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PUBLICATIONS

CONFORMITY ASSESSMENT WORKSHOP: MOBILE MACHINERY

Robert L. Gladhill
Editor

U.S. DEPARTMENT OF COMMERCE
Technology Administration
National Institute of Standards
and Technology
Office of Standards Services
Gaithersburg, MD 20899

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June 1992



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TECHNOLOGY ADMINISTRATION
Robert M. White, Under Secretary for Technology

**NATIONAL INSTITUTE OF STANDARDS
AND TECHNOLOGY**
John W. Lyons, Director

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Introduction

The National Institute of Standards and Technology (NIST) has co-sponsored a series of workshops with various private sector groups to identify the need for coordination and representation of U.S. conformity assessment interests abroad. The first workshop, on Pressure Vessels (NISTIR 4542), was held in January 1991; the second, on Electromagnetic Compatibility (NISTIR 4611), was held in April 1991 and the third, on Wood Products (NISTIR 4771), was held in November 1991.

A fourth workshop, on Mobile Machinery and Lifting Equipment, was held on November 12, 1991, co-sponsored by NIST and the Equipment Manufacturers Institute. The purpose was to explore ways in which the U.S. Government might assist that industry in conformity assessment activities in order to gain acceptance of its products on the most efficient basis in such international markets as the European Community (EC).

The workshop began with a series of oral presentations, followed by a panel discussion. The speakers and panelists were jointly selected by the sponsors. The workshop was publicized in trade media and the Federal Register.

This report presents the proceedings of the workshop and identifies issues considered important by workshop participants.

Executive Summary

The National Institute of Standards and Technology (NIST) conducted a hearing in April 1990 at which a panel of government experts explored possible ways the government might serve the needs of U.S. industry in international standards development and conformity assessment. One of the conclusions in the analysis of the hearing record states that "The government should sponsor or co-sponsor with interested parties from the private sector a series of workshops with various industry sectors..." (NISTIR 4367).

As a result, NIST undertook to schedule a series of workshops. On November 12, 1991, a workshop concerning mobile machinery and lifting equipment was held in Washington, DC, co-sponsored by NIST and the Equipment Manufacturers Institute. The purpose was to explore ways in which the U.S. Government might assist that industry in conformity assessment activities aimed at gaining more efficient acceptance of their products in such international markets as the European Community (EC).

Sixty-two persons attended the workshop. Ten individuals made formal oral presentations (see appendix), and 21 participated in a panel discussion.

The workshop panelists identified the following issues as important to facilitating U.S. interests:

1. Technical standards which are applicable to mobile machinery need international harmonization.
2. Information needs to be adequately disseminated in the United States on standards and directives being enacted by and within the European Community.
3. Where possible, U.S. regulatory bodies should harmonize their regulations with EC directives.
4. Both the private and public sectors in the United States must adopt international standards whenever feasible.
5. Coordination between U.S. private and public sectors in developing U.S. positions on EC 92 issues needs to be improved.

Background

In July 1989, the Department of Commerce (DOC) conducted its first hearings to determine U.S. private sector interests in the European Community's standard development and conformity assessment efforts. DOC's National Institute of Standards and Technology (NIST) conducted a second hearing in April 1990 at which a panel of government experts explored possible government roles to serve the needs of U.S. industry in international standards and conformity assessment. Sixty-five oral presentations were made, and 257 additional written comments were submitted for the record.

One conclusion of the April 1990 hearings record states that "The Government should sponsor or cosponsor with interested parties from the private sector a series of workshops with various industry sectors to specify more precisely the needs for coordination and representation of U.S. conformity assessment interests abroad. Then appropriate systems should be developed to meet those needs and promote effective application of these mechanisms in behalf of U.S. manufacturers and exporters. Particular consideration should be focussed on the division of responsibilities between government and the private sector in a cooperative mode of operation." (NISTIR 4367)

The information obtained from the two hearings was thoroughly reviewed by the U.S. Government's Working Group on Standards and Conformity Assessment (testing, certification, laboratory accreditation, quality assessment, etc.). The Working Group's suggestions were embodied in the recommendations of the U.S. Government's Interagency Task Force on EC-92, the principal EC-92 trade policy development body of the U.S. Government. A section of the task force's three-part plan states that "... in association with the NIST workshops cosponsored with interested private sector groups on general issues of international interests in conformity assessment, the USG should take advantage of this opportunity to seek the potential needs of industry to EC-92 'new approach' testing and certification."

Since that time, representatives of various industrial sector sponsoring organizations, in consultation with NIST officials, organized a series of workshops. The Mobile Machinery and Lifting Equipment Workshop was the fourth in the series.

The workshop was held on November 12, 1991 at the Department of Commerce in Washington, D.C. It featured twenty-one panelists, of whom 10 made presentations. The panelists represented domestic and international trade associations, the U.S. Government, testing laboratories, manufacturers representatives, and code groups. There were a total of sixty-two attendees, including panelists.

The workshop was chaired by Mr. Gerald H. Ritterbusch, Manager Product Safety and Environmental Control G.O., Caterpillar Inc.

Presentation Summaries

The following summarizes the oral presentations made at the workshop. Appendix C contains texts and or notes from all speakers except Ludolph and Kramer.¹

Samuel Kramer, Deputy Director, NIST

In opening remarks Mr. Kramer welcomed the participants. He conveyed the Secretary of Commerce's view that EC-92 presents a top priority challenge to increase the volume of U.S. exports. The U.S. currently exports to the EC alone about \$95 billion annually. The total annual U.S. exports throughout the world constitutes only 7% of the U.S. gross national product (GNP), whereas our major trading partners export approximately 19% of their GNP; Kramer urged that the U.S. figure must be increased.

Mr. Kramer added that (1) increasing U.S. exports to the EC means getting our standards and conformity assessment activities in order, and (2) the U.S. must find ways to assure transparency with our EC partners in standards development and conformity assessment. Transparency will also help us to monitor standards and conformity assessment procedures for products which are regulated in the EC but unregulated here.

Mr. Kramer concluded by urging the panelists to develop recommendations on how the U.S. Government should contribute in solving these and other issues.

Charles M. Ludolph, Director, Office of European Community Affairs, International Trade Administration, Department of Commerce.

Mr. Ludolph presented an overview of the European Community's move to a single market and its impact on the mobile machinery industry. He spoke of the harmonization of regulations, codes, standards and test methods, and conformity assessment procedures.

Christopher P. Marcich, Deputy Assistant U.S. Trade Representative For Europe and the Mediterranean.

Mr. Marcich provided an overview of the importance of a single market in Europe. He spoke of the importance of the workshops to keep government informed of the problems industry encounters so that the government can provide appropriate assistance. He indicated the importance of standards, certification and testing, and expressed the U.S. concern with the EC handling of these issues.

¹One written submission was received, see appendix.

Mr. Marcich discussed possible solutions for U.S. manufacturers to meet EC directives. He indicated that transitional problems may take time to work out. He also discussed government plans to deal with these issues.

Reinhold Nelissen, Manager, Product Compliance, John Deere, Dubuque Works

Mr. Nelissen spoke on behalf of the Equipment Manufacturers Institute (EMI). He stated that EMI has had a long history of promoting global harmonization of standards. He indicated that "harmonization of the many barriers to free movement of goods, services, people and capital should result in economic growth and increased competitiveness."

He presented an overview of conformity assessment activities in the machinery area and contrasted the "old approach" with the "new approach" EC directives. He concluded by stating that "it is essential that the private and public sectors cooperate closely in identifying possible concerns and expressing consensus positions for each industry sector".

Allen Schutte, Chief Engineer, Komatsu Dresser Co.

Mr. Schutte spoke on behalf of the Society of Automotive Engineers (SAE), describing the standards development process within SAE. He discussed how SAE standards become incorporated into international standards documents and indicated that he believes that the voluntary standards process is working, but that there are problems with the current systems. He stated that "The work is important to our society and should be relegated to a priority status to assure continued technological advancement and growth in this country."

Paul Young, Vice President, Engineering, Gehl Co.

Mr. Young provided a profile of his medium sized company which manufactures agricultural and construction machinery. He stated that his company's sales to Europe have significantly increased in past years. Expanding their international presence is one of their key strategies for future growth.

He voiced five areas of concern with EC directives: (1) Understanding the standards; (2) Providing the appropriate resources; (3) Cost of obtaining certification; (4) Testing requirements; and (5) Concern for future requirements.

Mr. Young suggested three action areas: (1) Manufacturers should be able to self-certify their products. (2) The U.S. needs a central point of contact to interpret standards. "Either a trade association like EMI or the government are logical sources to provide this service." (3) The U.S. needs more impact on the development of standards in Europe.

John Brookes, Quality System Certification Services, SGS Yarsley Quality Assured Firms

Mr. Brookes presented an overview of the ISO 9000 series documents and what it means to be certified to those standards. He discussed his company's approach to providing certification to others.

Manfred Bandmann, President, TBG, Germany

Mr. Bandmann stated that Council Directive 91/368/EEC amending the EC Machinery Directive now includes mobile machines, hoisting gear and mining machinery. He described the procedures and implications of the directive.

He stated "As a general rule, it can be assumed that all machinery provided with the EC mark and the declaration of conformity by the manufacturer complies with the directive. But, as long as the European type C standards are not published as harmonized standards, member states can make it more difficult to place machines on the market by demanding proof of conformity with the directive. It is still not clear what practical form this proof will take, but it does make it possible to create bureaucratic trade barriers."

Mr. Bandmann also stated, "It is not yet known whether certain EC member states will try to create new trade barriers by means of costly requirements for proof of conformity, so to get around the harmonization efforts being made by the EC and CEN. In this case we would be grateful, if we could obtain support from the U.S. in the GATT negotiations in overcoming such attempts. This support would also be very welcome in such detailed issues as the approval of working machines for use on public roads."

Berrien Zettler, Deputy Director, Directorate of Compliance Programs, OSHA

Mr. Zettler presented an overview of OSHA and its responsibilities. He stated that OSHA's main concern is the domestic American worker, and traditionally they have not had any international interests. That view is changing, and OSHA IS beginning to consider international issues.

He described how OSHA depends on standards and the long time it takes for them to promulgate new standards. He indicated that OSHA looks forward to the internationalization of health and safety standards.

James D. Schell, Industrial Truck Association

Mr. Schell presented the ITA position, indicating that the ITA basically believes in manufacturers self certifying their products. He said that he was glad to see that the

Government was asking the private sector for input in formulating any actions it planned to take. He indicated that there are many differences between European and domestic standards, and that we need to work to harmonize them as far as possible.

Peter Yurcisin, Senior Vice President, ANSI

Mr. Yurcisin provided an overview of ANSI and its plans for involvement in conformity assessment activities. He called for a combined Government and private sector approach.

Questions from the Audience and Responses

During the workshop, persons in the audience were invited to submit written questions to the panel for response by appropriate panel members. The questions and responses are summarized below.

Does a manufacturer need to be ISO 9000 certified in order to self certify products and affix the CE mark?

No. There is no requirement in the directive for any supplier to be ISO 9000 certified. However, individual customers may require a third party certification to provide them with greater assurance of product conformance.

Is it true that in the U.K. that ISO 9000 certification costs are subsidized by the government?

In general companies must pay for such certifications from their own resources, however, at the moment there are grants available from the Department of Trade and Industry to small businesses to help pay up to 50% of those costs. It wouldn't be surprising if other European Governments tended to lend a hand to their industry.

Does the U.S. Government plan to subsidize U.S. manufacturers to achieve ISO 9000 certification?

No such plans are apparent at the moment. Perhaps trade or professional associations could provide some assistance.

What will be the U.S. Government's role in educating U.S. Industry with regard to EC requirements?

There are various agencies, both public and private sector, currently providing information and education to industry on these matters. The Department of Commerce has been operating the Single Internal Market Information Service (SIMIS) since 1988 (Telephone 202-377-5376), and NIST offers an EC hotline (301-921-4164). Information can also be obtained from ANSI, ISO, EMI, NEMA.

Issues Raised

Based on the panel discussions and the formal presentations, the workshop panelists identified a number of issues presenting challenges for U.S. interests. The following issues were put forth as needing attention and contributions by both private and public sector entities to implement.

1. Technical standards which are applicable to mobile machinery need international harmonization.

Trade between the United States and the European Community is best facilitated when the technical specifications for products are harmonized. Thus, it is imperative that United States expertise be factored into the international standards development process in both ISO and CEN.

2. Information needs to be adequately disseminated in the United States on standards and directives being enacted by and within the European Community.

U.S. interests must have available full and complete information on the progress of the various directives being promulgated by the EC and the standards development work in CEN. Timely dissemination of information is necessary to allow U.S. interests the opportunity to provide input through all available means. U.S. interests also need timely and full information on the requirements of finalized directives and standards so that they are not disadvantaged.

3. Where possible, U.S. regulatory bodies should harmonize their regulations with EC directives.

Due to the global nature of the markets for mobile machinery, the fact that machines are essentially the same, and that the human factors aspects of safety know no boundaries, there is a need to effectively harmonize the regulatory requirements between Europe and the United States of America.

4. Both the private and public sectors in the United States must adopt international standards whenever feasible.

The United States must become part of the international standards community. That means that the United States must shoulder its part of the standards development process, and that once international standards are developed, it must apply these in both the private and public sectors. National, regional and local standards must be harmonized with international standards to the greatest extent possible.

5. Coordination between U.S. private and public sectors in developing U.S. positions on EC 92 issues needs to be improved.

Many forums are available for the presentation of views from the various public and industrial sectors of the United States. Examples are IFAC, DoC Advisory Committee, bilateral trade discussions, GATT and the voluntary standards opportunities of meetings with European standards bodies - CEN/CENELEC/ETSI. There must be coordination between the various U.S. public and private interests so that national positions are clearly presented in the European arena. Partnerships must be formed to fully represent U.S. interests on complicated issues, which require both private and public expertise.

Appendix A

Panel Members and Attendees

Mobile Off-Highway Machinery and Lifting Equipment Workshop
November 12, 1991

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Appendix B
Federal Register Notice

National Institute of Standards and Technology

Improving Acceptance of U.S. Products in International Markets; Opportunity for Interested Parties To Attend and Observe

AGENCY: National Institute of Standards and Technology Commerce.

ACTION: Notice of workshop.

SUMMARY: This is to advise the public that the National Institute of Standards and Technology (NIST) is cosponsoring a Mobile Off-highway Machinery and Lifting Equipment Workshop with the Equipment Manufacturers Institute (EMI). This is the fourth in a series of workshops designed to gather information, insights, and comments to determine conformity assessment related activities of: Declaration of conformity, application of the "CE" mark, technical construction file, requirements for type-examination and notified body responsibilities, (including the testing, certification, accreditation and quality assessment aspects) in which the U.S. Government can assist U.S. industry in gaining product acceptance within other markets such as the European Community (EC).

DATES AND LOCATION: The workshop will be held on Tuesday, November 12, 1991, from 9:30 a.m. to 3:30 p.m. in the main auditorium of the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Dr. Stanley I. Warshaw, Director, Office of Standards Services, National Institute of Standards and Technology, Administration Building, room A-603, Gaithersburg, MD 20899; telephone 301-975-4000, FAX 301-963-2871.

SUPPLEMENTARY INFORMATION: Consistent with the growing importance of international standardization and conformity assessment to the United States private and public sector interests, NIST is cosponsoring a Mobile Off-highway Machinery and Lifting Equipment Workshop with EMI to solicit views and recommendations on how the U.S. Government can assist the Mobile Off-highway Machinery and Lifting Equipment sector of U.S. industry in gaining product acceptance within international markets such as the EC.

Topics for discussion at the workshop are listed below.

1. Which EC requirements for conformity assessment are applicable to Mobile Off-highway Machinery and Lifting Equipment?

2. What specific tasks are associated with the requirements to attain conformity for Mobile Off-highway Machinery and Lifting Equipment?

3. Do the European regional standards (European Standards Organization—CEN or international standards (ISO) which apply to Mobile Off-highway Machinery and Lifting Equipment differ from U.S. standards?

4. To what extent do you feel that U.S. conformity assessment systems for Mobile Off-highway Machinery and Lifting Equipment are adequate for providing test data or other attestations of conformity by the EC member states?

5. Would Mobile Off-highway Machinery and Lifting Equipment benefit from developing mutual recognition agreements between U.S. laboratories or product certifiers and their EC counterparts?

6. How can the U.S. Government better utilize private sector input when developing official positions with regard to possible negotiations with the EC for Mobile Off-highway Machinery and Lifting Equipment regulations?

7. Should the "CE" mark of conformity be made acceptable in the U.S. marketplace? What are the liability implications of such acceptance?

8. Should U.S. regulatory requirements for Mobile Off-highway Machinery and Lifting Equipment be harmonized with EC requirements?

9. Do Mobile Off-highway Machinery and Lifting Equipment need a recognizable mark of conformity? Is a U.S. mark needed?

The workshop will be held on Tuesday, November 12, 1991, commencing at 9:30 a.m. in the main auditorium, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230. To guarantee space, persons who wish to attend and observe the workshop should submit a notice in writing to Dr. Stanley I. Warshaw, Director, Office of Standards Services, National Institute of Standards and Technology, Administration Building, room A-603, Gaithersburg, MD 20899, FAX 301-963-2871. Requests should contain the person's name, address, telephone and facsimile numbers, and affiliation. Requests should be received by October 25, 1991.

Dated: September 13, 1991.

John W. Lyons,

Director.

[FR Doc. 91-22573 Filed 9-18-91; 8:45 am]

BILLING CODE 3510-13-M

Appendix C
Presentation Texts

CHRISTOPHER P. MARCICH

NIST WORKSHOP-- MOBILE MACHINERY

November 12, 1991

- Speaking Notes -

I. OVERVIEW

Importance of Single Market

- harmonization, economies of scale
- now spreading to EFTA, Eastern Europe

USG Activities: 92 Task Force/Working Groups

II. INTRODUCTION

Important role of workshops

- inform government of industry needs and concerns
- ensure that industry has adequate information on which to make informed decisions and provide advice

Key questions set out in Federal Register notice

- particularly interested in views on whether mobile machinery community would benefit from mutual recognition agreements between U.S. laboratories or product certifiers and EC entities
- If so, what role should the U.S. government play? What role should the private sector play? These are key questions we will have to sort out soon

Issue of standards, testing and certification in the single market is extremely important

- for many industries, will determine degree of access to the single market
- the top priority issue for the U.S. Government with regard to the single market in 1991 and possibly beyond
- important that the U.S. Government and the U.S. private sector work together closely to ensure that U.S. interests are addressed satisfactorily

III. U.S. CONCERNS

The broad outlines of the testing and certification system being created by the EC are by now familiar

- set out in the 1989 "Global Approach" document and 1989 Council Declaration
- EOTC system for non-regulated sectors

A few salient points:

Establishing this system is a major undertaking, which is not proceeding as rapidly or as smoothly as originally envisioned by the EC Commission

- if constructed and implemented in an open, non-discriminatory manner, system should facilitate trade flows with the Community and between the Community and its trading partners
- if not done in this manner, could cause disruptions in trade flows, increased costs for U.S. exporters, and result in U.S.-EC trade disputes

System as presently proposed denies foreign manufacturers and conformity assessment entities adequate access

- proposed system requires that conformity assessment must be done by "notified bodies" within the EC
- costly, time consuming, and often duplicative

Potentially places U.S. manufacturers at a competitive disadvantage vis-a-vis European competitors

- must secure access to EC notified bodies
- may limit ability to be first to market with new products

Also prevents U.S. conformity assessment entities from participating in conformity assessment activities for the single market

- for small entities, this is a direct threat to their continued economic viability

U.S. objective:

- secure adequate access (for both U.S. manufacturers and conformity assessment entities) on sufficiently flexible terms
- ensure that U.S. manufacturers and conformity assessment entities receive national treatment in the single market.

IV. POSSIBLE SOLUTIONS

A. SELF CERTIFICATION

As a general rule, to the greatest extent possible, EC directives for the single market should provide for manufacturers self-declaration of conformity with single market standards

- easiest, least disruptive, cost-efficient means
- may not be applicable in all product sectors

B. SUBCONTRACTING

EC currently contemplates subcontracting by notified bodies of certain activities to entities outside the Community

- potentially a partial solution to concerns of U.S. manufacturers and conformity assessment entities
- would reduce costs for manufacturers and provide a certain degree of access for conformity assessment entities
- remains to be seen how much interest there will be in such arrangements on the part of notified bodies in the EC and entities in the United States

Scope of permissible subcontracting activities is unclear and must be clarified

- testing only? and only by bodies authorized to do more than just testing?
- evaluative functions?
- quality systems audits?

Provisions defining permissible subcontracting activities should not be the subject of negotiations between the EC and its trading partners

- should be determined by regulation

Recent EC Commission working document represents an effort to clarify terms and conditions for subcontracting

- a step in the right direction, clarifies some of above questions
- allows for quality systems audits
- allows for the inclusion of quality assessment activities
- also establishes artificial divisions of responsibility between notified bodies and sub-contractors (technical vs. assessment operations)

A flexible approach is needed in order to provide incentive for European notified bodies to enter into subcontracting arrangements. Recent Commission actions are promising.

C. MUTUAL RECOGNITION AGREEMENTS

Possibility exists for the conclusion of mutual recognition agreements between the EC and its trading partners in various sectors

- a potential means for U.S. manufacturers to satisfy conformity assessment requirements for their products in the United States; and
- for U.S. entities to engage in the full range of conformity assessment activities for the single market

As presently contemplated by the EC, the terms and conditions for mutual recognition agreements present a number of serious problems

- involves the assumption of certain obligations by U.S. entities
- implies acceptance of results of activities conducted by EC notified bodies and marks conveyed by them
- meshing of different regulatory systems in which products may be regulated in the EC and not in the U.S. and vice-versa

Key question of role of government versus that of the private sector--EC attempting to project its philosophy onto U.S.

- EC will require a "guarantor" of the competency of "notified bodies" in the United States -- the U.S. government;
- at present, this role is played by the private sector in most sectors
- recent indications seem to suggest that the EC may be willing to accept an "equivalent" guarantor -- i.e., accreditation systems run by the U.S. private sector

An insistence on reciprocity ("balanced situation")

- conditioning access to the single market on reciprocity requirements is unacceptable to the U.S.
- the U.S. market in general, and testing and certification schemes in particular, are open to EC products and firms
- no additional "benefits" exist to be gained by the EC through such agreements

Recent EC Commission paper represents an effort to clarify some of these issues and suggests some flexibility

- some clarification of the notion of "mutual benefits"
- suggestion of the possible acceptance of private sector accreditation programs in lieu of a governmental guarantee of the competence of U.S. conformity assessment entities
- potentially a step backward on the terms of a "balanced situation"
- national treatment should suffice, but indications are EC will apply additional criteria such as looking at technical rules, administrative conditions for market access, and geographical restrictions

These issues will need to be addressed satisfactorily in order for the USG to determine whether entering into mutual recognition agreements with the EC is desirable.

V. TRANSITION PROBLEMS

EC is falling behind in creating the standards required for the single market and constructing accompanying conformity assessment regime -- e.g., decision to postpone implementation of the EMC directive

- European standards-setting bodies (CEN and CENELEC) haven't been able to generate standards rapidly enough to keep up with EC directives
- as a result, deadlines for implementing EC directives have been postponed
- conformity assessment procedures have not yet been implemented on an EC-wide basis
- member states continue to demonstrate a great reluctance to accept each other's notified bodies

Requirements that will prevail during this interim period remain to be determined

- EC must take steps to deal with the potential confusion in order to ensure that trade is not disrupted; and
- to prevent certain member states from using confusion as an excuse to impose/retain protectionist measures

U.S. exporters should be prepared for a period of uncertainty until single market directives are fully implemented

EC has proposed some ideas to make the process more efficient--but probably not in time to make a difference in meeting the 1993 deadline.

VI. NEXT STEPS

U.S. and EC Commission have initiated and maintained a useful dialogue on standards, testing and certification issues

- we plan to continue to use this dialogue to address the problems described above

Expect the Commission to secure a mandate from the EC Council soon to begin negotiations on mutual recognition agreements

- the U.S. government will need to decide whether to negotiate such agreements; and
- if so, for which sectors and under what conditions
- also need to weigh the alternatives, e.g., sub-contracting, self-certification; and
- the interests of various U.S. industries

Finally, we must sort out the respective roles of the U.S. government and the private sector in this process

VII. CONCLUSION

- Issues before the workshop today are of great importance
- We'll need your advice -- and that of other industries -- in order to make informed decisions on these issues
- We look forward to working closely together in the coming months in order to address these issues satisfactorily

NIST - EMI CONFORMITY ASSESSMENT WORKSHOP
ON
EC MACHINE SAFETY AND MOBILE MACHINERY AND LIFTING EQUIPMENT
12 NOVEMBER 1991, WASHINGTON D.C.

Opening Statement by Reinhold J. Nelissen

INTRODUCTION:

Good morning. My name is Reinhold Nelissen, Manager of Product Compliance at Deere & Company. I am here today as current chairman of the Equipment Manufacturers Institute (EMI) External Liaison Committee. EMI is the major US Trade Association representing industry sectors for agricultural, forestry, earthmoving, materials handling and utility machinery. EMI has more than 150 active and 175 associate members.

Overhead 1 "EMI interface with external organizations"

For over more than 20 years, our industry has taken a pro-active role in promoting global harmonization of standards as a way to eliminate technical barriers to trade. The development of national voluntary standards which can be used as the basis for international standards is essential and successful because:

- the laws of physics are global,
- the concern for the health and safety of people and the environment are global,
- the interest in optimizing product safety and performance are global, and,
- our products are marketed globally.

Besides our continued effort in the standards arena, we have worked closely with other organizations such as the Committee for European Construction Equipment (CECE) and different branches of the US Government in monitoring regulatory activities and developed positions in support of the need and benefits of harmonized product requirements worldwide. Our experience affirms that such direct contacts and early involvements on raising issues have been beneficial to all parties concerned.

The EEC deregulation decision and reliance on voluntary European standards for product conformity to assure the free movement of goods in a "Single Market" under the "New Approach Concept" is precisely what we have been promoting over many years and as such, is very much supported.

Overhead 2 "Single Market"

Based upon most recent information, conditional agreement has now been reached to extend this "Single Market" to include all seven EFTA countries. Thus, the Western European market or "European Economic Area" will include 19 countries with some 380 million consumers vs. 250 million in the USA and 120 million in Japan. In the years to come, this alliance has the potential to grow further in a similar fashion as the North American Free Trade Act with Canada and Mexico.

Overhead 3 "Sales/Distribution"

Should we be concerned about a "Fortress Europe"? Neither we nor many other US industry sectors think so because:

- commerce among nations in fact is global
- EC and EFTA members are signatory to the GATT Standards Code
- For our industry, EC Directives adopted under the "Old Approach" refer to ISO standards
- CEN standards proposals are not a "Re-invention of the Wheel", they are based on available and acceptable ISO standards

In summary, harmonization of the many barriers to free movement of goods, services, people and capital should result in economic growth and increased competitiveness.

CONFORMITY ASSESSMENT PROCEDURE:

Now, let's turn to the objectives of this workshop. Conformity Assessment includes a detailed understanding of the implications of applicable directives, safety and performance requirements, CEN standards, declaration of conformity procedures, responsibilities, liabilities, product marking etc.

Because of the limited time available and the fact that other speakers will address specific issues in more detail, my remarks will be limited to providing an overview of how to get a conformity assessment of your products started, suggesting how each of us can contribute to the global harmonization process and identifying some unresolved concerns .

Overhead 4 "Old approach vs. New Approach"

First, it's important to note that agricultural tractor with a speed of up to 30 Km/h are covered by "Old Approach Directives" which are very detailed in their technical safety and performance requirements and for which third party testing and certification is mandatory.. It is encouraging that discussions are in process to raise the transport speed limit up to 40Km/h and mandate "Total Harmonization", which precludes less stringent requirements on a national level. In the event that the "Total Harmonization Concept" for Tractor Type Approval is adopted, industry sees an urgent need for (1) speedy revisions of directives to account for technical progress and (2) a single "clearing house" empowered to respond quickly to requests for deviations on grounds of technical progress and/or specific machine applications, function, safety concerns, etc..

With the noted exception of agricultural tractors, all mobile machinery and lifting equipment are covered under so-called "New Approach Directives" which specify only the general intent of the essential safety requirements and in most instances allow for manufacturers' self-declaration of conformity. The development of complementary technical specifications needed to design and test machine conformity has been delegated to the voluntary standards organization "Committee for European Standards" or CEN.

Overhead 5 "Status - EC Directives"

This overhead shows applicable EC directives to consider if you market your products in any of the 19 countries of the "European Economic Area" after 1992. Besides the Machine Safety Directives 89/392/EEC and 91/368/EEC, which are the principal focus of this workshop, the Commission has also proposed minimum safety requirements for "Used Machinery" in document III/4056/EEC which could have an impact on the manufacturer via our dealers and/or distributors. Directive 90/683//EEC addresses different modules or options in conformity assessment procedures such as manufacturers' self-declaration, third party type approval, third party product verification and quality assurance. The next seven directives listed cover specific safety components or systems and require, for the time being, third party conformity testing and certification.

Overhead 6 "Machine Safety Requirements"

This is a summary of the harmonized safety requirements addressed in the safety directives. There are many additional detailed requirements to consider to safeguard against foreseen and unforeseen hazards associated with the use of products. Contrary to the original objective of the "New Approach", namely to harmonize all technical barriers to trade in a common directive, some people are questioning if these harmonized requirements would also assure for safe operations on public roads. In my opinion, everyone familiar with the current national safety and road regulations must conclude that the harmonized Machine Safety Directives more than adequately address safety concerns for both on and off road applications. Many Europeans from industry, trade and standards associations, safety and test organizations are of the same opinion. EMI stated its position to the U.S. DOC last June for consideration in the continuous bilateral negotiations with the EC Commission at the highest level possible. If this issue is not resolved by the end of 1992, or 1994 at the latest, European as well as outside countries' industries will still be faced with the "Status Quo", that is:

- no free movement of our machines in the 19 countries,
- continued dual testing and declaration of conformity to (1) the harmonized safety directive and (2) different national road regulations which involve a third party test and certification agency and lastly, (*show overhead 7*)
- no realization of the potential cost savings in the conformity process as shown in this overhead.

Overhead 8 "Status - CEN Standards"

Earlier, I indicated that the Machine Safety Directives specify only the intent of the harmonized requirement. The development of the technical details required to design, test and certify machine conformance is the responsibility of the voluntary European Standards Organizations "CEN" and "CENELEC". CEN standards proposals have made excellent use of available ISO standards. Thus, industry sectors with a strong commitment to national and international standards activities should not see major surprises.

The overhead shown here lists all know proposals to be submitted to the first review or inquiry process. Because of EMI's interface with its European counterparts and with ISO through ANSI, we have and intend to continue to provide U.S. industry positions for consideration by the respective CEN Technical Committees.

The CEN standards proposals shown here are defined as "C" type standards because they define machine specific requirements. Article 5.2 of the Machine Safety Directive reads that conformity to the harmonized standards published in the "Official Journal of the European Communities" shall presume compliance with the essential machine safety requirements. If "C" type standards are not mandated by the Commission and are not published in the Journal, which is the current position of the Commission, manufacturers' declaration of conformity could be questioned by any member state due to the unofficial status of the "C" type standards.

Overhead 9 "Construction File"

To show proof of conformity to applicable directives and standards, the manufacturer must establish, maintain and make available, in case of a dispute, a so-called "Technical Construction File" as shown here. This file must be kept for at least 10 years. Although this type of file is currently required to obtain national approvals, the major new requirement is that the manufacturer has to document "internal measures that will be implemented to ensure that the machinery remain in conformity". This could be interpreted to require registration to ISO 9000 or the equivalent European EN 29000 standard for quality assurance, especially if the manufacturer chooses third party approval.

Overhead 10 "Sample - Declaration of Conformity"

This overhead shows a sample document for declaring conformity of machine and machine systems or components to the applicable directives and standards. It should be noted that the person signing the declaration must be a resident - not a citizen - of one of the Community countries. The signer is the official contact for member country authorities in case of questions and is legally responsible in case of non-compliance.

Overhead 11 "CE Mark"

Machine Conformity in case of self-declaration or third party testing and certification is indicated by the CE Mark shown here. The intentional difference between the two marks is undesirable because:

- it does not add to the safety of the machine and
- it may cause a barrier in regard to marketing the machine

Overhead 12 "Effective date"

I believe that most applicable technical directives and standards will be in place to take advantage of the harmonized European Economic Area as of 1 January 1993. For machines where this is not the case, the manufacturer continues to apply for national approvals until 1 January 1995 when Declaration of Conformity and application of the CE Mark becomes mandatory.

CONCLUSION:

Overhead 13 "Concerns"

In conclusion, EMI members welcome and support the harmonization efforts in Europe. Nevertheless, to keep the frontiers between Europe, North American and other World Regions as accessible as possible, I think it is essential that the private and public sectors cooperate closely in identifying possible concerns and expressing consensus positions for each industry sector.

Our concerns with the EC Conformity Assessment Procedures so far pertain to:

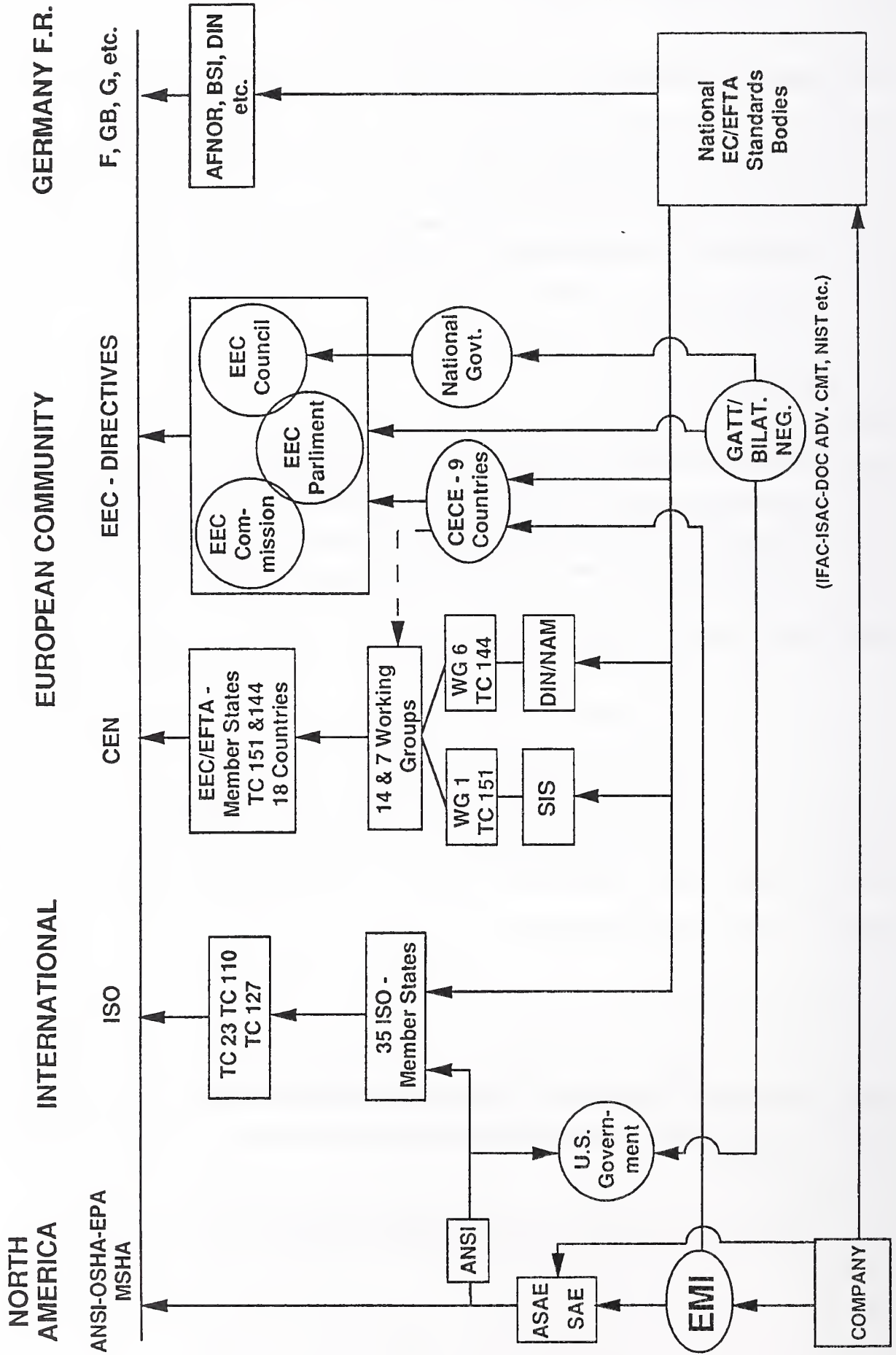
- (1) Completion of all Old Approach Directives for agricultural tractors with a transport speed of up to 40 Km/h.
- (2) "Total Harmonization" of the agricultural tractor type approval process.
- (3) Harmonization of all national safety and road regulations by the New Approach Directive for Machine Safety and Mobile Machinery and Lifting Equipment.
- (4) EC Commission Mandate for "C" type standards and publishing them in the Official Journal.

Overhead 14 "Act Now"

My presentation outlined only the general procedure for conformity assessment. Other speakers, I am sure will, provide additional and more detailed information. However, in order to succeed in exporting to and staying in the large European Economic Area, we must "ACT NOW" by: - see overhead -.

Good Luck and thank you very much for your attention.

EMI INTERFACE TO PROMOTE GLOBAL HARMONIZATION OF STANDARDS FOR EARTHMOVING/FORESTRY MACHINES



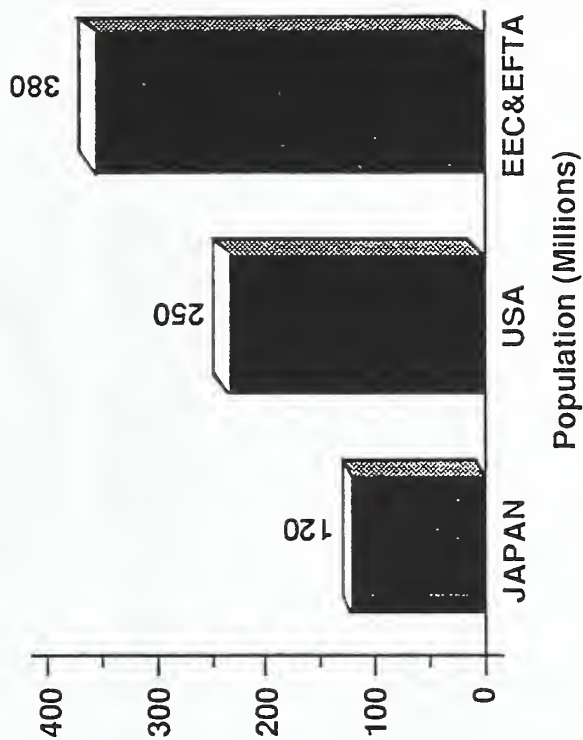
SINGLE MARKET - WESTERN EUROPE

EEC COUNTRIES

- BELGIUM
- DENMARK
- FRANCE
- GERMANY, FR
- GREECE
- IRELAND
- ITALY
- LUXEMBURG
- NETHERLANDS
- PORTUGAL
- SPAIN
- UNITED KINGDOM

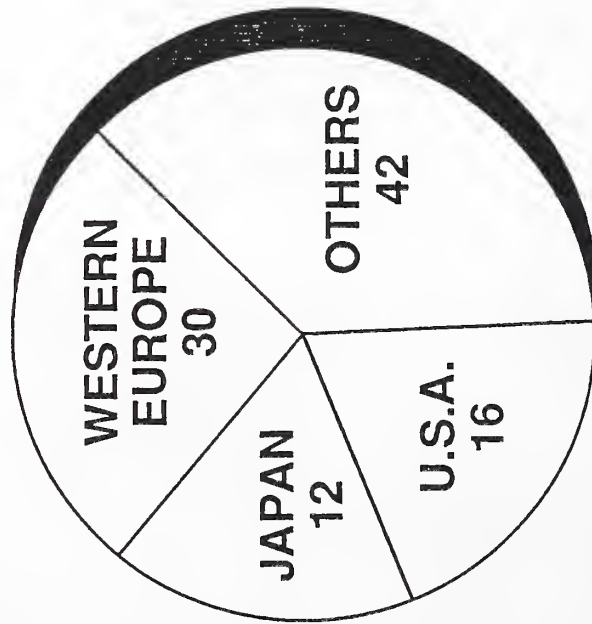
EFTA COUNTRIES

- AUSTRIA
- FINLAND
- NORWAY
- SWEDEN
- SWITZERLAND
- ICELAND
- LIECHTENSTEIN



FY 1990 - WORLD SALES/SHIPMENT % DISTRIBUTION

Agricultural Tractors



Earthmoving Machinery



EC CONFORMITY ASSESSMENT FOR AG/FORESTRY/CONSTRUCTION/LAW AND GARDEN MACHINERY

<u>Products</u>	<u>Safety Directives</u>	<u>Safety/Road</u>	<u>Remarks</u>
Tractors <30 km/h	No	Yes	Type approval required
>30 km/h	No	Yes	Tentatively type approval like <30 km/h
Combines	Yes	No*	Self-declaration
Forage Haravesters	Yes	No*	Self-declaration
Construction	Yes	No*	Self-declaration
Special Forestry	Yes	No*	Self-declaration
Lawn & Garden	Yes	No*	Self-declaration
Other Self-Propelled/ or Mobile Machines	Yes	No*	Self-declaration
Other Machines	Yes	No*	Self-declaration

*NEED FOR SEPARATE ROAD DIRECTIVE UNDER DISCUSSION

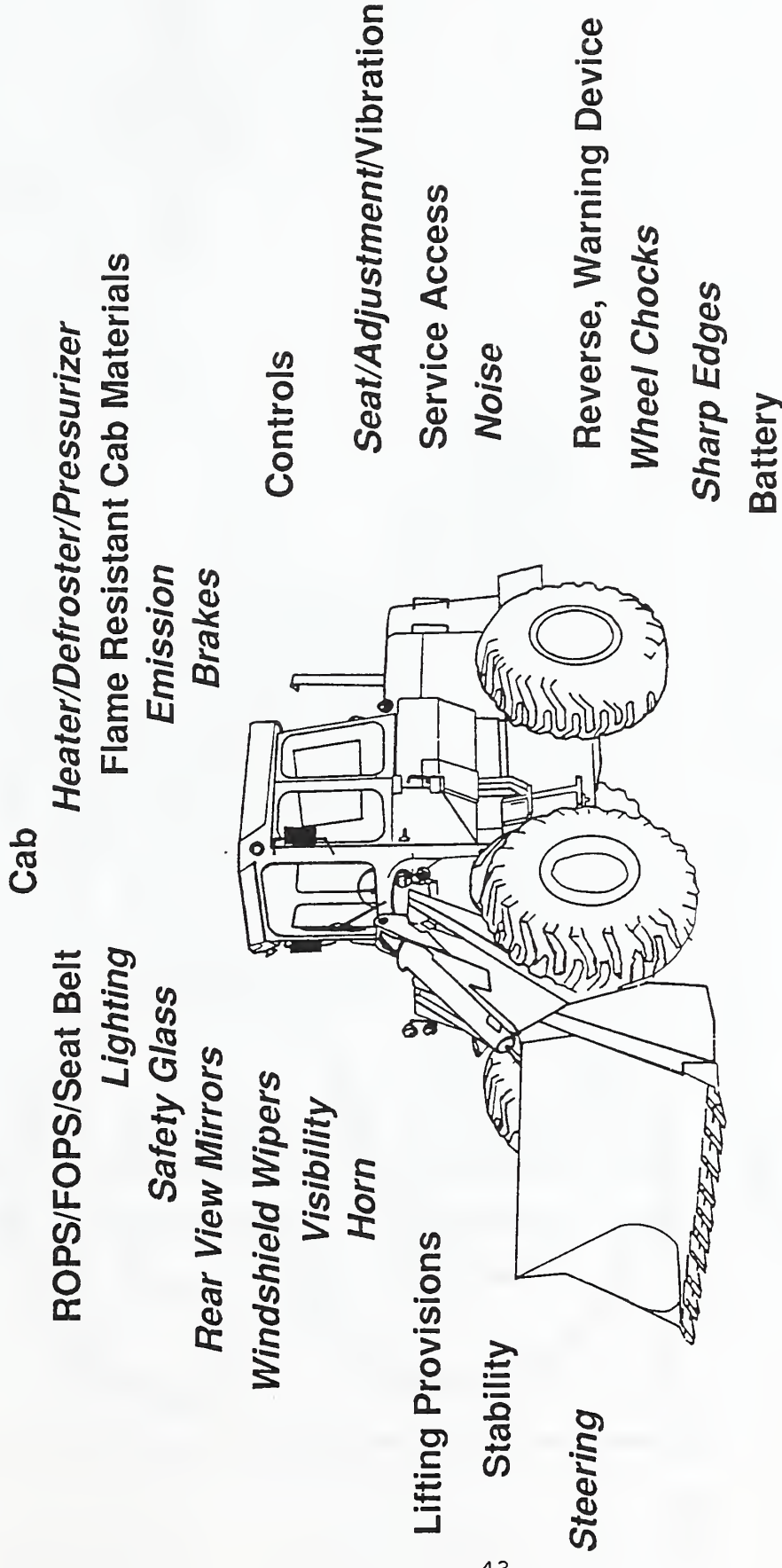
EC 92, STATUS LOG OF EC DIRECTIVES FOR
EARTHMOVING, AGRICULTURAL AND FORESTRY MACHINES

EC DIRECTIVES:	EFF. DATE	TITLE
• 89/392/EEC	31DEC92	Safety of Machinery
• 91/368/EEC	31DEC92	Amending 89/392/EEC and annex "Mobile Machinery and Lifting Equipment"
• III/4056/EEC	?	Proposal for "Safety of Used Machines"
• 90/683/EEC	31DEC92	Modules, Testing and Certif. - Global Approach
• 86/295/EEC *	30MAY90	ROPS, Earthmoving Machinery
• 86/296/EEC *	02JUN90	FOPS, Earthmoving Machinery
• 86/662/EEC *	24DEC88	NOISE Directive, "Static Method - EMM
• 89/514/EEC *	01JAN95	NOISE Directive, Dynamic Method - EMM
• 89/336/EEC *	01JAN92	Electro Magnetic Compatibility
• 87/404/EEC *	01JAN92	Simple Pressure VEssels
• 91/338/EEC	31DEC92	Cadmium, Restriction on marketing and use
• Com (91)145 F	01JAN93	"CE Mark of machine conformity"

* Third Party Testing and Certification mandatory

EC MACHINE SAFETY REQUIREMENTS

(89/392/EEC & 91/368/EEC)



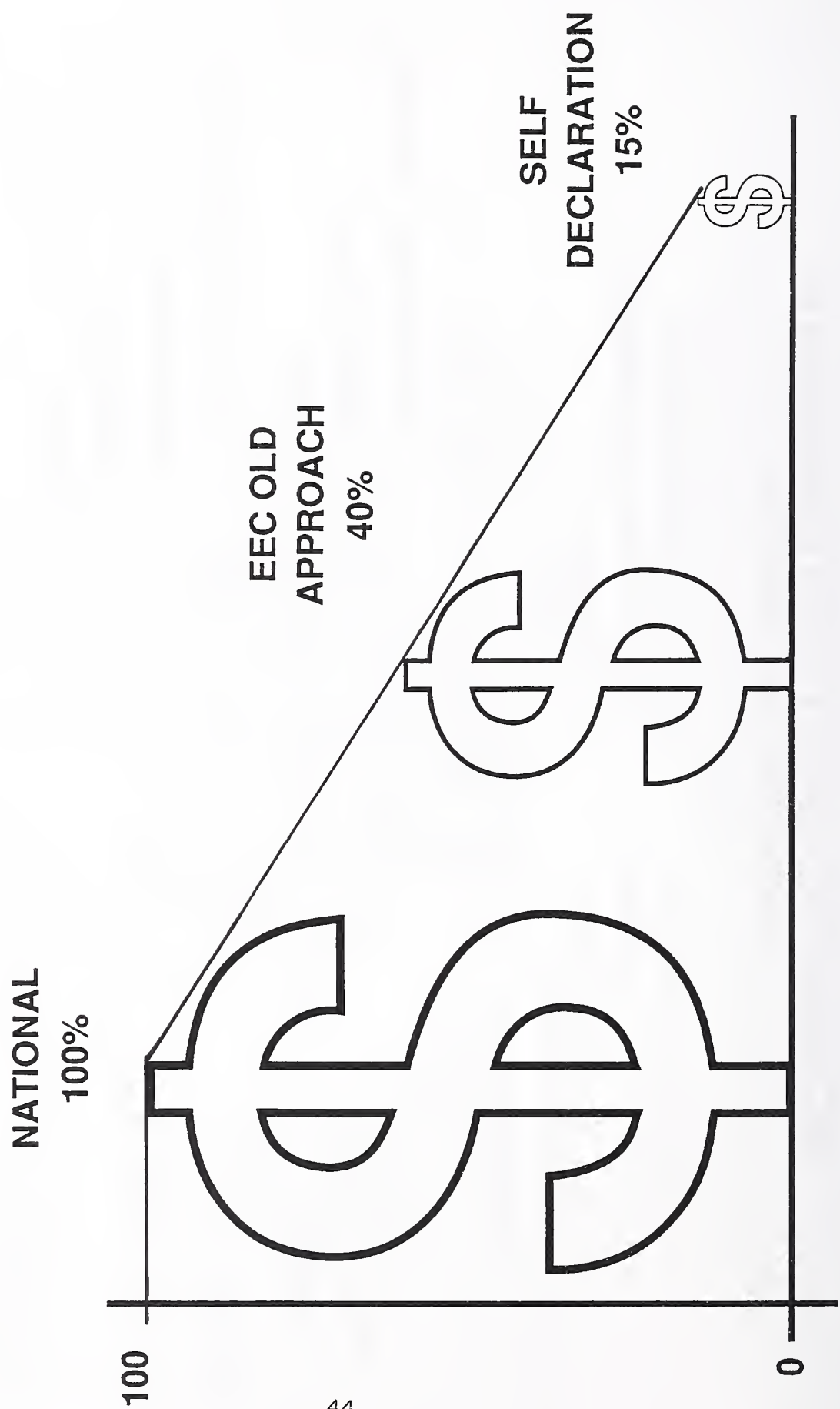
Self-Declaration
or Type Approval,
CE Approval Mark

Access
Emergency Exits

NOTE: Items not addressed

- Travel
- Mass
- Dimensions

HOMOLOGATION COST FOR EC COUNTRIES



EC 92 . STATUS LOG OF CEN STANDARDS FOR

EARTHMOVING, AGRICULTURAL AND FORESTRY MACHINES

CEN TC151 WG1 "EARTHMOVING MACHINERY - SAFETY":

- pr EN 474 Part 1 General Requirements
- Part 2 Specific Requirements for Tractors
- Part 3 Specific Requirements for Loaders
- Part 4 Specific Requirements for Backhoe Loaders
- Part 5 Specific Requirements for Excavators
- Part 6 Specific Requirements for Dumpers
- Part 7 Specific Requirements for Scrapers
- Part 8 Specific Requirements for Graders
- Part 9 Specific Requirements for Pipelayers
- Part 10 Specific Requirements for Trenchers

CEN TC 151 WG5 "ROAD CONSTRUCTION MACHINES - SAFETY:

- pr EN 500 Part 1 General Requirements
- Part 2 Specific Requirements for Road Milling Machines
- Part 3 Specific Requirements for Soil Stabilization Machines
- Part 4 Specific Requirements for Compaction Machines
- Part 5 Specific Requirements for Joint Cutters
- Part 6 Specific Requirements for Paver - Finishers

CEN TC 144 "AGRICULTURAL AND FORESTRY TRACTORS AND MACHINERY:

- WG1 N 56 General Safety Requirement
- WG3 N 35 Machines and Trailers - Vine Shoot Tipping Machines
- N 36 Slurry Tankers
- N 37 Manure Spreaders
- N 38 Rotary Mowers, Flail-Mowers
- N 41 Pick-Up Balers
- N 42 Silage Cutters
- N 43 Soil Working Machines with Powered Tools
- WG4 N 44 Portable/Pedestrian controlled Machines - Motor Hoes w/ andw/o drive wheels
- WG6 N 45 Forestry Equipment - Chain Saws
- N 46 Log Splitters
- WG7 N 34 Lawn and Garden Machinery - Powered Lawn Mowers and Garden Tractors

TECHNICAL CONSTRUCTION FILE OF CONFORMITY

(91/368/EEC ANNEX V)

- 1. DRAWINGS:**
 - A. Overall machine configuration**
 - B. Control circuits (brake, steering/hydr. schematics)**
 - C. Drawings/calculations required to check machine conformity**

- 2. LIST OF:**
 - A. Essential requirements of applicable directives**
 - B. Standards and other technical specifications used in design**
 - C. Description of methods adopted to eliminate hazards**
 - D. Test reports/certificates in support of conformance**
 - E. Operator Manual**

- 3. Description of the internal quality control methods to ensure that the product remains in conformity**

- 4. Maintain file for 10 years after last machine is manufactured**

EXAMPLE OF EC DECLARATION OF CONFORMITY

(91/368/EEC ANNEX II)

I, the undersigned, *
 (Surname, First name and Address)

hereby certify that the machine specified hereunder:

1. Category:
2. Make:
3. Type:
4. Type serial number of equipment:

Conforms in all respects to the harmonized requirements as shown in the table below:

In the case of EEC type approval	
No	Date
.....
.....
.....
.....
.....
.....

Done at
 (Date)

.....
 (Signature)

.....
 (Position)

*SIGNER MUST BE RESIDING IN ONE OF THE EC MEMBER COUNTRIES

"CE" MARK OF CONFORMITY


(Com (91) 145 Final)

SELF-DECLARATION

CE 93 

YEAR MARK IS AFFIXED

3RD PARTY DECLARATION

CE XXX 93 

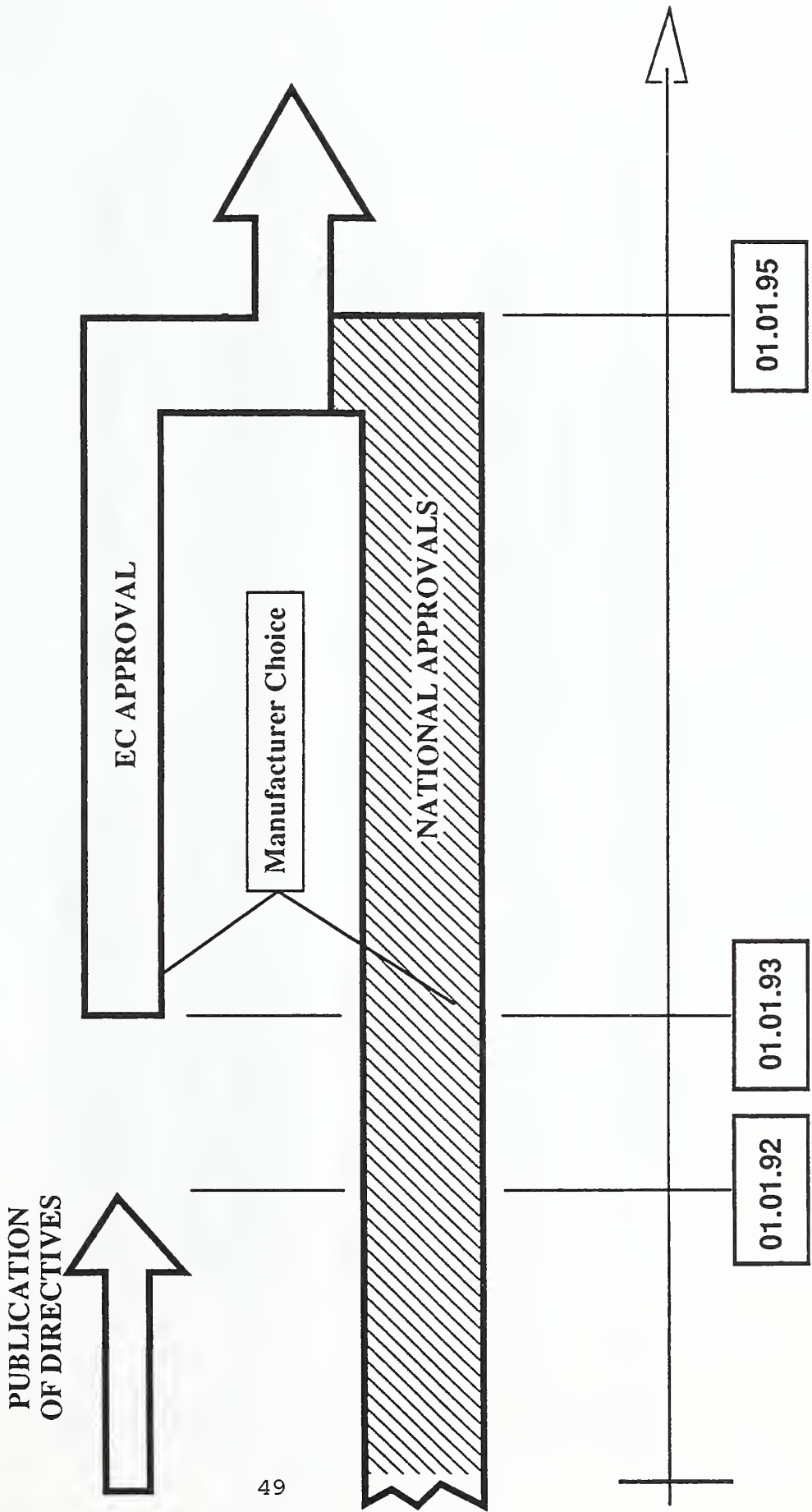
IDENTIFICATION NUMBER
OF NOTIFIED BODY

EC Mark graphic characteristics:

1. Letter style: Semi-circular letters.
2. Height: 5 mm or greater.
3. Thickness: One-fifth of height or greater.
4. Length of bar inside the "E": 80 percent of the outer radius of the semicircle or greater.

EFFECTIVE DATES FOR DECLARATION OF CONFORMITY

(ARTICLE 13, CLAUSE 2 OF 91/368/EEC AMENDING 89/392/EEC)



MAIN UNRESOLVED CONCERNS

- **Completion of all Old Approach Directives for agricultural tractors with a transport speed of up to 40 Km/h**
- **"TOTAL HARMONIZATION" of the agricultural tractor type approval process**
- **Harmonization of all national safety and road regulations by the New Approach Directive for Machine Safety and Mobile Machinery and Lifting Equipment**
- **EC Commission Mandate for "C" type standards and publishing them in the Official Journal**

"ACT NOW" TO SUCCEED IN THE SINGLE MARKET

Arm yourself with information (Directives, Standards, Contacts, etc.)
Consider the implications for your business (Technical, Manufacturing, Marketing, Financial)
Take part in standards work (National, Regional, International)

Note changes you desire
Organize their implementation (CEN, ISO, EMI, U.S. Government)
Watch out for new developments (Amendments affecting Conformity Assessment)

VISUALS

Peter Yurcisin

ANSI

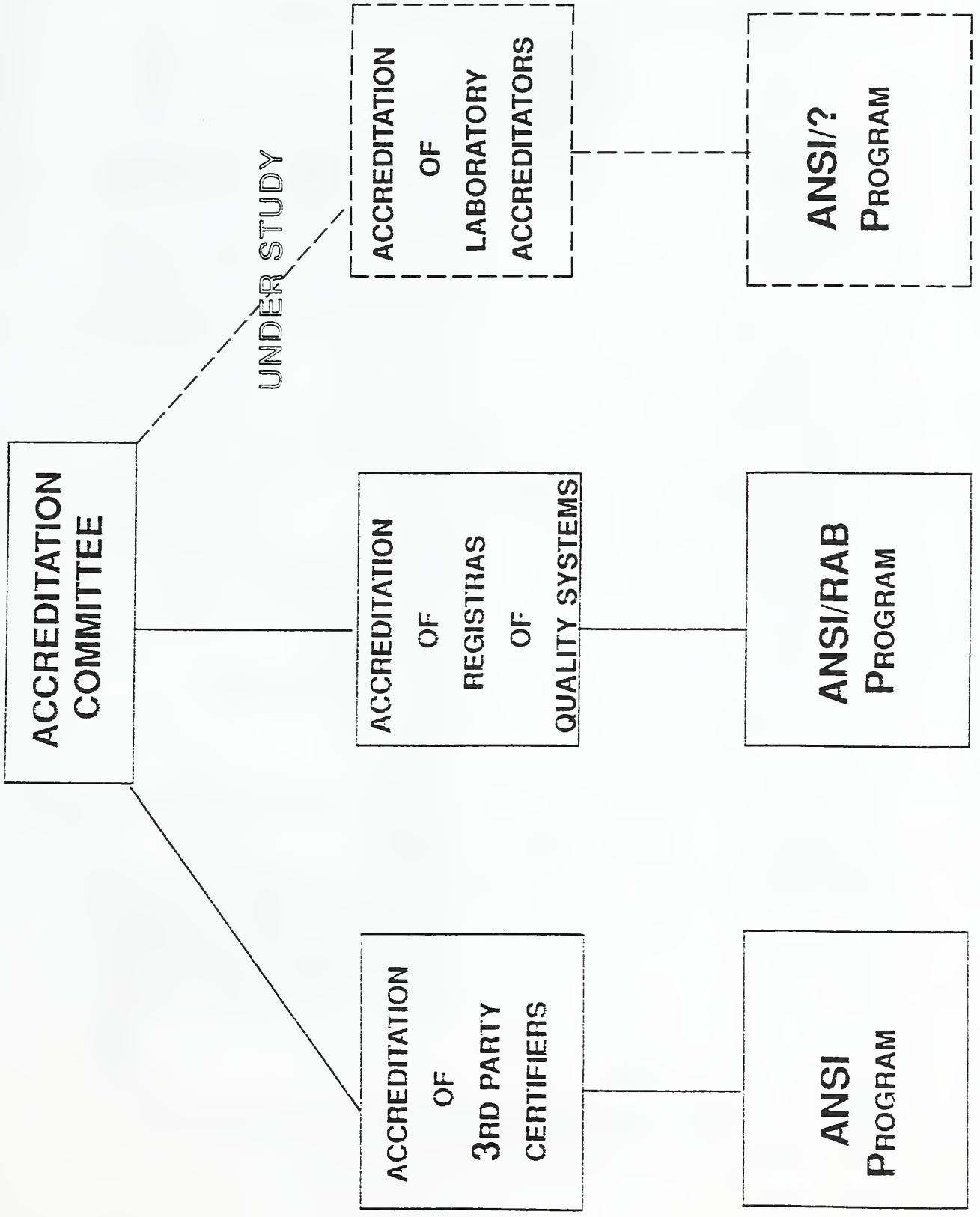


Figure 1A

1991-10-10

UP-DATED LIST BASED ON ANNEX TO CIRCULAR LETTER
120/IMPL.INST.9000 OF 1991-07-18

DIRECT ADOPTIONS OF ISO 9000 SERIES

Algeria	Malaysia*
Australia*	Netherlands
Austria*	New Zealand*
Belgium	Norway
Canada*	Philippines*
China*	Poland*
Chile	Portugal*
Columbia	Romania
Cuba	Singapore*
Cyprus	South Africa*
Czechoslovakia	Spain*
Denmark	Sweden*
Finland*	Switzerland*
France*	Tanzania
Germany*	Thailand*
Greece*	Trinidad/Tobago*
Hungary*	Tunisia*
Iceland	Turkey*
India	United Kingdom*
Ireland*	USA*
Israel*	USSR*
Italy*	Venezuela
Jamaica	Yugoslavia
Japan*	Zimbabwe*

Total: 48 countries

* Countries in which, to ISO/CS knowledge, there are one or more assessment and registration schemes in operation (31 countries as at 1991-10-10).

COUNTRIES ADOPTING ISO 9000 STANDARDS AS NATIONAL STANDARDS



KEY: ISO 9000-1-2-3-4:

Algeria, Australia, Austria, Belgium, Canada, China, Columbia, Cyprus, Czechoslovakia, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, India, Ireland, Italy, Japan (Fall, 1991), Mexico, Netherlands, New Zealand, Norway, Philippines, Poland, Portugal, Romania, Singapore, South Africa, Spain, Sweden, Switzerland, Tanzania, Thailand, Tunisia, Turkey, United Kingdom, USA, Venezuela, Yugoslavia, Zimbabwe, The European Community

ISO 9001-2-3:

Jamaica, Malaysia

ISO 9001-2:

USSR

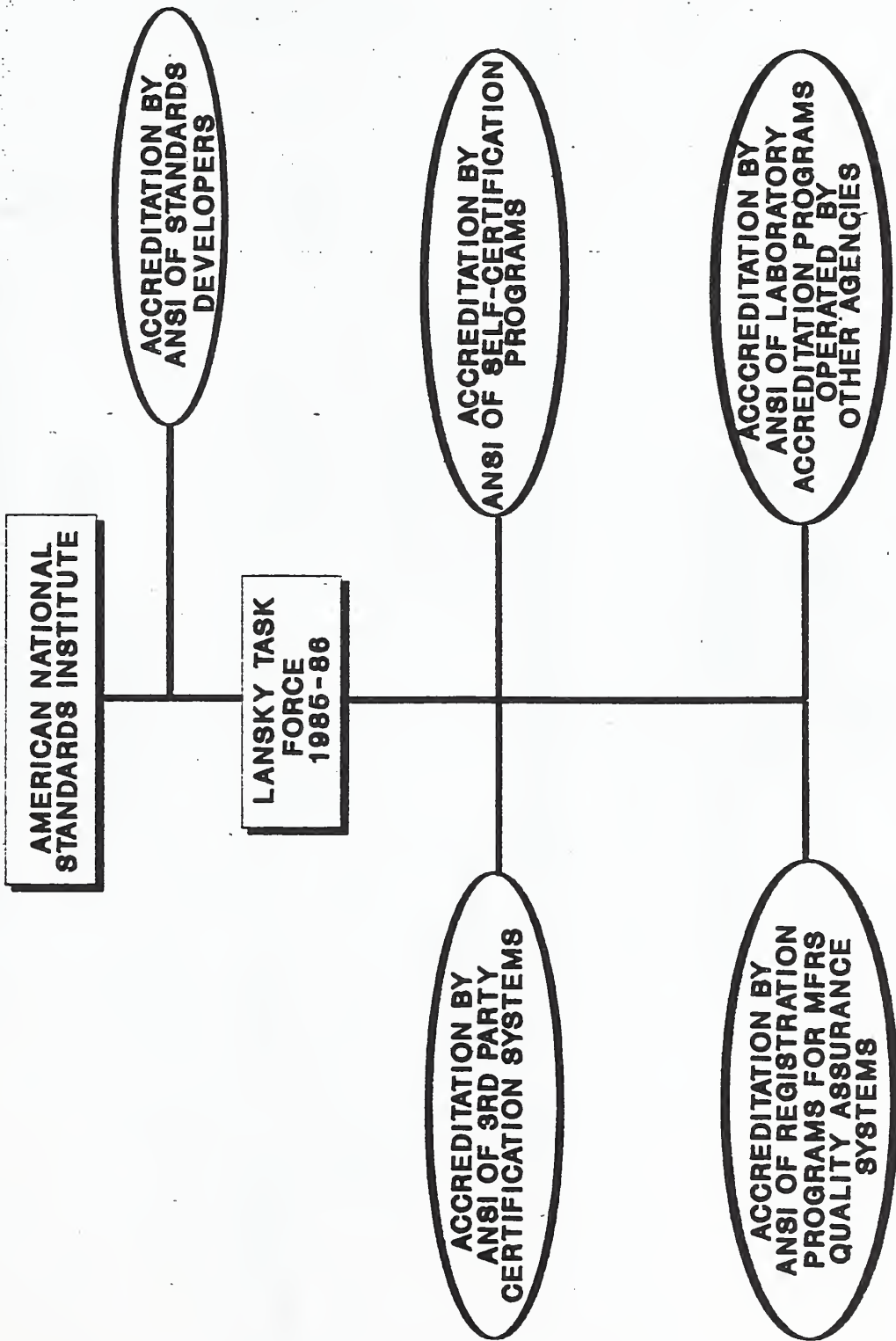
September, 1991

* Equivalent Standard

© Copyright 1991, Robert Peach and Assoc., Inc.
LaGrange Park, IL, USA; (708) 579 3400

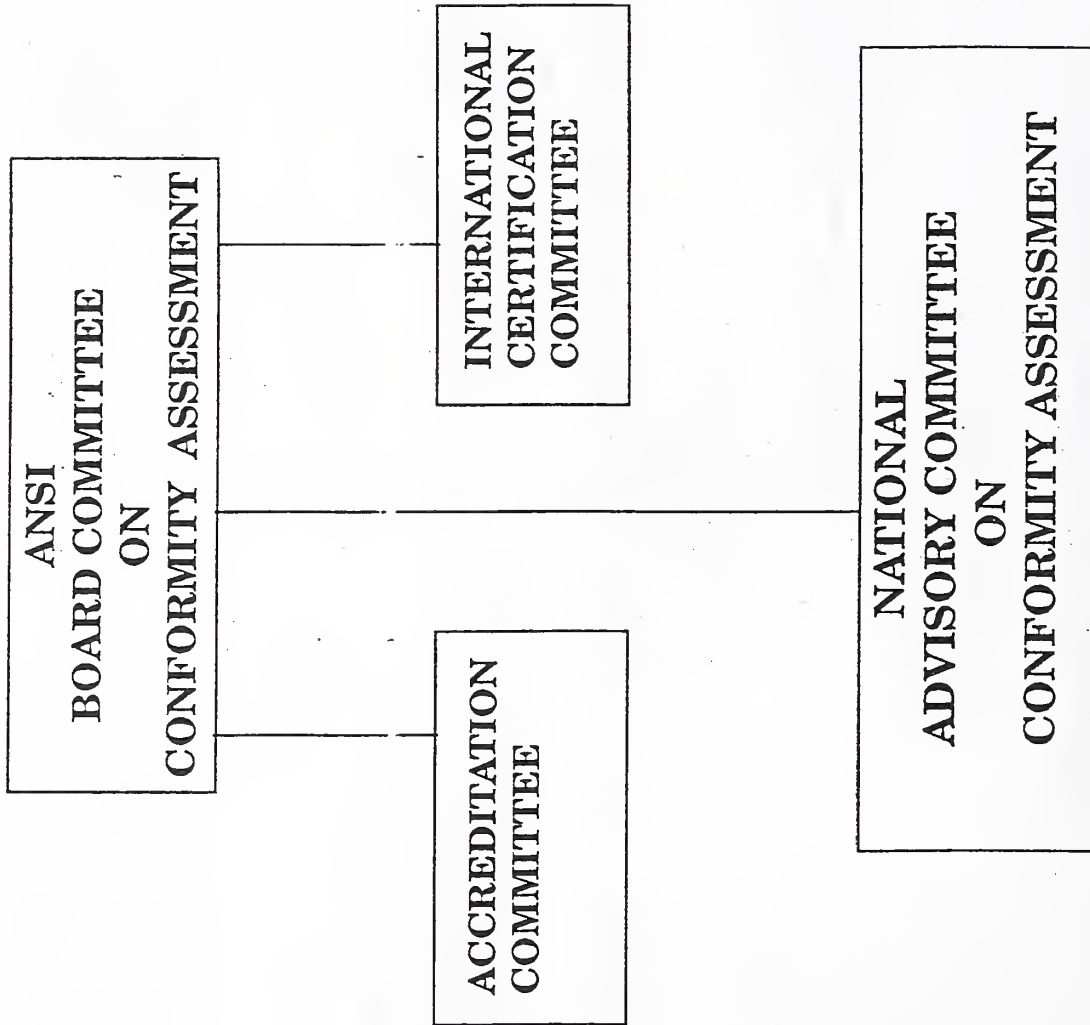
**ISO ENLIGHTENS
THE DARKENED WORLD**

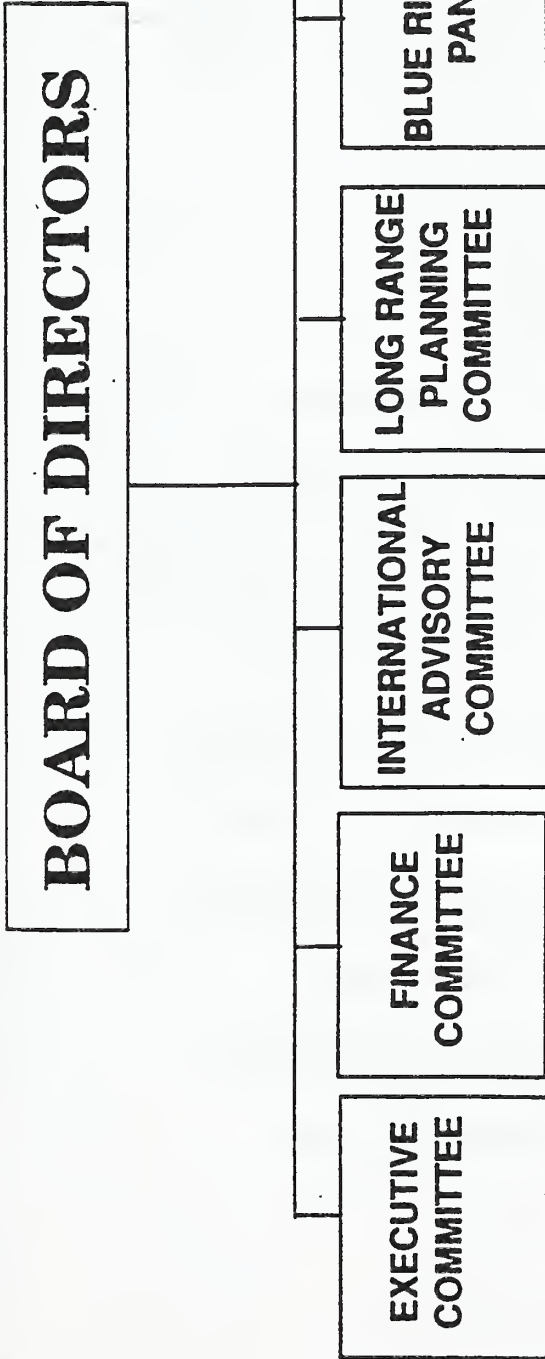
OVERVIEW OF ACCREDITATION



**CONCEPT FOR STRUCTURING
ANSI CONFORMITY ASSESSMENT
ACTIVITY**

FIGURE 1





ANSI BOARD REFLECTS VARIED INTERESTS SUCH AS:

- COMPANIES
- ORGANIZATIONAL
- GOVERNMENT
- CONSUMER
- ACADEMIA

ANSI/GOVERNMENT RELATIONSHIPS

Consumer Product Safety Commission

Department of Commerce

Department of Defense

Department of Education

Department of Energy

Department of State

Environmental Protection Agency

Federal Communications Commission

Food & Drug Administration

General Services Administration

Department of Housing and Urban Development

National Aeronautics and Space Administration

National Institute of Standards & Technology

Nuclear Regulatory Commission

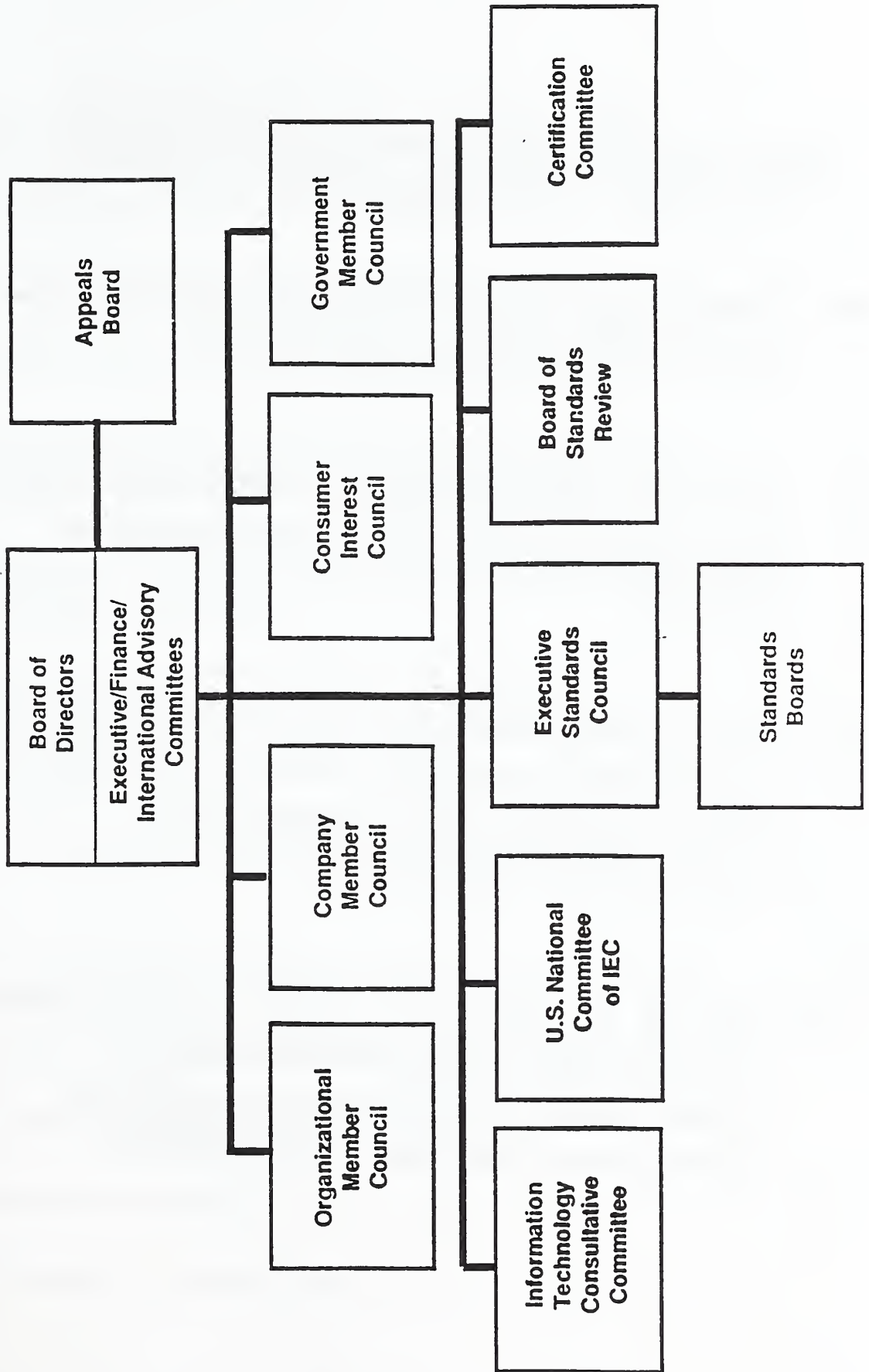
Occupational Safety & Health Administration

Rural Electrification Administration

Treasury

U.S. Trade Representative

ANSI FEDERATION ORGANIZATION



TECHNICAL ADVISORY GROUPS (TAGs)

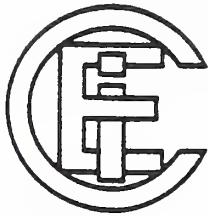
- **Participate in ISO technical activities through ANSI**
- **Advise ANSI on how to vote on international standardization issues**
- **Are responsible for selecting qualified people to represent U.S. interests at international technical meetings**
- **Work to ensure that the process of reaching U.S. positions on international issues reflects due process and consensus**

BENEFIT OF U.S. ANSI ADMINISTRATION OF INTERNATIONAL SECRETARIATS

- **Provides U.S. leadership in global standardization... and, oversight of process to ensure proper focus and integration**
- **Offers potential advantages to both U.S. vendors and users in implementation**
- **Reduces language and cultural barriers for U.S. participation**
- **Permits timely access to standards information**

...Plus ANSI umbrella provides for...

- **Proactive participation by “stake-holders”**
- **Equitable administration of process**
- **Implementation via due process**
- **Effective resource utilization**
- **Protection against anti-trust**



INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC)

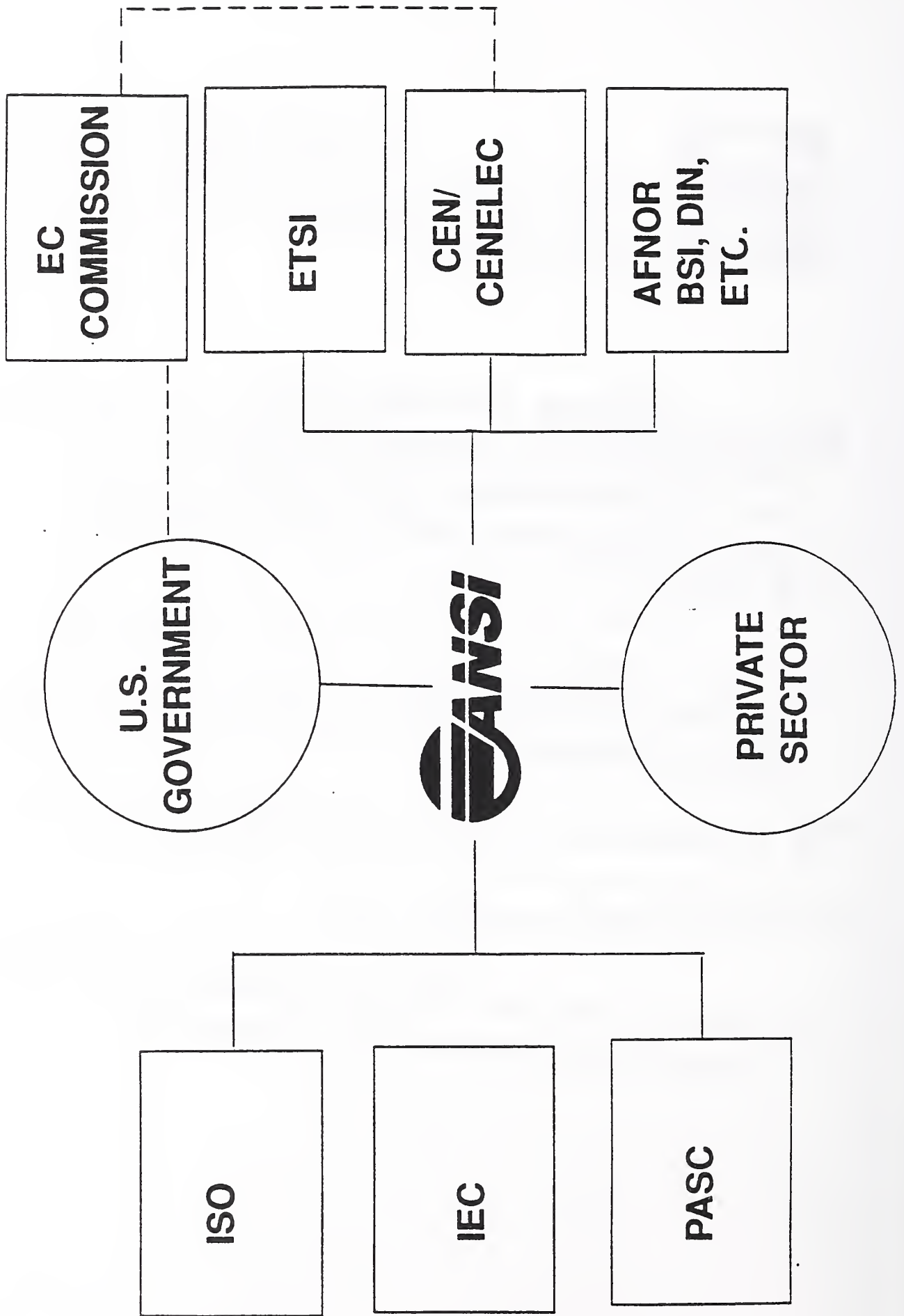
- **Develops and issues world standards in power generation and distribution, manufacture of electrical and electronics products, telecommunications, and other electrotechnical areas**
- **Standards are developed by 88 technical committees and more than 100 subcommittees assisted by several hundred working groups**
- **Members are national committees from 40 countries**



INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)

- **Coordinates and develops international standards that facilitate world trade and contribute to public safety and health**
- **Some 7438 current ISO standards cover all fields from information technology to agricultural products**
- **Technical work carried out by 169 technical committees and more than 2394 subgroups**
- **Members are the national standards organizations of 87 countries**

ANSI'S INTERNATIONAL RELATIONSHIPS





AMERICAN NATIONAL STANDARDS INSTITUTE

Key Thrusts

Coordinates U.S. voluntary standards system

Approves American National Standards

Represents U.S. in international standards system

Serves as clearinghouse for national and international standards information

ANSI COORDINATES VOLUNTARY DEVELOPMENT OF NATIONAL STANDARDS



ANSI's MISSION

To provide value added to its membership by conducting a cohesive cost-effective national and international standardization program... that continues as voluntary and consensus-based as well as self-regulating



**AMERICAN NATIONAL
STANDARDS INSTITUTE**

For over 70 years, the U.S. voluntary standards system has been successfully administered by ANSI.

The ANSI federation continues to serve the public and private sector's need for voluntary standardization.



**AMERICAN NATIONAL
STANDARDS INSTITUTE**

THE DEVELOPMENT OF STANDARDS
THROUGH
THE SOCIETY OF AUTOMOTIVE ENGINEERS

The Society of Automotive Engineers is a technical society whose members have common interest in the Ground Vehicle Industry and other related fields. As such, SAE provides a forum for sharing ideas and technology. This is done in large part by the development, publication and maintenance of Engineering Standards.

SAE has a technical board which directs the activities of the standards development process. The board is divided into five divisions or councils, each council is divided into general categories or committees and each committee has established subcommittees on specific subjects.

The majority of the work done to develop standards is done at the subcommittee level. Each subcommittee has areas of responsibility for both development of new standards and maintaining and upgrading existing standards.

Most subcommittee members are engineers from industry who have positions within their companies that relate to the subjects governed by their subcommittees. These members bring to the subcommittee expertise in a field based on their occupational experiences. These members can and do draw on the expertise of other employees from their companies to assist in the subcommittee activity. An elected chairman and vice chairman direct the activities of the subcommittee.

Once a subcommittee has been assigned a specific task to develop a standard, a formal process takes place to develop, then approve that document. Also, a very specific format and regulation for the document has been established by SAE to assure consistency for the appearance of the document. A sponsor is assigned by the subcommittee chairman. The sponsor is responsible for the technical content of the document. The sponsor is also responsible for maintaining the proper format for the document and also for expediting the document through the approval process. The sponsor will generally be a individual with a strong interest in the subject matter of the document and experience in the subject area. If the standard is of a lengthy or complex nature, an ad hoc committee chaired by the sponsor is formed to spread the work load.

The sponsor working independently or with members of a ad hoc committee will formulate the basic outline and first drafts for the document. If data is required to validate

criteria or specific values, members of the subcommittee are canvassed to acquire that data from their respective companies. During the draft formulation stage for the standard, other members of the subcommittee are available for consultation and for opinions on certain aspects of the draft. A key to this process is the pool of knowledge available to the sponsor through the subcommittee members to assist in the development of the document.

After a draft is completed, the balloting process begins first to the subcommittee members. For approval, balloting results must be unanimous. In the balloting process, the differing opinions on the document are debated. All disapprovals and comments for change must be resolved between sponsor and respondents.

Balloting approval is required at three levels for final SAE acceptance, the subcommittee level, the committee level and finally the council level. Here again is a key element in the standard acceptance process, the requirement of three levels of approval does assure a significant exposure of the document to qualified individuals in the voting bodies prior to approval.

Once approved, the document is published in the SAE Handbook which contains over 1400 standards, recommended practices and information reports.

Once standards have been established and published by SAE and other similar technical organizations, they become available to the International Standards Organization TAG committees for presentation to the ISO for adoption on a worldwide basis.

An example of the working of this process has been the establishment of the standard for qualifying ROPS (Roll Over Protective Systems) for off road machinery.

The request for the ROPS document and the development of the SAE criteria for ROPS took place in the mid 1960's and was first approved in 1967 as an SAE Recommended Practice. At the time this document was developed, some requirements for Roll Over Protection were in existence but none gave a concise consistent formula for ROPS qualification. This SAE document resulted from investigation by the subcommittee into existing ROPS requirements. The subcommittee drew together the best of the existing regulations, added data to the body of existing data and worked through government and manufacturing experts to develop the new test procedure and criteria. The result was a useful functional Roll Over Protection standard that has worked.

Several updates and improvements have been made to this

document over the years as new data became available and in fact a review is currently in process. As a result of the steady work of this SAE subcommittee this document has been established as the recognized standard throughout the world on ROPS qualifications.

As evidenced by the ROPS and numerous other successful documents that have been established it is obvious that the voluntary standards writing system that is in existence today is working, but there are problems. The basic process for the development of a standard is difficult, time consuming and requires experience and expertise on the subject. This work is done on a volunteer basis by engineers whose motives are often nothing more than an interest in furthering the development of technology in this country and the world. The process is totally dependent on these volunteers and individuals with that type of motivation are not always easy to find. An unfortunate effect of our current economic downturn is that volunteers become even more scarce. With cutbacks in engineering departments those left have little time for extracurricular activity. Also, travel budgets are reduced and research and test work required to substantiate standard criteria is also reduced. We can use help. Our numbers of active members are dwindling. As an example, representatives from OSHA and Bureau of Mines who would regularly attend and contribute to ROPS subcommittee are no longer active participants.

In summary the voluntary standards process is working. Numerous documents have been developed and in many cases these documents have been accepted world wide. The work is important to our society and should be relegated to a priority status to assure continued technological advancement and growth in this country.

Allen Schutte
Komatsu Dresser Company
Libertyville, Il. 60048

Manfred Bandmann
Tiefbau-Berufsgenossenschaft

Statement on NIST - EMI Workshop on EC-92

The Council Directive 91/368/EEC amending the EC Machinery Directive now includes mobile machines, hoisting gear and mining machinery in the areas covered by the Directive. Sections 3 to 5 have therefore been added to Annex 1 of the Directive "Essential health and safety requirements relating to the design and construction of machinery".

The Member States will apply the provisions of this Directive from 1.1.1993. As a transitional arrangement, machinery meeting the national regulations in force in the individual Member States will also be allowed until 31.12.1994.

On the basis of the self-certification procedure specified in the Directive, the manufacturer can usually himself decide how he wishes to comply with the essential health and safety requirements of the EC Machinery Directive. When a Member State considers that these essential requirements are not being met by the measures chosen by the manufacturer, the manufacturer is obliged to prove that his measures are appropriate.

If the machinery in question is, however, constructed in accordance with a harmonized standard, the burden of proof is reversed, so that the national supervisory body must prove that the EC Machinery Directive is not being complied with.

In the case of disputes between the manufacturer and national supervisory bodies, the Commission decides whether the measures taken by a Member State are justified or not, on the basis of the statement made by the standing committee set up there.

The requirements of Annex 1 of the EC Machinery Directive only apply if the hazard exists for the machinery in question, when it has been used under the conditions foreseen by the manufacturer. Annex 1 is therefore like a check list, from which the manufacturer chooses the provisions applicable to the machinery in question according to the hazards presented by his product. The EC Machinery Directive therefore allows the safety requirements to be adapted very flexibly to the needs of the particular product group.

In the case of machinery with a low accident risk and fast technical development, rigid design regulations are felt to obstruct technical progress. The manufacturer will therefore himself decide about what steps he wishes to take, in order to meet the requirements of the EC Machinery Directive.

On the other hand, machinery having a higher accident risk because of the way it is used, needs a clearly defined (~~European~~) state of the art, which makes it easier to verify conformity with the EC Machinery Directive and offers the manufacturers maximum security with regard to product liability.

For civil engineering machines we ~~should like to~~ propose the following procedure to the Member States via CEN/TC 151:

By 1.1.1993 the European standards for civil engineering machines will either be already published, or their technical content will at least be ready. Whether the EC Commission publishes these standards as harmonized standards or not, they represent a European state of the art for these machines, that is recognised by all parties. In most European countries, product liability is governed by a state of the art that is laid down in writing; there is therefore a great incentive for the manufacturers to produce machines in line with these European standards.

As a general rule, it can be assumed that all machinery provided with the EC mark and the declaration of conformity by the manufacturer complies with the Directive. ^{But} As long as the European Type-C standards are not published as harmonized standards, Member States can make it more difficult to place machines on the market by demanding proof of conformity with the Directive. It is still not clear what practical form this proof will take, but it does make it possible to create bureaucratic trade barriers.

In order to avoid this, TBG ^{with its test institutes} will in the future continue to offer voluntary inspections to certify conformity with the EC Machinery Directive. The abolition of national construction regulations for machinery, - some of which were very detailed, has meant that the institutions responsible for work safety and the machine users both want to have some guidance, so that we can see an increasing demand for these voluntary examinations.

At the moment ^{do TBG is} ~~we are~~ in the process of preparing ^{our} ~~its~~ inspection facilities for European accreditation, so that the tests will be recognized all over Europe. For the transitional period from 1.1.1993 to 31.12.1994 we shall perform the tests either on the basis of the European standards or in accordance with the national requirements valid up to now, as requested by the applicant. After 1.1.1995 the test will only be carried out on the basis of the European standards.

The EC Machinery Directive offers manufacturers, operators and authorities the chance to organize the whole complex matter of safety of machinery and the related issues of free exchange of goods, competition and product liability in the way that appears most suitable for that particular product group. In the case of civil engineering machines the necessary agreements will have to be reached mainly by CEN/TC 151. The European standards for civil engineering machines had to be drawn up under great time pressure, so

it will very soon be necessary to revise them. The Vienna Agreement on cooperation between CEN and ISO offers the chance of revising them jointly with the respective ISO committees, and so making it easier to exchange goods throughout the world.

And for the voluntary examinations certifying conformity with the EC Machinery Directive there are also many ways of developing cooperation across the borders of Europe. From placing the whole examination or parts of it with US manufacturers or test centres to realistic work sharing in ensuring quality, all procedures can be agreed in such a way that everyone gains some advantage.

It is not yet known whether certain ^{EC} Member States will try to create new trade barriers by means of costly requirements for proof of conformity, so as to get around the harmonization efforts being made by the EC and CEN. In this case we would be grateful, if we could obtain support from ^{the US} ~~America~~ in the GATT negotiations in overcoming such attempts. This support would also be very welcome in such detailed issues as the approval of working machines for use on public roads.

Whether it could come to trade restrictions between Europe and other countries in the future depends on factors which we can hardly influence. But we are in a position to influence at least the technical requirements being made as uniform as possible throughout the world, because technical trade barriers always lead to a drop in productivity, and that is to everyone's disadvantage.

11/12/91 Mobile Machinery Workshop

Berrien Zettler
Occupational Safety and Health Administration

Thank you very much. It's a great pleasure to be here. One of the things, of course, that's characterized OSHA since the beginning, and we are now completing our 20th year in existence, one of the things that's characterized OSHA is a decidedly domestic interest. OSHA has not been particularly concerned as a domestic agency with workers or what the effects of the standards might be beyond their impact on the American worker. I think that is gradually changing and I will refer a little bit later to some of the things which OSHA is beginning to do in the international arena. As all of you know, the sort of philosophy behind OSHA is number one, to regulate not the manufacturer but to regulate the user of the equipment. Now this, of course, has an effect in that it provides a considerable inducement to the manufacturer to manufacture equipment which will allow the user of that equipment to be in compliance with the safety and health regulations. OSHA is further interested only and solely in the impact that the use of this equipment has on the American worker, not on the public. So it is no so much a concern as to how manufactured equipment might be used outside of the workplace. The act is also basically structured in such a way as to be based on voluntary compliance. There is a significant enforcement mechanism built into the act and that's what OSHA nowadays gets most of the attention for, the enforcement of the standards against the user sometimes resulting in very significant penalties for failure to follow the standards. But nevertheless, the act, because of the very limited number of inspections which OSHA able to conduct in any given year, the act basically relies on voluntary compliance. Out of the 2 to 3 million workplaces which are covered under Federal OSHA alone, OSHA is able to conduct only about 35 to 40 thousand inspections, which leaves a very significant amount of covered employers uninspected, hence, the emphasis on voluntary compliance. Many of you may know that in the beginning of OSHA's history for approximately the first three years, the Congress allowed OSHA to adopt what are called consensus standards, such standards for example as developed by SAE, ASAE, ANSI, and other consensus standards making organizations. That authority lasted, as I say, approximately three years. When that authority expired it became necessary for OSHA to follow the Administrative Procedures Act requirements for promulgating standards. Under that Act there is the necessity to publish proposed rules, to keep a period open for notice and comment, to keep an additional period open for public comments on these things should hearings be requested. The end result of all of that is that the standards-making process as currently enforced under law is an extraordinarily difficult and time-consuming process. It is not unusual for OSHA's standards to take 10 to 12 years to become final from the time that an initial proposal is developed. We believe that we are making magnificent progress if we actually get a standard out within four years. That is a very

difficult and time-consuming process for us. It's not something that we like but it's something that unfortunately the agency is stuck with. There are alternatives to standards, as many of you no doubt know. There is in the Act what we call the general duty clause. In the general duty clause employers are required to conform not only with promulgated standards but also with recognized standards, that is to say, if there are recognized hazards existing in the workplace, the employer is under the obligation to remove those hazards to the degree possible. It is of great use to OSHA to have such organizations as ANSI, SAE, and the others to formulate, if you will, a position which is generally agreed upon by the manufacturing and using community which allow us to maintain that the conditions contrary to those standards are recognized. We have found and have worked very closely with many of the ANSI committees, Mr. Bode, who will be the panel member this afternoon, has worked very closely particularly with B-11 committees under ANSI. OSHA has been less active in working with some of the SAE committees and the ASAE committees. This has not been primarily because of a lack of interest but more because of a lack of, shall I say, resources. The agency, OSHA, has a very large mandate and a very small budget. The entire budget for OSHA, for example for the coming fiscal year, will be less than \$400 million. Four-hundred million dollars is a very, very small amount considering the programs that are existent in other agencies within OSHA, even within the Government, even within the Department of Labor. There is no likelihood in my opinion that funding level will be significantly changed in the near future. As a consequence of that, it becomes more and more imperative particularly if OSHA is to be moved to interest itself in such things as international standards to a degree more than it has been thus far, it is imperative that means to overcome the resource limitations be found. One of the previous speakers has suggested, for example, that it may be worth while, or has made the suggestion which leads me to suggest, that it may be worthwhile for legislative changes to be considered. It may be worthwhile, for example, to have OSHA reauthorize to accept or to adopt consensus standards once those consensus standards are put into place. Those consensus standards could very well be standards developed by ANSI in cooperation with ISO. There many, many difficult problems in doing that. Mr. Schutte already referred to one, namely the very difficult process of developing even a consensus standard. While consensus standards seem to be able to be developed once they are worked upon much quicker than OSHA can develop them, it nevertheless is true that the ANSI committees, the ASE committees, the ASAE committees are all volunteer-based committees. It is imperative it seems to me that the cooperating manufacturers, the business in whose interests these standards are being developed, fund those committees as much as possible and perhaps even consider the appropriateness of having OSHA once again authorized to accept consensus standards rather than the current APA procedures. To do that, of course, as I said would require legislative action. Although it seems to me that the framers of the act recognized the importance and perhaps had more wisdom than they knew when they applied or allowed this authority to exist for the first three years. I am not sure exactly why in

the legislative history the procedures were limited only to those three years, but so much is OSHA limited now to the Administrative Procedures Act that OSHA cannot even update its adopted ANSI standards as the ANSI standards are updated. Even that now requires, or would require, should we choose to update an adopted ANSI standard, for example, should we choose to update that in accordance with the updated ANSI standard, we would have to go through APA procedures to do so. It is a very difficult and cumbersome process which hopefully the trend toward internationalization of the safety and health standards will cause us all to think of different and new approaches to deal with this issue. As I said, OSHA has traditionally not been particularly interested or inclined to work with the international community. That is gradually changing. We are developing certain processes for recognized testing laboratories with Canada. We are also undertaking an initiative with Mexico. The materials safety data sheet, there is an international interest in making those standard and OSHA has begun to work in that area. These are very sort of limited and tentative steps for OSHA, however, and it's going to require a great deal of rethinking of our mission in order to bring us to the point where we can, I think, effectively participate in the development of international standards. Safety and health is not something that's peculiar to the American worker. Safety and health is something that is of interest to every manufacturer, to every employer, and to every worker. And it seems to me that the sooner we can recognize our international responsibilities as well as our national responsibilities and make the corresponding changes necessary, the sooner will we be able, I think, to become truly a community. Thank you very much.

CONFORMITY ASSESSMENT WORKSHOP, MOBILE EQUIPMENT
NOVEMBER 12, 1991
WASHINGTON DC

PRESENTATION BY: PAUL YOUNG
VICE PRESIDENT OF ENGINEERING
GEHL COMPANY

Good morning. I've come here today to explore some of the questions and issues surrounding EC 92 and their impact on small to mid-sized companies like Gehl. I frankly have more questions than answers, but believe that through forums like this one, we can come closer to getting our arms around EC 92. By doing that we can hopefully avoid some of the many pitfalls that are lurking out there as we venture forth to understand and apply standards as well as directives yet unknown.

To be honest, we at Gehl Company are struggling with EC 92. The issues we face include everything from understanding the standards to making business decisions about what products are appropriate to put through this costly and time-consuming process.

Gehl Background

I believe that we face what most of you face. We are a niche capital goods manufacturer of specialized equipment for agriculture and construction. We employ almost 1200 people in our two operating divisions, Gehl Agriculture and Gehl Construction. Our headquarters and main agricultural equipment plant is in Wisconsin. We have just open a new ag plant in Pennsylvania, and have construction equipment facilities in South Dakota and Georgia. From these facilities, our products are distributed worldwide.

Gehl Agriculture has 132 years' experience producing agricultural implements. Today, we're the leading non-tractor manufacturer of agricultural equipment in the industry. Sales from this division accounted for about 76% of our 1990 revenues.

We offer dairy, beef, hog and poultry farmers a broad line of implements including equipment for harvesting hay and forage crops, materials handling, waste handling, and feed making. We have elected not to build or market tractors or combines so that our products don't conflict with our dealers' major tractor line.

We have been exporting agricultural equipment for more than 40 years, and currently have 38 foreign distributors. Gehl implements are sold in Australia, Japan, New Zealand, Taiwan, Israel, Chile, Guatemala, Puerto Rico and throughout Europe. Last year we even shipped forage harvesters to farmers in what was the Western Soviet Union. Many of our products are sold internationally in small unit volumes, something we will have to consider as we prepare for EC 92.

The other industry we serve is the construction market. We added this second business segment to diversify our company in 1986. We had been marketing the Gehl skid steer loader in the European light construction equipment market for more than 15 years...and we leveraged that experience in the North American construction market.

Our construction equipment serves what are commonly referred to as the "earthmoving", "lifting" and "paving" sectors of the market. They include our skid steer loader, rough-terrain telescoping-boom and straight-mast forklifts, mini-excavators, and new asphalt paving line.

We currently export only skid loaders to Europe, but good markets exist there for our other construction products. In the past year, we established good relationships with customers and potential customers in the Soviet Union and Eastern Bloc nations. New distributors have been added in Korea and Chile. Our Korean distributor is now our second largest skid loader customer and they have just taken on our rough-terrain forklift line. Our largest skid loader distributor is Gehl GmbH in Germany who distributes into Europe, Africa and the Mideast. Last year they signed 16 new dealers in Hungary, Bulgaria, and what was East Germany.

In 1990, we also signed an agreement to license our rough-terrain forklift technology in the People's Republic of China. We had completed a similar agreement in 1988 for our skid steer loader technology.

For both our ag and construction businesses, international sales have more than tripled in the past three years to be about 16% of sales. Expanding our international presence is one of our key strategies for future growth. So you can see that we are vitally concerned, and somewhat frustrated, about EC 92.

Challenges for Small Companies

In looking at the EC 92 requirements, as best we understand them, I see five areas where Gehl and companies like ours -- small to medium sized organizations -- are going to be affected. While there will be positive consequences, I see more negatives because of the unclear and often conflicting definition of what we need to do, and the cost.

1) First, is just the process of understanding the standards. It is a time-consuming process to read, re-read and trace through all the standards and amendments in order to understand and interpret them, and to get answers to questions. Because of our size, we have no internal experts to help us find our way. We don't have staffs like larger companies who can spend the time it takes to digest the standards, to keep abreast of changes and to prepare the documents required to meet EC 92.

We also don't have a European counterpart manufacturing plant who is closer to the information on EC 92. This includes access to documents and knowing the right people to help sort things out.

In the US, there is no official organization to provide interpretation of the standards, no final authority. We have been using EMI and contacts at our larger competitors to sort through the jungle of confusion. And in many cases, the directives are seemingly contradictory or not available. We need a more direct route from Gehl to CEN.

I am concerned that we are plowing old ground, or worse, missing the boat by having to rely on ourselves when it comes to understanding the standards.

2) The second concern is resources. The economic times dictate that fewer resources are available for the purpose of conforming to EC 92 standards. We will have to steal precious resources from basic R&D, and from marketing and manufacturing functions in the company to address EC 92.

With limited resources and time, the question is, "Can we meet the deadline on all our products, especially given the current economic conditions under which we all operate."

3) Third, we are currently required under the standards to obtain certification of our machine ROPS, FOPS and sound levels from the EC Notified Body. This is a group of external, independent European testing organizations.

Obtaining certification could be a significant cost to Gehl, as it could be to other companies like us. In addition, it could exclude us selling existing products or introducing new ones. When we are at the mercy of the EC Notified Body who may work on their own timetable without regard for the manufacturers needs -- much like getting through customs. Our products will be lined up on European docks waiting to be processed only at the pace the certifier chooses to set.

If we don't get a timely response back from whomever we use in Europe, it could mean that we are unable to meet the deadline. This means we are precluded from doing business in Europe for some period.

That's for existing products. On new ones, there is the additional risk of exposure, prior to market introduction. The certification process could well show our hand to the competition before we have even had a chance to lay a card on the table.

Another certification issue, one on which we don't even agree among ourselves at Gehl, is the question of the certification of the manufacturing process under ISO 9000 quality systems. If we have to certify the manufacturing process, we'll need to document every aspect of our system from purchasing to training. Certainly this is a benefit to this exercise if European standards become world standards, but if not, it's an additional cost and burden.

Are both machine and process certification required? It comes down to one person's interpretation of the documents versus another's viewpoint. This is where a knowledgeable authority would be invaluable to companies like ours:

We are faced with two decisions. Do we certify to ISO 9000 quality standards? And do we have our equipment assessed for conformity through the EC Notified Body beyond ROPS, FOPS and sound? I expect that the answers to those questions will be driven by competitive realities. If we have to go that far to remain competitive, we will do it.

Certainly it is very positive that common standards are being developed that will enhance safety and allow each of us to know what is expected. We would like to see them become world standards. With new equipment, common standards will put us on solid, equal ground. The dilemma we face is with existing equipment. I expect that a lot of our machines that are sold in small volumes may not be certified the first year.

4) Fourth, certification may require a significant amount of testing to meet standards requirements. Files are difficult to assemble. I see a gut-wrenching experience if we have to create a file on a product that has been on the North American market for five to ten years. We have safe machines with good safety records. But that doesn't relate to EC 92.

When I look at creating a construction file on those older products built to standards designed a number of years ago, I have to ask myself, does Gehl have the time and money to do this, or are we better off to look for market opportunities elsewhere. If the intent of the standards is to limit competition, they may succeed.

5) The fifth area of challenge facing companies our size is the problem of dealing with standards that are not yet in place or those that EC Member States decide to impose over and above the unified standards.

It is very unclear to us how much time we have to meet new requirements as they are developed. And if member states have the right to arbitrarily impose more rigid standards than those set by the EC, we're really back to where we started, with no uniformity at all. How far can Member States go? I'm still trying to figure that one out.

Hazards

Given these challenges we face in doing business in Europe after 1992, I see two hazards.

1) First, a lot of us may stop exporting some existing products to Europe, damaging the balance of trade. And fewer new products will be taken to market because it will not be economically feasible, given the compliance costs of EC 92. The cost of taking low volume products to Europe may make them only marginally profitable. As North American manufacturers interested in Europe as a market where we can make money and build market share, our opportunities become more limited, not expanded as the EC claims.

2) The second hazard is to our vendors. Many of us face a change in vendors, such as those for drive lines, because they have to be certified by the EC Notified Bodies. This could have a significant impact on U.S. based suppliers. The experience of one of our vendors has

shown us that it is very expensive and takes a lot of time and patience to tackle certification.

Actions

So what do we do to address these challenges and mitigate the hazards? Here are three of the things I think need to be done.

1) For one, I would like to see ROPS, FOPS and sound as areas that we can self-certify as manufacturers. We've self-certified for years. We have good standards that were developed in the U.S. Self-certification would help level the playing field with European manufacturers and minimize the possibilities that costs and time constraints might keep us out of the market. It would mean a freer market and more choice for European farmers and contractors.

If we can't self-certify, the next step would be to get certification out of EC Notified Bodies. Ideally, certification could be accomplished by having a certifying representative observe companies conducting their own tests in the U.S.

2) Another action that needs to be taken is to have someone available in the U.S who is knowledgeable on standards and who has contacts in Europe for interpretation of standards. Either a trade association like EMI or the government are logical sources to provide this service. This is a critical step to help us understand and comply with EC 92.

Having this authority available will be particularly important to provide clarification of all standards applicable in member states, particularly where the main supporting standards are still being developed.

3) Next, let's try to have more impact in the development of standards. The frustrating thing for us is to feel totally powerless in helping influence decisions that literally impact our ability to grow and be profitable. We feel that we have some knowledge on the construction side because ISO standards are expected to be used, but the ag side is a mystery. I would like to know what standards are being considered on the ag side and how we can have an impact.

I want to leave you with my overall conviction that creating standards is a very positive thing, and that we as an industry should work toward world safety standards as our ultimate goal. Being able to compete in world markets is a critical strategy for Gehl Company and others like us. Certainly Europe is one of our most important markets. What we desire is assistance in understanding the requirements that will allow us to move through the process. We're not going to be left out, but it sure could be made easier.

I hope that by bringing up these concerns, we can together address these challenges of understanding standards and be able to minimize the time and cost factors to compete effectively in Europe. After all, our goal is the same as our European counterparts -- to give the customer a safe, quality product. We just want an equal shot at satisfying that customer's needs.



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COMMENTS OF JAMES D. SCHELL

TUESDAY, NOVEMBER 12, 1991

BEFORE NIST

BOARD OF DIRECTORS

Each Regular Member company is entitled to representation on the Association's Board of Directors. Currently, the following individuals serve as the Voting Member or Alternate. Associate Members are represented on the Board by the Chairman of the Suppliers Committee.*

Regular Member Companies	Board Members	Alternates
Baker Material Handling Corp.	Robert Crandell	
Barrett Industrial Trucks	Larry Borre	Yasuhiko Watanabe
Big Joe Manufacturing Co.	Edward M. Horwich	
Caterpillar Industrial Inc.	Richard Benson	Larry Wuench
Clark Material Handling Co.	James B. Bennett, III	
Crown Equipment	James Moran	Thomas Hoying
Drexel Industries, Inc.	Ned Ramm	Skip Russo
Elwell-Parker Electric Co.	Sheldon K. Towson, Jr.	Charles R. Herron
Hyster Company	Stephen Finney	Frank Schafer
K-D Manitou, Inc.	Serge Bosche	Frank Aucoin
Kalmar AC	Bengt Ljung	Bruce Bowman
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USA	Akira Otsuka**	Michael Howlett
Canada	Dave Meades	
Mitsubishi Heavy Industries		
USA	Richard Wagner**	Bruce Monica
Canada	Claude Dubois	
Multiton MIC Corporation	Dirk von Holt	
Nissan Industrial Equip. Co.		
USA	Gerry Kirkland**	
Canada	David A. Gordon	A. Ross Liddell
The Prime Mover Company (BT)	Steve Mullarkey	
The Raymond Corporation	Ross Colquhoun	George G. Raymond
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USA		
C. ITOH	H. L. Bickford	
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Deval Handling	Rene Couture	
Toyota		
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Canada	Eckhard H. Klietsch	
Yale Materials Handling Corp.	William P. Reichert	Edward W. Ryan

*Kenhar Products Inc.

William J. Harrison

** Voting Representative

SUPPLIERS COMMITTEE

William J. Harrison, Chairman
Martin M. Stanton, Vice Chairman

Kenhar Products, Inc.
East Penn Mfg. Co.

Objective:

To represent the interests of the Associate Members.

Responsibilities:

1. Instruct the Committee Chairman, or in his absence the Vice Chairman, concerning the committee's voting desires on Recommended Practices Final Ballots in the Board of Directors meetings.
2. Give guidance to the Committee Chairman, or in his absence the Vice Chairman, on all matters requiring Board of Directors' action.
3. Develop programs beneficial to the Committee's members which are consistent with provisions of the ITA Constitution and Bylaws.

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Aquila Corporation
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C & D Power Systems
Cascade Corporation
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T. A. Buckley

Ronald D. Varilek

E. J. Crosson

Michael Smith
Wayne Bostad
Satoshi Osanai

GOOD MORNING. I AM HERE FOR THE INDUSTRIAL TRUCK ASSOCIATION (ITA), A TRADE ASSOCIATION COMPOSED OF FORK LIFT TRUCK MANUFACTURERS AND THEIR SUPPLIERS WHO DO BUSINESS IN THE UNITED STATES AND CANADA. THE SITE OF MANUFACTURING THE FORK LIFTS IS UNIMPORTANT - HENCE ITA COUNTS JAPANESE AND EUROPEAN COMPANIES AMONGST ITS MEMBERSHIP. MOREOVER, ITA DOMESTIC MEMBERS MANUFACTURE IN, AND SHIP TO, COUNTRIES AROUND THE WORLD, INCLUDING EUROPE AND JAPAN. FORKLIFT MANUFACTURING IS A GLOBAL BUSINESS.

WHILE NOT AN EMPLOYEE OF THE ASSOCIATION OR ANY MEMBER COMPANY, I WORK WITH THEM IN THEIR EFFORT TO STAY ABREAST OF THE ACTIVITY TAKING PLACE IN EUROPE DURING THE PROCESS OF PREPARING FOR THE ONSET OF EC-92.

IT HAS BEEN DIFFICULT TO ORGANIZE A MEANINGFUL PRESENTATION AS THERE ARE MANY ISSUES ASSOCIATED WITH EC 92 THAT ARE EITHER VAGUE OR OUR MEMBERSHIP DOES NOT AGREE WITH. CONSEQUENTLY, MY REMARKS WILL FOLLOW THE TOPICS LISTED FOR DISCUSSION AND EMPHASIZE THOSE AREAS WE FEEL NEED ATTENTION. WE TRUST WE WILL MAKE A CONTRIBUTION TOWARD ACHIEVING THE NIST AND EMI OBJECTIVES GERALD RITTERBUSCH SET FORTH.

PREFATORY TO MY COMMENTS, I SHOULD ADD THAT ITA HAS, FOR MANY YEARS, ATTENDED MEETINGS IN EUROPE AT THE INVITATION OF THE FEDERATION OF EUROPEAN MANUFACTURERS OF FORKLIFT TRUCKS. IN RETURN FOR THIS, FEM HAS SENT ENGINEERING REPRESENTATIVES TO ITA MEETINGS TO KEEP US INFORMED OF DEVELOPMENTS OVER THERE. HAVING SAID THAT, HOWEVER, IT HAS ONLY BEEN WITHIN THE

LAST 6 MONTHS THAT U.S. REPRESENTATIVES, ALONG WITH OTHERS, HAVE BEEN INVITED TO PARTICIPATE AS OBSERVERS IN CEN TECHNICAL COMMITTEE DELIBERATIONS. THIS IS LATE IN THE PROCESS, BUT WE ARE EXTREMELY GRATEFUL FOR THE OPPORTUNITY; SPECIAL RECOGNITION AND THANKS FOR THIS DEVELOPMENT NEEDS TO GO TO THE BRITISH INDUSTRIAL TRUCK ASSOCIATION FOR THEIR EFFORTS. WHILE IT IS TRUE THAT SOME U.S. MANUFACTURERS WITH OFFICES IN EUROPE WERE ABLE TO PARTICIPATE IN CEN MEETINGS, THOSE MEMBERS WERE SOMEWHAT RELUCTANT TO SHARE THEIR FINDINGS WITH THE REST OF THE U.S. INDUSTRY. THAT SITUATION NOW APPEARS TO BE ENDED.

TOPIC # 1 - EC REQUIREMENTS FOR CONFORMITY ASSESSMENT.

THE PRODUCT MANUFACTURED BY MEMBERS OF OUR ASSOCIATION ARE COVERED UNDER SPECIAL DIRECTIVE 89/392 ANNEX V, WHICH PROVIDES FOR SELF CERTIFICATION BY THE MANUFACTURER OR HIS AUTHORIZED REPRESENTATIVE. SELF CERTIFICATION IS FAVORED OVER ANY OTHER ALTERNATIVE, HOWEVER, IT IS BELIEVED SOME OF THE BACK-UP INFORMATION REQUIRED TO EITHER BE ON FILE OR AVAILABLE UPON CALL, IS UNNECESSARY AND, IF PRODUCED FOR WHATEVER REASON, MIGHT LEAD TO THE DISCLOSURE OF INTERNAL OR PROPRIETARY INFORMATION. THOUGH IT IS INDICATED THE DOCUMENTATION NEED ONLY BE THAT NECESSARY FOR THE ASSESSMENT OF CONFORMITY, ANYTIME A QUESTION IS RAISED, THERE WILL ALWAYS BE A DEBATE AS TO WHAT DOCUMENTATION IS ESSENTIAL. UNDER SELF CERTIFICATION THE TRUCK MANUFACTURER IS RESPONSIBLE FOR CONFORMANCE UNDER ANY CIRCUMSTANCE, THEREFORE HE IS BELIEVED TO BE IN A MUCH BETTER

POSITION TO DETERMINE THE DOCUMENTATION REQUIRED TO CONFIRM CONFORMANCE; IT IS SUGGESTED THE DECISION BE LEFT TO HIM.

TOPIC # 2. SPECIFIC TASKS ASSOCIATED WITH THE REQUIREMENTS TO ATTAIN CONFORMITY?

I'M NOT SURE I UNDERSTAND THIS QUESTION, HOWEVER, FROM A MANUFACTURERS POINT OF VIEW ATTAINING CONFORMANCE COULD EASILY BECOME BURDENSOME AND EXPENSIVE. IT WOULD BE NECESSARY TO EVALUATE THE DESIGNS, REDESIGN IF NECESSARY, AND THEN PERFORM THE TESTING REQUIRED TO ASSURE CONFORMANCE FOR THOSE PRODUCTS ENTERING THE EC MARKET AREA. ONCE THOSE TASKS ARE COMPLETED, AND THE MANUFACTURER CONFIDENT HIS PRODUCTS CONFORM, IT APPEARS TO BE RELATIVELY ROUTINE TO IDENTIFY THE DOCUMENTATION USED IN THE PROCESS OF CONFORMANCE, AFFIX THE PROPER "CE" MARK OF CONFORMITY ON THE PRODUCT, IDENTIFY A COMMUNITY REPRESENTATIVE AND ADD HIS ADDRESS TO THE TRUCK NAMEPLATE.

TOPIC # 3. DO EUROPEAN STANDARDS DIFFER FROM USA STANDARDS?

THE ANSWER IS YES! AS INDICATED ABOVE, FOR MANY YEARS THIS INDUSTRY HAS WORKED CLOSELY WITH EUROPEAN MANUFACTURERS TO DEVELOP PERFORMANCE STANDARDS THAT WOULD SATISFY THE NEEDS OF BOTH AREAS. WITH THE EC MOVEMENT THAT EFFORT HAS BEEN BLUNTED AND U.S. LIFT TRUCK MANUFACTURERS ARE NOW DEALING WITH CONFUSING ISSUES IN THAT THERE ARE CURRENTLY REQUIREMENTS (STANDARD 86/663) FOR LIFT TRUCKS UP THROUGH 10,000 KGS RATED CAPACITY; YET THERE IS NOTHING FOR TRUCKS WITH RATED CAPACITIES GREATER THAN 10,000 KGS

HOWEVER, THAT SHOULD SOON CHANGE AS CEN 150 WG 1 IS NEAR COMPLETION OF A FINAL PROPOSAL FOR EEC CONSIDERATION.

SUBSEQUENTLY A COUNCIL DIRECTIVE 89/392 14 JUNE 1989 REQUIRES THAT 86/663 BE REPEALED ON 31 DECEMBER 1995. UNTIL THAT TIME, TRUCKS UP THROUGH 10,000 KGS CAN CONTINUE TO BE MANUFACTURED IN ACCORDANCE WITH 86/663. STARTING 1 JANUARY 1996 NEW STANDARDS MEETING THE REQUIREMENTS OF 89/392 CURRENTLY UNDER DEVELOPMENT BY CEN 150 WILL BECOME EFFECTIVE.

THERE ARE DIFFERENCES BETWEEN THE REQUIREMENTS IN 86/663 AND ANSI B56.1. THEY ARE NOT INSURMOUNTABLE, BUT ARE SIGNIFICANT SINCE THEY DEAL WITH SOME OF THE MAJOR AREAS OF THE TRUCKS. FOR EXAMPLE:

- OVERHEAD GUARD STRUCTURE
- BRAKES
- VISIBILITY MEASUREMENT
- STABILITY; WAREHOUSE AND RT TRUCKS
- NOISE MEASUREMENT
- MAN-UP TRUCK DESIGN

SOME EC REQUIREMENTS ARE LESS STRINGENT THAN SIMILAR REQUIREMENTS IN B56.1. THIS ONLY ADDS TO THE DILEMMA. OF HARMONIZATION.

WHILE THERE ARE DIFFERENCES BETWEEN 86/663 AND B56.1, ITA MEMBERS ARE SOMEWHAT FAMILIAR WITH 86/663 AND CAN WORK WITH IT. 89/392 IS ANOTHER SITUATION; MANY SECTIONS ARE WRITTEN IN SUCH VAGUE TERMS THAT THEY ARE IMPOSSIBLE TO INTERPRET. OTHER SECTIONS ARE WRITTEN IN SUCH ABSOLUTE TERMS THAT THEY ARE IMPOSSIBLE TO MEET. EXPERIENCE SAYS, THAT UNLESS THESE SECTIONS CAN BE CLARIFIED, IT WILL ONLY LEAD TO

PROBLEMS OF INTERPRETATION. PERHAPS WHEN ALL OF THE STANDARDS REQUIRED UNDER 89/392 ARE COMPLETED, THESE QUESTIONABLE AREAS WILL BE CORRECTED.

AS INDICATED, 1996 WILL BRING NEW REQUIREMENTS. BASED ON WHAT IS BEING PROPOSED, MANY OF THESE IF ADOPTED WILL REQUIRE SIGNIFICANT PRODUCT REDESIGN AND TESTING. SOME OF THESE NEW PROPOSALS ARE UNREALISTIC, IMPRACTICAL, IMPOSSIBLE TO MEET WITH CURRENT STATE OF THE ART AND, IN OUR OPINION, WILL CONTRIBUTE NOTHING IN THE WAY OF IMPROVED PERFORMANCE, ADD UNNECESSARY PRODUCT COST AND REDUCE RELIABILITY.

FOR EXAMPLE: ONE OF THE LATEST PROPOSALS, IF ADOPTED, WOULD REQUIRE THE INSTALLATION OF A LOAD MOMENT SENSING DEVICE ON LIFT TRUCKS. IN THEORY, THIS SOUNDS LIKE A GREAT IDEA, HOWEVER, IN ACTUAL PRACTICE, LIFT TRUCK OPERATION IS SO DYNAMIC AND THE CURRENT STATE OF THE ART IS SUCH THAT NO ONE HAS BEEN ABLE TO PROVIDE A SYSTEM THAT CAN COMPENSATE FOR SUCH FACTORS AS TRAVEL SPEED, BRAKING, HYDRAULIC OIL TEMPERATURE, LIFT CYCLE, SPEED OF LIFT, SPEED OF TILT, SPEED OF TURN, ETC AND GIVE THE REPEATABLE AND ACCEPTABLE RESULTS NECESSARY TO PROVIDE THE LEVEL OF SAFETY INTENDED.

TOPIC # 4. TO WHAT EXTENT DO YOU FEEL THAT U.S. CONFORMITY ASSESSMENT SYSTEMS ARE ADEQUATE FOR PROVIDING TEST DATA OR OTHER ATTESTATIONS OF CONFORMITY BY THE EC MEMBER STATES?

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IN GENERAL U.S. MANUFACTURERS HAVE VERY GOOD TEST DATA AND RECORDS. THEY WOULD HAVE NO

DIFFICULTY IN PROVIDING THE DATA REQUIRED TO SUPPORT CONFORMANCE WITH ANY REQUIREMENTS THAT PARALLEL THE APPLICABLE B56 STANDARD. HOWEVER, WHEN THERE IS A SIGNIFICANT DIFFERENCE IN THE REQUIREMENTS, SUCH AS IN VISIBILITY MEASUREMENT, NOISE MEASUREMENT, OVERHEAD GUARD TESTING, ETC., MANUFACTURERS WILL NEED TO CONDUCT ADDITIONAL TESTS AND COLLECT DATA FOR WHICH, THEY MAY NOT HAVE THE NECESSARY EQUIPMENT OR FACILITIES; IT COULD EASILY BECOME A SIGNIFICANT FINANCIAL BURDEN!

TOPIC # 5. WOULD THERE BE A BENEFIT FROM DEVELOPING MUTUAL RECOGNITION AGREEMENTS BETWEEN US PRODUCT CERTIFIERS AND THEIR EC COUNTERPARTS?

OBVIOUSLY MUTUAL RECOGNITION IN SOME FORM IS DESIRABLE. EXCEPT FOR UNDERWRITER'S LABORATORIES "CERTIFICATION" (APPROVAL) OF SOME PRODUCTS FOR FIRE SAFETY, THERE IS NO THIRD PARTY CERTIFICATION OF LIFT TRUCKS IN THE U.S. IF A PRODUCT MEETS A B56 STANDARD, THE TRUCK MANUFACTURER CAN SELF CERTIFY BY INDICATING COMPLIANCE WITH THE APPLICABLE PARTS OF THE APPROPRIATE STANDARD ON THE TRUCK NAMEPLATE. THIS PROCEDURE SATISFIES U.S. NEEDS SO THERE SEEMS LITTLE TO GAIN FROM MUTUAL RECOGNITION; THERE ARE NO OTHER LABORATORIES OR LIFT TRUCK PRODUCT CERTIFIERS IN THE U. S AND NO INCENTIVE TO MOVE IN THE DIRECTION OF THIRD PARTY CERTIFICATION. IT OPPOSES THIRD PARTY CERTIFICATION. IT PROVIDES NO ADDITIONAL BENEFIT BUT DOES INVOLVE HORRENDOUS COST WHICH MUST ULTIMATELY PASSED ON TO THE CUSTOMER.

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BEFORE MUTUAL RECOGNITION GETS TOO MUCH ATTENTION IT SEEMS PRUDENT TO WORK TOWARD

HARMONIZATION OF THE STANDARDS SO THAT DUPLICATION AND CONFUSION CAN BE AVOIDED IF AND WHEN MUTUAL RECOGNITION SHOULD EVER BECOME DESIRABLE.

TOPIC # 6. HOW CAN THE U.S. GOVERNMENT BETTER UTILIZE PRIVATE SECTOR INPUT WHEN DEVELOPING OFFICIAL POSITIONS FOR NEGOTIATION WITH EC?

IN GENERAL WE OPPOSE GOVERNMENT INTERVENTION IF THE SITUATION CAN BE RESOLVED SATISFACTORILY WITHOUT IT. IT IS UNFORTUNATE THAT IN SO FAR AS EC 92 IS CONCERNED, IT HAS TAKEN THIS LONG FOR THE GOVERNMENT TO ASK FOR PRIVATE SECTOR INPUT. HOWEVER, THIS IS TODAY AND WE CAN ONLY HOPE IT WILL GAIN SOME INSIGHT AND ULTIMATELY ASSIST.

THE LIFT TRUCK INDUSTRY HAS KNOWN OF THE EC DIRECTION FOR MORE THAN 10 YEARS AND, IN SEVERAL INSTANCES, CONCERNS WERE BROUGHT TO THE ATTENTION OF VARIOUS GOVERNMENTAL DEPARTMENTS; EVEN THOUGH LATE, IT IS REFRESHING TO SEE THIS INTEREST.

SOME GOVERNMENTAL UNITS, SUCH AS STATES, OFTEN USE ADVISORY COMMITTEES, PUBLIC HEARINGS OR SIMILAR FORUMS TO GATHER INPUT FROM THE PRIVATE SECTOR. WE BELIEVE THIS TO BE A VIABLE AND EFFECTIVE APPROACH, AND SUGGEST THAT, WITH ISSUES SIMILAR TO THE EC 92 MOVEMENT, THE GOVERNMENT HAS A RESPONSIBILITY TO INITIATE SUCH ACTION. HAD THIS BEEN DONE EARLIER IN THE EC MOVEMENT, THE SITUATION TODAY MIGHT BE FAR DIFFERENT. MANY TIMES THE PRIVATE SECTOR CAN PROVIDE CONSIDERABLE INSIGHT INTO THE BACKGROUND AND

MOTIVATIONS THAT LEAD TO THE DEVELOPMENT OF ANY PARTICULAR SITUATION.

TOPIC # 7. SHOULD THE "CE" MARK OF CONFORMITY BE MADE ACCEPTABLE IN THE U.S. MARKET PLACE?

AT THE PRESENT TIME IT IS BELIEVED SUCH A MOVE WOULD ONLY LEAD TO CONFUSION IN THE U.S. THE EC GOAL OF GLOBAL CERTIFICATION IS RECOGNIZED, HOWEVER, UNTIL STANDARDS ARE HARMONIZED AND ALL MANUFACTURERS CAN SELF CERTIFY TO THE SAME REQUIREMENTS, THERE DOESN'T SEEM TO BE ANY ADVANTAGE FOR THE U.S. TO ACCEPT THE "CE" MARK.

WHILE I CANNOT ADDRESS THE LIABILITY IMPLICATIONS OF SUCH ACCEPTANCE, THE SITUATION WHERE PRODUCTS ARE MANUFACTURED ACCORDING TO DIFFERENT STANDARDS, AND THEN SHIPPED GLOBALLY, OFFERS THE POSSIBILITY THAT, ONE NATIONAL OR SUPRA STANDARD, COULD BE USED AGAINST ANOTHER ONE IN LITIGATION. PRESUPPOSING THAT THERE IS A JUSTIFIABLE REASON FOR HAVING DIFFERING STANDARDS, THE COST OF PROVING THE REASONS COULD BE HIGH.

TOPIC #8. SHOULD U.S. REGULATORY REQUIREMENTS BE HARMONIZED WITH EC REQUIREMENTS?

AS DISCUSSED ,THE HARMONIZATION OF STANDARDS IS DESIRABLE. OVER TIME ITA HAS SPENT CONSIDERABLE TIME AND EFFORT TOWARD THAT END AND WITH FAIR SUCCESS. THE CONCERN IS HOW THE STANDARDS SHOULD BE HARMONIZED. THE INFERENCE WITH TOPIC 8 IS THAT THE US REGULATIONS SHOULD BE HARMONIZED WITH THE EC; ITA DOES NOT AGREE. IN RECENT TIMES THERE IS

A GREAT RELUCTANCE FOR EC TO ACCEPT ANY RECOGNIZED EXISTING U.S. STANDARDS EVEN THOUGH A SIMILAR ONE HAS NOT EXISTED IN EUROPE. IN THESE CASES THEY HAVE CHOSEN TO GO AHEAD AND WRITE THEIR OWN. THIS APPROACH DOES NOT ENCOURAGE HARMONIZATION; IT ONLY PUTS U.S. PARTICIPANTS ON THE DEFENSIVE. HARMONIZATION EFFORTS SHOULD BE STRUCTURED SO THAT STANDARDS FROM ALL PARTICIPATING AREAS ARE GIVEN FAIR AND EQUAL CONSIDERATION. FURTHER THIS SUGGESTS ONE VOTE FOR EACH. AT PRESENT, THE U.S. IS CONTINUOUSLY OUTVOTED BY THE EC COUNTRIES. NOT A GOOD SITUATION.

IT MAY NOT BE POSSIBLE TO HARMONIZE ALL STANDARDS AS THERE ARE CERTAIN REQUIREMENTS, SUCH AS THOSE FOR FIRE SAFETY, WHICH DIFFER BETWEEN THE EC COUNTRIES AND THE U.S. IN THOSE CASES CERTAIN NATIONAL REQUIREMENTS MAY NEED TO TAKE PRECEDENCE AND REMAIN IN EFFECT. HOWEVER, THESE CASES ARE MINIMAL AND OVER TIME IT IS SUGGESTED THE DIFFERENCES WILL DECREASE AND THE POSSIBILITY OF HARMONIZATION INCREASE.

TOPIC # 9. DO MOBILE OFF-HIGHWAY MACHINERY AND LIFTING EQUIPMENT NEED A RECOGNIZABLE MARK OF CONFORMITY? IS A U.S. MARK NEEDED?

AS FAR AS LIFT TRUCKS SOLD IN THE U.S. ARE CONCERNED, THERE IS NO REASON FOR A RECOGNIZABLE U.S. MARK OF CONFORMITY BEYOND WHAT ALREADY APPEARS ON THE TRUCK NAMEPLATE INDICATING COMPLIANCE WITH THE APPROPRIATE B56 STANDARD . NEITHER CUSTOMERS OR REGULATORY GROUPS HAVE REQUESTED ANYTHING DIFFERENT.

EC FEELS DIFFERENTLY. THEY PLAN TO REQUIRE A "CE" MARK OF CONFORMITY AND HAVE A PROCEDURE FOR THE DESIGN OF THE MARK AND THE AFFIXING OF THE MARK TO THE PRODUCT.

AT THE RISK OF REPEATING MYSELF, IF WE WERE ALL DEALING WITH THE SAME SET OF STANDARDS, IT MIGHT MAKE SENSE TO AGREE UPON SOME MUTUALLY ACCEPTABLE MARK OF CONFORMITY.

THIS CONCLUDES THE ITA REMARKS. THE OPPORTUNITY TO PARTICIPATE IN THIS WORKSHOP IS VERY MUCH APPRECIATED. THANK YOU!



ISO 9000 SERIES CERTIFICATION

INTRODUCTION

With the global market an ever increasing reality for all sectors of business, domestic and international competitiveness is essential if companies are to survive and prosper into the 21st century. To achieve these objectives, a company must sustain and improve its market share by consistently satisfying the requirements of a designated market in terms of price, delivery, and quality of goods and services provided. In recent years US industry has recognized the key role played by quality management systems in achieving success by improving:

- Business Effectiveness* - To meet all customer requirements. First time—every time.
- Management Efficiency* - To eliminate wasted time, materials, and effort.
- Overall Economy* - To pay off on the bottom line, providing improved profitability and funds for investment.

Many purchasers and certain international authorities are now requiring that suppliers and importers meet not only product and service specifications, but that they are also able to demonstrate implementation of an effective quality management system. This is accomplished by acquiring independent third party certification of compliance with the internationally recognized ISO 9000 series specifications for quality management systems. **SGS Yarsley Quality Assured Firms** is one of the longest established, and most respected, accredited certification bodies, providing this service throughout North America and the rest of the world.

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ISO 9000 Series Certification...Page 2

WHAT IS ISO 9000?

The ISO 9000 series standards have been developed by the International Organization for Standardization (ISO) in order to provide 'benchmark' minimum requirements to be met by organizations operating effective quality management systems. The requirements are general in nature, can be applied to any organization, and will not contravene any other quality program a company may wish to pursue.

In reality, there are five different standards, three of which (ISO 9001, ISO 9002, and ISO 9003) are intended as contractual documents; the remaining two (ISO 9000 and ISO 9004) being for guidance purposes only. These standards have been adopted throughout the industrialized world and published by many national standards authorities in the respective language of those countries. The requirements within such standards are, nonetheless, identical, e.g.:

International	USA	EC	UK
ISO 9000	ANSI/ASQC Q90	EN 29000	BS 5750 Part 0.1
ISO 9001	ANSI/ASQC Q91	EN 29001	BS 5750 Part 1
ISO 9002	ANSI/ASQC Q92	EN 29002	BS 5750 Part 2
ISO 9003	ANSI/ASQC Q93	EN 29003	BS 5750 Part 3
ISO 9004	ANSI/ASQC Q94	EN 29004	BS 5750 Part 4

Demonstrated compliance with ISO 9001, ISO 9002, ISO 9003 assures customers that a company has a management system in place which is capable of assuring quality from the time of an initial enquiry through to delivery, installation, and servicing (as appropriate). Used to complement other technical and contractual specifications, overall assurance is provided.

The titles of the five standards in the series are given below:

- *ISO 9000 Quality Management and Quality Assurance Standards - Guidelines for Selection and Use.*

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- *ISO 9001 Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing.*
- *ISO 9002 Quality Systems - Model for Quality Assurance in Production and Installation.*
- *ISO 9003 Quality Systems - Model for Quality Assurance in Final Inspection and Test.*
- *ISO 9004 Generic Guidelines for Quality Management and Quality Systems.*

WHAT ARE THE ADVANTAGES OF ISO 9000 CERTIFICATION?

Some of the advantages of an effective quality management system certified by SGS Yarsley Quality Assured Firms are given below:

- Optimized company structure and operational integration
- Improved communications and quality of information
- Responsibilities and authorities clearly defined
- Improved accountability of individuals
- Improved utilization of time and materials
- Formalized systems ensure consistent quality and punctual delivery
- Documented system provides useful reference and training tool
- Fewer rejects, therefore, less repeated work and warranty costs
- Errors rectified at the earliest stage and not repeated
- Improved relationships with customers and suppliers
- Use of recognized logo on stationery and advertisements

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- Improved corporate quality image
- Ability to tender for 'ISO 9000' contracts at home and abroad
- Continuous quality assessment by experienced professionals
- Reduced number of customer audits
- Improved records in case of litigation against the company

In summary:

- ENHANCED MARKETING STATURE → MORE OPPORTUNITIES FOR BUSINESS
- IMPROVED CONTROL → EFFICIENCY → PROFITABILITY → COMPETITIVENESS
- IMPROVED ASSURANCE → CUSTOMER SATISFACTION → SECURITY → SUSTAINED GROWTH
- GOOD MANAGEMENT

WHO IS SGS YARSLEY QUALITY ASSURED FIRMS?

SGS Yarsley Quality Assured Firms (SGS Yarsley) is an affiliate of the SGS group (Société Générale de Surveillance Holding SA). SGS is the world's largest independent inspection and test organization comprising 232 group subsidiaries operating in more than 140 countries. Operations in North America represent over one-third of the group's revenue, where eight subsidiaries employ over 6,500 professional personnel.

SGS Yarsley (UK) was established in 1985 in order to meet the growing demand for quality management systems certification in Europe. Since that time the company has successfully certified over 350 companies and expanded into a worldwide operation. Here in North America an agreement exists whereby SGS Yarsley operates as a division of United States Testing Company, Inc. (a major North American affiliate of the SGS group). ISO 9000 assessments are carried out by a combination of SGS North America and SGS Yarsley (USA) personnel; all trained and approved by SGS Yarsley (UK). Successful companies are awarded an internationally recognized certificate to demonstrate compliance with the appropriate standard for a defined scope of products or services.

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WHAT IS MEANT BY ACCREDITATION AND HOW IS CERTIFICATION RECOGNIZED INTERNATIONALLY?

SGS Yarsley has, since 1986, been accredited to perform ISO 9000 series certification assessments worldwide by the National Accreditation Council for Certification Bodies (NACCB). The NACCB is the most mature accreditation body in the world having been established in 1985 by the UK government's Department of Trade and Industry. The Council lays down stringent rules (incorporating those of the ISO/IEC Guide 48) with which all accredited certification bodies must comply. It also assures the independence and integrity of these private-sector organizations, monitoring, and regulating their operations. The NACCB system has been emulated by most countries, and the Council continues to lead the way toward developing worldwide reciprocal recognition of national systems. This program is already well advanced throughout the European Community.

The ASQC Registrar Accreditation Board is a similar scheme that has been developed within the USA. As yet, this scheme still lacks formal recognition outside of the USA; and, to be internationally creditable, a single national authority (requiring the backing of ANSI) will be necessary. Negotiations between ANSI and ASQC are underway, and **SGS Yarsley (USA)** intends to become a US accredited registrar (third party certification body) under this scheme once the situation is resolved.

HOW IMPORTANT IS THE EUROPEAN FACTOR?

From January 1, 1993 the European community (comprising 320 million consumers) effectively becomes the largest single market in the world when the remaining barriers to free trade are removed. This has an enormous bearing on trade to, from, and within Europe. Recognition of the value of ISO 9000 series certification in Europe is presently some four to six years in advance of recognition in North America, and an increasing number of purchasing organizations promote, or insist upon, the ISO 9000 series certification of their suppliers. About 50 American exporters have already recognized the need to become certified and have undergone a certification assessment. Hundreds more are currently pursuing ISO 9000 implementation programs.

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Articles in technical publications and other authorities within North America promulgate the idea that ISO 9000 certification will become mandatory for all exports to the European community. This is not necessarily true. Our understanding is that it will be mandatory at least for purchases involving funds from the 12 European governments, many local government purchases, and a number of technical and safety-related products (covered by EC legislation or other authority standards). Organizations in the private sector may, or may not require ISO 9000 series certification now or in the future.

Whilst ISO 9000 series certification may not be mandatory, all exporters to the European community should seriously consider their marketing position. In most cases they will find that their European competitors are already pursuing certification which could give them a marketing advantage.

Other organizations in North America view ISO 9000 from a different angle. That is, it will help to secure their home markets as competition from Europe, the Pacific Basin, and the rest of the world increases. (Many companies in the Far East are also pursuing ISO 9000 series certification.)

WHAT IS INVOLVED IN THE CERTIFICATION PROCESS?

- Confidentiality:

Secrecy is maintained concerning all confidential information divulged to **SGS Yarsley** employees or their agents.

- Proposal of Costs:

On receipt of a completed questionnaire, a proposal outlining the scope of the assessment and costs involved will be submitted to the applicant.

- Application:

On receipt of a completed application form together with first year fees and controlled copies of quality management system documentation, a Lead Assessor will be assigned. The assessment is progressed within 10 weeks.

SGS Yarsley Quality Assured Firms

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- Initial Assessment:

The initial assessment is carried out in two stages:

The Desk Study (Stage 1) involves scrutiny of the submitted documented system and preparation for the on-site assessment. Details of major shortcomings within the documented system are submitted to the applicant in writing.

The On-Site Assessment (Stage 2) takes place at the applicant's premises and (if applicable) remote site locations. Assessment findings are reported verbally both during, and on completion of, the assessment. The Lead Assessor's recommendation is also made known to the applicant at the end of the assessment, and a report is subsequently generated.

- Corrective Action Requests:

Noncompliances within an applicant's system will be the subject of Corrective Action Requests (CARs). A limited time is allowed for applicant companies to rectify the cause(s) of the non-compliance(s). CARs sentenced 'Major' remaining unresolved on completion of the initial assessment will result in a delay to the Lead Assessor's recommendation for certification.

- Certification:

When the Managing Director, **SGS Yarsley**, is confident that the applicant meets ISO 9000 series criteria, he will inform the applicant and issue a certificate (conditionally valid for three years).

- Surveillance:

Elements of the applicant's quality management system are re-examined at approximately six monthly intervals, at the applicant's premises, on prearranged dates.

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- Reassessment:

Reassessment takes place after every three-year cycle in the format described above.

- Extension of Scope:

Extension to a company's scope of registration is possible following a company's formal application. (Additional cost may be involved.)

- Suspension, Withdrawal, and Cancellation of Certificate:

In cases where Corrective Action Requests are not satisfactorily addressed, certificates are improperly used, or **SGS Yarsley's Codes of Practice** are contravened, certificates may be suspended and ultimately withdrawn. Certificates will be cancelled if a company does not wish to renew the certificate or ceases trading.

- Appeals and Complaints:

Client companies have the right to appeal to **SGS Yarsley's** independent Board of Directors against suspension or withdrawal of certificates. A system also exists should client companies wish to complain regarding the conduct of **SGS Yarsley** employees or agents of the company.

Note: The above information does not form any part of a contract with a client company and is intended for information purposes only. Full details of SGS Yarsley's current Codes of Practice are forwarded upon receipt of a completed questionnaire.

HOW LONG WILL IT ALL TAKE?

The time required to document and implement a quality system compliant with the requirements of ISO 9000 series standards will vary depending on the following:

- Sincere commitment from senior management
- Adequate provision of resources (chiefly time and training)

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- The nature, complexity, and size of the operations to be controlled
- The previous existence of a mature control system.

Typically, in our experience, the times required for companies to prepare their quality management systems to the stage where documentation is ready for submission to **SGS Yarsley** are as follows:

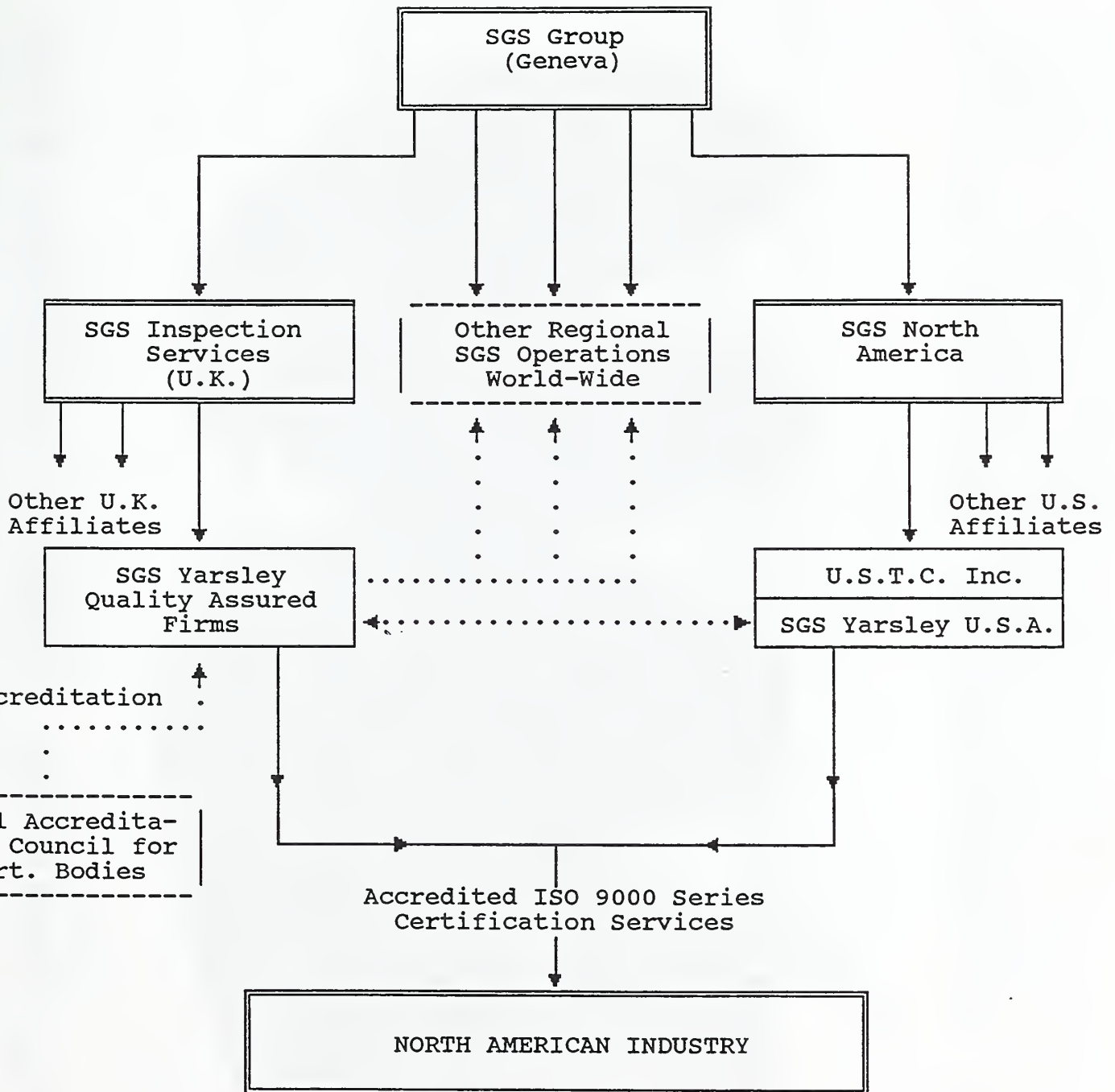
- A small service organization (10 employees)—
6 Months
- A medium-sized manufacturing company
(30 employees)—6-12 Months
- A large manufacturing/process company—12-18 Months
- A multisite manufacturing/process company—2-4 Years

The schedule for assessment by **SGS Yarsley** may vary in accordance with our fluctuating workload; however, the following schedule will provide some guidance. We endeavor to:

- Commence the assessment within four weeks of receipt of the appropriate documentation and fees.
- Complete Stage 1 of the assessment within six weeks.
- Complete Stage 2 within 10 weeks.
- Issue a certificate within four weeks of Lead Assessor's recommendation.

WHAT IS THE COST OF CERTIFICATION?

Costs vary considerably dependent upon the size, complexity, and nature of the applicant's business. A full proposal of certification costs for the three-year period will be submitted upon receipt of **SGS Yarsley's** completed questionnaire. It has been our experience that, in most cases, certification costs have been justified by the increases in efficiency and customer satisfaction client companies derive from quality management systems compliant with ISO 9000 series standards.



SGS YARSLEY
 QUALITY ASSURED FIRMS/
 SGS GROUP STRUCTURE

301-443-1111
- INFORMATION

US. DEPT. OF COMMERCE

202-377-5276

SGSARE

90/683/EEC

Directive For

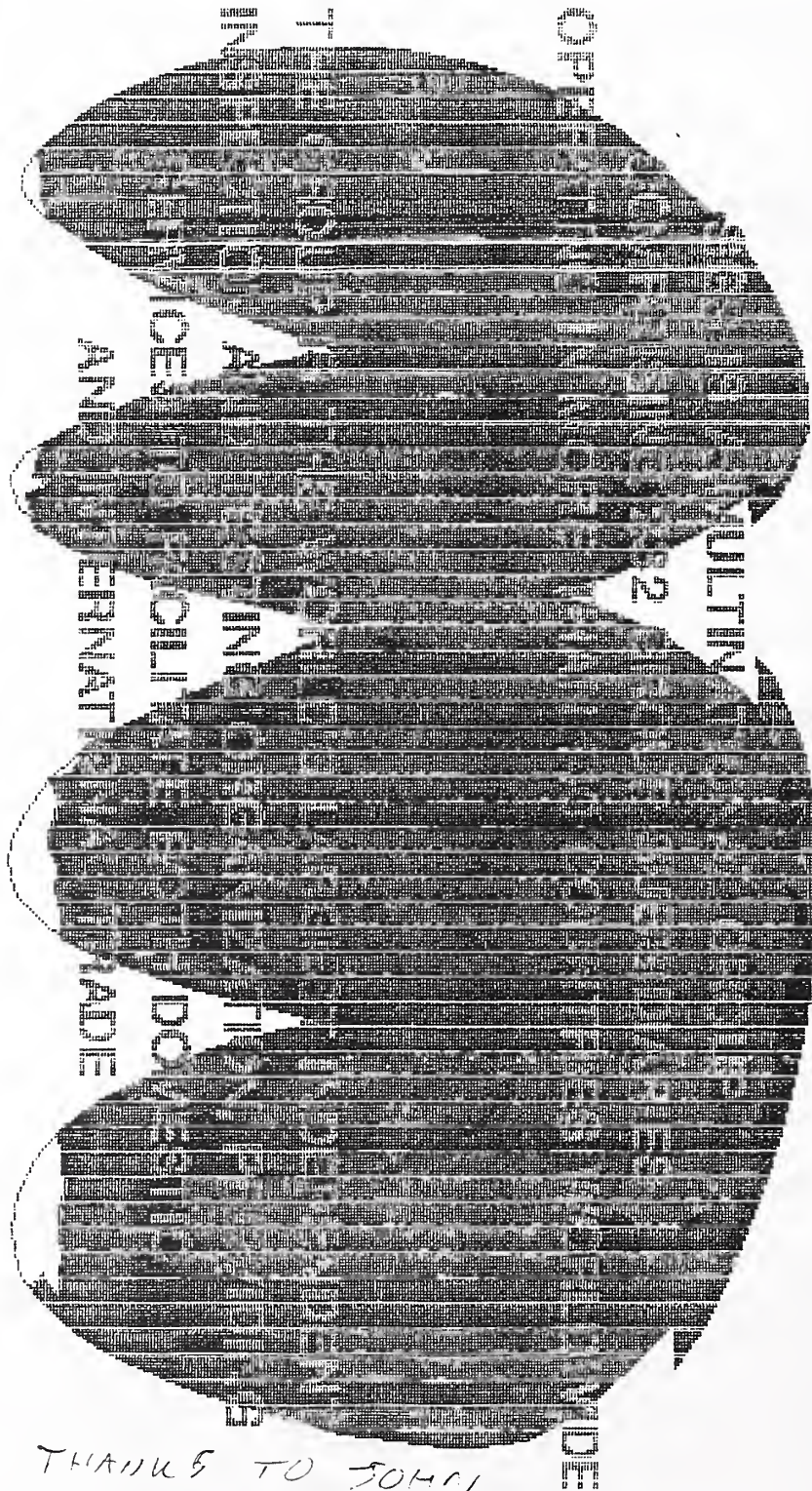
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SGS Yeasby Quality Assured Fines Limited
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... of North America, ... of ...
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CRANE INSPECTION BUREAU.

IN N. AMERICA SO'S OPER ... AS A DIVN OF USTC.
MAJOR AFFILIATE V/S GROUP INC 112 + ...

ISO 9000 SERIES SPECIFICATIONS

An outline of requirements

See Further Study Document Page

IN THE NEXT MINUTES : WE WILL PROVIDE AN INTRODUCTION TO ISO9000 113 (LAW WHERE IT WAS ORIGINATED)

EVOLUTION OF ISO 9000 SERIES

Ministry of Defence (UK)
Standards
MOD 05 series

Allied Quality Assurance Publications
AQAP Standards

U.S. Military Specification
MIL-Q-9858A

Other Procurement Standards

BS 5750 (1979)

BS Guides (1979)

BS 5750 (1987)

ISO 9000 (1987)

ANSI/ASQC Q90 Series

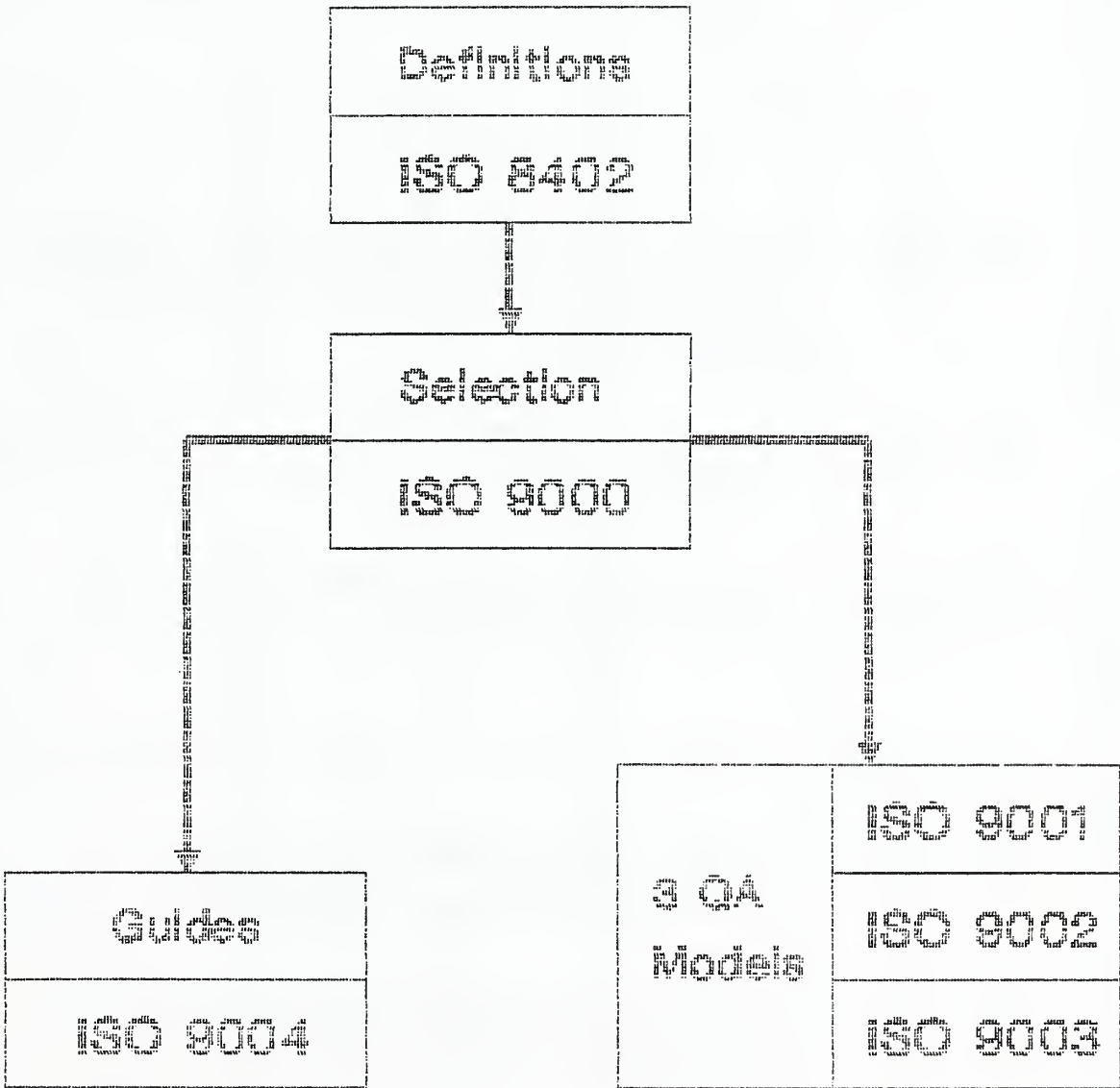
EN 29000 Series

Other National Standards

STATS Yearley Quality Assured Firms

ROA VARIOUS 74% OF ALL US 31-1115/1

ISO STANDARDS



ISO for Quality Assurance

3 STDS FOR CONTRACT
+ GUIDE FOR USE

PROCESS

ISO 9000 SERIES

ISO 9000 : Quality Management and Quality Assurance Standards - Guidelines for selection and use

ISO 9001 : Model for Quality Assurance in Design/Development, Production, Installation, and Servicing

ISO 9002 : Model for Quality Assurance in Production and Installation

ISO 9003 : Model for Quality Assurance in Final Inspection and Test

ISO 9004 : Quality Management and Quality System Elements - Guidelines

ISO 9004 (Part 2) : Quality Management and Quality System Elements - Guidelines for Services

ISO Family Quality Assured Firm

(90 INTERU)

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INTERNATIONAL EQUIVALENTS

INTERNATIONAL	USA	ES	UK
ISO 9000	ANSI/ASQC 090	EN 29000	BIS 6750 PART 0.1
ISO 9001	ANSI/ASQC 091	EN 29001	BIS 6750 PART 1
ISO 9002	ANSI/ASQC 092	EN 29002	BIS 6750 PART 2
ISO 9003	ANSI/ASQC 093	EN 29003	BIS 6750 PART 3
ISO 9004	ANSI/ASQC 094	EN 29004	BIS 6750 PART 4

SEE VALLEY QUALITY ASSURED FIRM

TO COMPLICATE USA 19 STANDARD AND ISO
MACHINE BY LOCAL 117 USE PATENT RIGHTS - UK IS CALIBRATED

WHAT IS ISO 9000?

- Developed by the I.S.O. (INTERNATIONAL ORGANIZATION FOR STANDARDIZATION) - 1987
- Specifies a series of MINIMUM REQUIREMENTS for Quality Management Systems
- Requirements are GENERAL in their nature and may be applied to ANY organization
- Meeting ISO 9000 Requirements will not contravene any other (Quality) Management Program

SSS Verulay Quality Assured Firm

WHY ISO 9000 ?

An effective ISO9000 system provides...

- FRAMEWORK for EFFECTIVE MANAGEMENT
- IMPROVED CONTROL
- INCREASED PROFITABILITY
- MARKETING ADVANTAGE

ISO 9000 AND EUROPE

Is ISO 9000 series certification mandatory?



FROM 1st January 1993 the

EUROPEAN COMMUNITY will

function as a SINGLE MARKET

Barriers to free trade

will be removed

Many purchasing organizations within

the E.C. already recognize the value of

ISO 9000 series certification of their suppliers

Certification is indeed required by certain E.C.

product conformity regulations, but MANDATORY

COMPLIANCE with contract requirements is

more likely for most exporters.

9000 series quality standard

11 EUROPE
2-3-1993
THAT MAKES IT
FOR PURCHASERS TO USE

ISO 9000 series certification
Q.A. systems are inherent
cannot be invented
by technical construction file

(NO OUTLINE)

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ISO 9001 OUTLINE

1 MANAGEMENT RESPONSIBILITY

1.1 QUALITY SYSTEM

1.2 QUALITY POLICY

1.3 QUALITY OBJECTIVES

1.4 ORGANIZATION

1.5 DOCUMENT CONTROL

1.6 MANAGEMENT REVIEW

1.7 MANAGEMENT SYSTEM EVALUATION, IMPROVEMENT & DELIVERY

1.8 PERFORMANCE MEASUREMENT

2 PRODUCT CONTROL

2.1 CONTROL OF PRODUCTING PROCESS

2.2 PRODUCT REQUIREMENT DETERMINATION

2.3 PRODUCT REALIZATION

2.4 PRODUCT IDENTIFICATION AND TRACEABILITY

2.5 PRODUCT RELEASE

2.6 CONTROL OF NONCONFORMING PRODUCT

2.7 CORRECTIVE ACTION

2.8 PREVENTION MEASURES

2.9 STATISTICAL TECHNIQUES

3000 Quality Assured Firm

SUMMARY (1)

ISO 9000 SYSTEM ADVANTAGES

IMPROVED ASSURANCE



CUSTOMER SATISFACTION



CONFIDENCE

SECURITY



SUSTAINED GROWTH

SUMMARY (2)

ISO 9000 SYSTEM ADVANTAGES

IMPROVED CONTROL



EFFICIENCY



PROFITABILITY



COMPETITIVENESS

34

(90 SUMM3)

SUMMARY (3)

ISO 9000 SYSTEM ADVANTAGES

ENHANCED MARKETING STATURE



MORE OPPORTUNITY FOR
INCREASING BUSINESS

SAS: Your Quality Assured Firm

A5

(FOURSTEPS)

enter step phase 50 900 set for in

THE FOUR PHASES

1 - Commitment

2 - Development

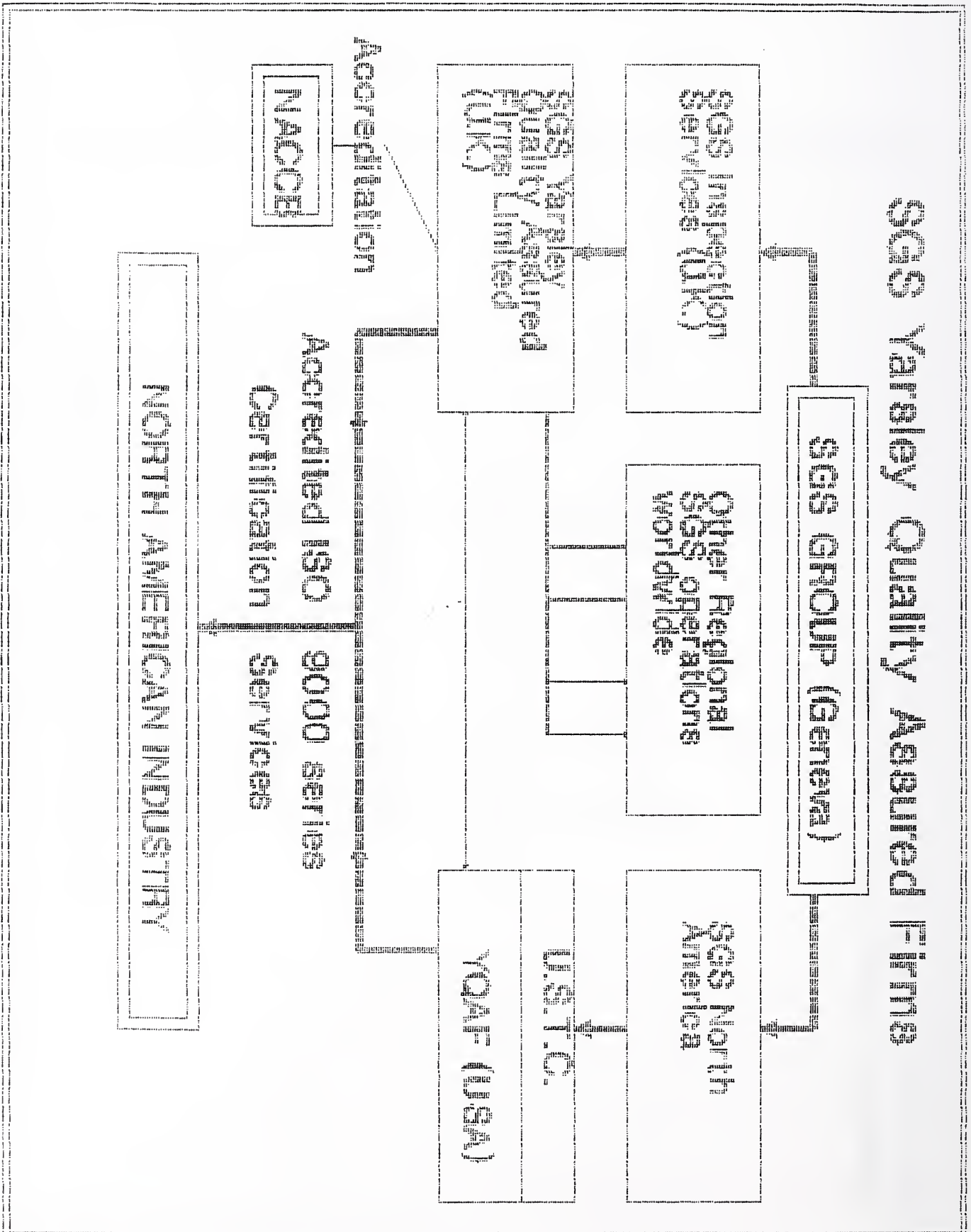
3 - Refinement

4 - Completion

THE FOUR PHASES

A4

(RELNSHP)



Toll Free: 1-800-356-9180
Wisconsin Call: 608-629-5101
FAX: 608-629-5666



Post Office Box 275
Readstown, WI 54652

Manufacturing Co., Inc.

November 15, 1991

Robert Gladhill
United States Department of Commerce
National Institute of Standards and Technology
Gaithersburg, MD 20899

Dear Mr. Gladhill:

As you may recall, I was a panelist at the recent Mobile Machinery Workshop held in Washington on November 12, 1991. At the workshop I advised Stanley I. Warshaw of my intent to submit a written commentary on the issue of ISO-9000 third party certification as it is being considered in the EC market.

Enclosed is my written commentary for incorporation into the written record of the proceedings of the workshop. I have gone to a considerable amount of time and effort to write this because I firmly believe there are considerable problems in the fundamental assumptions of those who believe such certification is needed.

I appreciate your assistance. Please contact me should you need anything further.

Sincerely,

A handwritten signature in cursive script that reads "Richard Lowe". The signature is written in black ink and is positioned above the printed name and title.

Richard Lowe
President

Enclosure:

Toll Free: 1-800-356-9180
Wisconsin Call: 608-629-5101
FAX: 608-629-5666



Post Office Box 275
Readstown, WI 54652

Manufacturing Co., Inc.

The Use of Third Party ISO-9000 Certification as a Regulatory Tool in the European Economic Community

Comments of Lowe Manufacturing Company, Incorporated. Submitted for inclusion into the written record of the November 12, 1991, Mobile Machinery Workshop sponsored by the Equipment Manufacturer's Institute and the United States Department of Commerce.

Date: November 14, 1991

By: Richard Lowe, President

Background:

Lowe Manufacturing Company, Incorporated (LOWE) was selected as a panelist for the Mobile Machinery Workshop. Our company was established in the mid 1950's and eventually incorporated in October 1973. As a small, family operated business, Lowe has manufactured a line of hydraulic-powered hole drilling attachments for skid steer loaders, backhoe loaders, cranes, and other light construction and general utility equipment since 1971. We have also produced a line of trenching attachments for skid steer loaders since 1985.

LOWE is also a member of the Attachment Manufacturer's Council of the Equipment Manufacturer's Institute. Within this council are approximately 25 other companies that manufacture attachment and implement products for use on various types of agricultural, construction, and utility equipment. Several of these member companies are also expanding their efforts to export products overseas.

Since the recession years of 1981-82, Lowe has seen a five-fold increase in its business and has undertaken efforts to penetrate the Canadian and European markets. Other nations and regions of the world are now under consideration for

further marketing efforts. This must be considered an aggressive effort by a company that gives new meaning to the phrase "small manufacturer." Indeed, on magazine advertising response cards, we check the boxes stating less than 50 employees and sales of less than five million dollars. This small size enables us to remain in close contact with our distributor and customer base.

LOWE is probably representative of the vast number of small businesses and manufacturers who are being relied upon more and more by the Federal and state governments to increase exports and therefore create the jobs and wealth this nation needs to remain as one of the major economic forces in the world.

Until the corporate year 1989-90, LOWE had virtually nonexistent direct product representation in the nations of the European Economic Community (EC). In the corporate year 1989-90, LOWE signed an agreement with a distributor based within the EC and proceeded to sell its products in Europe on a direct basis. That first year saw European sales well above initial expectations, with the next year seeing a very small decline due to recession and pipeline filling. For the first part of the current corporate year, sales of LOWE products are on a record pace that could see a doubling of LOWE's annual EC sales.

We project sales in the EC will continue to increase over the next several years, based on our analysis of the EC market and on our past experience in penetrating new markets. Such figures have and will constitute a substantial portion of our total sales.

Reports indicate that we are able to sell in Europe because no European competitor has yet been able to match our price, performance, or product quality. We are also miles (kilometers) ahead of our European competitors in the areas of product safety and labeling. If our European competitors were even equal to us, a small company such as ours, being based in the United States, would have no hope of being successful in the EC.

Like many other small manufacturers, LOWE is concerned that regulations and standards now under consideration in Europe may severely restrict or even eliminate the EC as a market for LOWE products.

We have monitored the development of the Machinery Safety Directive and will continue to do so. The subject of this document, however, will primarily be the proposed third party certification of manufacturing processes based on the ISO-9000 series of standards.

Description of ISO-9000

We have read the ISO-9000 standard, which consists of five separate parts. Although the standard never mentions a certification procedure requirement, an article in *INDUSTRY WEEK*¹ magazine, states that it is intended for a nation subscribing to the ISO-9000 standard to have a three-level administrative system to enact compliance. At the top is an accreditation group within each country which oversees the various registrars. The second level is the registrars themselves, which are firms that have been cleared by the accreditation group to perform audits and to award ISO-9000 registration to qualifying companies. The third level is the individual auditors, who must undergo training in the details of the standard.

This description of the certification structure was reinforced by two speakers at the workshop, Peter Yurcisin who represented ANSI (American National Standards Institute) and John Brookes from SGS Quality Assurance Firms.

The article further states that the ISO-9000 standard requires a company submit to surveillance visits twice a year once the initial certification is achieved. It is claimed that the EC will require all manufacturers of toys, simple pressure vessels, construction equipment, machine safety devices, personnel protective equipment, gas appliances, electromedical equipment, electromagnetic capability, and nonautomatic weighing instruments to undergo ISO-9000 certification by December 31, 1992, or cease doing business in the EC.

The cost of initial registration was estimated in an adjoining article at about \$500,000 for a facility of approximately 250 people². This figure included an initial failure to pass the first certification audit because the subject company had not convinced their people that it was a good idea.

It is extremely important to note that ISO-9000 is entirely about quality processes and conveys *no quality requirements on the end products themselves*. The standard is written in broad language and makes liberal use of the word *should*, avoiding the more demanding word *must*. Three of the five ISO-9000 documents (ISO-9001 through 9003) are written solely to address external quality

¹Tracy E. Benson, "Quality Goes International" *Industry Week* vol 240, no. 16 August 19, 1991 p.54-56

²"The Long and Winding Road to ISO-9000" *Industry Week* vol 240, no. 16 August 19, 1991 p.57

assurance programs such as might be found in a contractual agreement requiring process verification.

The standard acknowledges a company must offer products or services that, among other things, satisfy a customer's expectations and are made available at competitive prices³. Requirements dictated by the product user drive the processes necessary to attain the required quality. In fact, throughout the ISO-9000 documents, the standard discusses the needs of the company and of the customer with approximately equal weight.

We also note specific statements within the ISO-9000 basic document relating to its use, such as⁴:

"Note - It is not the purpose of this series of International Standards (ISO-9000 to ISO-9004 inclusive) to standardize quality systems implemented by organizations."

In the ISO-9004 document, we find further support of this position as follows⁵:

"1. This International Standard is not intended to be used as a checklist for compliance with a set of requirements."

It is obvious to anyone reading the standard in an objective manner that ISO-9000 was never intended to be used as a method to approve quality processes in a regulatory fashion. The authors of the documents had the good sense to see the myriad of problems that would arise by attempting to adhere to precise methods for quality processes and repudiated that approach a number of times.

However, we are concerned when we see information such as that provided in the INDUSTRY WEEK article. Our concern is further reinforced after hearing Mr. Brookes state that ISO-9000 is not a requirement for selling products in the EC at this time, but there may be changes in the future scope of this and other aspects of the EC-92 program.

This information leads us to believe that certain members of the EC are not following the statements or intent found in the standard. Instead, it appears they

³ISO-9000 Quality Management and Quality Assurance Standards-Guidelines for Selection and Use Ref no. ISO-9000: 1987(E) page 1.

⁴Ibid page 2.

⁵ISO-9004 Quality Management and Quality System Elements-Guidelines Ref no. ISO-9004: 1987(E) page 2.

are seriously going forward with plans to utilize ISO-9000 as a document to restrict the flow of goods into Europe to only those few companies that have been able to find the time and money to obtain ISO-9000 certification registration. This cannot be allowed if the EC is truly intent on a free, market-driven economy.

A Definition of Quality

If ISO-9000 is to have merit as a regulatory document, there must be a measurable and universal definition of quality. Yet the ISO-9000 documents themselves make no attempt to define quality. After searching in other sources, it appears achieving a suitable definition of quality is a considerable problem.

Simple dictionary definitions leave much to be desired. WEBSTER'S defines quality as⁶:

"a particular property inherent in a body or substance; an essential attribute or characteristic; character or nature; degree of excellence."

FUNK AND WAGNALLS⁷ doesn't fare much better. It defines quality as:

"1. That which makes something such as it is; a distinguishing element or characteristic. 2. The basic or essential character, nature, etc., of something. 3. Excellence: quality rather than quantity. 4. The degree of excellence. 5. A moral or personality trait or characteristic. 6. (Music) The timbre of a voice or musical instrument. 7. (Archaic) High or superior social rank or birth; also, persons of superior rank collectively- (adj) of superior quality.

None of the above definitions provide us with a distinct, measurable, and clearly defined entity upon which a standard based on quality processes can be reasonably based. We then must probe into the philosophical field where we find a lengthy discussion of quality in a book by Robert Pirsig entitled ZEN AND THE ART OF MOTORCYCLE MAINTENANCE⁸. As a professor in a University setting Pirsig initially sought to define quality. The task proved to be extremely difficult. As one

⁶Webster's Dictionary For Everyday Use (1981) pages 256-257.

⁷Funk and Wagnalls Standard Desk Dictionary (1976) page 541.

⁸Pirsig, Robert M. Zen and the Art of Motorcycle Maintenance (New York, NY: Bantam Books 1974)

of his students stated "I think there is such a thing as quality, but that as soon as you try to define it, something goes haywire. You can't do it."⁹

Pirsig later worked up a definition and presented it to his students for discussion. It read:

"Quality is a characteristic of thought and statement that is recognized by a nonthinking process. Because definitions are a product of rigid, formal thinking, quality cannot be defined."¹⁰

Then he wrote below the definition; "But even though quality cannot be defined, you know what quality is."¹¹

Of course, this type of definition of quality again does not give us anything upon which a process quality standard can be written. Pirsig went further in his discussion on quality to state that "Quality is shapeless, formless, indescribable. To see shapes and forms is to intellectualize. Quality is independent of any such shapes and forms. The names, the shapes, and forms we give quality depend only partly on the quality. They also depend partly on the *a priori* images we have accumulated in our memory."¹² The reason people see quality differently, says Pirsig, is because people come up with different sets of analogues.

According to Pirsig, this is why a class of college freshman composition students arrive at similar ratings of quality in written compositions. They all have relatively similar backgrounds and knowledge. But if a group of foreign students were brought in, or medieval poems out of the range of the class experience were brought in, the students' ability to rank quality would not correlate as well.

Perhaps this is why I received only blank stares when I asked Mr. Yurcisin and Mr. Brookes to *Define Quality*. No answer was received.

We need to consider the ramifications of this problem when we consider the merits of using ISO-9000 certification as a basis for regulation. If quality cannot be defined objectively or quantified, and/or is subject in large part upon the preexisting knowledge and values of the beholder, then quality processes cannot be objectively evaluated or defined, much less regulated in an objective manner by third party ISO-9000 bureaucrats.

⁹ibid. p. 200.

¹⁰ibid. p. 200.

¹¹ibid. p. 201.

¹²ibid p. 243.

Differing Expectations for Quality

That part of the inability to achieve an effective definition of quality is because so much of it is in the eye of the beholder is only part of the problem.

Pirsig's book also describes an event in philosophy where scientist Jules Henri Poincare pointed out discrepancies in the world of pure science that appear relevant to a discussion of the merits of ISO 9000. In his discussion, Poincare notes that a German named Reimann appeared years ago with a system of geometry which throws out the Euclidian geometry postulate and also the first axiom, which states that only one straight line can pass through two points.

Poincare mentions that there are no internal contradictions in the two geometries, only an inconsistency between the two. He also notes that Reimann geometry best describes the world we live in according to the theory of relativity.

Poincare concluded that axioms of geometry are conventions guided by experimental facts, but remaining free and limited only by the necessity of avoiding all contradiction. When the question came up as to which method of geometry is true, Poincare concluded the question has no meaning. "As well ask whether the metric system is true and the avoirdupois system is false; whether Cartesian coordinates are true and polar coordinates are false. One geometry cannot be more true than another; it can only be more convenient. Geometry is not true, it is advantageous.¹³"

By the same method of reasoning, we at LOWE are extremely concerned that any standard that attempts to define and regulate quality processes by measuring them against presumed absolutes which in reality do not exist, will have precious little relevance to the world of the small manufacturer. Bureaucrats trained in academia, typically versed in the way large corporations operate, and then trained in the technical details of an ISO-9000 training seminar will no doubt have culture shock at the very least when they attempt to examine and approve the quality processes of a small firm with potentially different quality values and approaches.

¹³Ibid. p. 257. The original author did not fully cite this source.

Innovation or Stagnation?

We predict problems of stagnation in business will occur on account of ISO-9000 as has happened to numerous other standards and regulations. No less of an authority than Dr. Michael Porter of the Harvard Business School stated at a September 30, 1991, seminar in Washington, D.C. that while product standards in many instances are desirable, process standards are misguided and wrong because they inhibit innovation¹⁴. Dr. Porter is considered by many to be the most sought after business consultant available today and advises several major worldwide corporations, as well as governments, on major issues of strategy and competitiveness.

Dr. Porter has also recognized that requirements for licensing (another type of certification) were an intermediate form of government regulation, tend to restrict entry to markets, and thereby provide entry barriers to markets¹⁵. He further went on to make a statement that can be applied virtually unchanged to the issue of ISO-9000 certification. That statement read: "Although such a requirement will be easily met by the larger companies, many smaller companies may be severely hurt by the increased overhead....."¹⁶

Proponents of ISO-9000 regulation seem to indicate that this is the type of approach that Japan uses with great success, yet here too we see flaws in their arguments. Our company sells hydraulic auger and trenching attachments to Toyota Industrial Equipment, a Division of Toyota Motor Company. It is still an unusual situation for a U.S. manufacturer to have such a relationship with a Japanese firm yet we now have several years of experience under our belt.

Our own experience, along with the trade journals and literature we have read, indicates that the Japanese are driven by the concern to produce products that best meet the needs of the customer with as high of quality as can be produced. Yet the processes required are determined by the needs of the product. There is no requirement of an ISO-9000 type regulation and none has ever been mentioned.

We feel that Japanese success in manufacturing quality goods has its roots in places other than ISO-9000 style regulation. In an interview during a visit to Japan

¹⁴ EMI Annual Convention (September 30, 1991) Washington, D.C. "We were there."

¹⁵ Porter, Michael E. Competitive Strategy, Techniques for Analyzing Industries and Competitors (New York, NY: Macmillen Publishing Company 1980) page 181.

¹⁶ Ibid. page 182.

in the early 1980's, a U.S. mission studying the Toyota production system met with the developer of the Japanese JIT (Just in Time) concept, Taiichi Ohno. When asked what inspired his thinking, Ohno replied "I learned it all from Henry Ford's book¹⁷" (TODAY AND TOMORROW, first published in 1926). As it turned out, the late Chairman Setsutarō Kobayashi's favorite passage came from a chapter in that book:

"It is not easy to get away from tradition. That is why all our new operations are always directed by men who have no previous knowledge of the subject and therefore have not had a chance to get on really familiar terms with the impossible. We call in technical experts whenever their aid seems necessary, but no operation is ever directed by a technician, for always he knows far too many things that can't be done. Our invariable reply to it can't be done is; Go do it.¹⁸"

Keeping this thinking in mind, it was interesting to listen to Mr. Yurcisin's response to an audience question that, in general, asked why ISO-9000 was needed if a company's products were accepted by the customer as being of excellent quality? His response stated his puzzlement at not believing a standard for anything is undesirable and he completely missed the point the questioner was attempting to make about ISO-9000 process certification by a third party. Apparently, ANSI is so smitten by the idea of a standard that it is guilty of exactly what Mr. Ford was talking about. In our view, we need to recall and re-word an old phrase; that ANSI never met a standards proposal it didn't like.

The need for constant change in the business world was emphasized in a recent article by John Huey in FORTUNE magazine. The article quotes Thomas Paine when he warned "a long habit of not thinking a thing wrong gives it the superficial appearance of being right.¹⁹" Our experience in observing the standards and regulation arena has clearly shown this type of thinking to be very commonplace.

Huey also notes: "In today's unforgiving business climate, more and more rule books are winding up in the trash.²⁰" He also quotes Ram Charan, a consultant to many Fortune 500 firms and a former faculty member of the Harvard Business School who says; "Quite simply, those who don't shift (with the shifting

¹⁷"Our Debt to Henry Ford" Business Tokyo vol 4, no. 4 (April 1990) p 44.

¹⁸Ibid. p 44

¹⁹Huey, John. "Nothing is Impossible" Fortune September 23, 1991. pp. 135-140.

²⁰Ibid. p. 140.

paradigms) will get shifted. And no company in the world, number one market share or not, is immune from becoming dust.²¹"

Based on these warnings and our own experiences, we feel our fears of stagnation in product refinement and development because of the ISO-9000 certification and renewal process are more than justified. An ISO-9000 technician will be extremely well versed in the processes and techniques required by the conventional wisdom found in standard regulation, but this may not be appropriate to the manufacturer's continuous quest to provide products that best meet the customer's needs. Alternately, such enforcement may become obsolete so quickly that following the standard will actually place a company at a distinct competitive disadvantage.

Then, under ISO-9000 certification, imagine what will be done with the person or company courteously called a paradigm shifter (and not so courteously called a rabble-rouser) who breaks the rules of conventional wisdom and provides a better product for the customer, with lower cost and improved quality. A bureaucratic mentality as illustrated by ANSI, fostered by regulation that is out of touch with the changing business world, would likely think this couldn't happen and refuse or revoke certification. We predict such instances will happen several times within the first year if ISO-9000 standards certification regulation is implemented.

ISO-9000 Regulation's Impact on the Marketplace

For such regulation and certification to be effective, the customer as well as the manufacturer must see value in it. Yet, in spite of promotional efforts by the backers of ISO-9000 certification, our reports from Europe indicate there has been very little in the way of customer request for it.

We have always had a concern as to what we feel is an underlying premise of the EC Machinery Safety Directive; that is, a condescending opinion of the product user and the underlying tone that the customer is somehow not the best judge of how well a product will safely and properly perform the required task. Proposed ISO-9000 certification requirements appear to take such a viewpoint and attempt to apply it in an even more extreme manner. Where does it all end?

For LOWE, there is absolutely no benefit to third party certification based on the ISO-9000 standard. Alternately, requiring the sheer expense of an initial ISO-9000

²¹Ibid. p. 140.

audit and the semi-annual surveillance visits shows clearly the potential of forcing us out of the EC marketplace altogether. This is not because we have a fear about our quality, but rather because we would be faced with a considerable operating loss for European operations.

At present, there are precious few authorities in the United States that are capable of certifying a company to ISO-9000 and the process itself requires approximately 12 to 18 months to complete. In effect, ISO-9000 certification and regulation is a trade barrier that blocks a substantial portion of U.S. businesses from viably exporting products to the EC. We view this as nothing more than an attempt at legalized extortion by a budding special interest group, or at the very least a type of privilege tax required to continue to do business in the EC.

Certification and regulation based on ISO-9000 also fails to take into account that oftentimes processes are a firm's primary competitive advantage and that their disclosure by an ISO-9000 examiner could seriously jeopardize a firm's competitive advantage, even though there is claimed to be a confidentiality provision. Regulation also imposes a third-party translator in the crucial link between a manufacturer and the user base which would restrict responsiveness to customer feedback and slow the development of improved products.

Numerous other small and mid-sized companies, both in North America and in Europe, will also be faced with another problem. Extend the onerous registration requirements to startup companies who already have a statistically high rate of failure and then ask how many products and innovations will never be developed and jobs not created because of ISO-9000 regulation?

The long-term effects on creativity and entrepreneurship could result in large company dominance and stagnation in several industries. Such stagnation and large company dominance would result in a lack of competition that no anti-trust laws could ever overcome.

LOWE is unwilling to allow itself to bury its head in the sands of ISO-9000 certification regulation. We cannot see the benefit of locking into the current conventional wisdom as it pertains to quality processes and we do not wish to spend precious time and hundreds of thousands of dollars on a redundant document that tells us nothing more than our customers haven't already told us. We also dislike running the risk of spending that amount of money and "failing" certification in a bureaucrat's eyes, thus having to withdraw from a growing and necessary market.

We would like to think this is not a serious issue but it appears otherwise. In our industry and perhaps several others, ISO-9000 regulation achieves a form of economic totalitarianism that can do nothing to improve the quality of products better than can be achieved by a discriminating buying public. As such, ISO-9000 certification and regulation is superfluous and unjustified.

And, as usual, the costs of such bureaucratic excesses will have to be passed on to the consumer in the form of higher prices.

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10. SUPPLEMENTARY NOTES				
11. ABSTRACT (A 200-WORD OR LESS FACTUAL SUMMARY OF MOST SIGNIFICANT INFORMATION. IF DOCUMENT INCLUDES A SIGNIFICANT BIBLIOGRAPHY OR LITERATURE SURVEY, MENTION IT HERE.) <p>On November 12, 1991, the National Institute of Standards and Technology (NIST) and the Equipment Manufactures Institute (EMI) cosponsored a workshop to explore ways in which the U.S. Government can assist the mobile machinery industry to meet conformity assessment requirements and gain acceptance of its products in international markets such as the European Community (EC). This report summarizes the discussions.</p>				
12. KEY WORDS (6 TO 12 ENTRIES; ALPHABETICAL ORDER; CAPITALIZE ONLY PROPER NAMES; AND SEPARATE KEY WORDS BY SEMICOLONS) <p>conformity assessment; EC 92, certification; international trade; ISO 9000; mobile machinery; testing</p>				
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