CPSC issues standards that address "unreasonable risks". In determining whether a voluntary standard is sufficient to reduce the level of risk to a "reasonable" level, the Commission will want to know what hazards the standard addresses and why those who prepared the standard believes those hazards will be reduced. See 16 CFR §1032.6(c).

would impose on a standard it would use directly in its regulatory program.[331/]

Adherence to the Standard. A standard may be technically adequate -- indeed it may be perfect for direct regulatory use -- and yet an agency would not feel comfortable in deferring to it because of a fear that it would not be followed sufficiently. Thus, when considering whether a voluntary standard is appropriate in lieu of a mandatory regulation, an important ingredient of that consideration must be an examination of whether the industry will adhere to it.

331/ Of course, if the voluntary standard addresses a question that would not be the subject of a mandatory regulation then the agency is not deferring action and the activity will therefore be wholly within the private sector. In that case, the agency is not in any position to review the standard in a similar fashion. Such a standard can still have important consequences for the agency, since it may reduce a hazard even further, even though the hazard was not "unreasonable" to begin with. Nor is an agency "deferring" to an existing standard when it decides that the issue addressed by the standard is not (or is no longer) of sufficient magnitude to necessitate the development of a mandatory regulation. In that case, the agency is not determining the adequacy of a standard by predicting its future effect, but rather is determining that the standard has already had beneficial results.

The question of under what conditions industry will voluntarily comply with a voluntary standard seems ripe for empirical research. Issues include: When will market pressures and/or threat of liability suits lead to voluntary compliance? What are the effects of industry structure on compliance, including the number of firms in the industry? What if many of the suppliers are foreign? What would be the effect of official agency recognition or endorsement of voluntary standards, including through an agency logo? If the voluntary standard is not followed, what would be the effect of agency threats to regulate or other forms of encouragement to conform to the standard?

Agency Review. If the agency has agreed to defer the promulgation of the mandatory regulation and instead rely on the voluntary standard to meet a particular issue, then the agency will need to periodically review whether the standard is having the desired effect. Thus, if it is a safety standard, the agency will want to review the overall accident statistics to see if the level of accidents caused by the product at issue is within an acceptable range; if it is then the agency can continue to defer. If the level of accidents is higher than is acceptable, the agency may check to see what the experience is with products that meet the

standard to see if the standard itself adequately addresses the hazard. If it does, then the agency may decide that the difficulty stems not from the standard but from the fact that not enough of the industry meets it, in which case the agency may use the standard in its regulatory program. However, in doing so, the agency should inquire whether the failure to adhere to the standard reflects a dissatisfaction with it, or whether it simply was not in a firm's interest to do so; if it was substantive dissatisfaction, then the agency may need to take that into account in deciding whether or not to use the standard as a regulation. If it appears the standard is not sufficient to meet the problem at hand, then the agency will either have to induce the revision of the standard or develop its own regulation.

Implications for standards writers. An agency may refrain from regulating because there is an existing voluntary standard. But first, it must determine whether the standard is adequate and being adequately followed by industry.

The agency is likely to apply a diluted version of the review process it would apply when considering using the standard directly, and there may be some differences in what an agency looks for in voluntary as opposed to mandatory standards.

But in general, an agency will be more likely to defer to a voluntary standard if standards committees develop the standard in essentially the same way, providing the same kinds of information, as for a standard that is to be adopted as mandatory.

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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.)*

The purposes of this report are: 1) to help standards-writing organizations prepare standards that are acceptable to regulatory agencies for use in regulations or as an alternative to regulation; and 2) to suggest how regulatory agencies might improve their relationships with private sector standards organizations. The report describes how standards are used in regulatory programs and discusses the requirements imposed on agencies by administrative law. From this analysis, it is possible to make some general suggestions - for example: organizations writing standards for possible regulatory use should prepare an accompanying rationale and procedural history. The report summarizes complaints of standards organizations about regulatory agencies, and suggests how agencies might improve their relationships with standards organizations.

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)* Administrative law; law; legal aspects of standards; regulation; safety regulation; standards organizations; voluntary standards.

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