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Proceedings of the Open Forum on Laboratory Accreditation at the National Institute of Standards and Technology October 13, 1995

Walter Leight and Lawrence Galowin, Editors

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Office of Standards Services
Technology Services
National Institute of Standards and Technology
Gaithersburg, MD 20899-0001

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U.S. Department of Commerce
Michael Kantor, *Secretary*

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Mary L. Good, *Under Secretary for Technology*

National Institute of Standards and Technology
Arati Prabhakar, *Director*

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FOREWORD

The following announcement for the meeting on laboratory accreditation at the National Institute of Standards and Technology was widely distributed in a flyer sent to potentially interested organizations. Information on registration and a program agenda were provided to encourage a broad cross-section of representatives to attend and participate in discussions. The issues all related to accomplishing changes in the U.S. multi-faceted approach to laboratory accreditation and to seek the establishment of a unified system to facilitate domestic commerce and to achieve international acceptance of the currently diverse arrangements for recognition of laboratory accreditation.

Announcement of Open Forum
Friday, October 13, 1995

National Institute of Standards and Technology

LABORATORY ACCREDITATION IN THE UNITED STATES

ACIL, ANSI, and NIST are cosponsoring an open forum to discuss issues in laboratory accreditation. It will offer an opportunity to define the needs for a more streamlined system to eliminate current duplication in approvals and unnecessary costs. The forum is intended to generate discussion on possible ways for achieving greater compatibility, coordination, and mutual recognition of competent laboratory accreditations.

Several task groups have assessed the problems encountered in their respective communities. The various stakeholders include laboratories and their customers, accreditation organizations, industry, and government both at the federal and state level. These groups and the National Environmental Laboratory Accreditation Conference will report on overlapping and contradictory requirements among regulations, contractual specifications, multiple accreditations and other voluntary applications, as well as the lack of reciprocity among bodies. There is widespread agreement that the current situation results in unnecessary burdens. This duplication of effort is expensive in time and money and seriously degrades U.S. competitiveness in domestic and global markets.

Laboratories, accreditors, manufacturers, the National Environmental Laboratory Accreditation Conference (NELAC), and government representatives, both federal and state, will present their views. They will discuss the cost of multiple accreditations for individual laboratories; conflicting requirements of those requiring accreditation; special programs tailored to narrow customer or supplier bases; non-uniformity of requirements and lack of reciprocity; international trade implications; and other pertinent factors.

THE VICE PRESIDENT
WASHINGTON

September 28, 1995

Dr. Arati Prabhakar
Director, National Institute of Standards and Technology
U.S. Department of Commerce
Gaithersburg, Maryland 20899-0001

Dear Dr. Prabhakar:

On October 13, 1995, you will open a meeting chaired by Mr. Sergio Mazza, President of the American National Standards Institute (ANSI) to discuss laboratory accreditation in the United States. Laboratory accreditation affects both domestic and international trade and the competitive position of the United States.

I commend you and your co-sponsors, ANSI and ACIL (formerly called the American Council for Independent Laboratories), for your leadership in this timely undertaking. The importance of laboratory accreditation, and concerns with the current process, were addressed this past spring by the National Research Council in its report, *Standards, Conformity Assessment and Trade: Into the 21st Century*. As the report indicates, unnecessary and duplicate accreditations add significantly to a product's final cost. The patchwork of certifications by various U.S. public and private sector entities is not accepted by foreign governments, and the attendant delays increase product market-entry risks resulting in lost revenues and lost opportunities for manufacturers and consumers alike.

As you proceed in your deliberations, I urge you to seize upon this superb opportunity to make an historical contribution to American competitiveness. We can all succeed by working together to make laboratory accreditation effective in ensuring public health and well-being without hampering competitiveness. I would appreciate being advised of the results of your October 13, 1995 deliberations, particularly with regard to efforts which should be addressed by this office.

Sincerely,

Al Gore

AG/wok

AGENDA
OPEN MEETING ON LABORATORY ACCREDITATION

Red Auditorium
National Institute of Standards and Technology (NIST)
Gaithersburg, Maryland
Friday, October 13, 1995

GOAL: A National Laboratory Accreditation Infrastructure
Co-Sponsors: ACIL, ANSI, NIST
Meeting Chair: Sergio Mazza, ANSI President

8:00	**Registration**		
8:45	**Introduction by Sergio Mazza**		
9:00	**Welcome to NIST - Arati Prabhakar**		
9:15	**Sponsors' Reports**		
	9:15	Initiation of Activities	Joseph O'Neil
	9:20	Process Description	George Willingmyre
	9:25	Prospects for the Future	Belinda Collins
9:30	**Task Group Reports**		
	9:30	Laboratories	Kim Phillipi
	9:45	Accreditors	John Locke
	10:00	Manufacturers	Steve Baldwin
	10:15	Governmental	Belinda Collins
	10:30	NELAC	Robert Stephens
	10:45	International	Richard James
	11:00	Recognition	John Donaldson
11:15	**Break**		
11:30	**Keynote Themes**		
	11:30	Domestic Issues	Charles Hyer
	11:55	Trade Needs	Charles Ludolph
	12:20	The International Scene	Bill Henderson
12:45	**Lunch**		

1:30	**Stakeholders Panel and Floor Discussion**		
2:45	**Break**		
3:00	**Vision and Principles**		
	3:00	Vision	Joseph O'Neil
	3:15	Principles	Walter Leight
	3:45	Options	John Locke
			Steve Baldwin
			Belinda Collins
	Discussion		
4:30	**Wrap-up and Conclusions**		
4:45	**Adjourn**		

SUMMARY

The American National Standards Institute (ANSI) and ACIL (formerly American Council of Independent Laboratories) requested that the National Institute of Standards and Technology (NIST) work with them in an informal Laboratory Accreditation Working Group (LAWG) to evaluate the current situation in laboratory accreditation in the United States. This group sponsored a Forum on October 13, 1995, to hear reports from various sectors and to arrive at some consensus on the need to improve the current situation and infrastructure for laboratory accreditation in the United States. Sectors included laboratories, accreditors, manufacturers, government (both federal and states), standards organizations, and international trade experts.

In the Forum, reports from the different sectors focused on the need for agreement on common procedures, reduction of overlap and duplicate programs, and development of coordination among sectors. The invited speakers presented examples of the high price in both time and money, as well as in lack of domestic (and international) acceptance of accreditation, resulting from the multiple, often duplicative accreditation required by organizations in government and the private sector. Examples given by many of the speakers included:

- multiple assessments of a single laboratory with similar testing protocols applied each time, increased total cost, and frequent conflicts among requirements;
- programs tailored to narrow customer demands but lacking recognition by other bodies;
- non-uniformity of requirements and lack of reciprocity among accreditors and those requiring accreditation;
- failure to recognize U.S. accreditation in international trade; and
- problems stemming from the need for compliance with regulatory programs without consideration of comparable private sector accreditation.

Keynote addresses provided:

- historical review of prior efforts to streamline the laboratory accreditation infrastructure;
- an overview of the effect of failure to accept testing by accredited laboratories on commercial trade relations, especially limits on the free trade of products designed for acceptance in overseas markets due to lack of common procedures and mutual recognition agreements; and
- a description of procedures used by both the United Kingdom Accreditation Service (UKAS) and European Council on Accreditation of Laboratories (EAL) organizations.

The LAWG Steering Group presented a "Vision" statement. This informal group consists of the three sponsoring organizations and representatives of each of the stakeholders: laboratories, accreditors, and the government and private sector entities that require accreditation of laboratories for their own purposes. The Vision statement was intended to provide a philosophy for developing broad cooperation

on accreditation procedures and infrastructure that would be much more effective than the present chaotic system and which would meet the needs of all those affected by laboratory accreditation. A set of "Principles" was also offered as a guide for developing a possible infrastructure. These principles include recognition of competent organizations that accredit laboratories, use of procedures and requirements based on international standards and guides, elimination of domestic barriers, and improved access to foreign markets for U.S. products.

Throughout the Forum, speakers supported the opportunity to achieve a coordinated, cost effective system for unified procedures for determining the competency of laboratories by qualified accreditors.

PRESENTERS AND AFFILIATIONS

Sergio Mazza (Chairman)	American National Standards Institute
Steve Baldwin	Hewlett Packard
Belinda Collins	National Institute of Standards and Technology
John Donaldson	National Institute of Standards and Technology
Bill Henderson	United Kingdom Accreditation Service
Charles Hyer	The Marley Organization, Inc.
Richard James	American National Standards Institute
Walter Leight	National Institute of Standards and Technology
John Locke	American Association for Laboratory Accreditation
Charles Ludolph	U. S. Department of Commerce
Joseph O'Neil	ACIL (formerly American Council of Independent Laboratories)
Kim Phillipi	Entela, Inc.
George Willingmyre	American National Standards Institute

ACKNOWLEDGMENTS

Transcripts of the presentations and comments from the floor were provided by STENOTECH, Inc.

The editors express appreciation to Susan Tassey and Marilyn Stream for their dedicated efforts in preparing this document, and to Judith Baker for work and assistance in organizing the FORUM.

INTRODUCTION

MR. MAZZA: Ladies and gentlemen, good morning. I'd like to welcome you to the Laboratory Accreditation Working Group's (LAWG) Open Meeting on Laboratory Accreditation.

U.S. industry is at a growing, competitive disadvantage with its counterparts in other countries because domestically our laboratory test results are not always readily accepted in foreign markets. U.S. testing laboratories are burdened by the need for multiple, overlapping, and duplicative assessments, accreditations, and requirements with little or no reciprocity among them. Industry, governmental and laboratory resources are wasted with the costs of inefficiency borne by testing laboratories, users of the testing and accreditation services and, ultimately, by the buyers of the tested products. In addition, increasingly, the multiple U.S. accreditations are being seen as a technical barrier to trade by foreign governments. I can tell you that literally yesterday I saw a paper written by the European side of the Transatlantic Business Dialogue where they identified this issue as one of their key issues to be discussed in Seville, Spain on November 10th and 11th with the Department of Commerce, the European Commission, and business leaders.

Let me give you some background. Many testing laboratories in the United States are accredited by one or more of at least 150 public and private organizations. Accreditation is sought for business reasons due to real or perceived requirements for such recognition. I will tell you that the Europeans think we have something like 2,700 such accreditations and recognitions, but I guess that's part of their negotiating position.

Governments and private sector organizations require accreditation in specific product or service areas and may designate the accreditation body to which to apply. We find that laboratory practices and accreditation techniques are not uniform and may not conform to internationally accepted criteria. There is little concern for reciprocity and, therefore, little opportunity for mutual recognition.

The typical U.S. laboratory with fewer than 50 employees may pay tens of thousands of dollars annually to achieve accreditations for serving clients in several markets. Foreign governments do not readily accept U.S. generated test data, even from an accredited laboratory, though some may do so for regulated products if the U.S. Government provides assurances based on recognition of the accrediting body.

Regional agreements, such as within the European Union, make it possible for test results from any laboratory accredited by an approved body to be accepted throughout the region. The United States currently has no such program.

What are we proposing? Our objectives for today are really to bring together representatives of manufacturers, testing laboratories, regulators, accrediting bodies, and other interested parties, to participate in this working session. We hope to obtain constituents' views, perspectives, and develop possible solutions to problems. What we're really trying to do is identify the problems facing those who accredit and those who are accredited, to initiate a dialogue on understanding the problems and, most of all, to develop a frame work for identifying and evaluating alternative approaches to possible solutions.

A little bit of general housekeeping, and then I will ask Walter to give us some information on detailed housekeeping.

We will be recording the discussion and providing proceedings. There will be a *Federal Register* notice summarizing participant views and another forum in late winter to discuss the ideas that we will consolidate from this discussion. We do request ideas, not only today, but after today, and please give them to any one of the three sponsors: ANSI, NIST, or ACIL.

We wish this to be an open dialogue, but we do ask you to hold your questions in the early sessions to those questions that clarify the speaker's remarks. We will have lots of time this afternoon for discussion and we hope that it will be a very lively discussion with much participation. If you have questions or points you wish to make in writing, as opposed to speaking at the mike, please write them down and, again, hand them to any one of the three sponsors.

Thank you very much. And I'll have Walter give us some details on housekeeping.

MR. LEIGHT: Let me remark first that there are still a few seats left up front, if any of the ones in back would like to come forward.

Let me also apologize for any inconveniences anyone may have suffered because of some errors in the announcement, and we're going to deal with the miscreants later.

As you exit the auditorium through the central doors in back, there are doors on either side. The most important doors, on the right side, lead directly to the restrooms. On the left side, the passageway goes to the registration desks, and that's the passage you'll use on your way to lunch. And those of you who have registered have a lunch ticket on the back side of your badge.

There are public telephones opposite the registration tables and there is material on those registration tables. In particular, there is a sheet of paper, that if you have questions or statements that you'd like to make this afternoon, please fill these out before lunch so that we can organize how people will be called up during the afternoon discussion.

As Sergio remarked, these recordings are being transcribed. There will be published proceedings. If you wish to make a statement or ask a question, please go to one of the microphones in the aisles and give us your name and affiliation so that can be included in the proceedings.

I'd like to remind everyone that there is no smoking permitted in this building, or any of the NIST buildings. You have to go outside if you feel compelled to smoke.

In the registration folder you'll find an agenda, which may be subject to minor adjustments during the day. There are summaries of the task group reports, a vision statement, and some principles that will be discussed this afternoon.

On the tables there is now, and there may be later, additional literature. Please check those tables and pick up anything that you might like to use. There is also NIST literature in the

area behind the Green Auditorium by the registration tables and in the lobby about NIST and its programs. Help yourselves.

And, if you need any help with your logistics, ask the people at the registration table. They may be able to provide some assistance.

Finally, for those of the Federal Government who are here this morning, we would appreciate it if you would sign a separate sheet that's near the registration tables. We'd like to keep track of the people from Government who are here so that we can make future contacts for additional work in the Governmental Task Group.

Thank you. Sergio?

MR. MAZZA: I would like to introduce our host for today, Dr. Arati Prabhakar.[1]

Dr. Prabhakar is the 10th Director of NIST, appointed by President Clinton in 1993. You'll notice, Arati, I did this by heart. I've done it before. I get to do this quite often, fortunately. It's a pleasure to introduce Arati to you all.

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[1]The Welcome address, given later in the morning, is presented here for consistency with the Agenda.

WELCOME TO NIST

DR. PRABHAKAR: Good morning everyone, and I apologize for not being here at the beginning. I'm going to be very brief, because I don't want to interrupt the excellent work that is already underway in this meeting.

I just wanted to welcome you to NIST; to tell you how much we appreciate ACIL and ANSI working with us on this very vital topic. I think, as a community, we all understand that laboratory accreditation is essential, but we also all agree that the system we have today is not what we need to do the job well; that it is not serving the needs of the users; it is not serving the needs of the testing laboratories; and it is not operating in as good a fashion as it can operate. And, given the competition that we face from every part of the globe today, given the competitive pressures and the rapid pace of technological advancement, we really can't afford to continue on the path we've been on. So I think it's so essential that all the parts of this community pull together to try to figure out how we can really create a system that will suit the needs of our nation and really help enhance our competitiveness ultimately. That is the point.

I know everyone has had a chance to get a copy of the letter that we got from the Vice President. I think it's an important message from him and a recognition of the role that efforts like laboratory accreditation play in our competitiveness in this country to have the Vice President even pay attention to this. I was delighted to get his strong support and, again, I think it's an indication of the level of attention that is paid to these kinds of issues.

I really want to commend all of you for joining together in this effort. We're glad to be hosting this open meeting as part of this process of establishing some newer and better ways of tackling the job of laboratory accreditation.

Thank you very much for letting me interrupt this morning, and I'll turn it back over to those of you that are making all this happen. Thanks very much, Sergio.

MR. MAZZA: Thank you for joining us Arati.

So, to get things started, I'd like to introduce our first speaker, Joe O'Neil. Joe is the Executive Director of ACIL. He is a member of the Board of Directors of ANSI and he is also a member of the Board of Directors of SBLC. Thank you, Joe.

SPONSORS' REPORTS

INITIATION OF ACTIVITIES

MR. O'NEIL: Thank you, Sergio. Are we going to have slides? May I have my slides please?

My charge is to give you, in 5 minutes, a brief perspective, or historical perspective, as to what led to the development of this forum. I represent ACIL which, as an association of testing laboratories, has had a keen interest in laboratory accreditation for 30 years or more. In the 1960's and 1970's, ACIL was involved in several constructive initiatives in the area of laboratory accreditation, such as the establishment of the E-36 Committee in ASTM for the standards relating to accreditation, involved in the establishment in the 1970's of the two major broad-based national voluntary accreditation programs. And, having been so involved, it came to the realization of the members of ACIL, and others in the testing community, in the 1980's, that despite these efforts, things were not as was felt they ought to be. The challenge of accreditation had not been met successfully, totally successfully certainly, despite the efforts of a lot of talented and energetic people. Even though some progress had been made, things hadn't arrived at the point that certainly the testing community felt they ought to be.

So we had, during the 1980's, several meetings in this--or maybe the Green--auditorium here at NIST to talk about the problem of accreditation, and we continued, as an association and as a group of laboratories, to make overtures and efforts and expend energy in efforts to improve this situation of laboratory accreditation in the United States.

We advocated reform. And what came to us as the single most significant missing piece in the U.S. accreditation situation was the fact that despite an increasing number of accreditation programs, there was no system within which these various programs could operate. The programs kept multiplying during the 1980's, in environmental fields, product testing fields, materials testing fields. In all areas of testing, it seemed, the numbers of programs kept multiplying, and yet there was no umbrella under which they functioned, nor were there any controls or common approaches among all the accreditors. So, each accreditor was doing what it felt was the best thing for its particular needs. I think the laboratory community got a special insight into the degree to which this problem was growing.

That brought us into the 1990's. It happened in 1991 that ANSI, the American National Standards Institute, began to look into laboratory accreditation. ANSI, as many of you know, had a traditional activity in the accreditation of certifiers. They then had a growing interest in the accreditation of quality system registrars. And, they logically began to look into the area of laboratory testing and the accreditation of those entities to see what role ANSI might play there.

They formed, at that point, a Board Committee, ANSI's Board Committee on Conformity Assessment, the BCCA, to cover the whole gamut of conformity assessment activities, including laboratory accreditation. In that particular area, ANSI still was not sure what role it ought to play, and that led ACIL to come forward and to speak to the ANSI leadership. We stressed that, in our opinion, ANSI should not form another accreditation program because there was already a plethora of those. We persuaded ANSI that what is needed is a system; that there are plenty of programs; that, generally, the program side of things was perhaps out of control, but the need for a system was more and more evident. And so we talked with ANSI about the important role that they could play in helping to move toward creation of a system in the United States that

would, in some way, mirror what was going on throughout the rest of the world, where accreditation "systems" were being put into place. ANSI listened and has been very helpful since then in the effort to create a U.S. system.

Early in our discussions, it became clear that the U.S. Government has to play a role; that this cannot be successful if it's a purely private sector activity. And so, in May of 1994, ANSI and ACIL representatives came out here to NIST and met with Belinda Collins and other officials of NIST and threw them the challenge to come and join us in the effort to create a system so that we, like the rest of the world, could have a harmonized, coordinated, and integrated approach to laboratory accreditation. And NIST listened. And the three groups, in May or June--I guess it would have been--June of 1994, began to meet to discuss the lack of a system in the United States and what might be done to fill that void.

Now, I'm going to pass at this point. To bring you from June of 1994 to the present I'm going to turn to George Willingmyre of ANSI.

Thank you.

PROCESS DESCRIPTION

MR. WILLINGMYRE: Thank you. I'm George Willingmyre. I'm Vice President of Public Policy in ANSI's Washington Office.

ANSI is certainly very pleased to be a part of this effort because we see it as a building block in reaching ANSI's overall conformity assessment goals. ANSI's conformity assessment goals are to reach a state where a single declaration, a single test, a single certification, or a single registration could be performed one time, at the location of choice of the supplier, and have that test, registration, declaration, certification, registration, accepted throughout the global marketplace.

As Joe has explained to you, we view laboratory accreditation as a key building block. ANSI's Board Committee on Conformity Assessment's Laboratory Accreditation Task Force had reached some conclusions but the BCCA advised it that we need broader constituency involvement. We need more widespread information. That led us to join with ACIL in approaching NIST to form this effort we now call the Laboratory Accreditation Working Group to really get widespread involvement and advice on what are the proper solutions.

Essentially, a group met in August 1994, to begin to define what the problems might be and what might be appropriate solutions. But even in that meeting it was agreed that we needed further work. So there were a number of industry and various laboratory accreditation groups, manufacturers, governmental groups, folks interested in environmental laboratory accreditation, folks interested in the international side of acceptance of declarations, and folks involved in Government mutual recognition agreements, and each of these groups were charged with going out and saying, "From your point of view, what's the problem? But don't just tell us the problem; define it in quantifiable terms of how is it hurting trade, how is it costing you money. What is the criteria by which you measure this problem? What is your solution? How would you fix this problem from your vantage point--the laboratories, the accreditors, the industry, the Government--and so on? And, in fact, if your solution was accepted, how would it impact the problem? Would there be more trade? Would there be less cost? Would there be a greater efficiency? Are there winners and losers? If there is a single laboratory accreditation, are there losers because there are multiple laboratory accreditation schemes in the United States? Who are the stake-holders?"

Finally, each of these groups were charged with going out and taking their own approach. Some of the groups employed surveys, some of the groups met and tried to hold workshops and consensus groups. And today, what you will hear are the results of these various groups that represent the constituencies that we believe are interested in the laboratory accreditation issue.

There was also a group of leaders of the various groups that met periodically throughout the year and have essentially planned this workshop to bring us together today.

The final speaker in this portion of the meeting is Dr. Belinda Collins, who will sort of take us from where we are today to the vision of where we would like to be tomorrow.

PROSPECTS FOR THE FUTURE

DR. COLLINS: Thank you very much, George.

As you can tell, my voice is not 100 percent, but we'll keep on talking anyway. Again, I'd like to welcome all of you to NIST and tell you how pleased NIST is to be hosting this forum. NIST has a long history of working with industry and with Government together to solve national problems in standards and measurement technology. I think it's important for us to realize that no standard can be effective until it's implemented, and one of the ways of determining if a standard has been implemented is through the process of formal conformity assessment, including laboratory accreditation. Laboratory accreditation plays a key role in ensuring that a testing laboratory is competent, and that is really what we're focusing on today and for the future.

So, where are we going to go next? Well, we have started and will continue the process of an open dialogue. We want to get input from all the participants here, and those who aren't here, on what their views for the future of laboratory accreditation are. We've had a report published by the National Academy of Sciences, their National Research Council, on "Standards, Trade and Conformity Assessment for the 21st Century." I commend all of you to read that, to look at the ideas it espouses, and to listen today to what people say and think about it. As part of our efforts to support an open dialogue, we will provide proceedings to the participants on this forum. We ask you to read these Proceedings and to continue to provide input to us, the sponsors, so that we can get some common ideas of what the situation really is, and the extent of problems. We recognize that the issues vary tremendously from sector to sector and from interested party to interested party; that the problems facing the Federal Government are different, and yet sometimes the same, as those that affect manufacturers; and that we need to work together to solve these problems to begin to move toward a solution in the United States that will be acceptable to us, ourselves, first, and then to our trading partners throughout the world.

All of this means that we will continue to talk, hopefully with better voices, and then convene a subsequent forum in January/February, to talk about the issues that have arisen here and to continue to try to build, together, a system for laboratory accreditation in the United States that really meets the needs of all parties.

Thank you very much.

MR. MAZZA: Thank you. I would invite those of you that are a little warm in here, please take off your jackets, make yourselves comfortable. This is a working session.

I would now like to introduce the Task Groups and have them give their reports. The first report is that of the Laboratory Task Group. Speaking on behalf of the group is Kim Phillipi. Kim is President of Entela, Inc., in Grand Rapids, Michigan. This firm now comprises over 125 employees with branch offices in Taipei, Taiwan and Livonia, Michigan.

Thank you. Kim?

TASK GROUP REPORTS

LABORATORIES

MS. PHILLIPI: I'm here today representing the Laboratory Task Group. Laboratory accreditation has been a very large and important issue for laboratories, as Joe has mentioned, for a long, long time. Usually when laboratories get together and when task groups get together on this particular subject, we can keep each other awake because it's a very hot subject for us and has been for a number of years.

To introduce the Task Group: The American Council of Scientific and Engineering Firms, ACSEF, representing over 400 engineering and scientific firms; the Association of Environmental Testing Laboratories; the National Conference of Standard Labs; the National Sanitation Foundation, Technical Management Consulting, and Underwriter's Laboratories.

It wasn't very difficult for this group to actually define problems because we've been involved in the problems for a number of years. So, actually, what we set out doing is defining what the goals of the Task Group were, and it's a simple goal. It sounds simple and it can be said in one statement, an efficient, cost-effective U.S. accreditation system. It's a pretty easy statement, but not so easy of a solution.

There are many factors that the Laboratory Task Group feels really enter into actually achieving that goal:

Coordination among accreditors. We need some type of forum where accreditors actually meet with each other, review each other, and a forum where there is some type of coordination of activities among accreditors.

Reciprocity of accreditors. We have to get reciprocity of accreditors, especially from the laboratory perspective and, today other industry groups are also feeling the need for reciprocity even more from other industry group perspectives. The duplicative systems, the redundant systems, and sometimes the inefficient systems, reciprocity among accreditors would be good for all of these items. It's something that needs to happen.

High-quality accreditations. This is really important on two fronts. One front is within our own organizations it's important that we have high-quality accreditations--we want the accreditations to mean something to our organizations and to our people. High-quality accreditations must also be important to the industry and be recognized by the industry as something that recognizes us from everyone else. Accreditations must be high quality.

International acceptance of test data. There are many places that this is currently being worked on. The NVCASE Program was actually established to address some of those issues. There are many MRA negotiations currently taking place with Europe. But whatever form is addressed for the domestic system, I think we have to make sure that the domestic and the international systems, in some way, shape, or form, mesh together.

Educated users of services. This is probably one of the most difficult to get your arms around. There is a lot of education that needs to take place, both with industry accreditors and laboratories. What standards do we use? How many accreditations do we need? Who is going to recognize those? One group wants one accreditation and one group wants another

accreditation, and a lot of this really, in some ways, is purely just education, education of our customers for one.

It's already been mentioned by Belinda that the National Research Council recently put out a study. The Laboratory Task Group decided to endorse this study, particularly Recommendation No. 1 of this study. If anyone hasn't seen this study, I do have a copy with me so that you can get the information needed to pick up this study.

Recommendation No. 1, in simple terms, basically says, "Congress should provide NIST the statutory mandate to phase out Federally operated conformity assessment activities." Now, this is a very difficult subject, particularly, for the government and for the federal and state operated programs. We do, however, have a lot of redundant programs and we do have more and more programs being formed within government every day. There is also the issue that there are several private sector alternatives and, in many ways, these private sector alternatives are duplicating some of the government's already existing programs, and the government is inventing new programs and not utilizing private sector alternatives.

"NIST should also form a National Conformity Assessment System Recognition Program." They always seem to find very big, long terms for these programs. What that should establish is, "It should recognize accreditors of testing laboratories, product certifiers and quality system registrars." Actually, what's being suggested here is something analogous really to the NVCASE Program representing international issues. So why can't we use a similar or the same vehicle for domestic accreditation issues?

The study also says that, "This program should be developed and implemented by the year 2000." I think that would be a wonderful goal. I think that we have a lot of work to do to even make that goal achievable. Compared to what many of us have been through in the accreditation arena, if we could make that goal by the year 2000, I think many of us would be very happy.

A couple of concerns of the Task Group in actually establishing this program within NIST is that we still have to be careful of obtaining two objectives. One of those objectives being transforming conformity assessment activities from the public to the private sector where again we feel that we can reduce redundancy, as well as increase efficiency. The second objective is that we can't forget the reciprocity and to foster acceptance of mutual accreditation programs. It's not enough that a program like this will just recognize the accreditors, but we have to have reciprocity someplace in the process or it will not meet all of our needs. In fact, it will not meet our needs.

We need to work together on taking the next step. The problems with laboratory accreditation have become obvious to almost everyone. I think how we work together to actually come up with solutions and implementation is the hardest part. So, the hardest part is still yet to come.

So, possible next steps may include NIST conducting a study and benchmarking other programs that are out there, whether it's European programs or other programs. There are many organizations, such as NELAC, IAF, EOTC, QSAR, and others, that have different forums established for laboratories and accreditors. This is a forum where these groups can work

together in terms of reviewing peers, work on reciprocity and find solutions to some of the problems we're having with the U.S. system.

I'm sure NIST is familiar with these programs; it's just that we need to establish if NIST is going to be responsible for this. There is no need to reinvent the wheel if we know there are examples and forums we can use to benchmark.

Maybe there will be time for some of the task groups that are here today to actually get together and define some common grounds. I think we've all defined the problems and maybe some potential solutions, but we need to find some common ground where we can actually work on overcoming the problems and how we're going to do that, and attacking them, as well as how we're going to implement putting a system in place. I think it's time for us to all work together, maybe not separately, on those issues so that we can make some additional progress.

Potential future problems. I guess these aren't hard to define. There may be a Government reluctance to provide statutory mandates for NIST to phase out Federally operated programs. This is a primary area of concern, in fact, maybe it's not even possible. Again, I think if some of the various task groups actually work on attacking that problem, we could determine if it's possible or not.

NIST funding, as with many Government agencies and programs right now, that's a very major issue. Again, if we had a constituency maybe behind and supporting that NIST needs to run this program, maybe we can assist somehow, some way, with helping to assure that there will be some type of funding.

We are going to have conflicts between various groups. There is no way around that. But I think that we're far enough along in the process that it's time to find some common ground. There will have to be give and take on some issues--but let's at least work on the common ground and try to move on from here in terms of making progress on getting over some of our problems and implementing some of the solutions.

Once again in addressing the domestic situation, we must also be addressing the international. Although there is currently a great deal of activity with international accreditation and acceptance of test data, there has to be some mix of the two and some coordination among the two to make sure that we don't develop anything completely separate. We need a domestic and international accreditation system.

Thank you very much.

MR. MAZZA: Our next speaker is John Locke. John is the President of A2LA and he will represent the Accreditors Working Group. Thank you, John.

Laboratory Task Force Summary

Laboratories Task Force:

- ★ American Council of Scientific & Engineering Firms (ACIL)
- ★ International Association of Environmental Testing Laboratories (IAETL)
- ★ National Conference of Standards Laboratories (NCSL)
- ★ National Sanitation Foundation (NSF International)
- ★ Technical Management Consulting (TMC)
- ★ Underwriters Laboratories (UL)

Goal of Task Group:

An efficient, cost effective US Accreditation System

- ★ Coordination Among Accreditors
- ★ Reciprocity of Accreditations
- ★ High Quality Accreditations
- ★ Internationally Accepted Test Data
- ★ Educated Users of Services

Laboratory Task Force Summary

Recommendations:

Endorsement of Recommendation #1 of the National Research Council's Study on "Standards, Conformity Assessment and Trade into the 21st Century"

Recommendation #1 NRC Study

- **Congress provide NIST with statutory mandate to phase out federally operated conformity assessment activities.**
- **NIST should form National Conformity Assessment System Recognition (NCASR) program.**
- **NCASR would recognize accreditors of testing laboratories, product certifiers, and quality system registrars.**
- **The program (NCASR) should be developed and implemented by the year 2000.**

NCASR MUST ACHIEVE TWO OBJECTIVES TO BE SUCCESSFUL.

- **Transfer of conformity assessment activities from public to private sector.**
- **Reciprocity and foster acceptance of multiple laboratory accreditation programs.**

Laboratory Task Force Summary

Next Steps

- **NIST should study existing examples such as WELAC, IAF, EOTC, QSAR, etc.**
- **Laboratory task force may combine with industry task force or others to define common objectives and develop action plan.**
- **Develop action plans for implementation of solutions.**

Potential Future Problems

- **Government reluctance to provide statutory mandates for NIST and phase out of federally operated programs.**
- **NIST funding**
- **Resolving conflicts of interests between laboratories, accreditors, and industry.**
- **Solutions must extend beyond international trade barriers to a domestic system.**

ACCREDITORS

MR. LOCKE: Thank you, Sergio. Good morning. I'd like to tell you a little bit about what the Accreditor Task Group did. We started last fall, after the LAWG meeting in August, 1994, by contacting about 180 agencies, accrediting bodies, and others, for whom we had addresses. We used Mr. Hyer's database, and we added additional people that we knew about inviting them to meet. We eventually ended up on December 8 at a meeting of accreditors with about 20 people.

One of the first things we talked about was trying to define the need for cooperation a little more definitively. One of the things we used was an ANSI paper that was prepared in April of 1993 by a Task Group of the Conformity Assessment Committee. We went through that document on the need, and basically agreed with it. That document also had been distributed in August at the general meeting, so the need was pretty well defined.

The next thing we did was to look at some of the related activities. The first was existing bilateral agreements and how they work. Next we looked at multilateral relationships between laboratory accreditation systems in the United States, Europe, and the Asia-Pacific area. Most were built on bilateral relationships, that is to say one laboratory accreditation system established a relationship with another laboratory accreditation system in another geographic area by developing and signing bilateral agreements. These agreements were expanding considerably. There were, perhaps, 20-25 bilateral agreements throughout the world in the middle of the 1980's.

The next thing we talked about was the Fastener Quality Act. Here is a case where we have Federal legislation which requires that NIST recognize existing laboratory accreditation systems, as well as accredit laboratories themselves. Here was legislation devoted to this issue of recognition--cooperation. In this particular case, we felt that the Fastener Quality Act, if it is ever implemented, would demonstrate a process of recognition of other programs.

By the way, there is probably about 8-10 pieces of legislation dealing with laboratory accreditation that are all over the map in terms of relationships established. So, part of the problem we face in any cooperation is that legislation varies considerably.

We have a similar kind of legislation, for example, in the National Lead Laboratory Accreditation Program run by EPA. There is a requirement in that piece of legislation for EPA to determine if there were private sector laboratory accreditation systems that could accredit lead testing labs and, if so, to establish a way of evaluating them. And that really was done: EPA used Guide 58; requires accreditors to use Guide 25, and on this basis recognizes two private sector systems.

Other pieces of legislation, like the program for asbestos, dictated that NIST run the laboratory accreditation program. In the Clinical Laboratory Improvement Act Program, there is a requirement that the Health Care Financing Administration recognize other private sector programs. Sometimes the legislation does recognize other programs; sometimes it does not.

The NVCASE Program can also provide some sort of recognition of laboratory accreditors, when there is a need to get U.S. Government recognition by a foreign government.

We talked about the NELAC Program, sponsored by EPA, which Mr. Stephens will talk about, as a more formal approach of putting together some sort of coordination.

We mentioned ISO's Quality System Assessment and Recognition, QSAR, as yet another possibility although QSAR is not including, at this point, laboratory accreditation. It does focus on recognition of quality system registrars and product certifiers, but it's not far from a model which could be expanded into laboratory accreditation. It's useful to follow the evolution of this because, as laboratory accreditation becomes more readily recognized as one of the three legs of the conformity assessment stool, then somehow it's going to be folded in sooner or later.

We talked about Mutual Recognition Agreements and their evolution. I think this development is very important since the bilateral agreements were wearing thin on accrediting bodies. Assessing each other required as much as two person weeks, a week for two people, in each other's operations and on laboratory assessment to make sure that each was judging the laboratories in a similar manner. It was concluded that there wasn't enough money to keep these bilateral agreements going and we needed to have some sort of a multilateral recognition agreement.

The mutual recognition agreement process was demonstrated by coordination in Europe through the European Cooperation for the Accreditation of Laboratories (EAL). The evolution of the language used and procedures was established through the International Laboratory Accreditation Conference (ILAC) starting in 1988. There has been a lot of evolution of Mutual Recognition Agreements and there is, now, in the Asian-Pacific Area, an attempt to follow the same kind of model in that area.

How can this experience be applied in the United States? One thing we agreed to at the meeting is that we probably need a little bit better idea of the situation, so we agreed on the laboratory survey. There were three systems that agreed to work together on polling their membership of their accredited laboratories. AIHA, A2LA and NVLAP worked together and received about five hundred respondents.

We were wondering how many multiple accreditations were at the laboratory level, and we thought they would be considerable, so we used categories, 1-5; 6-10; > 10; etc. But there weren't as many multiple accreditations as we thought and we probably should have used more like 1, 2, 4, something a little smaller. I plotted the data showing each organization as a percent of the total. The total now is about 550 laboratories. I wanted to show that the distribution is pretty much the same, regardless of which system you talk about. In Figure 1 we have about 65 percent with 1-5 accreditations, 18 or so percent for 6-10 accreditations, and so on. So, down here in the area of 11-15 and 16-25 we end up with about 5 percent. Nonetheless, we continue to hear a lot of stories about people developing rooms in their laboratory just for visiting dignitaries, because there's always somebody in there and they have to have some place to sit them. We know of some other cases in the calibration area where they have 123 accreditors in one lab, and 56 accreditors in another, and so on, but there weren't many calibration laboratories who responded.

The number of site visits per year for maintaining their status is plotted in Figure 2 in the same way. So, most had only a few site visits. So I think the problem with the multiplicity might be larger than it really showed to be in the data we have.

In trying to explain this, we looked at our population and concluded, that the population from NVLAP included some 500 or so, laboratories that were only accredited for asbestos testing. The A2LA population included perhaps 300 laboratories meeting requirements from General Motors for the first time and only time, in a laboratory accreditation system. And the same for the AIHA, which are primarily involved in industrial hygiene. Most of these laboratories are seeing a gradual addition of requirements.

What's the annual cost of maintaining these credentials? Figure 3 shows these data. Some explain that the cost is less than $1,000. I'm not sure where that number came from since our application fees, without assessments, typically run that much. Most put the cost at less than $10,000, but you can see there are quite a few over $10,000 per year. It's not an inexpensive business I'm talking about.

And finally we have some information on the number of proficiency programs per laboratory presented in Figure 4. We are of the opinion that proficiency testing had a significant input and I think these data verified that. In the evolution of laboratory accreditation programs there is more and more concern about the actual performance of the laboratory and adding proficiency testing expands cost of our programs.

So that kind of summarizes what we found out. We took another step after that, which was to come up with a possible approach to cooperation, but I'll talk about that this afternoon.

Are there any questions related to the last two presentations, questions to clarify the presentations, before we move on to the others?

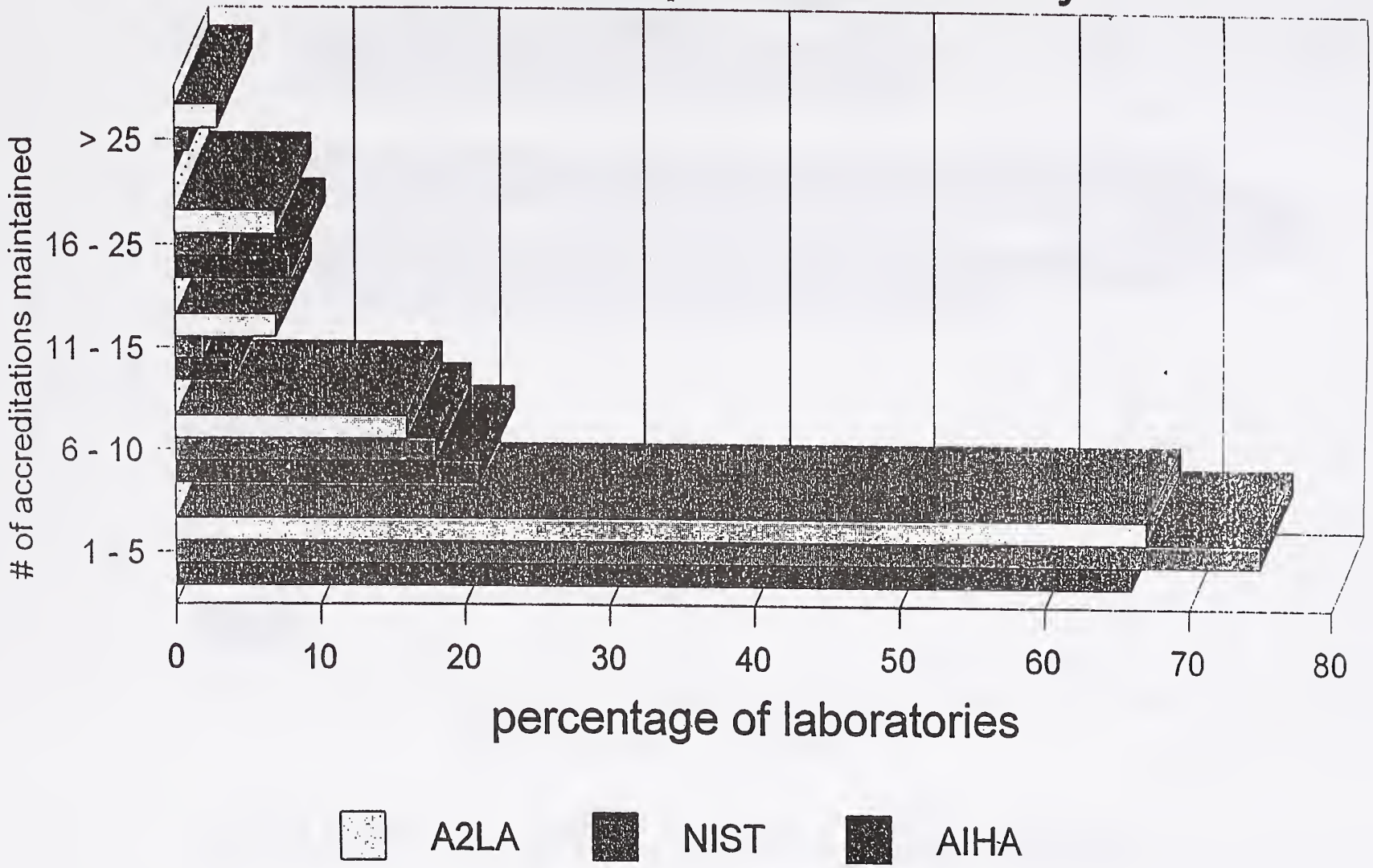
(No response.)

MR. MAZZA: Boy, you guys are crystal-clear today. Perfect.

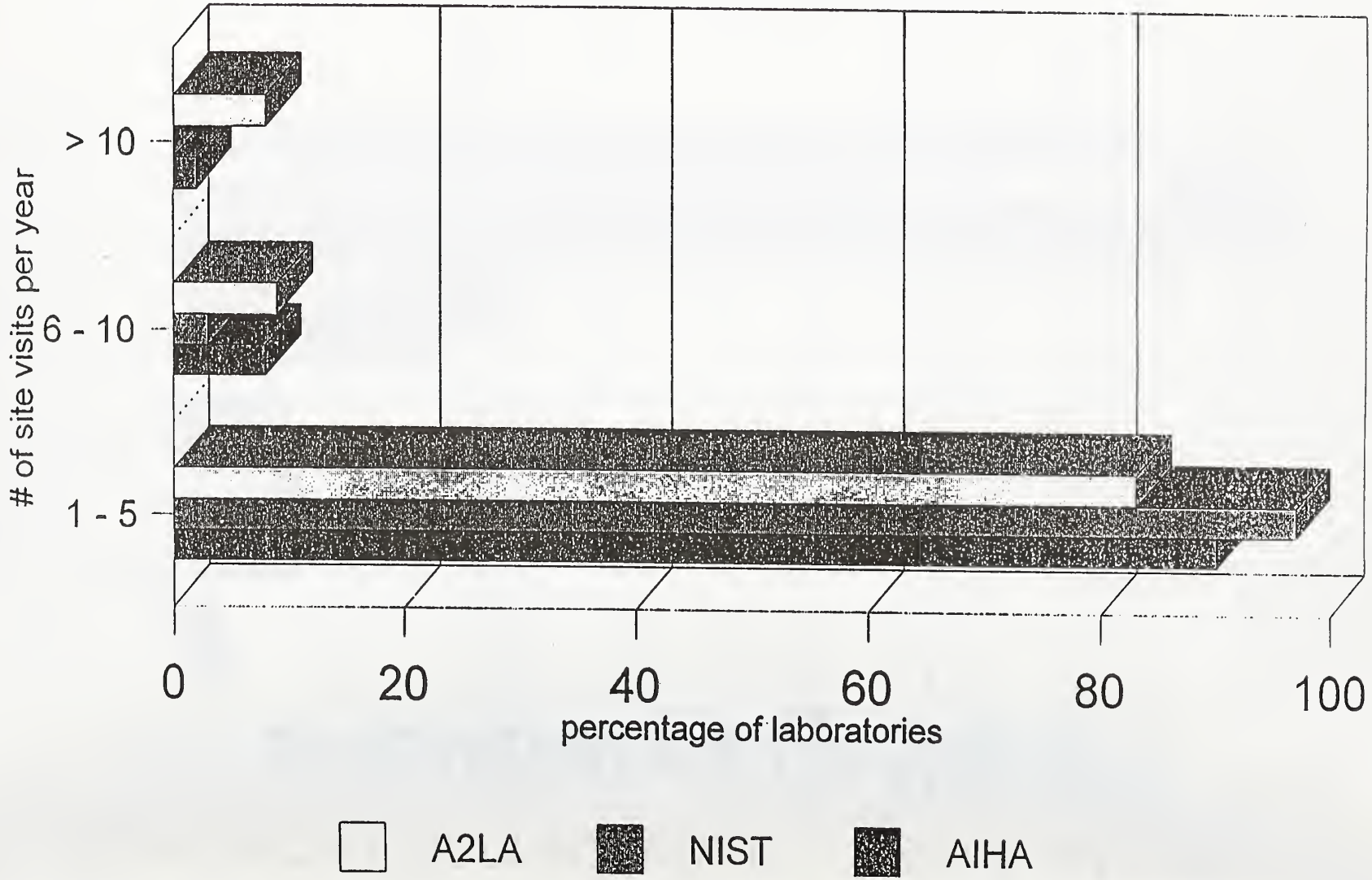
Well then, we'll move on. Our next speaker, representing the Manufacturers' Working Group, is Steve Baldwin. Steve is the Program Manager for International Product Requirements at the Hewlett-Packard Company. He is Chairman of the Environment and Safety Management Committee of the Information Technology Industry Committee.

Steve?

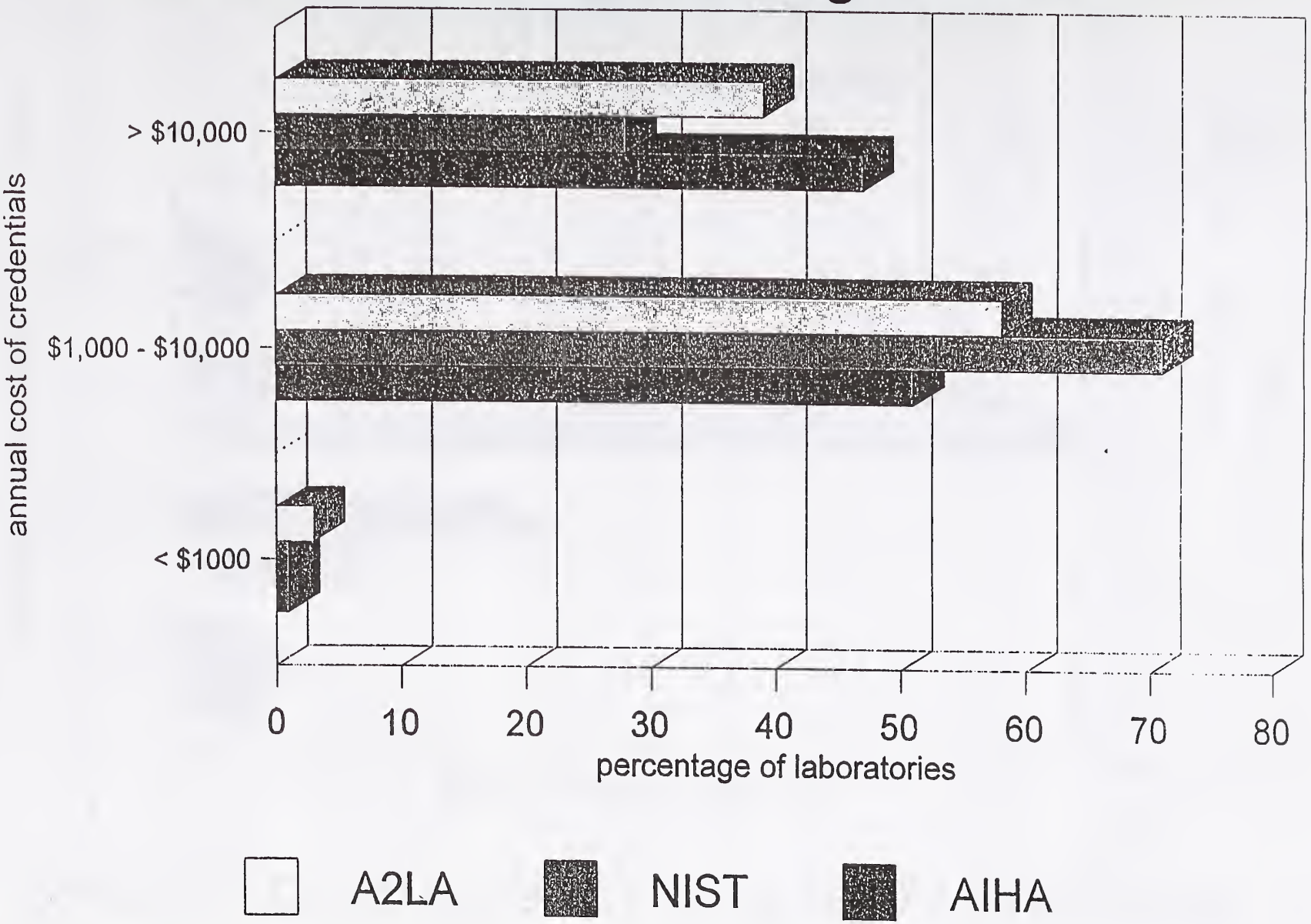
Number of Accreditations, Certifications, or Approvals per Laboratory



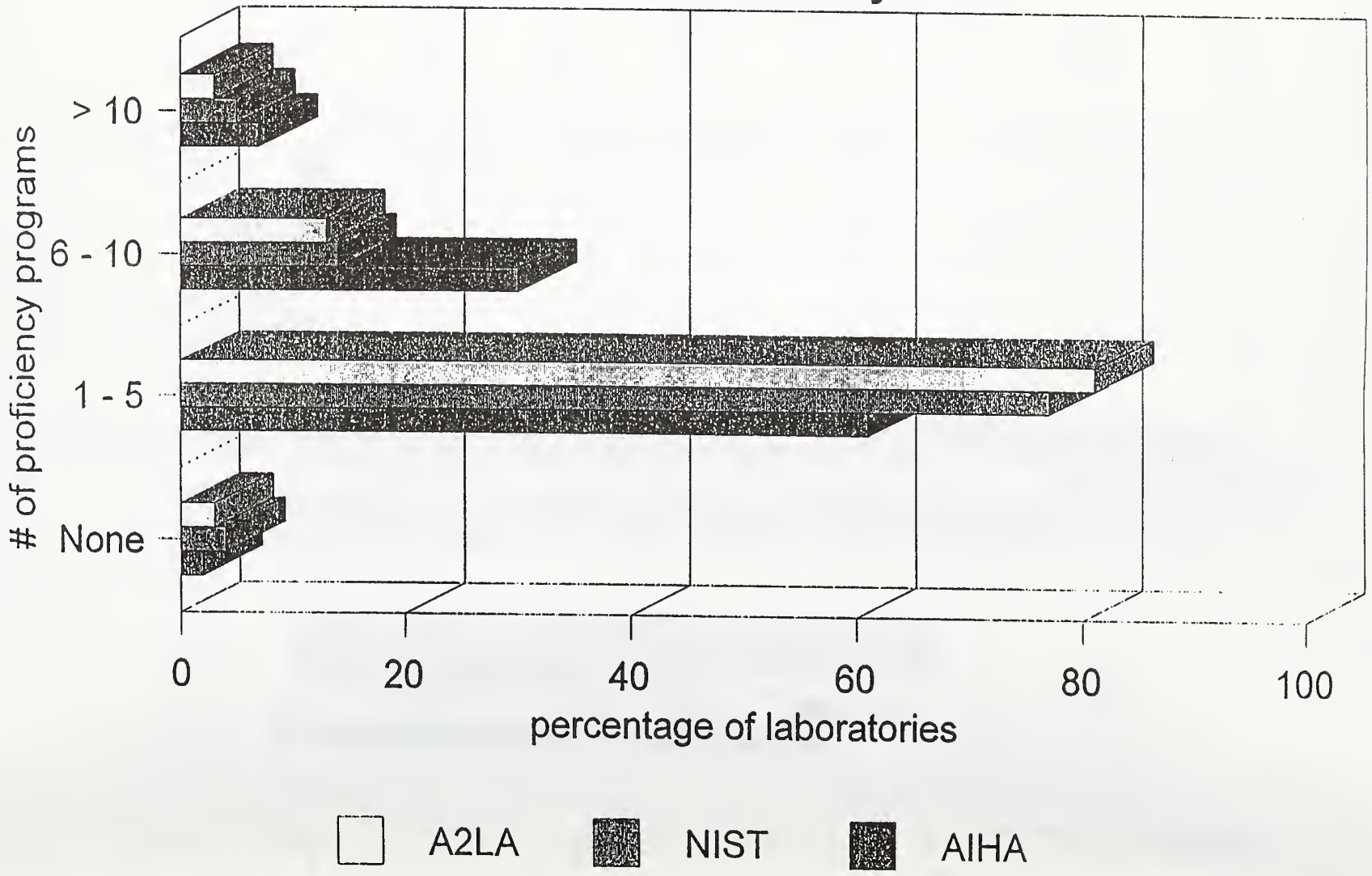
Number of Site Visits Per Year to Maintain Status



Annual Cost of Maintaining Credentials



Number of Proficiency Evaluation Programs per Laboratory



MR. BALDWIN: Thank you, Sergio.

It's a pleasure to be here. Fourteen months ago I was in this meeting, or one like it and, as a manufacturer, we feel we're one of the major customers of the laboratories and, as such, we have a stake in what happens with laboratory accreditation. So my thanks go to Belinda Collins, who asked me to pull together the industry position on laboratory accreditation.

So, over the past year and some, Lou Dixon of the Ford Motor Company and myself have pulled together the Industry Working Group that represents 17 major U.S. industries with another dozen industries waiting to see what's going to happen. I think that what was really exciting about all this is, with the amazing divergence in industries from textiles to pharmaceuticals, that we would actually be able to work over this period of time and come up with a common vision. I think maybe the best way to state that vision would be that we would like the reputation of our companies for integrity and competence, that any goods, products, or services that we provide or produce, will be accepted on the basis of our saying that we met a set of requirements, that we didn't need a third party or validation by anyone else. So that would be our actually ultimate vision, or goal, would be to see something like that happen.

The way to maybe articulate it is this way, and that is worldwide acceptance of our products, processes and services based on our declaration that it conforms with the specifications.

Now, that's not laboratory accreditation. But we feel that we need to really set the stage here for what it is we value and hold as something we'd really like to see. We recognize that this isn't the reality we live in today, so what are we going to do about that? We agree that laboratory accreditation is important and has a value when it meets a market need, either customer demand or a legal requirement, and it serves a very real need with sometimes the manufacturers themselves with a customer. What we really want is something even more than that though, superior value.

I think you saw this in Kim's slide earlier. There is a lot of agreement between our groups. We would like worldwide acceptance and acceptance within the United States of any test data from a lab that has a single accreditation. Now, accreditation that carries that kind of weight, if it's affordable, there will be a market for it. So, what we're looking for is what kind of work is required, and what do we need to do, within the United States and internationally, to create an environment that permits a single accreditation to carry that kind of weight?

The goal of our task group was to identify problems facing the industry and to identify or articulate the elements of an acceptable solution. The framework for that solution, we believe, is an internationally credible architecture supporting laboratory accreditation as part of an overall U.S. Conformity Assessment System. You can't really look at laboratory accreditation apart from that.

As we focus on this, the elements that we believe that we would like to see come out of this overall structure, namely:

Domestic and international acceptance of test results;

Eliminate the duplication of Federal, state, and local systems;

As Kim Phillipi reported, utilizes private sector resources. They're out there and they're really under-utilized; and, of course,

A system which recognizes the validity of a Supplier's Declaration of Conformity. You see, that word keeps coming up. What we're looking for is a series of choices that are driven by somewhere between the buyer and the seller and the selection is up to the individual transactions and that there is validity to a Supplier's Declaration;

Identifies a single U.S. entity for recognizing accreditors. That's perhaps one of the more controversial objectives. This is a U.S. Government focal point that would be recognized internationally and would serve to recognize accreditors and again Kim and I have the same goal;

We'd like to see equal standing for a laboratory of either a manufacturer or an independent test lab, so that the results of those labs would be seen as carrying equal weight, and the ability to accredit a laboratory would be independent of whether it is an independent lab or a manufacturer's lab; and, last, but not least,

Take a non-sectoral approach to the overall system. It doesn't have special favors or exceptions dependent on the industry.

And we feel we have a long way to go in this, and not the least of which is education of our own industry. And I think my co-chair (Lou Dixon) -- I'd just like to share the podium here with my co-chair, because we have some really interesting and revealing data. Lou sent out a survey on behalf of our working group and the results of that, I think, are really important to hear in the context of this overall presentation.

MR. DIXON: Thank you, Steve.

We thought it was important to share some of the results of the survey with you, if only to whet your appetite for discussion. Just to give you a little bit of background, we made some good attempts to get the views of a cross-section of the industry, and I think we did, to a very large degree. The first slide shows some of the areas, primary product areas, of the 246 responders to our survey.

We also spanned a wide range of businesses, from those of less than $1 million dollars of annual sales, to those of over $500 million.

The key bit of information I'd like you to focus on here is that a relatively small number of these industries use only in-house or first-party registration labs. We noticed that most of these responders used external labs. It sets the stage for what we'd like to think is a need for standardization or accreditation of laboratories.

Again, do the companies audit the labs they use? And, to a large degree, most of them said, "No, we don't." Just about half of them said "Never" or "No answer." So then we need

to ask the question, "On what do you rely for the reliability of the test results from the labs that you use?"

In the same light, we're beginning to see what part of the problem is. We asked the question, and I'll read it as it was stated on the survey so you can better understand the results, "Does your company require certification of material or component suppliers?" We gave examples of standards, ISO 9000, QS 9000, ISO Guide 25, or other. This is only a partial list of the standards to which the companies felt that they were asking their component or material suppliers to certify.

Coming back to the real issue of lab accreditation, we asked another question, and that was, "Does your company require certification of the laboratories to these given standards?" On this slide you will find what I think demonstrates a major part of the problem. We, the customers, are not sure what we're asking people to certify to. When we asked about requiring certification of labs to ISO 9000, a large number of companies responded that they were doing so. On this next slide, you'll see the long list, and this is a two page list and I won't bore you with the second page. I wanted to share these results with you to highlight what we think is the major problem. We think it's a large need for education.

Lastly, in response to the question, "Have you or your company had problems or concerns with laboratory accreditation?" I was amazed to see the answer of 215 of the 246 respondents saying "No." I think it's because we are not sure what we're getting. We're paying a large amount of money for lab testing. We are accepting some of it. Some of us who dive deeper into it are recognizing the problem.

With that, thank you for your attention.

Steve?

MR. BALDWIN: We're done.

MR. MAZZA: Are there any questions for this working group?

MR. FULTON: Mr. Baldwin?

MR. MAZZA: If you could go to the mike please?

MR. FULTON: Hello, Mr. Baldwin. My name is Ron Fulton. I'm with the FDA. And you mentioned--I guess it's point number five--"Identifies a single U.S. Government entity for recognizing accreditors." And are you talking about a present agency, or are you talking about a new entity? I'm thinking, because we're talking about down-sizing the Government, so what exactly are you addressing?

MR. BALDWIN: Okay. That slide probably wasn't clear. I'm glad you asked that question for clarification. This is really a role we see for NIST in accordance with this Conformity Assessment Report from the NRC on, you know, Conformity Assessment in the 21st Century." This is really the same thing that was really in Kim Phillipi's slide regarding NIST

having this role of recognizing accreditors, and so this is what we're looking at as focusing on a single Government organization and we think NIST is appropriate for that.

MR. MAZZA: Okay. Any other questions? John?

MR. LOCKE: Steve, I was wondering if Hewlett-Packard has thought through the issue of acceptance of all of its suppliers on the basis of Supplier Declarations and, if so, what kind of concerns would you have with the testing part of the information that you're getting from the suppliers?

MR. BALDWIN: I wish we could say we accept all the Declarations of our suppliers. Again, you know, at NIST, from one division to the next, they don't always accept declarations.

(Laughter.)

MR. BALDWIN: So it is true that the reality is we have some ways to go, which doesn't mean we still aren't going to push in that direction. And, as I said, we wish people would accept our products based on our Declaration. What can we do to get there? You know, I think we're still wanting to move in that direction.

MR. MAZZA: John?

MR. DONALDSON: I'd like to pick up on what John Locke just said to Steve. One of the things that concerns me, while I support what you said about the Manufacturer's Declaration, it puts into mind two points. Number one, that by the General Agreement With Respect to Technical Barriers to Trade under the World Trade Organization we must treat suppliers from all countries the same as we treat our own suppliers. And I think, then, what that says next, is if we then base everything on Supplier's Declarations, then we have to do that for suppliers from every country in the world and, in a worldwide market, that means a lot of countries.

I think that that's the problem that we see, and I think it's the same problem you see internally when you're taking suppliers from all over the world. I think we have to look at that in a very careful light of where the supplier is coming from, where, if they have an internalized quality management system and so forth, what is the basis for the assertion and how is that credible within the context of the country that it's operating in.

MR. BALDWIN: I do want to respond to that. That's an absolutely valid point. I guess the theme here is we would like the Manufacturer's Declaration to be one of many things from which we can choose. There are cases when a Manufacturer's Declaration of Conformity doesn't need any third party. For example, a camera that you buy, you're not looking for approval. And there are a number of cases where, like if you buy an automobile, how many people are checking to see if it's approved? So you see, if you believe it's going to meet the specs, it's going to meet all the safety specs and everything else, you're not looking for some approval from the Department of Transportation on that automobile. So I think there are cases where a Manufacturer's Declaration is viable and is actually utilized today and we're hardly even aware of it.

MR. MAZZA: Could you come up to the mike please?

MR. PERAKIS: I'm David Perakis, the NMI Group. The very last statistic that you showed, the 246 respondents, did I understand you to say that none of them, in other words, found any problem with laboratory testing? Is that what you said?

MR. DIXON: 215 of the 246 checked the box that says, "No we don't have any concerns or problems with lab accreditation." The others who checked did have concerns that we had noted in our two industry-wide meetings.

MR. PERAKIS: I would like to say that I'm in the laboratory business and we have several thousand customers, and we rarely have a complaint, and I think you'll find that's true of most independent laboratories. I think your statistic is really not surprising at all.

MR. DIXON: Well, that's what we were looking at too. We accept the numbers and what we're looking at is we're paying some money and we're saying, "Why are we paying so much money and are we completely satisfied with the results?" And the answers seem to be saying, yes we are. We don't see a problem.

MR. MAZZA: Okay. Then let's move on.

Our next speaker is, again, Belinda Collins, to deal with the conclusions of the Government Working Group.

PRIMARY PRODUCT SUMMARY

What is your Company's/Unit's primary product area (Select ONE)

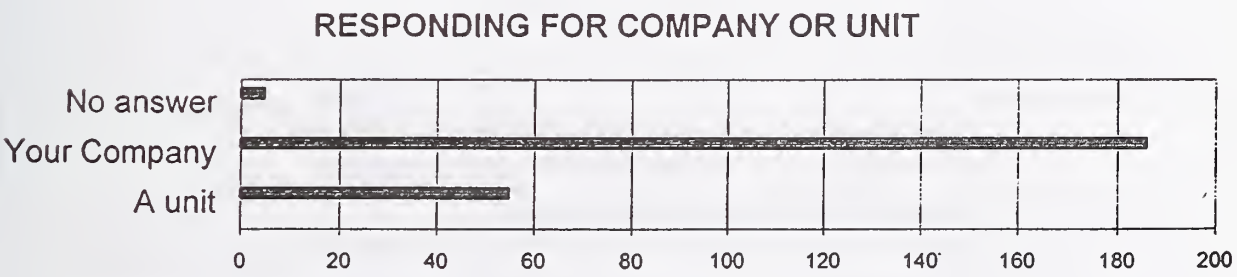
Product	Count
Aerospace	4
Agricultural Machinery	5
Automotive	9
Building Construction	5
Chemicals	6
Computer Equipment	9
Construction Machinery	20
Cosmetics	1
Electrical Equipment	20
Electronics	7
Fabricated Metal	28
Food & Beverage	2
Furniture & Fixtures	2
Glass/Ceramics	1
Health Service Industry	3
Household Appliances	7
Industrial Machinery	24
Instruments	10
Lawn & Garden Equipment	1
Lumber/Wood Products	1
Medical Equipment	13
Other	3
Paper	1
Petroleum	5
Pharmaceutical	2
Plastics	4
Primary Metals	3
Retired	1
Rubber	4
Service Industry - General	39
Telecommunications	3
Textiles	2
Toys	1
	246

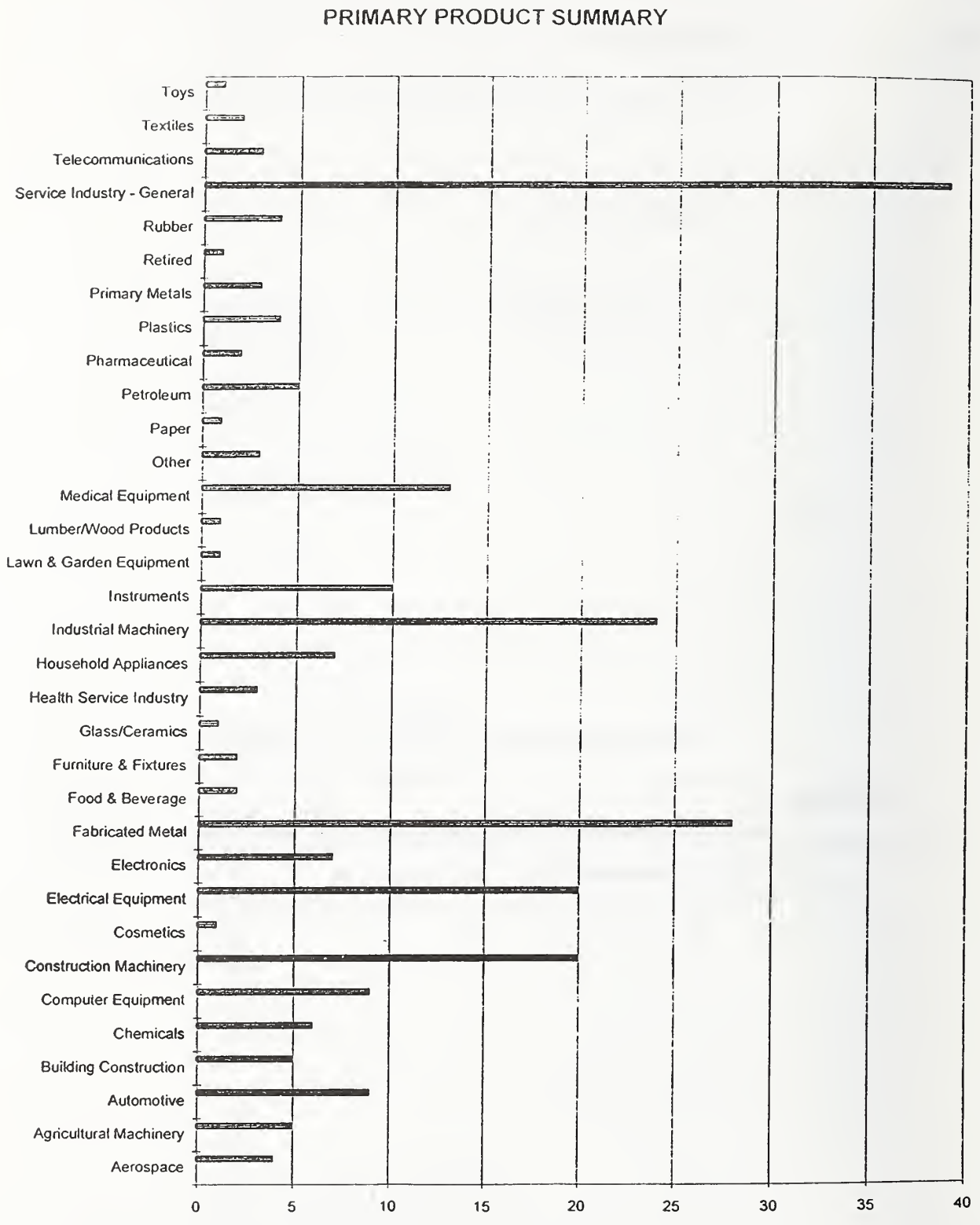
RESPONDING FOR COMPANY/UNIT SUMMARY

Please Indicate if you are responding for:

a) Your Company b) A unit (Department/Division) of your Company

Responding for	Count
A unit	55
Your Company	186
No answer	5
	246



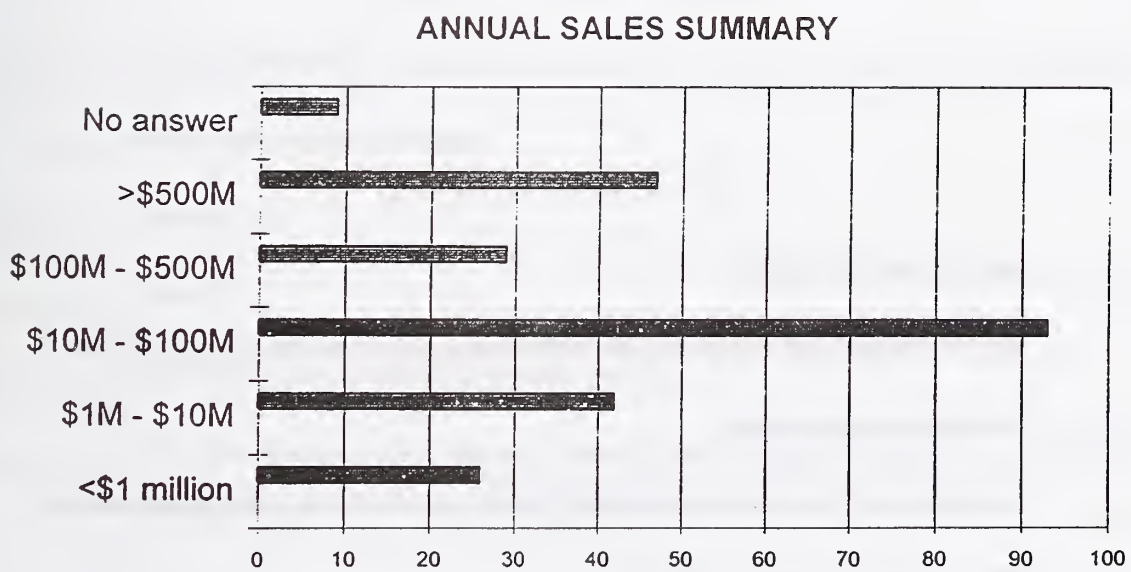

PRIMARY PRODUCT SUMMARY
Toys
Textiles
Telecommunications
Service Industry - General
Rubber
Retired
Primary Metals
Plastics
Pharmaceutical
Petroleum
Paper
Other
Medical Equipment
Lumber/Wood Products
Lawn & Garden Equipment
Instruments
Industrial Machinery
Household Appliances
Health Service Industry
Glass/Ceramics
Furniture & Fixtures
Food & Beverage
Fabricated Metal
Electronics
Electrical Equipment
Cosmetics
Construction Machinery
Computer Equipment
Chemicals
Building Construction
Automotive
Agricultural Machinery
Aerospace
0
5
10
15
20
25
30
35
40

ANNUAL SALES SUMMARY

What is the approximate "size" of your Company/Unit?

Company Annuals Sales

Annual Sales	Count
<$1 million	26
$1M - $10M	42
$10M - $100M	93
$100M - $500M	29
>$500M	47
No answer	9
	246

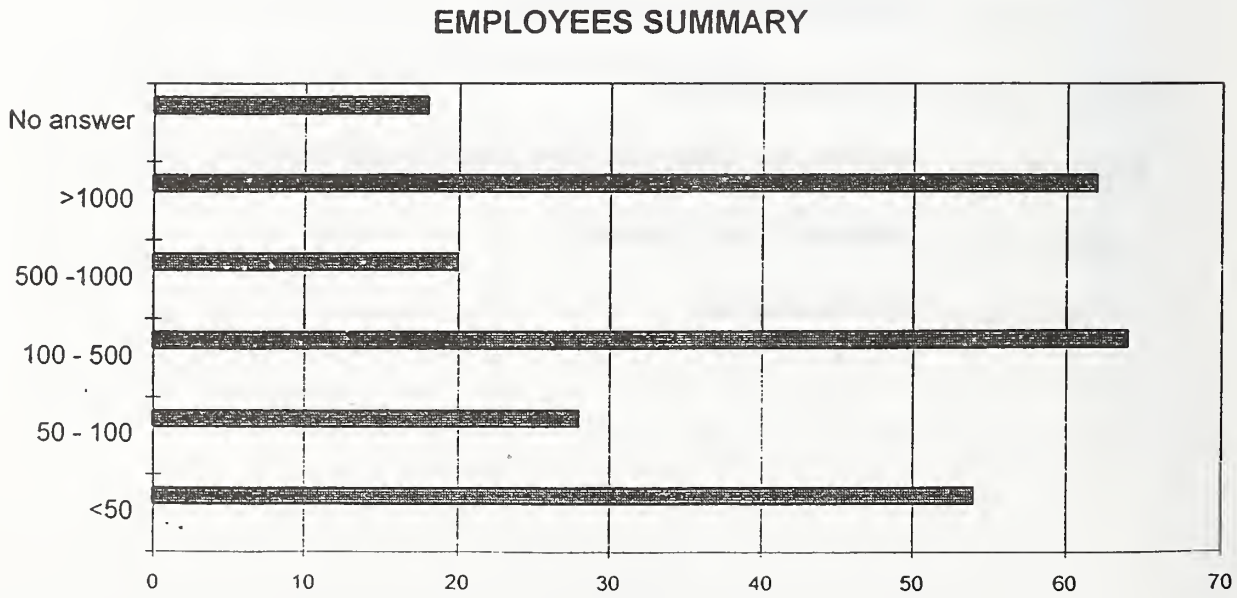


EMPLOYEES SUMMARY

What is the approximate "size" of your Company/Unit?

Employees

Employees	Count
<50	54
50 - 100	28
100 - 500	64
500 -1000	20
>1000	62
No answer	18
	246

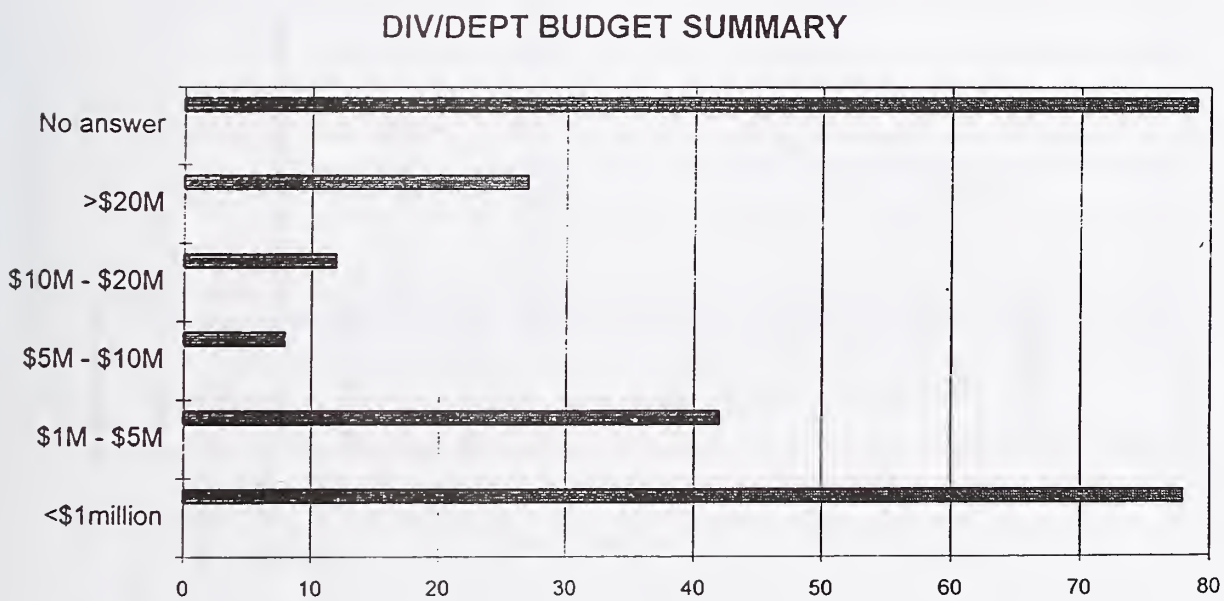


DIV/DEPT BUDGET SUMMARY

What is the approximate "size" of your Company/Unit?

Dept/Div Budget

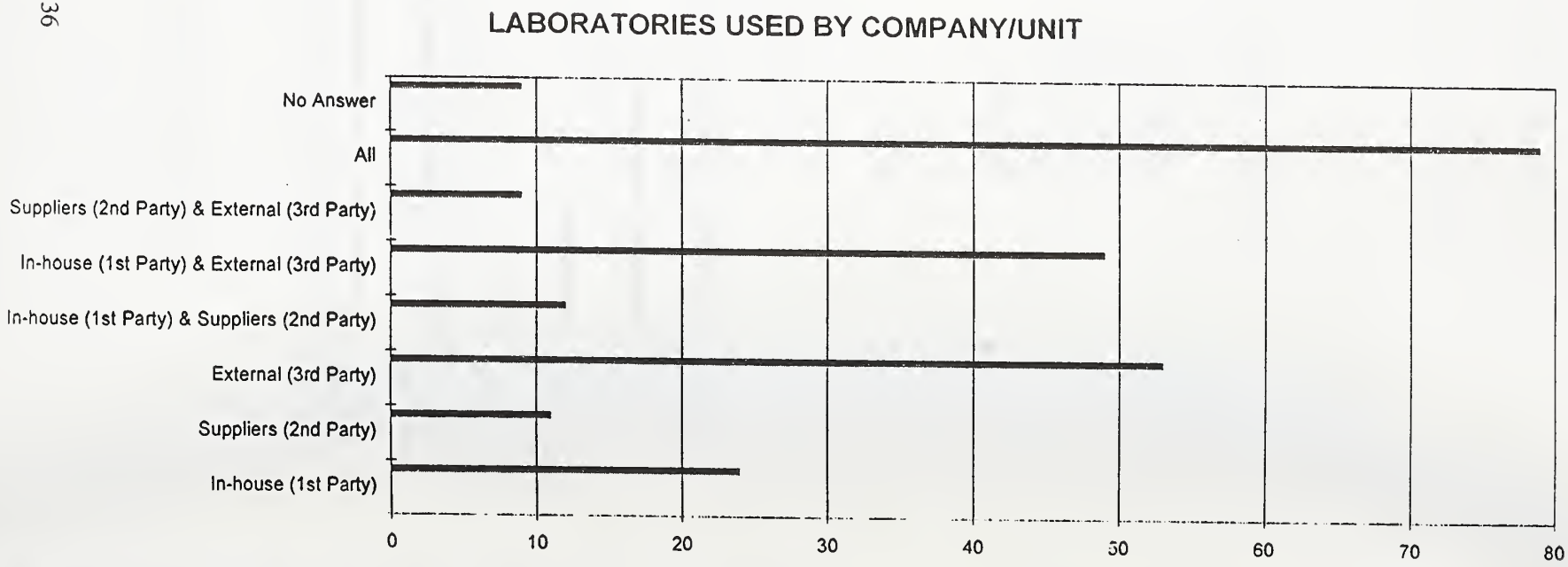
Dept/Div Budget	Count
<$1million	78
$1M - $5M	42
$5M - $10M	8
$10M - $20M	12
>$20M	27
No answer	79
	246



LABORATORIES USED BY COMPANY/UNIT

What laboratories does your Company/Unit use (directly or as the source of test results)?

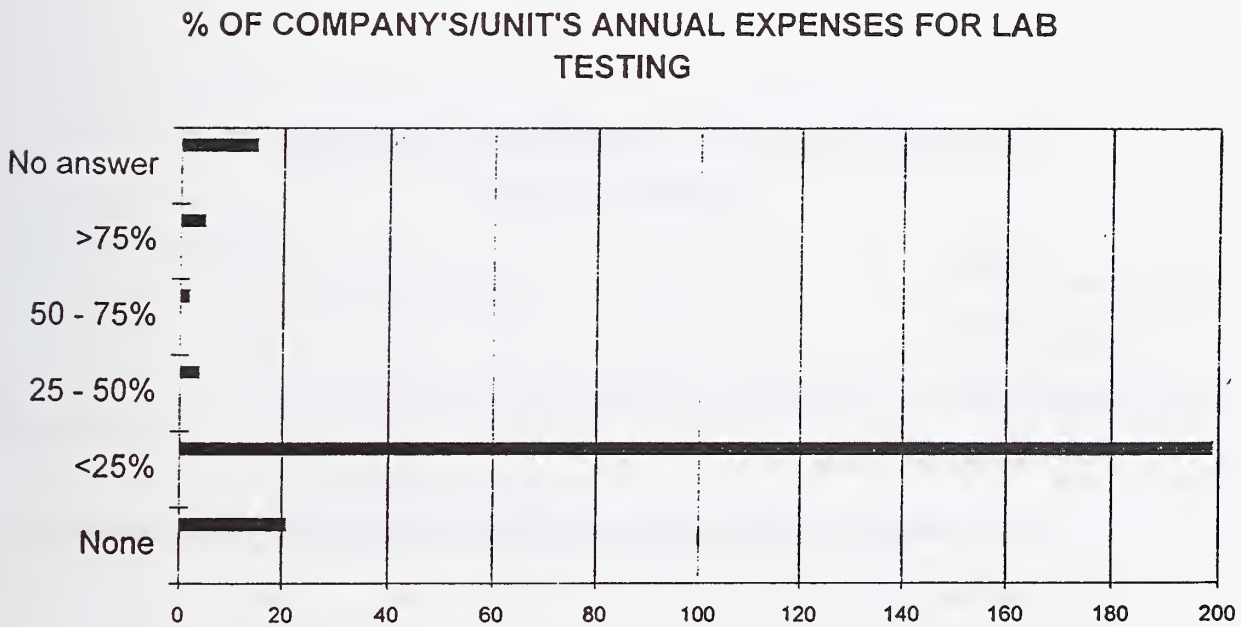
Laboratory	Count
In-house (1st Party)	24
Suppliers (2nd Party)	11
External (3rd Party)	53
In-house (1st Party) & Suppliers (2nd Party)	12
In-house (1st Party) & External (3rd Party)	49
Suppliers (2nd Party) & External (3rd Party)	9
All	79
No Answer	9
	246



PERCENT OF COMPANY'S/UNIT'S ANNUAL EXPENSES

What percent of your Company's/Unit's annual expense is for laboratory testing?

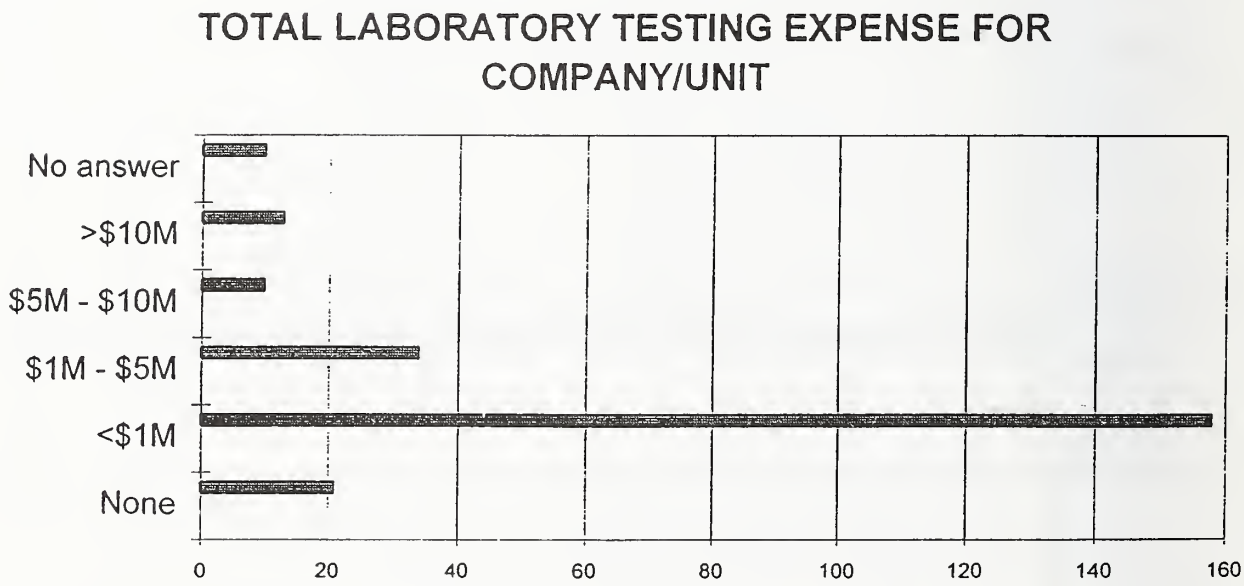
% of Annual Expenses for Lab Testing	Count
None	21
<25%	199
25 - 50%	4
50 - 75%	2
>75%	5
No answer	15
	246



TOTAL LABORATORY TESTING EXPENSE FOR COMPANY/UNIT

What is the approximate total laboratory testing expense for your Company/Unit?

Lab Testing Expense	Count
None	21
<$1M	158
$1M - $5M	34
$5M - $10M	10
>$10M	13
No answer	10
	246

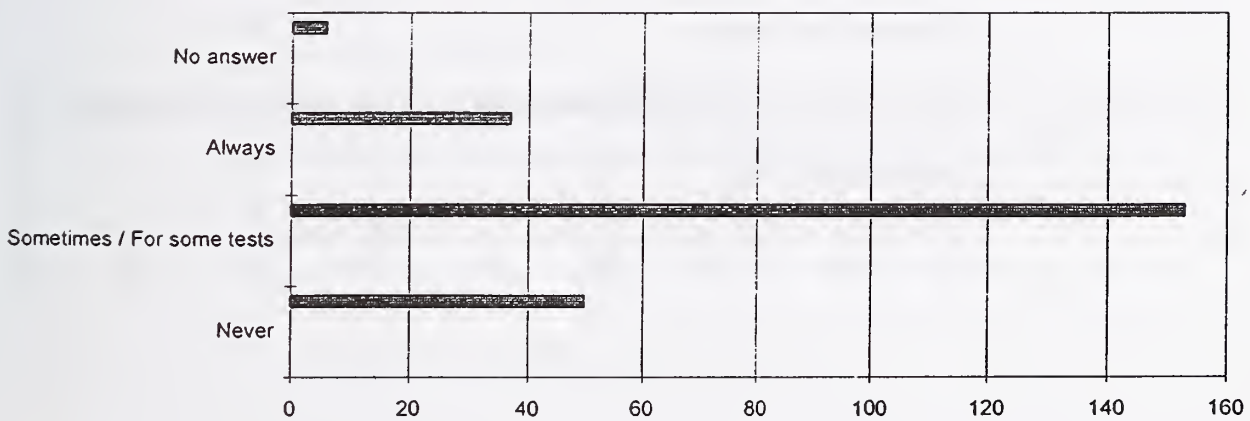


CUSTOMERS REQUIRE LABS TO BE ACCREDITED

Do your customers require the laboratories you use to be accredited? .

Customers require Labs to be accredited?	Count
Never	50
Sometimes / For some tests	153
Always	37
No answer	6
	246

CUSTOMER/UNIT REQUIRES LABS TO BE ACCREDITED

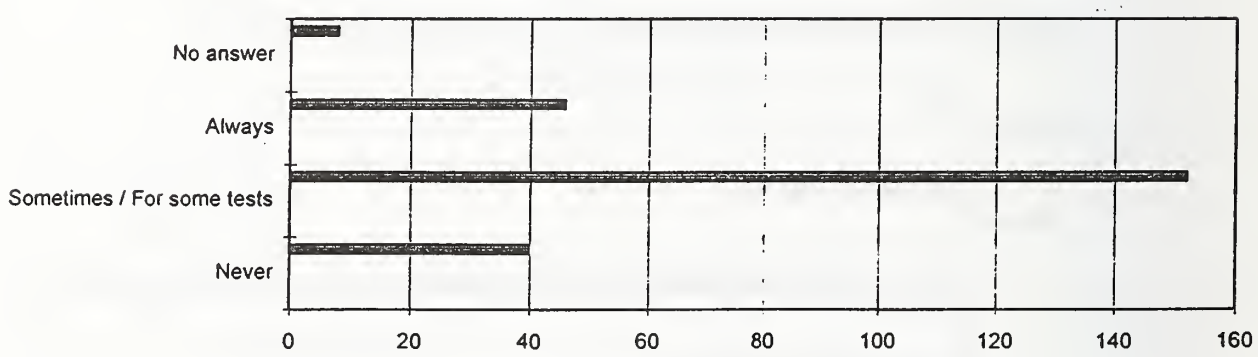


COMPANY REQUIRE LABS TO BE ACCREDITED

Does your Company/Unit require the laboratories it used to be accredited?

Company require Labs to be accredited?	Count
Never	40
Sometimes / For some tests	152
Always	46
No answer	8
	246

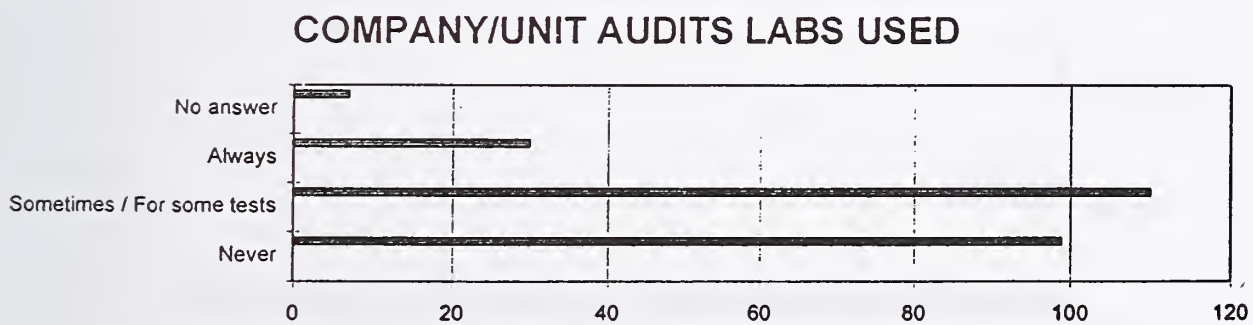
COMPANY/UNIT REQUIRES LABS TO BE ACCREDITED



COMPANY/UNIT AUDIT LABS USED

Does your Company/Unit audit the laboratories it uses?

Company audit Labs it uses?	Count
Never	99
Sometimes / For some tests	110
Always	30
No answer	7
	246



COMPANY/UNIT PROBLEMS/CONCERNS SUMMARY

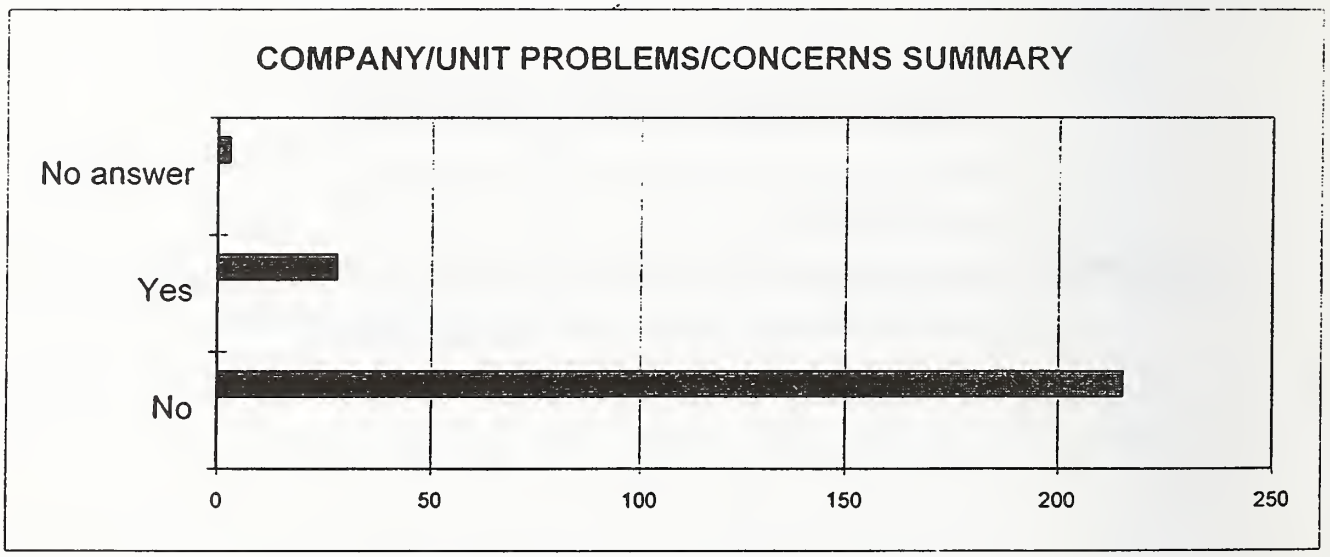
Have you or your Company/Unit had problems or concerns with test laboratory accreditation?

☐ No ☐ Yes Please use a separate sheet to describe

a) the problems/concerns and quantify if cost is a factor

b) two actions that would alleviate your problems/concerns with laboratory accreditation

Problems/concerns	Count
No	215
Yes	28
No answer	3
	246



COMPANY/UNIT REQUIRE CERTIFICATION OF MATERIAL OR COMPONENT SUPPLIERS

Does your Company/Unit require certification of material or component suppliers to (check all that apply)

☐ ISO 9000 ☐ QS 9000 ☐ ISO Guide 25 ☐ Other ☐ None

Require certification of material or component	Count
ISO 9000	47
QS 9000	3
ISO Guide 25	7
Other	12
None	104
No answer	8
45662EL	1
AALA	1
AMPSPEC. 102-45	1
ANSI	1
As required	1
ASME Section VIII	1
ASTM	1
ASTM, ANSI	1
Company's requirements	1
Deere (audit) certification	2
Documented Quality System	1
EEC/EU	1
Industry Standards	1
Internal	1
Internal stds	1
ISO 9000 & A2LA	1
ISO 9000 & ASTM/UL	1
ISO 9000 & Internal guidelines	1
ISO 9000 & ISO Guide 25	4
ISO 9000 & ISO qualified for cert.	1
ISO 9000 & MIL Pur. Spec.	1
ISO 9000 & MIL-Q-9858	1
ISO 9000 & NSF	1
ISO 9000 & or equivalent	1
ISO 9000 & Other	1
ISO 9000 & Our company program	1
ISO 9000 & Our supplier (preferred) program	1
ISO 9000 & QS 9000	4
ISO 9000 & ISO Guide 25	1
ISO 9000, ASME-Section III, NCA-380	1
ISO 9000, FDA, GMP's	1

COMPANY/UNIT REQUIRE CERTIFICATION OF MATERIAL OR COMPONENT SUPPLIERS

Require certification of material or component	Count
ISO 9000, QS.9000, ASM, ANSI	1
ISO 9000, QS 9000, ISO Guide 25	2
ISO 9000, UL, CSA, FM, CE(EN)	1
Material Specification	1
MIL Stds	1
MIL-I-45208	1
Moving to ISO 9000	1
Not yet	1
NQa1	1
O.L.	1
Per material specs	1
Purchase specification	1
QS 9000 & Auto companies	1
QS 9000 & Automotive	1
QS 9000 & ISO Guide 25	1
QS 9000 & NQA-1	1
Required specified properties	2
SAE	2
Sometimes	1
Specifications	1
Supplier audit	1
UL, CSA, TUV	1
Various	1
When available	1
	246

COMPANY/UNIT REQUIRE CERTIFICATION OF LABORATORIES

Does your Company/Unit require certification of laboratories to (check all that apply):

☐ ISO 9000 ☐ QS 9000 ☐ ISO Guide 25 ☐ Other ☐ None

Require Cert of Laboratories	Count
ISO 9000	30
ISO Guide 25	6
QS 9000	1
Other	12
No answer	11
45662EL	1
A2LA	2
AAMA	1
AL3	1
ALA	1
AMPSPEC 102-119	1
ANSI/NCSL 2540-1	1
ASME	1
ASTM	1
Auto companies	1
EEC/EU	1
EPA	1
EPA/NSF	1
FCC/UL	1
IEEE	1
Interested in ISO 9000	1
ISO 9000 & ASME-Section III, NCA 3800	1
ISO 9000 & FDA	1
ISO 9000 & FDA, GMP's	1
ISO 9000 & ISO Guide 25	2
ISO 9000 & MIL-Q-9858	1
ISO 9000 & NIL Pur. Spec.	1
ISO 9000 & NIST/UL	1
ISO 9000 & or equivalent	1
ISO 9000 & Other	2
ISO 9000 & QS 9000	2
ISO 9000 & SIO Guide 25	1
ISO 9000, Contrac Lab Program (CLP) run by EPA	1
ISO 9000, EN, ISO 29000	1
ISO 9000, QS 9000 & ISO Guide 25	1
ISO 9000, QS 9000, A2LA	1
ISO 9000, QS 9000, ISO Guide 25	2
ISO Guide 25 & A2LA	2
ISO Guide 25 & ANSI	1
ISO Guide 3	1
MIL-STD-45662A, ANSI 2540-1	1

COMPANY/UNIT REQUIRE CERTIFICATION OF LABORATORIES

Require Cert of Laboratories	Count
NIST	3
None	127
Not yet	1
NVLAP, TUV, VCCI	1
OSHA (NRIL)	1
OSHA,Stds Council-Canada,IECEE for IEC countries	1
QS 9000 & GP10	1
QS 9000 & ISO Guide 25	1
QS 9000 & NQA-1	1
Rarely	1
Supplier audit	1
Traceable to NIST	1
UL	2
UL mostly	1
When available	1
	246

PROBLEMS/CONCERNS

1.) Standardization 2.) Mutual Recognition

A high voltage laboratory is not easily calibrated by "non-interested" parties. Only a very few people know the problems and requirements to calibrate 200kV and up. Our society and government (USA) is not ready to fund

NIST to provided this calibration nor can the user afford the expense of having a very costly yearly calibration.

This answer pertains to item #8: If we have contract performance problems, we try to resolve or use another facility on future projects, i.e. take our business elsewhere

After I got home today, I realized that it may have been more appropriate for me to have passed this on to someone else to complete since I have officially retired from the company. On the other hand, I have worked for the organization for over 38 years as Engineering Manager (and other positions) and been active in SAE committees even longer.

The following comments should be taken within the context that a laboratory accreditation process was implemented corporate wide in an attempt to provide an alternative to replace duplicate testing within the corporation for PPAP approvals. It was felt that dropping duplicating testing without having some alternative assurance policy that the supplier had the competence to perform the required testing was not appropriate. The accreditation process has served that function very well.

1.) As a corporate guideline for PPAP, the process was not uniformly implemented or supported by all divisions.

2.) Third party accreditations can not differentiate between critical testing for higher risk issues and "lower risk" testing issues. All laboratories are treated equally and all test procedures are treated equally which adds costs to the overall accreditation process.

3.) Continual effort has been required to explain and justify laboratory accreditation versus quality systems registrations. This was due primarily because all three domestic automotive companies did not agree as to the value or support laboratory accreditation.

4.) Lack of 3rd party laboratory accreditation organizations utilizing ISO-25 guidelines as criteria for accreditation, very little competition available to help hold the cost down.

5.) Uncertainty of the equality of international accreditation organizations utilizing ISO-25 guidelines for off shore supplier laboratories as compared to organizations similar to A2LA. The concern obviously is whether a laboratory accredited by an off shore accreditation service is equal to or better than an accreditation issued by A2LA or similar.

6.) In a true effort toward a single/common process it is difficult to justify lab. Accreditation for PPAP when only one of the three automotive companies require it for PPAP.

7.) QS-9000 could severely hinder the long term viability of laboratory accreditation within the domestic automotive market.

8.) Cost of accreditation is a problem - our best estimate on third party accreditation, based on an average size scope is an initial cost of $3,000 per laboratory site with yearly ongoing costs of $1,000 to $1,500.

B.) ACTIONS THAT MAY ALLEVIATE OUR PROBLEMS

1.) An agreement between all three domestic automotive testing communities that laboratory accreditation is important and then our ability to sell this concern to the Supplier Development community at our respective organizations.

2.) An international understanding that Quality System registration and Laboratory Accreditation are independent issues and both necessary.

Each technical person selects the lab he wants to use & satisfies himself about the need for accreditation. I, personally, would like to see a universal accreditation system in place.

PROBLEMS/CONCERNS

Cost - it is good if all gage companies in the future must comply.

A.) Driven by both customer and legal needs, it is necessary to involve third parties to inspect/evaluate and approve our test facilities. One evaluation is never considered or utilized by the next inspector and so there is redundancy of effort, time
and cost. Also, there is no value added to our processes as a result of the evaluation (accreditation). B.) Action 1: A US system of laboratory accreditation must be developed which eliminates duplication of effort and is
credible at the local, state, and federal levels and internationally. This US system must be characterized by flexibility - allowing a number of acceptable options for laboratory accreditation.
This system must make use of the private sector and should involve governments at a recognition level only.
Action 2: The acceptability of this system must be effectively communicated to those who require accreditation; both to governments domestic and foreign) and to the private sector.

Determining whether accredited
National Accreditation Standard, List of Accredited Labs

At this time, most 3rd party certification can be done at out plant where a technician from the 3rd party laboratory witnesses these tests. Where these tests have generally always passed, a copy of the results has always been kept. What we object to is the taking of the results from the plant with the technician, the technician writing the results on a new form, and telling us that we have passed the test.
The requirement of 3rd party certification comes from countries where laboratories exercise a lot of power over the government and large purchasing bodies by lobbying their "knowledge" and "expertise" in product testing. These companies or laboratories then force the supplier to have all tests verified by a "competent" person, who travels first class, has expensive meals, charges for his time from the time he leaves his house, etc. For example, the cost for testing 3 machines for noise was $12,000. This cost needs to be added to the units sold to the countries requiring this test over the next 2 years (length of certificate life).
Then customers in those countries complain that we our units much cheaper in the U.S.A. No wonder, if every test requires $12,000, the units quickly become inaffordable. These tests had already been done and approved internally.
Was this cost value added? In the true definition of the word NO 3rd party certification should be similar to the USDA system where the results of the tests are presented and approved by the laboratory. If a question

arises, the complainant should pay for the expenses unless he can prove the results were erroneous or wrong.

U.S.A. No wonder, if every test re

Was this cost value added? In the true definition of the word NO 3rd party certification should be similar to the TIC-MS, Inc. is a Metrology Laboratory and while this survey does not technically address our business, I want to seize the opportunity to get a few things on the record.

Mattel is in a unique position of being both a user and developer of test data. It ships a portion of its products to major U.S. customers in FOB programs. Since the retailer is the importer of record, they require 3rd-party test and certification to government regulations and voluntary toy safety standards. Although believed to be significant, it has not been determined what is spent by Mattel manufacturing facilities to attain certification for products being shipped under these terms. There is no
Mattel has invested a great deal of money in all of its facilities to assure the quality and safety of its products. A large portion of the investment goes to maintaining test labs to qualify products before production start. A goal for the company would be to get independently accredited a t all facilities. We hope that our customers will recognize that accreditation and eliminate our reliance on independent testing by a 3rd-party
lab. Because of the obvious financial and logistical advantages to this, Mattel would like to pursue accreditation that is widely accepted by the toy trade and government, regardless of the market country.

PROBLEMS/CONCERNS

To this end, eliminating redundant accreditation or establishing mutual recognition between accrediting bodies has to remain a primary goal of the LAWG Industry Work Group. Improvements in this area would be beneficial even if Mattel continued to be required to attain certification of its products by an independent laboratory.

DR. COLLINS: Thank you very much. I hope that you can hear me. I'm glad to be following the Manufacturing Group because I think some of the issues that they outlined are actually true for the government as well. And I'd like to say that the Governmental Group is probably lagging the other groups and recognize that we know we have more work to do.

Federal agencies participating in the governmental working group include agencies ranging from Food and Drug Administration, Occupational Safety and Health Administration, the Environmental Protection Agency, NASA, the Federal Trade Commission, HUD, FCC, the Department of Transportation, the Public Health Service, the Veterans' Administration, the Department of Energy, Mine Safety and Health Administration, and the Department of the Interior. This broad spectrum gives you some idea of the issues and concerns of the Federal Government.

We have also involved state agencies in the working group because we realize they are caught in the middle of all of this. They have their own needs, but they also have the needs imposed by the Federal Government.

This has been a working group under the sponsorship of the Interagency Committee on Standards Policy (ICSP) and also part of the general activities going forth under the laboratory accreditation activity here. We find major issues affecting our participants, such as regulatory jurisdiction, and another important issue that I don't think has been addressed yet today; namely, that of data quality. A major concern for governmental agencies is how do we know that the data provided by a testing laboratory are any good?

In terms of our progress to date, first of all, it is very clear that not everybody in the government is clear on what we mean by laboratory accreditation. We find Federal agencies using the terms "licensing, certification, accreditation, and/or registration," sort of interchangeably, each agency knowing what the terms mean for it, but different agencies not agreeing on terminology. That, in fact, led us to put some definitions in the hand-outs that we gave you today.

Obviously, the Federal Government is concerned about a host of different product sectors, be it medical devices, drugs, computers, communication, safety equipment, inefficient equipment, agricultural products, transportation products and systems. You name it, the Federal Government is involved with all of these areas and has programs in all these areas--and the programs all differ. I think the one defining theme is that they all differ. They differ in needs, differ in programs, differ in requirements, different ways of thinking about things, and different ways of approaching things.

Furthermore, there are different statutory requirements given to us by the Congress and these vary again, between agencies, and in fact, often within an agency. As Steve Baldwin mentioned, in Hewlett-Packard, it may be true that one division doesn't know what another division is doing, and that is, unfortunately, true in the Government as well. We find different procedural bases for laboratory accreditation within and between agencies.

I think a bottom line concern throughout all the Federal agencies is the awareness that we are there to help protect health, safety, and the environment; that these are key issues and reasons for regulation; and that we have a mission to achieve in these areas. And so the governmental group spent considerable time talking about products versus systems, and the issues that arise from how best to ensure the safety and health of those in this country.

We recognize that we have begun to share our experiences and needs among Federal and state agencies, and we certainly have more work to finish this sharing. As the gentleman from FDA brought out, we are aware of dwindling resources. I don't think there is a Federal agency in town that has increasing budgets, and we want to ensure we are able to carry out some of these programs, despite budget limitations.

To begin to address the issues facing governmental agencies, first of all, it is clear we need more data about the kinds of programs that we operate. What are we--as government agencies--doing to everybody else in the system? What are the problems, and how do we ensure the goal of data integrity, quality, good accreditation, without accrediting people to death?

To begin to achieve these goals, we will continue to interface strongly with the NELAC efforts. This is the National Environmental Laboratory Accreditation Conference operating under the sponsorship of EPA and other concerned Federal agencies and state interest groups.

We also need to be aware of activities going on with the National Conference of Weights and Measures, which brings together all state and local officials concerned with weights and measures and which also operates an Accreditation Program.

We need to increase awareness of Guides 25 and 58, the ISO Guides, which can serve as a basis for continuing to do laboratory accreditation. If you think back to the data presented by the Manufacturers, they mentioned that some people were talking about ISO 9000, but that isn't actually the Guide that's recommended for laboratory accreditation. Again, we have confusion over what we actually mean by "accreditation," much less which guides and procedures should be used to begin the process and determine how to do it properly.

We need the Federal Government to look at those issues related to statutory requirements and where we feel there are opportunities for change. And let me point out that, lest you think you cannot picture the Federal Government getting its act together, there has been major action in most Federal agencies to focus on the issue of the quality management system requirements such as ISO 9000. We have actually had Federal agencies come together, and sign a Memorandum of Understanding under the Government Industry Quality Liaison Pool, that they will require only one quality system for a given supplier in a given location. Now, it may not sound like very much, but until recently, one supplier would have to keep a set of quality books for the Navy, the Army, NASA, had to file with the contract, and perhaps with other Federal agencies, and so we had about 58,000 different sets of books. They needed another room.

Consequently we, in the Federal Government, came together and said, "Okay, just one set of books for this guy." We did not say anything about whether or not the suppliers had to use ISO 9000, or be registered to ISO 9000. We simply agreed to just one requirement for one quality system in a single facility. And I think that is an example of how the Federal Government can come together, work with the private sector, and identify where there is a

problem in conformity assessment and work together to resolve it. I think you'll see more of that activity in the laboratory accreditation arena, whether or not it is as formal as something like the National Conformity Assessment Recognition System. We need to consider whether or not that really will meet Federal agencies' needs. Again, we would like your input on that kind of system, as well.

We're also trying to get the issue of laboratory accreditation higher on the agencies' attention, to bring more resources to bear on understanding the problems and possible solutions. This will allow us to continue to review the system procedures. For example, agencies believe they know a "quality lab" when they see it. What does that mean? I mean, what criteria do they use to judge whether a lab is high quality or not? Obviously, we could license people to make this decision or use formal accreditation procedures or do something else. As I say, the options run the gamut, and often vary greatly within a single agency. We will continue to ensure high quality, rigorous accreditation by the people that we use and we'll continue the dialogue with all sectors and we welcome ideas from the audience today.

Thank you very much.

MR. MAZZA: Are there any questions for Belinda at this point? Questions of clarification of her presentation from anyone? Lou?

MR. DIXON: Yes. I want to agree with Belinda that a problem is the user of labs in the Federal and State Government arena, as well as in the manufacturing arena. And the last two slides that I had put up there were an attempt to show that while we, in our myopic way, don't recognize what we're causing when we don't say, "I need my lab accredited to ISO Guide 25, or some recognized internationally acceptable standard," then we're allowing a number of different standards to be used and maybe none, and that's where we have all the confusion.

DR. COLLINS: Thank you very much, Lou. I think it's interesting to realize the impact of some of our actions.

MR. JOHNSON: Jim Johnson, T&V Products Services. Dr. Collins, the last paragraph of Vice President Gore's letter to us this morning says, "As you proceed in your deliberations, I urge you to seize upon this superb opportunity to make an historical contribution to American competitiveness." And I'm sorry, Dr. Collins, I didn't get any sense that your report had anything in any way to reconcile with what the Vice President is challenging us this morning. "Seize" is a very active word.

DR. COLLINS: I would remind you that it's not mine to seize; it is all of ours to seize; that we're beginning the process today, not ending it, and that's why we're calling for an open dialogue.

I am reminded that it is incumbent upon us in the United States to get our system organized or we'll be having accreditations done by foreign entities on U.S. products. And I think we need to think seriously about that. But I think we don't have the solution as yet.

MR. MAZZA: If I could just add to that? It is ours to seize, "ours" in the broadest sense. That is why we have brought so many people together here from so many different

interested constituencies. It's not something the Government is going to be able to do for us; it is something we are going to have to do together with the Government and, the "us, together with the Government," are all the different interested parties. It's the manufacturers, it's the accreditors, it's the test labs.

Questions?

MS. TROVATO: Hi. My name is Ramona Trovato and I'm from the Environmental Protection Agency. I was curious about the statutory requirements that you thought were serving as barriers that needed changing.

DR. COLLINS: Certain agencies have said that they must do things in a particular way because it has been mandated by Congress. A case in point is that we have a number of programs in the NVLAP Program, the National Voluntary Laboratory Accreditation Program, where Congress has suggested that the NVLAP procedures be used for a particular application. That is pretty close to a mandate, which happens for a specific area, but not in another. This "spotty" happens across the board with different agencies. We think that there are ways, when we understand where these mandated programs are happening, that we might be able to work for change through the Reinventing Government, or through OMB, or determine where we don't need a change and our actions actually are meeting the needs of the constituents.

MR. MAZZA: If you could introduce yourself?

MR. UNGER: Pete Unger. Belinda, actually I'm asking this question as ASTM's E-36 Chairman. What is the status of the Interagency Committee on Standards' Policy on Laboratory Proficiency, published, I think, March 5, 1985? Has that been renewed, reviewed, withdrawn, reconsidered?

DR. COLLINS: It needs to be brought back to the table and it will be during next year and it should serve as a vehicle again to help us start seizing this opportunity in laboratory accreditation.

MR. MAZZA: If there are no questions, we'll move on to our next speaker.

MR. DONALDSON: Sergio? I would like to add a postscript to what Belinda said in answering one of the questions. I think that the Congress is a very good source for some of our problems, and I think that Belinda chose well in her example, and I'd make it slightly even more specific. There has already been reference, I think, by John Locke, to the Fastener Quality Act. The Fastener Quality Act, when it does ultimately become implemented, directs NIST to do something which is, in fact, inconsistent with international policy guidelines, and is inconsistent with executive policy guidelines. It directs NIST to both accredit laboratories and recognize others to do the same things.

Now, any one of the guides from ISO/IEC tells you that you don't both accredit others to do the same thing you do and do it yourself. That's a conflict of interest. And yet, we're directed by law to do it. I think that's a perfect example of a problem. In terms of directing NIST to offer a program in Fastener Quality Accreditation, we have no choice. That's where we have a mandate and it directs us as to how we should do it. So, I think that Belinda has a

very good example, and I think that as you go through each of the mandates, they come out of different committees in the Congress and I would be the last to suggest that they coordinate what they're doing.

(Laughter.)

MR. MAZZA: Our next speaker is Dr. Robert Stephens. Bob is the Chief of the Department of Toxic Substance Control of the Environmental Protection Agency of the State of California. Bob is here with us today as the Chair of NELAC, the National Environmental Laboratory Accreditation Conference.

NELAC

DR. STEPHENS: I'd like to thank Belinda for inviting me to come and make some remarks about NELAC. Two housekeeping issues to begin with. I'm afraid I may stumble a little bit today in reading my notes. All of my glasses are at the bottom of a still warm pile of ash in California and I'm having a little hard time seeing my notes, but I'll try to do the best I can.

What I'd like to do is to discuss what is, in my judgment, some information on experiences that NELAC has had as it's proceeded through this process of trying to solve many of the problems which we've heard about this morning. I'm here really talking as the Chair of NELAC. I've not discussed these issues with the Board in any detail and don't have any official sanction from them to give these opinions, but my general opinion and knowing what their views are on these issues, I think they concur with the remarks that I'm going to make.

It's not my intention to go through and give a lot of details about NELAC and its organization and its members and all of that. There is some of that information in the paper which is included in the package, and NELAC has been written about quite a bit already in various general publications which have wide circulation, so I don't think I really need to do that here.

What I'd like to do, again, is to discuss some of the issues that NELAC dealt with in terms of solving, or in an attempt to solve, some of our problems. I'd like to also emphasize that I think NELAC represents one particular model built around one sector's needs for accreditation, and that sector really is regulation in public health and the environment. This model may, or may not, apply to other types of accreditation and product conformity. I think there may be some similarities and there may not be some similarities. And I think there probably are a variety of models which are going to be developed, given the diversity of programs that are represented, both in Government and in the private sector. What I'd like to discuss though, really, is what we've done in terms of approaching finding solutions to our particular problems in this sector.

A little background on how we got started, or kind of the perspective that we're approaching this problem from. And first is kind of the general concept, that the public, through its legislative bodies, has given clear responsibilities to the public agencies to do certain things, particularly in the arena of the environment and, in the exercise of this responsibility, which includes identification and evaluation, understanding and management, and remediation of environmental problems, laboratory data plays a key and central role in the public agencies' ability to do that and to carry out that responsibility.

Understanding this, agencies at the Federal level and across the country responded with many different approaches to assure, or to improve, the quality of data which flows into their programs that allows them to exercise their mandated responsibilities. And I'd like to emphasize that the authority to manage the environment and public health is widely distributed around the country, that authority generated by legislative bodies across the country, and there is no central authority existing in the public health and environmental arena. It's widely distributed.

This has, in essence, created the NELAC problem statement, that there is this plethora and diversity of accreditation programs which have grown up and with the legitimate goal of agencies trying to improve the quality of data that they have to rely on. But the fact is too many people did it in too many different ways, resulting in what we all know now, particularly in our area of environmental protection, is a very costly system which frankly wasn't working very well, or isn't working very well, in the sense of its main goals of producing quality data that supports the environmental programs and doing this in a cost-effective manner.

So, what's the solution? The solution was considered by many stakeholders, and there are many stakeholders in this issue. Even though the legislative bodies have given the public agencies certain clear responsibilities, there are a lot of players in this game at the Federal level, in Federal public agencies, state public agencies, local public agencies, the laboratories themselves, accrediting organizations and the regulated community, the users of the laboratories, and the nongovernmental organizations, the NGOs. They all are clear important stakeholders in this problem.

Now, these stakeholders gathered together to consider solutions. Accreditation was determined as the most cost-effective way to approach the problem of producing better quality data in the most cost-effective way. There were other solutions that were considered in terms of product certification data, in terms of certification of professionals, a variety of models or other approaches were considered. But, amongst the stakeholders accreditation was determined to be the most logical, or the most cost-effective, way to deal with the problem that we had before us. But, accreditation had to be to a single standard, used by everyone, all authorities, with mandated reciprocity amongst the authorities. That was the problem--that was the challenge--that we had, to create that.

There are two important points to make about this objective. One that led to real problems is that if you have a common standard, which standard do you use, and how do you agree to it? There are a lot of standards for laboratories floating around. Some are local, some are national, some are international. Which standard do you use, and how do you get everybody to agree to it? We did not want to, in our efforts, create another standard. There were already too many. So, we want to use one that exists, modify it, if necessary, to make it more directly applicable to our problem of environmental protection, but use, to the degree possible, existing standards.

The other major problem is there is no authority existing in the country to require it. We cannot, EPA cannot, NELAC cannot, mandate a uniform national standard. This means that we have to do this by consensus. It's got to be by consensus, it's got to be of high enough quality, that people will agree to do it. So that was really the context in which we entered into this.

With those kinds of boundary conditions, we fortunately had Al Tholen in this group and he educated us about the National Conference on Weights and Measures, which seemed to be an ideal model for bringing diverse interests together to address a standard in an area where there was no central authority to mandate standards, come to a common agreement, and then everybody go home to their separate authorities and adopt the common standard. That had worked for 90-plus years and we thought it would work in the environmental standards area.

Now, there are a couple of important features of the weights and measures model which apply to NELAC that we wanted to build into NELAC, and those are that there are many interested, i.e., affected, and necessary parties to the decision process. Each brings a different set of expertise, different resources, different responsibilities, to the process, and the process must allow that to happen in order for it to be successful.

The other main consideration is the science and technology we're dealing with in the environmental laboratory arena is rapidly evolving--new and better ways generated by companies like Hewlett-Packard are coming on line quickly--and we did not want to create a system which would shut down that progress.

Okay. Where is NELAC now in an attempt to challenge these goals? The institution has been established. As you know, we met last February for the first time, so we're about 9 months old now, and we'll leave it to your judgement about what level of maturity that puts us at 9 months old. We are clearly not mature, and I'm not sure we've reached puberty yet. We're pretty young. We're 9 months old.

We've had broad participation in the process. Essentially all the affected Federal agencies who are concerned with environmental issues are players in the process. Essentially all the states and territories are involved in the process. A wide array of laboratories and other private sector interests and environmental NGOs are in the process.

We have established a draft Constitution and By-Laws and adopted it, which creates the organization and the process for consideration of the issues and the standards. The mechanism involves, as it does within Weights and Measures, a series of working committees which take pieces of the standards and writes them, debates them, revises them, and then proposes them to the conference. The working committees are working as I speak. They have made tremendous progress in the last 6 months. There is broad participation of both public and private sector in this process of the working committees.

Upcoming critical milestones are the interim meeting, which will occur in Washington the first week in December. And at the working meeting the working committees, or what we call the Standing Committees, will come to the interim meeting, meet face-to-face in a public forum with the issues as they have developed them over the last 6 to 8 months, and put various issues on standards to a vote. Those will be presented in a plenary session for adoption as-- They have been adopted as draft standards. Those standards will be published in *The Federal Register*. Approximately 6 months following the interim meeting, we will have our next annual meeting, at which the proposed standards will be adopted and final, hopefully.

The goal, my personal goal, is to adopt sufficiently complete standards at the next annual meeting that there is a critical mass of standards that the various accrediting authorities, like California, can move towards them and begin to adopt them and begin to work down this conflicting diversity of standards. But, until we actually have the documents, which are the uniform national standards, we, as the accrediting authority, can't really move toward those. So, that's our goal, to do that.

So, in conclusion, I'd like to say I think NELAC has faced some of the issues which are before LAWG. We've learned from both some successes and some mistakes we've made, and

we would suggest to LAWG that NELAC may be a model that they would like to consider, recognizing that we have special needs in the particular sector that we operate in. But we think we've made some progress right now, and we think that maybe LAWG might consider of value to learn from our experiences.

Thank you.

MR. MAZZA: Are there any questions for Dr. Stephens to clarify his presentation?

MR. O'NEIL: Bob, I have one question. You mentioned the standards that are being developed now. As far as you can tell at this point is ISO 25 going to be a base, at least, upon which the ultimate standards will be built?

DR. STEPHENS: Within the organization of developing the standards, the ISO Guide 25 principally relates to the quality systems process, and the original draft standards, or proposed standards, were approximately built around Guide 25, but there were some fair differences.

What has happened within the Quality Systems Standing Committee is that that section of the standards has been almost entirely rewritten and with a goal of making it as consistent with Guide 25 as possible. It will be "the" basis for the quality systems part of the standards.

Larry?

MR. GALOWIN: Larry Galowin of NIST. My question is very much along the same lines as Joe's. You are distinguishing a quality standard parallel to ISO Guide 25 or its derivative put together by your committee, but what are you doing in the area--or what are the committees doing--in the areas of the technical standards? Are you trying to bring those together as well from the different laboratories that may be accredited toward a technical performance requirement?

DR. STEPHENS: I'm not sure I know what you mean by "technical" standards. We're not writing methods, if that's what you mean. We're not writing methods. That's not our role. There is certainly a performance evaluation component to the standards and there are certainly technical standards that are built into the performance evaluation system for levels of performance. In terms of methods, the way the standards and accreditation system has been structured is really with a philosophy of promoting performance-based standards for methods and to allow, when the agencies at the Federal and state level move towards performance-based standards for methods, that would be easily adapted into the NELAC standards.

MR. GALOWIN: So that EPA, or the groups involved with EPA, are pushing for the diversity of the test methods toward the same end of measurement, but are willing to accept some diversity, rather than going to specific test methods for a given purpose?

DR. STEPHENS: There is nothing in the NELAC standards that forces use of specific methods. We're consciously avoiding that.

MR. MAZZA: Our next speaker is Rick James-- Oh, I'm sorry. There is another question.

MR. MacALISTER: I'm Ray MacAlister of the American Crop Protection Association. I'm not real familiar with the whole NELAC process, but I observed there has been some reluctance to a lot of involvement of, shall I say, the customers of the laboratories that would be involved in the process of establishing standards; that they have not been allowed any voting relationship on these various committees. Is that going to change?

DR. STEPHENS: Certainly, involvement of the customers of laboratories, we'd like their involvement. We have the National Manufacturer's Association's represented, the IA is represented. If you would like your organization, or your company, if you're a user of laboratories, would like to participate in the process, see me afterwards. And anybody else that goes for. We would like your participation. We recognize the need for that. We're out recruiting people.

MR. MAZZA: If there are no further questions, our next speaker is Rick James. Rick is the Director of Conformity Assessment at the American National Standards Institute, and he will deal with the International Working Group conclusions.

INTERNATIONAL

MR. JAMES: Good morning. My co-chair today, Mary Saunders, is unable to be with us today. She's on international travel.

The expansion of global trade is increasingly important to the economic growth and productivity of the United States. The Uruguay round of the General Agreement on Tariffs and Trade has resulted in increased awareness of the importance of technical barriers to international trade. Developing cooperative relationships through Mutual Recognition Agreements between national laboratory accreditation systems from other countries can be an effective mechanism for overcoming many of the current problems caused by technical trade barriers.

The International Committee of the Laboratory Accreditation Working Group has begun accruing information on various committees and activities and organizations throughout the world as they relate to laboratory accreditation, and I would like to take this time to summarize some of these organizations. We looked down the road, put together more of a briefing book that could be disseminated out to the industry on the updates on these activities, and then hopefully we can receive feedback.

Alphabetically, we begin with APLAC, which is the Asian-Pacific Laboratory Accreditation Cooperation, as part of the Asian-Pacific Economic Cooperation. APLAC is an informal assemblage of national laboratory accreditation bodies comprised of countries that rim the Pacific Ocean which have come together for the purpose of establishing cooperation in mutual and regional multilateral agreements. A memorandum of understanding has been produced and approximately 20 laboratory accreditation systems from 16 countries have signed on.

As we move ahead, we get into a little bit of analytical chemistry with the Cooperation on International Traceability in Analytical Chemistry, CITAC. CITAC was established to improve the comparability of chemical measurements in different laboratories in different countries. Key is the establishment of traceability to internationally recognized reference materials and methods, and it provides input to the ISO, ICC Reference Material Committee, and is comprised of Government and private sector laboratories worldwide.

Let's move along to the European Cooperation for Accreditation of Laboratories (EAL). It was formed as a result of the merger of the Western European Calibration Cooperation and the Western European Laboratory Accreditation Cooperation in May of 1994. EAL is one of the recognized agreement groups under the European Organization for Testing and Certification. They address issues such as international traceability, measurement uncertainty, technical competence, and interlaboratory comparisons proficiency testing. Within EAL, 12 accreditation systems and 11 test laboratory accrediting systems have signed multilateral agreements. Non-European labs can enter into an MLA, once they've demonstrated compliance to ISO Guide 58, which is "Calibration and Testing of Laboratory Accreditation Systems: General Requirements of Operation and Recognition."

Talking about the European Organization for Testing and Certification, it was established approximately in April, 1990, under MOUs signed by the Commission, the European Free Trade Association, and the European Standards Body to constitute the focal point in Europe for all issues relating to conformity assessment. The mission of the EOTC is to establish mutual

confidence between all parties concerned with conformity assessment issues, to facilitate circulation throughout Europe of goods and services that have demonstrated conformity with their technical specifications. EOTC does this by promoting and implementing criteria and procedures for technical capabilities, operational performance, and maintenance of competence of operators.

The International Accreditation Forum, brings together accreditation organizations from many countries to discuss issues related to conformity assessment activities. Some of the objectives of the IAF are: to exchange information; participate in IAF joint activities; harmonization of accreditation of body members' operating procedures; participation in regional groupings; participation, evaluation, and re-evaluation of programs based on peer review of accreditation body members or regional groupings leading to worldwide multilateral agreements. IAF supports implementation by accreditation, certification bodies of IAF's LIE Standards and Guides, and to establish and maintain IAF multilateral agreements based on equivalence of accreditation programs. Originally, a multilateral agreement was produced and signed by 12 countries.

The International Organization for Standardization Committee of the General Assembly on Conformity Assessment, CASCO, is ISO's Development Committee on Conformity Assessment, reporting to the ISO General Assembly. Some of CASCO's objectives: to study means of assessing the conformity of products, processes, services and quality systems to appropriate standards and other technical specifications; to prepare international guides relating to testing, inspection, certification of products, processes, services, and the assessment of quality systems testing laboratories, inspection bodies, and their operation and acceptance; to promote mutual recognition and acceptance of national and regional conformity assessment systems; and the appropriate use of international standards for testing, inspection, certification and assessment and related purposes.

Within the CASCO they have developed work programs which review existing guides on product certification, assessment of quality systems, certification bodies, inspection bodies, testing laboratories, suppliers declaration, and preparation of guides in response to requests arising from the International Laboratory Accreditation Conference, and studying ways to promote recognition and acceptance of certification systems established on the basis of ISO/IEC guidelines.

Speaking of ILAC, International Laboratory Accreditation Conference, it began in 1977 as an informal international forum of laboratory accreditation systems. Its principal aim is to achieve acceptance of test and calibration results. ILAC is involved in various aspects of laboratory accreditation and is the driving force for ISO Guide 25, "General Requirements for the Competence of Calibration and Testing Laboratories." ILAC also has developed an *ad hoc* Working Group in Review of Guide 43, which is "Development and Operation of Laboratory Proficiency Testing," and it was presented to ISO.

Some of the objectives of ILAC are: to define and advance the principles and practices of laboratory accreditation through consensus agreement and technical working groups; exchange and disseminate information on laboratory accreditation systems and other assessing of quality test results; to cooperate and collaborate with interested international organizations on matters relating to laboratory accreditation; and to facilitate and encourage acceptance of test results from accredited laboratories through bilateral and multilateral recognition of laboratory accreditation

systems. Currently there are approximately 12 laboratory accreditation systems that have entered in an MRA.

To get to more of a little specific committee group that looks at chemistry activities is the International Union of Pure and Applied Chemistry, IUPAC. This group has been formed to address harmonization of analytical quality control and standard methods. The group development of protocols in areas such as acceptability of test results, repeatability, and reproducibility of tests. Some of the groups include the Federation of Clinical Chemistry, the International Dairy Federation, one of my favorites the International Brewery Convention.

The ISO Committee on Reference Material, REMCO, established in 1975, carries out and encourages a broad international effort of harmonization and promotion of certified reference materials and their applications. REMCO's tasks include calibration, promotion, accreditation and sampling. REMCO looks to assess the need for reference material producers; collect, assess, and analyze viewpoints and documentation concerning the accreditation of reference material producers; to coordinate future revisions of ISO/IEC guides; to provide an internationally recognized system for traceability of chemical measurements, to draw up rules for accreditation of reference materials in order to ensure full traceability.

And finally, the Committee on Standardization Principles, STATCO. Currently, 40 countries participate in this committee with another 32 listed as observers. This committee provides an international forum for the exchange of views and sharing of experience relating to fundamental aspects of standardization to conduct those studies that are entrusted to it by the Technical Management Board related to standardization, including methodology and terminology.

We hope that this list will continue to grow and expand as we gather more information. We envision that a book or a briefing paper will come out of this in the future, in which we will continue to give you updates on some of the activities of these committees.

Thank you.

MR. MAZZA: Thank you, Rick. Are there any questions for Rick? Anyone? (No response.)

MR. MAZZA: If not, we will move on. Our next speaker is John Donaldson. John is the Chief of the Standards Applications and Assistance Programs of the Office of Standards Services of NIST, and John will talk to us about recognition of accreditations.

Laboratory Accreditation Working Group
International Task Group

Speaker- Richard D. James

Expansion of global trade is increasingly important to the economic growth and productivity in the United States. The Uruguay Round of the General Agreement on Tariffs and Trade has resulted in increase awareness of the importance of reducing technical barriers to international trade.

Developing cooperative relationships through mutual recognition agreements between national laboratory accreditation systems from other countries is an effective mechanism for overcoming many of the current problems caused by technical trade barriers.

Presented below are the international committees and organizations established for the purpose of harmonizing accreditation systems and building cooperative relationships.

Asia-Pacific Economic Cooperation (APEC)

Asia-Pacific Laboratory Accreditation Cooperation (APLAC)

Co-Operation on International Traceability in Analytical Chemistry (CITAC)

European Cooperation for Accreditation Laboratories (EAL)

European Organization for Testing and Certification (EOTC)

Industrial Advancement Administration (Korea)

International Accreditation Forum (IAF)

International Organization for Standardization/Committee of the General Assembly on Conformity Assessment (CASCO)

International Laboratory Accreditation (ILAC)

International Union of Pure and Applied Chemistry (IUPAC)

ISO Committee on Reference Materials (REMCO)

Committee on Standardization Principles (STACO)

Raad voor de Accreditation (RVA) Dutch Council for Accreditation

Standards Council of Canada (SCC)

SWEDAC

RECOGNITION

MR. DONALDSON: I long ago learned that you should always start with a joke, but I don't know any jokes about laboratory accreditation.

(Laughter.)

MR. DONALDSON: I noticed that preceding report-persons did not seem to identify all of their collaborators on the working groups. The people that I worked with in our Recognition Task Group are: Charlie Hyer, of TMO, Leonard Frier of Met Labs, and Rick James, a previous speaker, of ANSI. The three of them and I met on a number of occasions to discuss the problem that we were assigned as the recognition task with regard to laboratory accreditation.

Not surprisingly, the concept of recognition is fairly straightforward. With respect to an accreditation body, it's simply the determination and identification that the accreditation body is competent to perform its stated functions. That's a simple enough definition. The interpretation and application can go quite far. Some of us have had a little bit of experience in anticipating doing that. It was mentioned earlier that the Fastener Quality Act, assigns to NIST the responsibilities for doing just that. About 3 or 4 years ago we developed the basis for implementing the legislation that would permit us to recognize laboratory accreditation programs. But the regulations are still on hold, but I think we could resurrect them, if necessary. So, that's basically the recognition task.

Now, what's the problem that we're dealing with? When we got together to discuss what it was we thought we were concerned with, we stated the problem basically was how could we minimize the number of accreditations that a laboratory must submit to in order to have its test reports accepted by all authorities? Now, authorities could be equally interpreted to include the users of accreditation beyond the official authorities, but in this case the authorities, of course, would mean those who represent Government, but let's say the officials for competence as well. So, basically if we minimize, obviously, the optimum number would be one. I don't know if it's practical, but certainly do we want to minimize it such that when a test report is issued by the laboratory based on its accredited status that all those users of that test report would immediately find that to be credible? And that's the problem that we thought we were dealing with.

As John Locke indicated, there are quite a number of different bodies that are involved in accreditation. As Belinda Collins mentioned, in the Government we have many different names for them. But, all in all, there are quite a few different entities that perform some form of evaluation of the activities of laboratories so that one can have a wide variety in their test reports. In order, therefore, to recognize what is going on among accreditation bodies, if one wants to provide recognition that would, in fact, solve the problem we just defined, there are several possibilities.

One is, we could establish a situation in which we create monopolies. There is an area that is identified, and that area is identified as being that assigned to a particular accreditation body. And once that accreditation body has been decided, no other accreditation body would be accepted as functioning in that area. That could be done by law, or it could be done by a matter of practice. That's certainly one way but not exactly the one you would expect to happen in the

United States. I think that we're all well aware of the fact that this country has thrived on a pluralistic approach to what we do and, generally speaking, for domestic purposes that's served us quite well. Sometimes when the competition is with international firms, that causes us a problem. And I think that's partly what we're looking at now, how to organize ourselves to compete more efficiently, more effectively, abroad. That's, I think, in part--I might interject--one of the reasons for some of the results of the surveys we were hearing earlier. I think that domestically we still are awakening. I don't think that the hinterlands of this country quite understand the competition on the world market yet. I think, as we see more of the effect of international competition on our domestic producers, I think you will see more of an awakening. And the reason why there aren't problems with the accreditation, the reason why there aren't that many accreditors and so forth, is because the international situation is not what they're concerned with--it's domestic--and our system has worked reasonably well domestically.

So, we have this pluralism approach. We have many accreditors. Now, if we want to end up where we can reduce that and minimize the number of accreditors that have to be applied to any one situation, one way it could happen is the accreditors could get together. The accreditors could just decide to get together and form a council of accreditors and in some way agree to cooperate. You can call them Mutual Recognition Agreements among themselves, but in the end, the council could be created by the accreditors that become part of the council. They do an evaluation of one another and find that, in fact, that they are competent, so that once you're in the council, you're competent. It is agreed that any member of the body, an accreditation body belonging to the council, its accredited laboratories would then be listed by the council and, once listed and entered into the council's list, that would be sufficient. Therefore once the laboratories gain inclusion on the list they don't need any more accreditors. Now, that's one way of dealing with pluralism. It allows all the accreditors to continue to work, but they do it cooperatively and that reduces the burden on the laboratories.

I don't know what the incentive is to make accreditors do that. The system is working as far as the accreditors are concerned. In the United States we thrive on incentive, and in our discussion, as we talked about it recently, what is the incentive to make the accreditors come together?

The last approach is that you could designate a centralized authority that will, in fact, recognize among this plurality of accreditors those who, in fact, are competent. And once you have been recognized as a competent accreditor, that's all you should need, in theory. That is another approach to retain the pluralism, the many different approaches, the many accreditors, but recognize those that stand out as being truly competent.

One revelation of this activity over the last year was from laboratories that said that for $50 they'd be given accreditation from XYZ Accreditor. Of course, they never saw that accreditor. Well, clearly, such an accreditation is rather questionable and certainly an accreditation issued under those terms would never be seen as a reliable accreditation based on prevailing ISO/IEC Guide 58, to which we've heard several references.

Anyway, these are the logical approaches. I'm sure you could probably interpolate and come up with some others. But they are variations on a theme. Basically they are, a monopoly, you could have the groups getting together and cooperating, or you can have some central authority identify the ones that do it and then go from there.

In our Task Group we decided that, well, fine, if you want to create monopolies, the only way to do that reasonably, at least at the national level, is to have an Act of Congress, and the Congress has to stipulate it. We don't go around exactly identifying monopolies in an off-the-cuff fashion. So, that's got to be left to the Congress.

In terms of creating a council, I've already indicated a council could be created, but the accreditors have to come together and we, the overall community, have to find an incentive for that to happen. If you're running an accreditation body and thinking you're doing a good job, you have to see the reason for coming there.

The other one is to designate some body within the Federal establishment, or elsewhere, as a body that would recognize among the many accreditors those that comply. It's been suggested already that perhaps NIST is the body that could do that. Now, obviously, from what I've heard this morning, that's not a unique idea.

I will not review it in detail, but Kim Phillipi has already mentioned, and subsequently others did too, the National Research Council Report that was mandated by Congress to look at Standards, Conformity Assessment, and Trade Effects. This was a group study. The group was composed of a number of very knowledgeable people from both the standards community and from the trade policy community. They started by a year of deliberating on the matters and they produced 10 recommendations in the report that's already been recommended to you.

Of the 10 recommendations, two are pertinent to what we're talking about this morning. The first recommendation is extremely pertinent. It was alluded to earlier. And that is, basically that the Congress should give NIST the mandate for coming up with a policy, and implementing it, that would do away with conformity assessment being practiced within the Federal Government and, to go a step further, that we should rely on private sector, or non-governmental, laboratory accreditation and other forms of accreditation. Now, to do that is to create a new acronym, which is the National Conformity Assessment System Recognition Program (NCASRP). Basically, in this particular situation, there should be created at NIST a Recognition Program for private sector accreditation bodies.

So, that's what the NRC says. So, when we talk about the third alternative, to identify somewhere within the Federal Government, a body that would take on that responsibility, NRC says NIST should do it and, further, that the Congress ought to give a mandate to do certain aspects, give NIST a certain job to do.

The important part of the second recommendation really is that NIST is also supposed to develop a network which is going to bring together the authorities that are concerned with use of accreditation and within that network they will create Mutual Recognition Agreements to accept the results of the accreditation programs that they are requiring as official bodies. Now, the notion that NIST should establish this network is fine. That's the recommendation. It's not really clear how that is to happen.

The conclusion of our Task Group was that:

Number one, certainly NIST could establish the National Conformity Assessment System Recognition program but, if it's to work, the laboratories have to want it. Above everything else,

this is a necessary condition, and a large group of the laboratories have to want it. They have to push for it. That's the only way it's going to get done. NIST isn't going to simply walk out and say, "Here we are." There has to be a strong demand for it. NIST has the capability and can do it.

The second part, in terms of establishing the network, as I said earlier, to bring the authorities together they have to want to do that. We could have a network, and we could advertise it in *The Federal Register* but, if the authorities who are affected don't want to come to the party, we can't force them to come to that party. So, again, NIST is very good at doing such things and providing what I would call the "catalytic" influence to make these things happen, but there have to be all the proper reagents involved in that reaction and they have to want to be there.

I think those are the problems that we have and they are going to be there. If the constituencies, if the various industrial sectors that are affected, feel this is the way to go, then they've got to push for it.

So, the conclusion of our subgroup was that, yes, NIST could do these things and can be responsive to the NRC Report and, in fact, then deal with what was the charge of our task group, but there would have to be some very strong constituent requirements for those things to happen. And that's the report of our Working Group.

MR. MAZZA: Thank you, John. Are there any questions for John? Clarification of his presentation? Yes, John Locke?

MR. LOCKE: John, did your subgroup explore any alternatives to NIST, I mean like ANSI or private sector alternatives or other kinds of alternatives to accomplish this same kind of thing, or any consortium between NIST and ANSI? You know, did you look at any other alternatives?

MR. DONALDSON: In terms of the third alternative -- Well, we looked at several alternatives and we got to the third alternative in terms of the ones we were looking at, which is the centralized authority. As far as the notion of looking at ANSI as another alternative, no. I think we thought that what we were looking at really is a Government body, so that what we're dealing with is something that would be acceptable to the other governments around the world as well. If you're going to do it for domestic purposes you would like to just do it once and do it one time only so you don't want to have one program that's going to do it for international recognition and one for domestic.

The corollary to that, as we discussed in our subgroup, was that while the NVCASE Program has been initiated to deal with requirements of foreign government regulations, in a sense what we're talking about here is dealing with state and local governments as the corollary to that, and what we're really talking about, in my view, is a domestic program that would be an analog to NVCASE to satisfy state and local governments.

Now, that recognition would be to any private sector accreditation program. If ANSI wanted to have an accreditation program for laboratories, that's a separate issue.

MR. LOCKE: But most of the foreign governments are privatizing their bodies that do exactly what we're talking about, so we have UKAS now, a privatization, we've got the Dutch privatization.

MR. DONALDSON: That's the accreditation. Yes.

MR. LOCKE: That's the recognition of the--

MR. DONALDSON: No. That's the accreditation. Those are the accreditation bodies in the private sector, and I think that NIST is simply saying, "Here, fine, we'll have private sector bodies," but what they're doing in those countries, as you know at least as well as I do, if not better, in those countries essentially they're creating a monopoly and, in having a monopoly, then they're saying, "This is it. We'll go with that." If we want to retain a pluralistic approach, as we have in this country, then we need to have some way of recognizing within that pluralistic approach those that are competent. So we're saying, "Okay, NIST can do that, and you can have as many private sector accreditation programs as you want, as long as they are competently run."

MR. MAZZA: I think this is going to be part of our discussion this afternoon, a very interesting discussion this afternoon, I'm sure.

Another question here? Oh, I'm sorry. There is a gentleman up there.

MR. SHOCK: Harvey Shock. John, recognizing that one of the best methods of obtaining efficiency is elimination, did your group consider the elimination of regulation and the use of the existing legal system to enforce the obligation of the laboratories, for example in product certification you have Standard V34.1 using a third party and C30.2 using the self, and did you consider this?

MR. DONALDSON: We did not consider that as part of our assignment. We'd be happy to do it, but we did not. We saw our problem as saying, "Okay, you have a number of laboratory accreditation bodies doing a variety of accreditation programs and, if one wanted to provide recognition, and therefore added credibility, to their function, what are the approaches that one might take?" And that was what we saw as our task. So the answer, Harvey, is no.

MR. MAZZA: A last question before we move on?

MR. BREDEN: Les Breden. John, did you ever consider using Guide 25 as the basis of how the system would start? In other words, the idea of having 1,000 flowers that bloom, pre-empting all the states and creating a monopoly seemed a little unpractical to me. But by having NIST encourage the use of ISO Guide 25 as the basis of accrediting laboratories, that is anybody can be in the business who wants to be in the business, but Guide 25 would be the underlying constitutional document that we would encourage you to use so you can build some credibility and quality data. Is that a function you looked at?

MR. DONALDSON: We did not get into that level of detail, Les, in our Sub-Task Group. But as I sat here listening this morning, I was thinking there is a certain irony. We have a law that says that wherever appropriate we should be adopting international standards and

guides and, in fact, we have adopted International Guide 25 as a national standard as well through E-36 and yet, even having done that, in terms of having a law, we still have no way of causing people to use it. And so I think your question is very good. There aren't any penalties for not following the Trade Agreements Act of 1979, as far as not adopting international standards is concerned, where you would think it was in our best interest.

So, the answer is, we did not look at it, and there is no leverage for making that happen today.

MR. MAZZA: Okay. Thank you.

A couple of housekeeping matters. There is coffee located at the end of the hallway past the cafeteria. I ask all the speakers to please deliver two copies of their slides, one for the recorder and one for us to make copies from. And then I also need to remind you that coffee and food are not to be brought back into the auditorium please.

We will reconvene at 11:30 sharp, to hear our keynote theme speakers.

(Whereupon, at 11:16 a.m., there was a brief recess and resumed meeting at 11:40.)

KEYNOTE THEMES

MR. MAZZA: I'd like to introduce the first of our late morning speakers dealing with some of our keynote themes; the first is Charlie Hyer. He is the Executive Vice President and Founder of the Marley Organization. He is the Editor and Publisher of *The TMO Update Monthly Newsletter* on national and international developments and issues concerning Government and voluntary standardization, testing, laboratory accreditation, product/process service certification, and quality systems registration. Thank you, Charlie.

MR. HYER: The name of this paper is "The Status of Laboratory Accreditation in the United States." That's for identification purposes. Nobody may recognize it.

By way of introduction--small "i"--to an Introduction--capital "I"--I'd like to quote Lawrence Berra who quoted the now profound phrase, "It's like deja vu all over again." As an Introduction--capital "I"--we have titled this paper "The Status of Laboratory Accreditation in the United States, Part II," in order to bring to attention, as much as possible, NBS Special Publication 632, "Laboratory Accreditation: Future Directions in the United States," a copy of which is turning yellow in my office, but it's here.

This publication was issued in March of 1982, with a report on the proceedings of the NBS Workshop on Laboratory Accreditation held at NIST November 16-17, 1981. At this event we presented our right now forgettable Part I paper with the following abstract:

"This presentation briefly describes the status of laboratory accreditation at the time of the publishing of my work, 'The Principle Aspects of Laboratory Accreditation Systems' in July of 1980. NVLAP, A2LA, IEEE and IECQ systems are described to present updated information. The current and near future environment that does and will affect laboratory accreditation is discussed. The size of the problems addressed and a prediction of the possible outcomes and reasoning is offered.

"Under the subheading 'Near Future Environment' we included in this paper the following paragraphs:

"The foregoing discussion attempts to bring to current status some of the important factors in any look at laboratory accreditation. Now it would be well to look at the near future environment for such laboratory accreditation activities. The name of this era, as we see it, is 'Economics.' The public sector's lack of funds in the form of reducing Government budgets will see the move to reliance, where possible, from the private sector. The multiple drains on the private sector will call for a merging and consolidation of programs. Laboratory accreditation is one such program tied, as it is, to voluntary standardization and product certification."

As a comment, I really don't think everything got consolidated since 1981, and now we're back into another term of reducing budgets, et cetera.

"As we concluded our paper with, from the week commencing June 29th of this year through the week ending October 30th, we reported procurement notices placed by GATT Treaty Partner Governments totalling 483 separate requirements. Most of these notices mention forms of pre-bid qualification. These listings were for goods ranging from carpets through computers,

from apparel through medical supplies. A form of laboratory accreditation which would allow for U.S. laboratories to become the on-site approval agencies for foreign purchasing is an obviously idea for near future environment for accreditation.

"To sum up, we know of no laboratory accreditation program on which we have reported which our ongoing monitoring is not feeding back concerns for cost of operation and support. The number of Federal, state and local agencies looking for credible alternatives to current accreditation methods grows and will continue to grow and accelerate. The number of specific area expensive-to-be-accredited programs will peak with the IEEE Program and alternatives will be the near future environment for accreditation."

That was pretty prophetic right there, because the IEEE Program cost IEEE almost a million dollars and it was never accepted because when the program was developed as a laboratory accreditation for safety devices being used in the nuclear industry two things were missed: IEEE didn't get the support of the companies that were going to be members of the accreditation program; and, they forgot to get the approval of NRC to adopt the accreditation.

Two items that I think we have to keep in mind, and I think the previous speakers have mentioned. If for no other reason than to support the Quality Products List concept employed by the public procurement entities the world over, we see an economic need for the expanded use of laboratory accreditation. Now, that's the first part of it.

Now, we went on to say--and, by the way, I'm not trying to assume, or even to suggest, that you visit the past in order to develop the future; what I'm saying is visit the past in order to avoid repeating the failures of the past, that's all--this 1981 workshop was held at a time when the Government focal point for the interface with the voluntary standards community and related conformity assessment interests was the Office of Product Standard Policy. The proceedings editor for the report was John Locke who, at the time, at the Department of Commerce, held the position of Coordinator of the National Voluntary Accreditation Program. Since that time, John has left Government, I think we all know, and currently heads the private sector non-profit organization, the American Association of Laboratory Accreditation.

John has recently announced his plans to retire. Now, that means, really what I'm trying to say is, at the time this started, and all of these concepts started, we were all a lot younger, and most of the people who have experienced some of this stuff are getting very old and we may not be around so, before you make the same mistakes we did, listen.

In addition to editing the report, John presented a paper at the workshop with the title, "Purpose of Laboratory Accreditation." This is John Locke speaking as Head of NVLAP. The abstract for the paper reads:

"Task Force C of the International Laboratory Accreditation Conference has prepared a report which describes a number of needs for laboratory accreditation. Detailed examples illustrating each need are presented. Objectives of laboratory accreditation systems are described. The effects on all the segments of the laboratory accreditation community are summarized, as well as the effects on international trade."

John's highlighting and further detailing of the work of Task Force 6 ILAC, under the chairmanship of Australian's John Gilmore, who still heads NADA, which is Australia's accreditation activity, prove to be an important insight into the future. The standardization of the ILAC Task Forces became the drafts for many of the accreditation and certification guide documents produced by the International Standards Organization's CERTICO. In my day it was "CERTICO;" later it became "CASCO," the ISO's Committee on Conformity Assessment.

In that part of Locke's paper which dealt with the need for laboratory accreditation in the United States, he opened the subject with the following paragraph:

"The need for accrediting laboratories in the United States is clearly demonstrated by the existence of a large group of accreditation systems. Charles Hyer, in his report entitled 'Principal Aspects of U.S. Laboratory Accreditation Programs,' published in January of 1979, describes some 56 systems then in operation. He then identified some 50 private organizations which operate laboratory accreditation systems and concluded by stating:

"'The detailing of private sector programs was not pursued because it was reliably reported from several sources that, considering the contractual requirements of the National Aeronautics and Space Administration, the Nuclear Regulatory Commission, and the Department of Defense, well over 8000 programs existed.'"

Here, Locke, in discussing the international aspects of laboratory accreditation, picked up through the reference toward domestic detail a factor that has led the world, and especially the international trading world, into what I feel has been an unfortunate diversion. The 8000 private company programs referred to programs, for example, operated to meet contractual responsibilities created by military quality standards such as MILQ 98, 58, 665, et cetera, requirements that had each major or prime contractor accrediting subcontractors, suppliers, et cetera. The system, when privatized by the British Military through the U. K.'s private organization British Standards Institution, evolved into the ISO Quality Management System series, a diversion which has too often resulted in the confusion between the registration of quality management conforming to ISO 9000 series and the certification of products conforming to Products Standards through tests conducted by laboratories accredited as conforming to Guide 25.

Having provided a few details that were reported in the NBS Special Publication 632, it seems logical at this LAWG conference to discuss the motivation behind the 1981 workshop. Some 10 years prior to the workshop, another accreditation meeting was held here at NBS--now NIST--initiated by member laboratories--I have to apologize; I was at that one too, and I was also at the 1961 one where we started all this--initiated by members of the laboratories of the American Council of Independent Laboratories with others. It was called at a request that the Government develop a program of voluntary testing laboratory accreditation. Testing laboratory assessments for acceptance of data, or approvals, were costly redundancies resulting in little, if any, value of the resulting accreditation beyond the immediate purpose of the review.

As a result, NVLAP was formed but, instead of a fields of testing NVLAP, which was based on general activities, NVLAP was formed on the basis of specific test standards. For the small, multidisciplined commercial testing laboratory, the NVLAP system seemed to offer only limited value through a system that would develop very slowly and at a considerable cost of

accreditation. Accordingly, the private sector organization, the American Association for Laboratory Accreditation was formed to provide a broader base of accreditation. Ten years later, in 1981, ACIL suggested that NVLAP significantly change its procedures from the accreditation of laboratories to the accreditation of systems for accrediting laboratories such as the A2LA. That's an unusual thing. It might even be an idea we have today.

Notices of these requests were published in *The Federal Register* and representatives from ACIL, A2LA, and other interested parties were invited to assist in preparing the agenda for the workshop at which the key issues could be explored. Written comments were requested both before and after the workshop.

From the forward of the workshop we quote:

> "The workshop program, as stated in the brochure inviting all interested parties to attend, was developed around the following key issues:
>
> "Whether the Department of Commerce (DOC) should abandon its present role and substitute in its place a program to accredit organizations which, in turn, would accredit private sector testing laboratories;
>
> "What, if any, additional measures should be taken to assure that an effective U.S. presence remains in international laboratory accreditation activities, including bilateral arrangements?
>
> "What action, if any, can be taken by the private sector or the Government to reduce the proliferation of inspections and paperwork arising from duplicative accreditation activities within the United States?"

I submit a review of the list of those that made presentations at the meeting, as well as those whose comments were published in the report represents a substantial cross-section of all those in the United States interested in, or materially affected by, the subject.

Six consensus findings of the meeting were reported:

1. There is a need for laboratory accreditation.

2. NVLAP should not abandon its present role in accrediting laboratories.

3. Coordination of accreditation activities at the national level is desirable.

4. NVLAP involvement in international laboratory accreditation activities should continue.

5. There is no single best way to accredit laboratories.

6. Both national and international organizations demonstrate that accrediting laboratory accreditation systems is feasible.

This consensus pointed to the need for more coordination among all interested parties and NBS/NIST suggested it would support the formation of "a quasi-national laboratory accreditation council with certain tasks and goals to be accomplished." Revision of the NVLAP procedures and improving NVLAP operations were also provided with a series of goals.

Just as background for a study, U.S. laboratory accreditation might start with "the plan of self-qualification of laboratories." Now, this is the one we started with, not version 1960. We couldn't get anybody together at that time. Laboratories at that time still cried redundancies, expensive operations, et cetera, and there was no accreditation system.

The report was developed by A.T. McPherson, who was, at that time, the Associate Director of NBS and published in Bulletin 246 of the American Society of Testing Materials. If they haven't thrown everything away in their move from Philadelphia to wherever it is, they might have a copy of it left. There were extensive comments in that proceeding or in that paper.

By the way, the interesting part about those comments were that when we started out NIST, or at that time NBS, suggested that an outside third party assessor was very questionable and controversial and that the best way to get around everything would be to have the laboratories self-qualify themselves. A very interesting paper. You might find a few chuckles in that one.

NBS Special Publication 632 is the center of many of these remarks that have been made, but many valuable recommendations and findings have also been published that may well add to such a developmental study as I think should be done of the past in order to present every one of you with an idea of what has been tried and what way to go.

It is our feeling that publications such as the March, 1989 GAO Report "Laboratory Accreditations--Requirements Vary Throughout the Federal Government," I know everything has changed differently since 1989, but the GAO found that there was some variations in the way Federal agencies handled laboratory accreditation. They offer specific information that should be considered, as does the broad-scoped publication--and if I was convinced that I didn't have to say this, I wouldn't, but I have to--there is a publication called NISTIR-4576. It's called "Laboratory Accreditation in the United States." I recommend the reading. It really discusses the subject in-depth and how the subject inter-relates with other subjects.

It is my belief that analyzing and assessing these reports, as they provide a basis for, or may be reconciled with, the recommendations of the National Research Council contained in their report "Standards, Conformity Assessment and Trade in the 21st Century," will supplement the findings and open the forum on laboratory accreditation.

Now, I recently submitted a proposal to Walter Leight--he is the Deputy Director of the Office of Standards Policy--to allow me the opportunity of putting together a combination of development report information issues coming from these various publications with the hope that maybe I would come up with some kind of a paper that would assist in what might result in one-stop shopping, as is very commonly used, that expression, just one place that a person using laboratories, a laboratory, or those that have an application might come to get started.

In the words often used by organizations in the conformity assessment field, I would hope that to offer a suggestion for a coordination and cooperation approach would lead to this one-stop shopping.

We recently received word that our proposal has been funded. Please, believe me, not a lot of funding, but funded.

I look forward to your collective findings as LAWG and solicit your individual comments. And, in ending, let me explain something to you. I started in 1960 as an employee of a commercial laboratory called York Research Corporation at that time. By 1970 I was working for Electrical Testing Laboratories, now it's ETL. By the 1980s I was on my own. In 1977 I founded the Marley Organization founded with two London supervisors called Ebenezer Scrooge and Jacob Marley.

Now, since that time I've been publishing a paper. I'm one of the few people who have been constantly involved, especially over the last 25 years, in laboratory accreditation that doesn't run a laboratory and I haven't had any particular subjective operation there. I'm just saying that I'd like to put this together, but I'd like you to realize that there is an awful lot of background in our domestic issues. If you noticed, this paper primarily talks about domestic issues. It is the international issues that have increased their drive since that time. It's my feeling that you're in the field of starting the next conference 10 years from now, or you're in the field to avoid another conference 10 years from now. I think it's all your choice and I see enough young heads that you can make it another 10 years, but I can't make the next 10-year meeting so please give it a shot.

Thank you very much.

(Applause.)

MR. MAZZA: Thank you, Charlie. I think that was an extraordinary demonstration of the value of gray-hair institutional memory and the need for these recorders.

(Laughter.)

MR. MAZZA: The bad news is our next speaker is not yet with us, Charles Ludolph. The good news is that might put us back on schedule. It really is unfortunate because Charles works for the International Trade Administration of the Department of Commerce, along with the USTR. They lead the negotiations for Mutual Recognition Agreements with the European Union. And, as Charlie just said, really what we have added recently is the international perspective on what is really a very old issue.

So I would like to move on and get a perspective from one of our colleagues from the other side of the Atlantic. We have with us Bill Henderson. He is the International Director of the United Kingdom Accreditation Service and he is the Deputy Chairman of the European Cooperation for Accreditation of Laboratories, EAL.

THE INTERNATIONAL SCENE

MR. HENDERSON: I am delighted to be able to participate in this event because I fully share the vision of the universal acceptability of the results of any valid test or calibration performed by a competent laboratory accredited by any recognized accreditor working to international standards and wish to do what I can to see it realized.

The signing of the World Trade Agreement in Marrakesh and with it the agreement on Technical Barriers to Trade requires us to accept the results of conformity assessment procedures in other member states, to enter into negotiations for mutual recognition, and to work towards harmonizing the standards and guidance we use. The signing of the WTA has put a whole new impetus behind mutual recognition and wherever I look I see wagons really beginning to roll: in Europe, in the countries around the Pacific rim, South East Asia, Middle East and North Africa and, as evidence here today, in America.

The goal is achievable and I see many of the pieces already falling into place but it is no easy walkover. The "tested once accepted everywhere" concept can have no hope of realization unless the ultimate user of the test results has absolute confidence in the competence of the tester. This is where we as accreditors come in. We must be seen to be working to the same standards and procedures with transparently proven equivalent rigour so that the reports of the laboratories we accredit can be accepted as equivalent.

Where does that leave us this morning; each of us in different ways round the world are putting in place the pieces that will enable us to make the world machine work and we need to share our ideas. I am here to tell you something about how things are evolving in Europe and also about some very recent and quite dramatic changes in the operation in our system in the UK which may be useful input as you plan the development of your national approach.

Before I go any further I would like to remind you of the international definition of accreditation so that my remarks are seen in the correct context.

Accreditation

Formal recognition by an authoritative body that a body or person is competent. On the other hand certification or what you call registration: written assurance by a third party that a product processor service conforms to specified requirements.

The European Scene

Prior to 1985 the European market was 18 different countries each with its own idiosyncrasies. At this time United Kingdom, Denmark, France and the Netherlands had accreditation systems. The rest did not. Gaining access to the market, even for EC members, was difficult because:

- every country had its own laws for example on product safety;
- in many cases these laws differed widely;

- many authorities would not accept results of tests on products conducted elsewhere.

Products had to be adapted to meet the laws of each market and had to be re-tested all of which took time, cost money and restricted the free movement of goods. The EC solution was the New Approach to technical harmonization and standardization in May 1985 which promoted:

- a single community wide regulatory regime; (based on common "essential requirements");
- a limited role for community legislation;
- an enlarged role for European (EN) Standards;
- a major role for test laboratories and certification bodies.

Flesh was put on the bones of the new approach in December 1989 with the Council of Ministers resolution on the Global Approach to testing and certification. This resolution outlined the machinery by which the Commission envisaged the new approach being implemented. In particular it recommended that the following should be promoted nationally and at Community level:

- the use of the EN45000 Series of standards;
- the development of national accreditation schemes;
- mutual recognition agreements;
- the use of intercomparison techniques;
- harmonized standards and "new approach" directives;
- the setting up of the European Organization for Testing and Certification (EOTC);
- the CE mark.

This was followed in January 1993 by a resolution on Making the Single Market work, which encouraged the development of mutual recognition agreements between accreditation bodies, testing laboratories and certification bodies within the framework of the EOTC.

EOTC

The EOTC's objective is to constitute a focal point for the rationalization of conformity assessment related activities in Europe and thereby to contribute to free-circulation of product and services by providing the conditions under which all interest in the market can have confidence that products; services and processes, once tested or certified will not need repeat testing or certification for the results to be accepted by different parties or in different countries.

Members are the national interests of 16 European countries together with the representatives of 14 European cooperative organizations in the industrial, sectorial, quality certification, testing and accreditation fields.

EOTC, operating through sectorial committees, actively encourages the setting up of agreement groups composed of sectorial interests operating in the certification and testing field and the formation of mutual recognition agreements between the members of these groups. The technical criteria adopted for the eligibility of these groups invokes the EN45000 Series of standards, their international equivalents and the ISO EN9000 Series.

Recognition by EOTC is primarily to achieve acceptance of testing and certification in these areas of economic activity not governed by regulations. Nevertheless, as the focal point for conformity assessment in Europe, EOTC is expected to give technical support to legislation and to assist the regulatory authorities.

MRA's with Third Countries

The European Union has always recognized that in removing internal barriers it had also to ensure that the GATT principles of facilitating trade with countries outside the Union had to be preserved. Negotiations on mutual recognition are already underway between the United States, Canada, Australia and New Zealand and in these negotiations the Commission recognizes that it must address:

- identification of conformity assessment procedures;
- identification of systems of notification and accreditation of conformity assessment bodies and evaluation of their competence.

International Evaluation

The completion of the European Single Market gave European countries a strong remit to put accreditation systems in place and to link these through mutual recognition agreements. This had changed the attitude of accreditation bodies to MRAs from being no more than an interesting international dimension to an otherwise predominantly national activity, to their being a major requirement from accreditation. To achieve one-stop testing there needs to be confidence in the competence of the testers and in the validity of their methods. This is what IEC/ISO Guide 25 and EN45001 were designed for. The Standards ISO Guide 58 and EN45003 also provided tools for mutual evaluation. Given the need and the current availability of international standards, mutual recognition between nationally recognized laboratory accreditation bodies is probably the most practical and most transparent means of achieving an auditable and consistent level of competence in testing worldwide.

The promotion of the EN45000 series and accreditation in the Global Approach emphasized to the European accreditation bodies the need to develop a more formal, open and accountable medium for mutual evaluation than had been employed hitherto. There was an additional need to be able to demonstrate "due diligence" in reaching agreement. Some procedures were developed in the cooperations (WELAC and WECC) which preceded EAL and are now used both within the Union when members states are being evaluated and also when

countries outside the Union wish to develop an agreement with the EAL group. These procedures have been published and are now embraced in the ILAC agreed procedures.

The procedures cover:

- how applications for agreement should be made;
- pre-conditions for agreement;
- the selection of evaluation teams;
- the evaluation procedure;
- decision on recognition based on evaluation reports;
- means by which mutual recognition should be maintained.

In the United Kingdom there has been a debate on the value of mutual recognition agreements; particularly on the meaning of the word "recognition." "Acceptance" rather than merely "recognition" is what the user wants. For a mutual agreement to have value it was proposed by potential users that the parties to the agreement (the accreditation bodies and those accredited) should be able either to:

- claim and use the accreditation (and its mark) of each of the signatories; or
- use a European mark of accreditation common to all bodies accredited by the signatories.

It was left that anything less would not eliminate the need for multiple accreditation and would therefore diminish the value of an agreement in the market. The former concept presented difficulties of delegation from these bodies operating as part of governments and whose mark included a national emblem. However the second option had no such problem and the European accreditation cooperations have the introduction of a European accreditation symbol as a priority action.

EAL

All of this work in Europe is being conducted in the European cooperation for the Accreditation of Laboratories (EAL). EAL was formed in June 1994 on the merge of the Western European Calibration Cooperation (WECC) and the Western European Laboratory Accreditation Corporation (WELAC). It is a cooperation between 18 European countries 16 of which are part of the European Union plus Norway and Switzerland. Its members are the nationally recognized accreditation bodies of each European country. Most of those are part of their national government but an appreciable minority operate in the private sector whilst still enjoying their position of national recognition. Between them EAL members are responsible for the accreditation of some 3000 testing and 1000 calibration laboratories.

You will notice an implicit assumption in all my remakes about the development of the "European" systems that accreditation is a national activity. Pre "Global Approach" those of us who had laboratory accreditation systems had developed them as National Systems to cater for the needs of both the regulatory and the voluntary field and for acceptance in the regulatory field they had to be such. The Global Approach itself, to our great relief, turned away from a federal European Accreditation system based in Brussels and encouraged us each to develop our own and create the European system through mutual recognition.

This "national" pattern is also the model developing in the Asia Pacific region and one can see in the middle distance the prospect of inter-regional MRA between EAL and APLAC.

I have noted John Locke's ideas on the European and the U.S. models in the latest edition of the A2LA news. As usual, I find myself both agreeing strongly with some elements but also disagreement just as strongly with others.

I should like to make clear that European accreditation bodies are not actively competing either inside Europe or anywhere else. The only body which has been operating in this way in the past is the Rad voor Certificatie (RVC), the Dutch accrediting body for registrars. On the laboratory side a quick check in France, the Netherlands, Spain, Sweden and the United Kingdom reveal the current total of 7 laboratories accredited by a European accreditation bodies in the United States. Each of these has been undertaken in response to strong requests by the laboratory. Outright refusal to comply is unsustainable in law.

The attitude of RVC may change following its recent restructure.

I am not aware that EAL or anyone else has denied MRA because an applicant was acting in a competitive manner.

I would think that there is every prospect of a U.S.-North American LAC being accepted as a regional cooperation like EAL and APLAC with whom we could have inter-regional agreements. But please do not force all the rest of us to fit John's U.S. model.

The UK Scene

May I now offer you a brief outline of recent events in the United Kingdom which may be helpful to you in grappling with accreditation as a private sector venture in a national context.

Laboratory began in the UK in 1966 with the foundation of the British Calibration Service (BCS) so that more routine calibration work could be devolved from the National Physical Laboratory at Teddington to a series of competent organizations in specialist fields more suited to offer a commercial service. In those days, before the upsurge of interest in quality assurance standards, the concentration of assessment was on the technical competence of laboratories.

During the 1970s pressure for accreditation of test laboratories grew. As mentioned above, laboratories were suffering from a multiplicity of second party assessment. Simultaneously the introduction of legislation and regulation in the fields of environment, health and safety led to a demand for testing by customers who did not have the experience to select a competent laboratory themselves. There was a need for an independent but competent third party

who could judge laboratories against a set of agreed criteria acceptable to them as test customers and on whose judgment they could rely. The setting up of the National Test Laboratory Accreditation Scheme by NPL, as an agent of government, ensued in 1980. At this point six other regulatory bodies who until then had each been assessing laboratories ceased doing this and used NATLAS accreditation instead. A great deal of multiple assessment was eliminated at this point.

The two limbs of laboratory accreditation, BCS and NATLAS were drawn together in 1985 to become the National Measurement Accreditation Service (NAMAS). The objectives then set for the service which still pertain were:

- to establish the widespread recognition of competence of laboratories;
- to improve the quality and standard of testing;
- to reduce or eliminate the need for multiple assessment;
- to develop mutual recognition agreements;
- to publicize the competence of accredited laboratories.

NAMAS operated to these objectives as a Division of the National Physical Laboratory which was an agency of the Department of Trade and Industry until the 31 July 1995.

Since its inception NAMAS accreditation has been used as much by government in support of the regulatory function as by the private sector in its normal activities.

During the mid 1980's the national awareness in the United Kingdom in the principles of quality assurance was gathering momentum and there was signs of a market developing in the supply of certification of quality systems in manufacturing enterprises and of the certification of products to BS 5750 (ISO9000). In 1985 the British government set up the National Accreditation Council for Certification Bodies to assess companies offering certification to BS 5750 and, through accreditation, to offer confidence to the customers of these certification bodies by assuring them of their competence.

On 1 August NAMAS was separated from the National Standards Laboratory, merged with the NACCS and launched as a company limited by guarantee in the Private Sector known as the United Kingdom Accreditation Service (UKAS).

UKAS is a "not for profit" company owned by 11 corporate members representing all interests in accreditation in the United Kingdon. It is run on a day-to-day basis by a Board of Directors: four non-executive and three executive and advised on all technical policy issues by a comprehensive advisory structure.

Despite the strong predisposition of the Major administration in the United Kingdom at present to privatizing elements of Government and to competition it has deliberately avoided encouraging accreditation to be a competitive activity. Through a memorandum of understanding with UKAS the Secretary of State for Trade and Industry has recognized UKAS as being the sole

nationally recognized accreditation body in the United Kingdom and it has granted it the sole license to use the Royal Crown in its logo which can appear on test reports, calibration certificates, etc. Government will monitor this MOU and license through annual audit. This route was pursued following strong representations in the United Kingdom from both the laboratories and the user community during a widespread consultation exercise conducted during 1994 that accreditation should be a "National" activity and close to Government.

Conclusion

In summary then:

In Europe we have had to develop a system of mutual recognition agreements at the behest of the EC and to do this we have had to develop criteria and procedures to give credibility to the admission of accreditation bodies to these MRA's. These have now been absorbed into the ILAC Guidelines. This experience could be a basis on which to develop a worldwide system.

We have favored the concept of "nationally recognized" accreditation systems because our customers and stakeholders want to have the authority of accreditation underlined. In the U.K. and with laboratory customers round the world, our Royal Crown symbol offers a high measure of confidence. May I suggest that the federal insignia of the United States is universally regarded with the most enormous respect and would bestow confidence and integrity on which ever report or certificate it might appear.

What we are looking to the United States for is a coherent system of competence of laboratories working to recognize international standards and shown to be such through accreditation - once again to recognized international standards. We are not probably too concerned about who runs it - Government or private sector - as long as it is effective and transparently working to the same standard. My example of the new U.K. system shows how the whole process can be delegated away from Government except for the ultimate recognition which brings confidence.

The view in the rest of the world is that accreditation as opposed to registration or certification should not be a competitive activity and we have organized ourselves accordingly. Perhaps it is for the United States internally to decide how it shall operate its own system but it would have to ensure maintenance of standards by some mutually agreed surveillance system.

Thank you.

Mr. Mazza: Thank you Bill. It's good news, bad news time again. The good news is Charles has joined us. Unfortunately he was delayed by some traffic. The bad news, its either going to be lunch or questions. I think we can prevail upon the speakers --Charles-- to finish up and then we'll break for lunch and take questions after lunch.

Charles Ludolph is the Director of the Office of European Union and Regional affairs of the International Trade Administration of the Department of commerce. He is a participant and the lead negotiator for Commerce in the U.S. - E.U. MRA discussions.

TRADE NEEDS

MR. LUDOLPH: Thanks very much, Sergio. I'm very pleased to be invited here to address you. I apologize for being late. At least I'm not absent. But I am mindful that I am the only thing that stands between you and lunch, and that comes as a heavy responsibility. But I do want to take the opportunity to share with you some of the perspectives I've gleaned from my association with another form of MRAs. I was very heartened, and also frustrated, by the previous speaker's presentation at the progress and the accelerated schedule for the development of MRAs, his kind, within Europe.

MRAs among private parties on accreditation, as well as mutual recognition of testing and other things, probably runs faster and more effectively among private sector voluntary standards systems than it does between governments. And I'm going to tell you a tale and I'm going to give you a little bit of a structure on why the tale is important regarding Mutual Recognition Agreements that deal with third party product approval and process approval systems that governments worry about.

Someday all of what the previous speaker presented, and what I will present, will come together. They will converge. It's all of our hopes that Government can be taken out of the accreditation and the mutual recognition business. But we have two different systems--that's clear--Europe and the United States. We are placed in an international context that makes it even more important as competitors to look at mutual recognition. And at this point regulators who I represent frequently, regulators like the Food and Drug Administration and the FCC, the Federal Communications Commission, don't trust accreditation. They have no experience with it. And so a lot of my presentation today is going to be talking about what we need to do to build confidence among governments on the use and reliance of such private sector systems as accreditation, recognition and other systems.

It's very hard to explain to a U.S. business person what accreditation is and why it's needed because, until a few years ago, a U.S. business person spent 95 percent of his or her time selling products within the continental United States. Only 5 percent of product in 1987 was exported, and so the demands of accreditation didn't exist in the United States. And it's very hard to tell a U.S. business person, even today, that Europeans, or foreigners want accreditation because today in the United States our system is held together by product liability. I know that's perhaps a very controversial statement, but I've thought long and hard about this. Why do people get along building safe products in the United States without somebody overseeing them? Why does manufacturer self-certification work in the United States? We don't have higher accident statistics, we don't have more deaths than anybody else, and where does accreditation come from? And, of course, the glue that holds us together is the manufacturers' fear of product liability and other tort.

So, there is no product liability in the rest of the world, and that means that someone does have to oversee the rest of the world's manufacturers. The United States therefore has to live in two systems. If it's going to export, and if it's going to be doing international business, it has to play the game like the rest of the world, because nobody has a product liability system out there like the United States, no manufacturer out there is competing on the basis of a product liability system like the United States. It's not the discipline for foreign manufacturers and for foreign marketplaces.

Government oversight is a discipline in foreign markets, and so the first thing that I always have to remind myself when talking to U.S. business people is that it's going to be a strange message to be talking about Government, or third-party, oversight to build a regulatory or a contractual or a procurement system, because they do it themselves here.

But no one in another market trusts what a manufacturer does in the United States anymore. In the old days, even 5 years ago, a U.S. manufacturer could comply with a domestic requirement--U.L., Factory Mutual, any of the electrical safety labs that have built themselves into the NRTL System, or the other requirements for electrical safety--and a company that meets an FAA certification, which is a U.S. airplane certification, a company that meets an FDA certification for medical devices or drugs, could go to virtually any third country market, present the certificate issued domestically for sale in the United States and almost any third country market would accept that certificate. They would say, "Fine. If it's good enough for the United States, it's good enough for us."

Today that's not true. I had the pleasure, the other day, of sharing a program with the Chief Regulatory Engineer for the Dell Computer Company. This guy has a big job. You think you people, as accreditors and test lab people, conformity assessment professionals, have a big job. This guy introduces 180 new products a year and, in 1991, his business required him to get five regulatory approvals. He had to get something for local electrical sales, and he had to get a certification from a local electrical lab, he had to get an FCC approval, he had to get a VDE approval. He also wanted a TOV approval, and he got a CSA approval. Five of them, for the world. And Dell sells worldwide on catalog and export.

In 1996 he projects that he will have to get 26 approvals around the world for his 180 products he introduces per year. In Europe alone, instead of getting two approvals and using Germany as the basis for the approvals, he also has to get the two German approvals, he also has to get the CE mark, and he also has to get a bunch of Scandinavian marks, and he expects that he will have to get a mark for Slovakia and he will also have to get a mark for the Ukraine.

Mexico now has a mark, Japan now doesn't require marks but it does require certification to European standards. Several ergonomic standards are now being required by Japan, and the basis for that are EN standards.

This guy is faced with an unimaginable bill for redundant certifications that could well be accelerated and reduced by a well built international accreditation system. The absence of an accreditation system--of course the absence of regulators to cooperate and harmonize--the absence of harmonized standards but, even more importantly, the absence of a regulator's recognition that a test certificate, or a process registration certificate, from a single entity accredited internationally as acceptable in world markets presents him with a high cost bill.

Not everybody in this room is selling in 85 markets and introduces 180 products per year. Not everybody is faced with that kind of challenge. But more people are now getting an international bill for regulatory acceptance than they ever have before. It's an unacceptable situation. You can no longer use a U.S. based or a European based certificate to go around international trade. Our international trade has increased, has doubled--the U.S. international trade has doubled--in the last 7 years from about 5 percent of GDP to 10 percent of GDP. That's a very deceiving number because you think, "Well, 10 percent, you know, 10 percent of my

costs? I don't have to do that business." But most of this business is concentrated in computers and medical devices, in airplanes and machinery, and if it's concentrated in all of these businesses it means it's not 10 percent, but 30 percent and 50 percent of their business is not international.

My experience with Mutual Recognition Agreements for the last two and a half years presents a frustration. U.S. and European regulators, the people behind the CE mark, behind regulation in the United States, are not ready to be confident in each other's systems. It's not their mandate. It's just not their responsibility to be worried about international trade or business concerns. They don't have the dedication to international trade that is fast overtaking the U.S. and European business community. So it becomes, for me, an interesting proposition. Certainly it becomes a huge contrast with the previous speaker. As I see the progress and the rush to develop Mutual Recognition Agreements in accreditation, I see in the private sector a wonderful example of how effective the private sector can be in responding to market demands.

Today, U.S. agencies have accreditation systems. They don't really call them "accreditation" systems, but they have lists of labs that they maintain, and they have criteria that they introduce. They are very informal lists. They're not anything like a real accreditation system where people actually go and spend a lot of time auditing and vouching for the competence of a laboratory or the competence of a registrar.

The FDA relies, for example, in their testing programs on something called OECD Good Laboratory Practices, as does the EPA, and they maintain somewhere a list and, if you call the EPA up and say, "I've got to test a chemical. Can you tell me a list of labs that are capable of doing that?" they'll tell you some labs that they think are capable. That's not a way to go about business. No European can get on that list. It's very hard to even find the person that's in charge of the list.

The FCC has a list of laboratories deemed capable deemed capable of testing to their requirements for certification for attachment to the network and for electromagnetic compatibility. I'm not sure that anybody-- Everybody, of course, knows who is on the list, and the list is public, and the list is published. I'm not sure that everybody is clear that all these laboratories in this list are equally capable of carrying out the responsibilities that the FCC expects.

There is no consistency in these lists. When there is no consistency and when there is a competitive erosion in confidence in the FCC marking system around the world, simply because there are other people in the same business who are offering a better product, a more consistent system, you have a competitive loss for U.S. business. U.S. business says, "Well, I got tested by a lab that's on a list in the FCC that they maintain," and the people in Pakistan say, "Who is that?" You lose business in this way. And you say, "Well, my product is good because I've got product liability insurance," and they say, "We don't understand that. We don't have product liability."

So I'm here to pitch the fact that the U.S. business community needs regular accreditation systems just to compete in non-regulated sectors, and U.S. regulators and the U.S. business community need to develop and accept accreditation systems because there is no credibility outside this country in the *ad hoc* lists that have been developed historically by regulators to fulfill their domestic obligations.

So it's very important to pay attention, I think, to all of the presentations being set up here today on how people are going about their international business and their regional business of doing what they call Mutual Recognition Agreements. My Mutual Recognition Agreements between governments are now bogged down. I will have Mutual Recognition Agreements by the end of this year, but they will be Mutual Recognition Agreements for confidence building. It will take 2 to 3 years, if the Europeans accept this concept--I think they will; I think it makes sense--that our systems are so different and our systems are so interdependent--the force to have an agreement is interdependence, the force to retard, constrain having an agreement is the profound differences between the two systems--that we need a period of confidence building.

Confidence building, for me, the way we're negotiating, is confidence building between regulators. What's missing? Confidence building between the private voluntary testing and certification community. And there are very few contacts between accreditation bodies to facilitate regulatory requirements between the United States and the European Union. There is no regular basis by which you would have FDA regulators, European Union regulators, the private sector bodies that the Europeans use to approve products, medical devices, drugs, and the private and public sector bodies in the United States that FDA uses to get together and decide what system is low-cost enough and sensible enough to be the basis for mutual recognition to suit regulators' needs.

So, we all know also that the U.S. Government is going out of the regulatory business, and is going out of that business for a lot of reasons, but most of all because budgets and resources are not available to hire a lot of inspectors to go out and do all the business internationally, if not even domestically, to run a regulated economy. The FDA is not expanding. Certainly other agencies-- The FCC's budget is constrained. They are not able to conduct the system of regulation that they foresee. They are then, as I'm sure most of you are aware, going into rulemaking to decide whether they should use private sector bodies in the United States. The FDA has test programs to have private bodies do evaluations of medical devices for 510K reports. They are looking at the possibility of using ISO 9000 type programs and, perhaps in the future, using private sector registrars to do those ISO 9000 inspections.

Throughout the U.S. Government we are looking and developing and going into a major transition program to privatize the conformity assessment aspects of regulation.

So then, the U.S. Government says, "Well, how can we be sure that all these bodies are doing what we know Government employees do? An FDA inspector is a Government employee. How can we be sure that they do that? And how can we be sure that a European actually knows how an FDA inspector and an FDA product should be approved?" And it's the job of accreditors, it's the job of private sector bodies who are capable of assessing the competency of bodies, internationally, nationally, and regionally, to take this challenge up.

So, we're going to have MRAs in regulated sectors. At the end of this year we'll have an MRA, and the MRA will say, "Let's start small and let's get to know each other and let's get the regulators in the same room, and let's trade ideas about how to approve products and, in 2 years, 2 to 3 years, let's have a mutual recognition of the entire system of product approval, and this would go for medical devices and it would go for telecommunications equipment and it would go for computers that are attached to the network and it would go for EMC aspects of

products and it would go for electrical aspects of products and it would go for drugs and for pesticides and for chemicals."

What's missing in this equation is that none of the regulators in the United States know of what an accreditation system is, what CASCO Guides are. They know what the OECD GLPs are, they know what their own Listing Programs are. These programs have to be supplanted with something regularly understood on an international basis.

So, when we finally draft and complete the MRAs my next job, Belinda's next job, I see it as Joe O'Neil's and Sergio's and John Locke's next job, is to put together a system of actors in the conformity assessment system that can begin to internationalize what the regulators need. And it will be a 2 or 3 year timetable. And I think if I can put to you no other challenge, these MRAs will die on the vine. We'll have MRAs, the regulators will sign MRAs, but if they don't work, if the resources and the technical capability doesn't rise up out of the voluntary private sector community on both sides of the Atlantic and respond to the demands that NIST will present once these agreements are implemented, the agreements will fail. There will be no effective mutual recognition. The FDA will slip back into its self-contained system. And so it's very important to pay attention to manufacturer's self-certification and supplier's declarations. That's a great way to go. And it's very important to pay attention to mutual recognition of private sector ISO 9000 systems. It's a very important way to go. But it's also very important to make sure that regulators understand that they can be confident in private sector accreditation programs as the means to bridge the huge trade demands that will be coming to the U.S. business community in the next 3 to 5 years.

Thank you very much.

(Applause.)

MR. MAZZA: Thank you very much, Charles, and thank you all.

What I'd like to do is break for lunch at this point. Lunch will be in the cafeteria, at the back; the same place where you found coffee and doughnuts at the morning break. Please use the yellow ticket you will find in the back of your name tag.

Since we're breaking a little late, I would suggest we get back here at 2:00 o'clock sharp please. We will start at 2:00 o'clock with the Q&A session.

Okay. Thank you very much.

STAKEHOLDERS PANEL AND FLOOR SESSION

MR. MAZZA: I would like to ask the speakers from this morning to please come back up to the podium. Let's see, Charlie, it is a continuous process. In many schemes of accreditation a laboratory is visited once a year. They go through a process. They can fail at that time and then we throw them out. We don't monitor them continuously, but we certainly do it at least on an annual basis, and they have the opportunity to be thrown out at that time if they're not up to snuff.

MR. MAZZA: John, if you'd care to answer that?

MR. LOCKE: Yes. I think our experience has been that most of the issue with respect to this is to keep the laboratory scope of accreditation in line with its capability. And this is where some difference comes in between, say, environmental and the general requirements, because in environmental we have an agreement that follows the EPA set of requirements which says if a laboratory fails the proficiency testing program at EPA, I think it's three times, it is automatically removed from our accreditation list for that analyte. And I would say that that goes on with probably 20 percent to 30 percent of the laboratories. They automatically-- Certain parameters are eliminated from their scope of accreditation because of their proficiency testing programs.

Also, when we go back and do a reassessment, and a big key to the reassessment is the checking to see that they are still competent at all the things that are on their scope of accreditation. And that's really a critical item, and so we see scopes of accreditation changing quite a bit.

When you say we throw a laboratory out, that would have to be a very gross kind of problem. Now remember that laboratory accreditation includes not only compliance to Guide 25, but also competence to do the specific tests and types of tests, and so you get into quite a bit of detail on the tests, and that's where you see most of the activity going on with respect to taking away accreditation, taking away accreditation for certain capabilities in the laboratory which it can't demonstrate that it has or continues to have.

Certainly, we have lost a couple of laboratories for gross problems, but generally it's more frequent that we change the scope of accreditation to accommodate what the laboratory actually can perform.

MR. MAZZA: I believe Bob Stephens would like to make some comments and then to UL.

DR. STEPHENS: The NELAC experience has been that most of the authorities which have environmental accreditation programs recognize, as you do, that de-accreditation is a very important part to the overall process, number one.

And number two is, is that our experience is that of the 50 or 100 different environmental lab accreditation programs around the country, everybody had different policies on how to do this and how their performance on PE samples related to de-accreditation, how other deficiencies

related, how they were handled, how many chances people got. So, there were a variety of different systems.

There was a reluctance in a lot of the authorities to buy into a common national standard which did not have a clearly defined process for de-accreditation that they agreed with, that functioned. So, this is a central issue in NELAC being dealt with jointly by the Performance Evaluation Standing Committee and the Accreditation Process Standing Committee, and they work together on this. But it was recognized as a central issue and they are trying to come up with a policy that's a consensus policy that ensures, to the degree possible in an accreditation program, that substandard laboratories are not accredited and they move out of the system, but they aren't treated unfairly, because in many areas of the country accreditation in the environmental arena is not just a nice thing to have for business; it is an absolute business license. And I know in my state you cannot do work in the state unless you are accredited, and when you lose your accreditation you go out of business. So it's something that's a very substantive sort of decision to lose your accreditation, and that has to be taken into consideration.

MR. MAZZA: Keith, did you want to-- Okay, go ahead.

MR. DONALDSON: I just wanted to qualify slightly in terms of Les Breden's question. De-accreditation is sort of a vague statement. You've got two choices. You can suspend accreditation or you can terminate accreditation. And suspension usually takes place when the condition that's found in the laboratory is believed to be remediable and can be fixed in a period of time, in which case you're not going to terminate their accreditation, you'll suspend it. But I think Les knows that.

In the case of termination, presumably you've found some condition that either they violated some part of the contract in some reprehensible way or something has changed in a way that's permanent and can't be remedied. So, I think you have to be more specific whether you mean suspended or terminated. And typically a failure in proficiency testing would result in suspension until whatever the condition was that led you to fail to perform correctly in that can be rectified.

MR. MAZZA: Keith?

MR. MOWBRY: I heard two comments this morning that it would be great if I could get some feedback from the panel on.

The first--and I agree with both of them--but, first, John Donaldson observed that there is no incentive for laboratory accreditors to cooperate in the United States.

The second observation, I would paraphrase Charles Ludolph, by saying there is no incentive and there is confidence by regulators in the United States to significantly rely on conformity assessment systems to a greater degree.

My question is, in your view, how close are these concepts to the root cause of our problems in laboratory accreditation in the United States and, if they are a big part of our problem, what do we do to strike at the root, as opposed to hacking away at the leaves of this problem?

MR. MAZZA: Any volunteers?

DR. STEPHENS: Well, first of all, I would say that I do not agree with you that regulators don't have confidence in third party accreditation systems. I don't think that's true at all. It's what role they play and what's their relationship with a responsible agency. And, if that relationship can be proper and the standards meet the requirements of the regulatory agency, there is no reason why that can't happen. And I know NELAC is constructed to allow it to happen. And in my estimation, once we get the standards, they will largely be operated by third party accreditors. I think that's the way it's going to go. And what we're attempting to do is to create a uniform contract, if you will, that will be what the accreditation system ought to look like. And people will go to people like John Locke and say, you know, like even in my own state, and say, "This is what I want you to run and we'll write you a contract to do this." Right now they don't have that. And there are a lot of people who have the authority to accredit in the environmental area that frankly don't know what accreditation is, and they have a hard time talking to John about it, because he knows a lot more about it than they do. And, hopefully, if you've got something that's a universally agreed to document that is a good quality system that everybody agrees to, then that's what John can run, or whomever the third party group is.

MR. MAZZA: John?

DR. LOCKE: The key to it, I think, is to get the users to recognize it. That's why I talked this morning a little bit and asked the question of our colleague from Hewlett-Packard about when are they going to recognize their suppliers' capability, because that's where the profound number of reassessments has gone on, at least from my experience in the automotive industry. I'm working with General Motors and, at one time, General Motors, all of its divisions, were doing assessment of laboratories and often they would be in the same laboratory with different divisions.

Now, one of the things that they did over the last 10 years was to consolidate that, so finally they got one division that would take responsibility for everything that was in that laboratory. But when the assessment went from there to Tier 2 suppliers, Tier 3 suppliers, Tier 4 suppliers, we end up with multiplication of assessments down at the steel mills, et cetera, et cetera. So, we need to have some recognition, I think by the manufacturers that--I hate to say--what's good for the goose is good for the gander, but if they can start to implement their system, seeking, if you will, supplier-manufacturer supplier declaration from their subcontractors and rely on their subcontractors to provide the data, then, in fact, we can start to put this system together. But, as long as we don't get that recognition, to me, the biggest part of laboratory accreditation is not going to be resolved. So, I don't think it's the accreditors as much as it is the users.

And we have a big problem now with-- Well, we've got General Electric has a system, is pushing a system, through SAE called PRI, which is doing one thing, and then we've got the aerospace industry doing something, and we've got API doing something, we've got CSMA--the chemical manufacturers--we've got chemical specialty manufacturers doing their own thing, so we've got a lot of this stuff going on without recognition for what's happening in the supply chain once they set their requirement up for their primary focus. So I think we'd have to somehow get the issue to the users, to the manufacturers, and I think that's the only way we can get some progress, I think.

MR. MAZZA: Belinda, you wanted to add to that?

DR. COLLINS: Yes. I think one of our problems in the laboratory accreditation arena is the same one that we have in the standards community generally, and that is that it tends to be very sector-specific. So you have somewhat coherent, or very coherent, programs in a given area, such as the environmental area, or the food area, or the drug area, and you find different responses by different users of accreditation in these areas. I think bringing us together to talk about the situation and to look across the boundaries of sectors is a very important thing to do to see what common procedures and ways of attacking the problem can we come up with. And I think doing that sort of thing will maybe force us further along into a system that can be a recognizable one.

MR. MAZZA: There was a gentleman there.

MR. UNGER: Pete Unger, A2LA. In the interest of perhaps getting some more information with regard to alternative models if I could ask Bill Henderson to elaborate a little bit more on the relationship of EAL, the European Cooperation for Accreditation of Laboratories, and it's Multilateral Agreement Group and its recognition by EOTC, the European Organization for Testing and Certification, and its relationship to the European Commission, the governmental body?

MR. HENDERSON: This is complex, I'm afraid. And EAL is a member body of EOTC at the moment and sees itself as a sort of technical agreement group, if you like. It's one of the tools that EOTC would wish to use to establish the criteria by which the Sectorial Agreement Groups would operate. But it is a consortium, if you like, of the testing accreditation standards throughout all of these, just as our sister body, EAC, on the certification side, will be another tool that EOTC will use in establishing the criteria for acceptance of agreement groups. The laboratories themselves, the Eurolab Group, is another member of the EOTC which brings the technical side, from the laboratories, into that. But the whole concept of EOTC is to develop agreement groups on the voluntary side in particular sectors so that products can move freely between countries. And the EAL, EAC, and Eurolab are seen as the technical tools that EOTC would use.

Now, when one moves to the European Commission you're into the regulatory sector. I would say that EAL and EAC and Eurolab are still tools which the Commission would want to use, and we're still working on that. And the Commission, having said that we should develop these tools in the first place, is now taking on board the use of these tools but it hasn't got a complete set yet. There are some countries in the European Union which do not yet have established accreditation bodies in them, so it cannot lay down rules yet saying that anything has to be-- It can't talk in terms of using accreditation yet, but it's getting very close to that. And even when it's looking at its Mutual Recognition Agreements abroad, it will be looking-- And certainly when we are looking now in the Mutual Recognition Agreement between the Commission and the United States, and with Canada, and with Australia and New Zealand on the mutual recognition of conformity assessment bodies it is all but saying, "Yes, that we'll be using accreditation as the yardstick there." It has certainly done so in the Australia-New Zealand side, and with the United States that idea is being floated. So, it is becoming a more and more credible tool.

The other area where accreditation is likely to play an important role is in relation to directives, EC directives, on EMC, toys, personal protective equipment, whatever, machinery. We have all--national governments-- have all had to appoint notified bodies, who are the organizations who will certify these products as conforming to the directives. At the moment there is no uniform criteria for judging the standards throughout Europe on these, and again accreditation, both on the certification side and on the testing side, is seen as the obvious way to go. And although it hasn't made the decision yet, it is very likely that accreditation for EAL and EAC will be the tool that will be used for achieving harmonization of the standard.

MR. CRASSIUS: I'm Dave Crassius of the MMR Group, and I've been authorized to present the essential characteristics that the ACIL believes should be in an accreditation system. I have a couple of friends who are going to pass these sheets out.

MR. MAZZA: Do you have overheads that perhaps you can use here?

MR. CRASSIUS: I don't.

Keep in mind, the ACIL, among its membership, represents about 2000 independent laboratories. We have five characteristics:

There must be reciprocity in current standards. Qualified accreditors operating in the same field must recognize each others' accreditation within the limits of the special needs of an industry or a Government program. Common use of generally accepted international accreditation standards will make this reciprocity possible.

If I can add an explanatory comment, we see no reason why right now some of the accrediting organizations can't begin to work together through mutual reciprocity.

Number two. Shared governance. If, in an accreditation program all stakeholders--the laboratories, the users, the Government and accreditors--among others should share in the decisions and the policy-making process.

There are some accreditation programs now in existence, being developed--this is an additional comment--which allow the laboratories little or no share in the governance. Who better to help decide what should happen in the laboratory industry than the laboratories themselves?

Three. Principally divided sectors. There is nothing inherently governmental about laboratory accreditation and there is ample expertise in the private sector to conduct accreditations of all types.

Four. I'm not supposed to read the full thing. Government oversight. We believe the spirit of the National Research Council's recommendation that NIST be given authority to "organize" the accreditation system should be followed. We support that recommendation.

Five. Adequate funding. It is important there be sufficient funds to enable accreditors to meet high standards for thoroughness and quality. One essential component is a cadre of well

qualified and well trained assessors. Ideally, the costs of accreditation should be shared among laboratories, accreditors and users.

And, if I may add now, there is a perception in the laboratory industry that while there are many stakeholders, the laboratories are paying the freight.

Thank you.

MR. MAZZA: Does anyone care to comment?

DR. COLLINS: Do you have copies of that statement over at this side of the thing?

MR. MAZZA: Do you have extra copies?
Any other questions? Yes?

MR. SHOCK: Harvey Shock. One stakeholder that is not present in this forum is the assessors. In the case of the quality systems registration and the question of the new environmental regulations coming out the TC-207, particular attention has been given to developing standards for those, the ISO 10,000, 11,000 and so forth. I would like to suggest that one of the topics the panel should address is this matter of commonality of requirements and criteria for assessors and also the views on the recognition of the variation in assessor competence being one of the main reasons for differences in the various accreditation bodies, and I'd like the panel to address that.

MR. MAZZA: Any volunteers from the panel? John?

MR. LOCKE: Getting consistent assessors is always an issue. It is always a problem. There is some belief, however, that somehow you can clone assessors in some way by training them but, in our judgement anyway, a vast--not a vast, but perhaps a large--part of the differences of perception of what an assessor does is based on personality. Now, to try to clone personalities of assessors is a pretty tough thing to do. We certainly believe that training is important. How much training is enough? In the environmental area we've been pushing our assessors to be trained for 5 days in an ISO 9000 type of a course which is focused on laboratories. We've had them in a 5-day EPA course in Cincinnati. We have them in a 2-day Lead Program, a Lead Course, for lead testing laboratories. Now we're getting something like 12-14 days worth of training, and we're still going to see variations because we see personality differences, and some assessors doing the same thing can be perceived as doing something quite different because of their personalities. So, I don't think that problem is ever going to go away. I think we're all concerned about the consistency of the findings. That's the key. Are the deficiencies the same? And I think this is what we look at when we look at other laboratory accreditation systems in the world.

When I travel to NAMAS or STARELAB and go through an assessment at a laboratory, my first question is, would our assessors come to the same conclusion? That's the key. Now, if that laboratory should complain about the assessor treating them one way, or another way, now we get into all kinds of other things that are very difficult to control and to try to develop.

There are some courses developing in personality kinds of issues. I know the Australians offer that course, but it's not been found to be that effective.

Anyway, that's where we are on that.

MR. MAZZA: Bob Stephens?

DR. STEPHENS: I'll respond to both the last two comments, the last one first. I think there is another stakeholder which is also not present for certain kinds of testing, particularly what John just referred to in environmental testing, and that is public interest groups. And, in fact, I think this relates to also the previous comment for that, that I guess I would take exception to the comment that--or partial exception to the comment--that laboratory accreditation is principally a private sector function and is not inherently a Government function. I would certainly agree with that in certain areas, but I would disagree with it in other areas. And I think that the approach that many of us in NELAC are taking is that the laboratory industry is really a product supplier and that the Government regulatory agencies are the purchasers and consumers of their products. In that relationship, where there is a supplier and a consumer, it is ultimately the consumer which sets the standards for that product in that when the activity that the consumer is carrying out--and in the case of NELAC it is environmental regulation, and management, and remediation, and all the other things--so long as the public bodies and the legislatures have given that responsibility to public agencies--and they may choose to give it to other people--but as long as they've given it to public agencies they are responsible for consuming all of the product and going to a supplier for a quality product and setting the standard for that quality product.

As in any supplier-customer relationship, the customer of the data needs to involve the supplier of the data to the maximum extent possible so that reasonable standards and reachable standards are placed on the product that we are purchasing. And often--and this may be the case within the laboratory industry--much of the knowledge on how good quality data and good quality product is generated resides within the laboratory industry and, therefore, they need to be party. But it is not the seller, it's not the supplier, of that product which ultimately determines the product which is going to be purchased by the consumer of that product. In any kind of transaction that doesn't happen. And so I think, in the areas where--at least in this country and in many countries--where, in the area of the environment, it is the public agencies which have been given the responsibility to make the ultimate decisions. It is inherently a Government function for them to set the standards for accreditation.

That doesn't necessarily mean they have to run it and, in many cases, they may not, but they've got to set the standards for it.

MR. MAZZA: This gentleman here?

MR. BOBER: I have some flimsies I'd like to show.

MR. MAZZA: By all means.

DR. COLLINS: I'd like to point out that Mr. Bober is representing the State of Maryland and is presenting yet another view of a regulator, a regulator who is both regulated and regulates, and I think this provides yet another view of a slice of this pie we're talking about.

MR. BOBER: Good afternoon.

I represent another culture. I work for the State of Maryland. And what we do in the State of Maryland is that we're regulated and we regulate other people, and we look at the certification and accreditation, any of these different terms, as a pain, but a necessary one. But we also have to understand our philosophy of life. We're a regulatory agency an enanthema to what we think of as privatization. Privatization is a--if my father was alive he would use it as profanity--but we have to realize that expertise in analytical chemistry or the measurement of an electric current, or an evaluation of a safety device for a miner, you don't have to be a Government employee to be able to do it; you just have to know your business. And what we attempt to do is try to do all of these things as well as we can.

And why are we interested in accreditation? We're interested because we need quality, reliable data to make decisions. If we can get data that's reliable it doesn't matter if it's done by a governmental laboratory or if it's done by a private laboratory. We have to be able to get data so that we can make reliable decisions so that we can protect the public.

How many of you, since you've been here in Gaithersburg, have drunk the water? Has any of you had any water to drink?

(Whereupon, there was a show of hands.)

MR. BOBER: Okay. I did too. Thank us. We make sure it's okay. A small matter, but this is important. Okay? Simplification. One of the problems that I've heard here all day, listening to a lot of things, is that we're pleading for simplification. We have many tasks to do and some of them I think the paperwork is more complicated than what's necessary. I'm talking about a user of some of these things.

One of the things that we'd like--and I like the phrase "one-stop shopping" so I put on this flimsy--is that it's a hell of a note to have all these people come in and review us and interview us, study us, and we do it over and over and over again. We get pretty good. We're almost as good as that person this morning who said they had a special anteroom for their visitors.

Then the next word which is very important as far as we're concerned is reciprocity. We review 175 environmental chemistry laboratories that analyze drinking water in our state. It's not really reasonable, because a good portion of these people, nearly 35 percent of them, have some sort of recognition in another state, maybe even in another country. Why do we have to do it over again? It would be very nice if we had reciprocity.

And also uniformity. Now, this is one of the things that is very difficult. You talk about appraisers when they come in and they have different qualities of how they look at things, their depth of interest in what they're doing. Even though they have the training, the 12 days or the 2 weeks, and they may have 20 years of experience at the bench someplace or measuring some sort of system, they have to be able to do things in a same sort of way.

Now, there are certain states, for example, that say, "What the EPA says is minimum, we accept." There are certain other states that say, "That's only the minimum. We have our

own standards which are much above that." So you don't have uniformity in evaluation. So, poor Maryland, which has a very, very high standard, has difficulty in competing, as far as cost is concerned, with a state who just says, "We'll take the minimum standards."

Inefficiency. Well, here again it's a problem and we all know how to spell that one and I apologize about that. But what I'm really looking for is to show you the complex operation we run and what we want you people to do here. In fact, one of the reasons I'm here is--because I want to help--is that we ourselves are accredited--and I hate to use that word all the time because I don't know if it's really the right one or not--for our procedures in drinking water. EPA comes in once every 3 years and looks us over. We do all sorts of things in the interim. But this takes a little bit of effort. We even usually clean off our benchtops and sweep the floor before they come in.

(Laughter.)

MR. BOBER: You know, someone thinks this is an important factor. If we don't pass our review it's quite embarrassing, and the specter of privatization will loom even a little bit higher.

But then what we do is we look onward and look at, through our privacy agreement with EPA, which is a nice way of saying certification or accreditation, we look at all laboratories that test drinking water. One of the easy things that I never could understand is that all we have to say is that we will not accept any data that we need for any of our projects or procedures unless it's been done by an accredited laboratory. I think it would be very nice if we could achieve that.

Okay. The Department of Interior, they're interested in the ground water run-off and all that sort of thing, and so they come in periodically and look at us too. So, we do ground water surveys and the tests that we do are very, very similar to what we do for EPA. Slight differences. In one they say 7.1 pH, and in the other one they say 7.15 pH. But they have little differences. And I can't understand, if we are certified by one, why are we not certified by the other? So, these are some of the things that we have to address. And we poor people who have to do both sides of the fence are interested in it.

All right. Fluoridated drinking water. The Center for Disease Control has a dental requirement, and we analyze water periodically for its fluoride content. Once every 3 years? No. No way. Once a month. It doesn't change. But anyway, we do fluoride. This is one of the things we have to do. Bulk asbestos fiber is another one. They have a nice deal. One item costs us $6,500 a year. And that's a huge sum of money. Al Tholen is going to enjoy his retirement because we paid for it.

(Laughter.)

(Applause.)

MR. BOBER: It's a great system that they have. They enjoy it. They have a peculiar idea that it should pay for itself; that whatever they do in NVLAP, but especially the asbestos group, it should pay for itself.

It's interesting. It took all my ingenuity to get that amount of money. The Attorney General of Maryland has been paying that fee because we have to go to court and he wasn't ready to go to court unless we had NVLAP endorsement, so I got the money from him.

Okay. PCB analysis. We're validated by another office of EPA, even though we do certain kinds of PCBs in drinking water. And this is a group that's out in Denver. And we do that.

Then we work with the Chesapeake Bay, which is a grand, grand system. It's a marvelous national resource and we do everything to preserve it and to work on it. They are on a completely different level. Their data requirements are usually one level better than what EPA has for drinking water, which is an interesting thing. This also takes a good deal of our time.

And then radon, and especially here, in the Gaithersburg/Mt. Airy area, is one of the high spots for radon in Maryland. So, many of you who are stuck in a hotel and they put you in the basement, be careful.

(Laughter.)

MR. BOBER: But we certify these things. And we used to be able to buy these radon detector kits and evaluation kits in the corner supermarket. We were sort of worried about that.

However, the next thing I have here is the Radiochemistry Division. We monitor milk for strontium^{90}, we look at water all the time. We have to be careful because there are some nuclear energy plants in this area and we monitor fluoride in water, et cetera. So, we also have to be monitored by all of these groups. And all of these things are interacting.

Then we come to NIOSH. We have our MOSH, which is the Maryland version of NIOSH and OSHA, and we do all of the types of tests to protect the Maryland worker at his place of employment. And here what's interesting is that the AIHA, a private third party person, does the certification of our laboratory. And they have a nice system. They send us samples periodically and we analyze them and we get our results back from them and sometimes we cry a little bit, but we're all right.

Then, to go on further now, is the problem that we have in this country with the poisoning of children, lead poisoning, lead. And this has been a great effort. And we try to look at children in Maryland very early on to see, especially in certain areas, if they have any signs of lead poisoning. And here again, even though in Maryland, in the middle 1930's to early 1940's, some of this work was pioneered between the Health Department in Baltimore City and Johns Hopkins University, we go through the system of getting certified and all this takes time, even though it's somewhat related to what we do for OSHA and it's sort of related to what we do for other people, with the EPA, but we work on that, which is interesting.

Then our Milk Program through the FDA. And it's interesting because what we do there is we look for certain antibiotics which are interesting, but we do the phosphatase test. This is an indication of whether the milk has been pasteurized or not. We have to be certified for that. So, we spend a lot of time being certified.

And the last one, which I think is extremely interesting, and this goes back to the oysters and mussels and other kinds of seafood that we get out of the Chesapeake Bay. The Chesapeake Bay is a fantastic protein factory and we joined this round robin that we do periodic samples and we work with them. They don't certify us, but they sort of list that you're in control, out of control. And here we're interested in protecting the public.

In the State of Maryland we have an additional dichotomy. The water is the province of the Department of Natural Resources. The contamination in the Chesapeake Bay is the province of the Department of the Environment. But once you take the oysters out, or the crabs out, and you get them on shore, it's the province of the Department of Health and Mental Hygiene. So we have three groups that work on the same project. We need to get along.

And then we have some additional things, and I just told you about our environmental province, but we have a public health province. Well, there are problems. These are the things we have to do and I think it's pertinent, from what I have here, what we have to work on. And there it's interesting. To help us do as good a job as any, they give us 50 percent of what it costs, which is better than what we get out of EPA, but that's something else.

Then we have another law, which is the Maryland Medical Laboratory Licensing Law. And this is something that we have because we wanted to be a little bit more stringent in certain areas. And we have that to consider.

All of these things that I'm mentioning means that we would like to have one-stop shopping, get it all organized, that panacea, all done nice and easily. Okay.

The American Blood and Tissue Bank Law, that's the only one in the country, as far as I know. Unfortunately, someone harvested the corneas and they transplanted them, and then 6 months later the transplanted people came down with AIDS. No one ever checked the vigorous young person who died in an automobile accident and they harvested these organs and we have this problem. Well, this led us to this particular law that's on our books, and any bank has to be able to follow certain kinds of rules and regulations.

The Forensic Chemistry Laboratory Oversight. This is especially directed against forensic laboratories and, most of them, are governmental laboratories--state, county, or municipality--and they have to be able to show us how they do things, what their quality control is, so we can make sure that when they get evidence it's handled right and analyzed properly. Pardon the expression, Mark, but maybe Los Angeles County could have used some of that.

Then Newborn Screening. This is a fantastic thing that's been going on for many years, and from a couple of drops of blood we are now doing 28 different heredity, or possible heredity, diseases of young children. We'd like to be able to do this within a very short time after birth. This is not just what we do in Maryland; this is done in many, many states, and it certainly is worth it. Even though sometimes we save a family and a child from a miserable life, we only find maybe one in 100000 or one in 200000, but this is something that we work on.

So, this is all done--the newborn screening--is all done in our own facility. However, there is no reason why this can't be done by private organizations. We have no lock on technical ability. Private laboratories can do just as well as our governmental laboratories.

We have a different kind of philosophy, and one of the things that we would like to be able to do is to continue on our way to serve the public and make sure that the health of the Maryland people is as good as it possibly can be. But, there are things that can improve it. We have a problem with money. No one has said anything much about that. But we get less and less money and we have these responsibilities, and it would be interesting to see how private laboratories will be able to pick up the slack when there is no money around.

I thought it would be appropriate to show you, as a user, what we do so that you can see the time we spend on preparing all these things that, if we could get it all together--a fantasy of course--in one nice package so that we would be able to do our really important job of protecting the health of the people of Maryland.

MR. MAZZA: Could I please see a show of hands of who would like to take a quick break, first, and then the option is we just keep running through the program, because we are running late. Who would like to take a quick break?

(No response.)

MR. MAZZA: Since no one raised their hand, I presume you'd rather try to run through the program and get it done this afternoon. Fine. Then let's move on. Let's take a couple more questions and then we'll move on to the Visions and Principles discussion.

I'm sorry. The lady there.

MS. LEHMAN: I'm Liza Lehman with the Food and Drug Administration, and I just had one question concerning ACIL's handout. Did they not have a working group? Were they not represented? Is this something in addition to the comments that were made this morning?

MR. MAZZA: Joe, can you answer that?

MR. O'NEIL: Yes. We're one of the sponsoring organizations, and one of our groups wanted to make known specifically the ACIL position in terms of essential characteristics which, as you see, pretty much reflect what we've been hearing from a lot of different sources this morning.

DR. COLLINS: And I'd like to add that if other people have similar sorts of positions that they want us to know about, please get them to us. Okay? It isn't just that we're going to only hear from ACIL. We want to hear from everybody.

MR. O'NEIL: May I make one comment on that though, because I thought Bob Stephens characterized-- I don't think there is a difference in what Bob is saying with regard to private sector, public, and what we're saying in that position. I think the big distinction is between authority, responsibility, and implementation. And I don't think it's the intent of that paper to say that authority responsibility is a private sector role in the particular context of Bob's responsibilities, but rather the actual implementation or delegation, the carrying out, of the responsibilities can be carried out in the private sector. That's the key distinction I think.

MS. LEHMAN: Right. My confusion was just that I thought that ACIL was represented in the Laboratory Working Group specifically.

DR. COLLINS: It was. It was.

MR. O'NEIL: It is represented in it, but that position statement is not the task force position statement; it's one association's.

MS. LEHMAN: Okay. The other question was I wonder if the panel could briefly address the issues of Federal laboratories being accredited under this program. Would it be, if we established some sort of accreditation program, are we going to be subjected to third party certification by the accrediting bodies?

MR. MAZZA: Belinda?

DR. COLLINS: One possible scheme would be that we, at the Federal level, would work out some way of accrediting each other. Certainly I know that NIST has been accrediting calibration laboratories run by some of the Federal labs, so I think-- Please do not think that we're coming up with-- We haven't yet got a system together, so we're still working on it and we want to know how it ought to work.

MR. MAZZA: I should emphasize, on behalf of everyone here, that the intention is to collect ideas. No one has come forward with a proposal and said, "This is the model. Say 'yea' or 'nay'." What we're trying to do is collect ideas so we can construct the model.

DR. STEPHENS: There is a model in NELAC, in the environmental arena, and the Federal laboratories and state laboratories will be accredited under that system. And there is a body that is designated with the authority to accredit Federal and state laboratories. And several agencies--not FDA--but particularly DOE and DoD have expressed strong interest in having their laboratories accredited under the system. And they would be accredited by the same set of standards that everybody else would be accredited by.

Now, we don't have that yet, but that's the current proposal. There was some anxiety in creating that system amongst the Federal laboratories who didn't really want to be subject to this set of standards, but that's the way we're proceeding.

MR. MAZZA: And the model Bob is referring to is the model for the NELAC Program. It's not necessarily the model that we will adopt in this area, but that is a model to be considered.

DR. STEPHENS: Right.

MR. MAZZA: John?

MR. LOCKE: I just wanted to say that in the health area that CLIA has programs now which recognize six or eight different laboratory accreditation systems including CLP and so there is a lot of activity already going on in the health area. They were invited and they did attend the December 8 meeting, but we haven't heard from them since, so we're not sure where they stand with respect to this activity here, although we know that they know about it.

MR. HENDERSON: Just a quick comment. In launching our accreditation system, the British Government said that it would set an example by requiring all of its Government laboratories to become accredited in appropriate fields. In fact, one of the reasons why we were able to keep our monopoly is because there is a huge program of market testing and privatization, and part of the cost of that was to have a Government monopoly on the accrediting function at the end of the day because a lot of the rest of the activity and testing was put to the private sector.

MR. MAZZA: On the floor? Question?

LANKIN: My name is Jim Lankin. I'm with Climax Research Services. I was struck by something that Charles Ludolph said about how we are unique with regard to the rest of the world in that we depend upon product liability fears to ensure product safety. That being the case, perhaps there is one other stakeholder that isn't present here that should be, and that's the product liability insurance industry. Perhaps they could go a long ways in creating an environment for incentives to get these different accreditors working together.

MR. MAZZA: I think you make a very, very good point. Does anyone care to comment on that? Yes? Belinda?

DR. COLLINS: At the Federal level, also, we have the Federal Trade Commission that has, in fact, investigated false claims related to laboratory accreditation. They had hoped to be here today, but I think because of budget shortfalls a lot of Federal agencies were not able to pay the attendance fee.

MR. MAZZA: One last question before we move on to our next session.

MR. ANDERSON: This is not a question. It's a comment that's intended to describe an alternative model and to really ensure that it gets included in consideration. I'm Glen Anderson. I'm from Performance Review Institute, an affiliate of the Society of Automotive Engineers.

As most of you probably know, SAE is a standards development organization, most commonly known for the Oil Viscosity Standards that are used every time you purchase a can of oil. But SAE has thousands of standards that have been published, many of them in the ground vehicle area, but surprisingly a preponderance in aerospace. And there is a model that has emerged in the aerospace sector that I think should be commented on. John Locke alluded to it earlier when we talked about PRI.

But basically I would highlight several points that were made earlier. We're in a change process. Change is always disorderly and, until it gets finished, the debate continues.

The second thing is, change has to be motivated. And it appears to me that right now there is the beginning of a coherent motivation in limitation of funds. Where everybody had enough money to do what they chose, diversity ruled. Anything could happen.

The third point that was raised by Mr. Ludolph was the need for plurality, for a pluralistic systems. And that's the plus to my comment here. All the alternatives that have been

alluded to had some source, it had some need that was the agent of causation. And there remains in place certain conditions where the third party model is not deemed acceptable, at least acceptable at this time, and PRI has a program called NADCAP, the National Aerospace and Defense Contractor's Accreditation Program, that is not a third party model; it is a conformity assessment program. It is a shared second party model in which the aerospace prime contractors jointly participate in defining requirements.

And that is similar to what the automotive industry did as it developed the OS-9000 system, but it didn't get to the point where it's third party. And in this National Aerospace and Defense Contractor's Accreditation Program you have vibrant participation by the stakeholders, all of them, the users, Government, the suppliers, but you preserve responsibility and authority in those responsible for the product and that is the prime contractors that are involved in defining the auditor requirements, they're involved in defining the standard and criteria for audit, and they're involved in the decisions flowing from that audit. It's a different model and it may eventually be outgrown, but right now it's perceived as needed, and that kind of diversity should at least be considered in the total schema of conformity assessment.

MR. MAZZA: I would invite you to submit a paper outlining your comments. Some of the models we have are well documented so they're easy to incorporate. Some of them are not necessarily well documented, at least not to the working group.

I think at this point we ought to move on to the next session, so I will turn it over at this point to Joe O'Neil, who is the first speaker. We're going to try to look at visions and principles, some sort of at least initial summary of today's discussions.

Joe?

VISION AND PRINCIPLES

VISION

Sponsors' View of Future for Laboratory Accreditation

for the 21st Century

A U.S. laboratory accreditation[1] system that includes a cooperative relationship among the public and private sectors and that achieves the following:

For the testing laboratory, a single accreditation in a given field of testing, with worldwide recognition of the laboratory's competence.

For the user, a test performed once, with worldwide acceptance.

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1 Accreditation based on uniform criteria is intended to assure that a laboratory is qualified to provide data of consistent quality.

VISION

MR. O'NEIL: Could I have the slide please?

The working group concluded that it was important to have some type of vision which might guide our efforts. The Working Group appointed a task force that included representatives of all interested parties, at least all the ones we felt had interest in this issue, all the stakeholders. And that task force came up with a vision that was then sent to the full working group, and this is the result of that deliberation about vision.

What is the vision that the steering committee feels is, you might say, the pole star for this effort for a U.S. System? Our vision is that we have a U.S. Laboratory Accreditation System that includes a cooperative relationship among the public and private sectors and that achieves the following:

For the testing laboratory, a single accreditation in a given field of testing with worldwide recognition of the laboratory's competence;

For the user, a test performed once with worldwide acceptance.

We don't have a great deal of time, but I guess we could have time for one or two comments. Does anybody care to make any comment about this vision? As we've said several times, obviously we welcome input as follow-up to this session and hope you'll all submit your ideas. But, if anyone has a burning desire to make a comment at this point about this vision, he or she may so do. If not, we're going to move on to a discussion of some of the principles, and I'll turn the microphone over to Walter Leight of NIST, who has some principles that also have been crafted by the steering group.

MR. LEIGHT: The first time anybody thought I had principles.

MR. O'NEIL: Oh, yes. David?

MR. Freedman: David Freedman from EPA. One comment on that. I guess the second part of that--

MR. O'NEIL: Excuse me. Can you flash that slide on there again please, that was just had? The vision? Well, maybe not.

MR. Freedman: The first part talks about competency of a laboratory. The second talks about confidence in data of an analysis. And no laboratory accreditation program can ever assure that any given dataset is going to be good data. And I think that causes a lot of confusion I've seen in a lot of people. They think just because it's an accredited laboratory, that means you can trust all the results that come out of that laboratory and that one test of something is valid. And I think if you continue to use that second part in there it's going to be detrimental to getting by that first part.

MR. O'NEIL: Thanks. Thank you for that comment David.

MR. LEIGHT: That's a slide for later, I believe.

Before I get to the report on what the steering group came up with on principles, I'd like to make a couple of remarks which had occurred to me earlier and, I'm happy to say, that they conformed and agreed quite well with a number of things we've heard today from other speakers. And to sort of pull some of these ideas together, in my mind at least, from the point of view of somebody who is buying something, whether it's a domestic buyer or a foreign buyer, the buyer wants and needs confidence in the product that he's getting. In the same way, the public wants to have confidence with regard to health, safety, and the protection of the environment. And, to this end, we have invented the concept of standards and then we decided that maybe somebody ought to test the product, or test the water--whatever it is--to see that it conforms to the standard. We invented the concept of laboratory accreditation, or perhaps the certification of a product, or perhaps quality registration. And finally we have the notion of recognizing the authorities that do the accrediting of the laboratories on down the chain.

And the point I would make is that, depending on the degree of need, we may not use the whole process. Certainly I, at least, and I think most of you, want to have a lot more confidence in the prescription drugs that we buy, or the toys that I buy for my grandchildren, for example, than I need to have in the shoelaces that I spend a few cents on. So, that's part of the problem of what we're all here to discuss. How much accreditation are we talking about, where do we need it, and what are the concepts for bringing it all together?

And, unlike my colleague John Donaldson, I do have a story which I think pertains. I first heard it when a Secretary of Commerce--I think it was Secretary Peterson, but Charlie Hyer has a better memory than I do, so I'm not sure that that's the right Secretary--he came up on this platform and told us the story of a man who visited a rug merchant at an ancient bazaar, and the rug merchant clapped his hands and he said, "Ali, bring me the measuring stick for the carpets." And Ali came and he said, "Excuse me, Master, did you want the measuring stick for buying carpets or the measuring stick for selling carpets?"

That's where we need the confidence in the testing, the measurement, the accreditation and so on.

I want to make one other preliminary comment. The principles I'm about to discuss came out of a lot of sessions of the steering group where people came from as far away as North Carolina and sometimes California. And sometimes Steve Baldwin got up before the crack of dawn to get on the telephone hook-up with us and talk to us here at 9:00 o'clock in the morning, so he deserves a special commendation for that.

The principles that I'm going to discuss represent a strong consensus of the members of the steering group. And that does not mean that we were unanimous on all the points, not necessarily. I think we were on some of them. And we're calling them "principles," but they really describe the desirable features of a laboratory accreditation infrastructure. And the members of the group all recognized that there are undoubtedly going to be problems in creating an ideal system, but we think that these problems can be overcome.

May I have the left-hand slide please? Well, we got the right one.

This essentially shows some key points. The principles were in the registration booklets, and I'd like to go over them one at a time.

If I can have the first right-hand slide?

The first statement is that we think that the vision is a very worthwhile goal. It's namely the universal acceptability of the results of any valid test or calibration performed by a competent laboratory accredited by any recognized accreditor. And there are a lot of very important words that I've tried to stress there. We're talking about "valid" tests, we're talking about "competent" laboratories, we're talking about "recognized" accreditors and, as you'll see in just a few moments, the questions are how do we get to the stage where we can have the confidence in these things.

The second item represents the need for some streamlined efficiency which we think is vital to our economy. As Charles Ludolph suggested, this sort of thing is vital to trade, to our competitiveness in global markets, our competitiveness here at home against foreign products, our competitiveness abroad in any markets of the world. We need to eliminate duplication and inefficiency in the current laboratory accreditation process and that's the way we can enhance our competitiveness.

The third item really talks about the fact that we need to have a high quality system, the real assurance of the competence of the accrediting and testing bodies. Reliance on assured competence will lead to universal acceptance of results. And this is something which is very crucial. May I have the next right-hand slide please? It is crucial, particularly to our regulators, who are responsible for protecting the health and safety of the public and the protection of the environment. They have to be satisfied because they have statutory responsibilities. They have to be satisfied that adequate safeguards are in place. And, along these lines, I would like to quote for you something I just read in a *Federal Register* notice put out by the Food and Drug Administration.

It said, and this is a direct quote, "FDA should accept, where legally permissible, the equivalent standards, compliance activities and enforcement programs of other countries, not necessarily the people in the United States, by the way, provided that FDA is satisfied such standards activities and programs meet FDA's level of public health protection."

And I think this is a crucial point with regard to that top bullet shown on this right-hand screen.

The next one represents the fact that the European Union and other governments have already indicated that they have a desire for the official backing of the U.S. Government for some chain of traceability and responsibility for the validity of test results. So, the laboratories that do the testing may have to be accredited by a body which is recognized by the U.S. Government, at least for some things that, for example, are regulated in foreign markets. That, of course, does not mean that the U.S. Government has to supervise the accreditation of private sector laboratories for unregulated products anywhere in the world.

And the last item on that slide is that multiple interests in laboratory accreditation must be served, not necessarily with equal voice. We've been trying so far, and we've had some suggestions today as to stakeholders who are not represented so far, but we have been trying to get participation by all the stakeholders we've thought of up to this point--the consumers, the laboratory customers, the testing laboratories, the accrediting bodies, and the public and private sector organizations--that require accreditation.

And I guess I can do this one myself.

Next, we're talking about the fact that the global nature of commerce has led to greater reliance on international agreements on standards and conformity assessment, and therefore we think that we should be conforming to the international guides and standards whenever we recognize qualified laboratories or accreditors--and here is the proviso--unless this somehow conflicts with the requirements of Federal and state regulatory bodies, which may have to come first as a matter of law and enforcement of law. And this, presumably, will encourage the universal acceptance of U.S. generated test results both domestically and internationally.

The next bullet talks to the ability of laboratories, whether they're third party laboratories or manufacturer's laboratories, to apply for accreditation. We think that the procedures may differ among sectors, but even-handed treatment should be accorded to all parties in the same field. That means the same ground rules for accreditation should apply whatever the laboratory is, whatever it does, wherever it operates.

And then finally--this is less a principle than a recognition of a hard fact of life--if we're going to implement the vision, this may require the establishment of some coordinating groups, a secretariat and balanced input from all interested parties.

Now, I'd like to recognize that among sectors there may be differences, with different coordinating groups or councils, or whatever we choose to call such things if we have them, and that balance doesn't necessarily mean equality of representation. Certainly it doesn't imply preemption over governmental authorities.

Now, those are the principles we've come up with and we'd be very happy to hear comments, if any, of why they're no good, or how they could be made better.

Thank you.

MR. Freedman: I saw nothing in your principles about sources of funds.

MR. LEIGHT: We talked about that. The principle is that you have to have money to do any of these things. But actually we thought of a number of things which apply to implementation, and funding is one of the things that comes up when you go to implement anything. This is really, as I say, a set of guidelines of what we think the attributes of the final system, whatever it is, might be. And what we think we want to live up to how we get there, including how it gets funded is still unresolved.

MR. Freedman: But it's very important, I think, because, if the example of the past was extended to the present I think the laboratories see there is really only one source of funding at the moment.

MR. MAZZA: My experience tells me that if we build a system that truly adds value, those who see the value will come up with the funds. If we are not clever enough to build a system that truly provides value, the funds will not be forthcoming and we will have failed in our effort.

MR. Freedman: But, sir, shouldn't that be added as a principle, building a system that has enough value to--

MR. MAZZA: That would suit me just fine.

MR. LEIGHT: The principle that we talked about, which I think does apply to that, is that it be comprehensive and rigorous enough so that we recognize all qualified bodies, and that will promote acceptance of results. It's got to be a high quality system, otherwise who is going to play?

MR. MAZZA: I think that the comment was different. Quality and value aren't necessarily the same thing. A lot of people think that the Rolls-Royce is a very high quality automobile, but don't see a heck of a lot of value. I think the concept is that--

MR. BOBER: I'd like to comment on money. We don't need the money. If we had the guidelines that gave us an encouragement to couch our rules and regulations and laws in international language we could do this. We have a lot of laws on the books now and, if we go in and we change something, we need to tell our state legislature that we're just changing the language to be in conformity to international practices and to Federal practices, and there is no debate and we can move through.

If we come up and say we want to have a new law or a new principle, we'll have a heck of a time getting it through.

So, if we have guidelines that are established, this is one of the things that will allow us to be ready for this international collaboration once we achieve it, and once we do it, we will turn it into money.

MR. MAZZA: I would agree with you. There is already the practice in many states, and in some Federal agencies, and even in some Federal laws, to adopt by reference standards. More and more those standards are becoming the American national adoption of international standards. Further, there is encouragement in the WTO, World Trade Organization, "Technical Barriers to Trade" chapter. That agreement is an agreement to which the United States is a signatory body that encourages the United States to encourage its states to do exactly that.

I think, in many of these areas, we all see the writing on the wall. We just have to get on with doing just that, as you've suggested. But it's something that's going to have to be done state-by-state, municipality-by-municipality, regulator-by-regulator. What we're trying to do is hopefully create a framework that will accelerate that process in an orderly fashion.

MR. LEIGHT: I think some of this has already been done, certainly by the National Conference on Weights and Measures. I think that NELAC, if I'm not mistaken from what I heard Bob talking about, is trying to do the same sort of thing in the environmental area, where we get general agreement centrally and then get the states to adopt instead of everybody inventing his own wheel.

MR. MAZZA: Walter, can we move it on next to the Options Section?

MR. LEIGHT: By all means.

MR. MAZZA: The first one is John Locke.

I'm sorry, John. Did you want to make a comment?

MR. DONALDSON: I just wanted to make one, quick comment. It's something that came up earlier and it's involving principles, and I'm a little bit ambivalent about it, but I thought I'd throw it out for your consideration.

Whether you include the manufacturer's laboratories in the set that are admissible for whatever purpose, we have had a problem recently with Mexico where Mexico required that the products to be accepted have to be tested in an accredited laboratory. In Mexico, the only accredited laboratory is a manufacturer's laboratory. Some of the suppliers in the United States are finding it very difficult to accept the concept that they have to admit that their products were tested in that manufacturer's laboratory.

As I said, I'm ambivalent, but if that's the only act you've got, it's the only act you've got. But it is a principle and I think we need to take that into account.

Thank you, Mr. Chairman.

Proposed Principles
for a Laboratory Accreditation Infrastructure

- Realize the Vision: universal acceptability of the results of any valid test or calibration performed by a competent laboratory accredited by any recognized accreditor.

- Eliminate duplication and inefficiency in the current laboratory accreditation process and enhance U.S. competitiveness in domestic and global markets.

- Develop a comprehensive and rigorous system for recognizing all qualified testing and accrediting bodies, both governmental and private sector, to promote acceptance of their results by domestic and foreign regulators and product purchasers.

- To ensure satisfaction of regulatory requirements, exercise appropriate government oversight at federal, state, and local levels.

- So that other governments will readily accept test results, laboratories may have to be accredited by bodies recognized by the U.S. Government.

- Consider the needs of all parties to laboratory accreditation (i.e., consumers, laboratory customers, testing laboratories, accrediting bodies, and the public and private sector organizations that require accreditation).

- Conform to appropriate international guides and standards when recognizing qualified laboratories or accreditors unless in conflict with special requirements of federal and state regulatory bodies. This will encourage the universal acceptance of U.S.-generated test results, both domestically and internationally.

- Ensure that all laboratories (i.e., manufacturers' and third-party independents) are equally eligible to apply for accreditation, and that equivalently rigorous procedures are used to accredit each laboratory in a given field.

- Implementing the Vision may require establishment of one or more coordinating groups, a secretariat, and balanced input from all interested parties.

OPTIONS

OPTIONS

MR. LOCKE: I'd like to start with a couple of comments. First of all, my colleague from the United Kingdom, Bill Henderson, was talking about the system for cooperation in Europe, and that's one reason why five years ago we asked ANSI to get involved. We believe that whatever is done in coordinating laboratory accreditation in the United States will provide the basis upon which states and federal regulators, and original equipment manufacturers can adopt principles that are agreed to by all involved, just as is done in Europe.

Mr. Henderson talked about competition, and we've had some discussions for about 4 years about mutual recognition. We don't seem to be getting anywhere because of calibration issues, so we now have more and more laboratories seeking recognition in Europe. If we can't get mutual recognition agreements with systems in Europe, we believe they will have created a market for their services in the United States, and that's what I mean by competition. I'll have more discussions with Mr. Henderson about this subject tomorrow morning.

Anyway, let's talk about models.

MR. HENDERSON: Tomorrow morning?

MR. LOCKE: Mr. Henderson and I will meet tomorrow morning to talk about agreements.

Charlie Hyer this morning talked about history and, the more I listened, the more tired I got. So, what do you do when you get tired? You retire. (Laughter) I'd like to work out an agreement with the Europeans before I retire next March.

MR. LOCKE: I want to talk a little bit about what happened after our discussions among the accreditors last December 8. We talked about the model that was developed basically by the International Laboratory Accreditation Conference (ILAC) and was implemented in EAL, and we said, "Well, maybe we could implement something like this in the United States?"

First of all, I want you to know that we're not doing what the Europeans do because the Europeans are doing it. We were all involved in ILAC in the evolution of these mutual recognition agreement (MRA) principles and we were happy to see the Europeans try the model, because they identified some of the flaws in the concepts that came out of ILAC. The model is better because of it. These changes occurred between the first draft of the principles being in 1988, and the fourth draft in 1994.

What are the basic concepts? All accreditation bodies must use Guide 25. All accreditation bodies must meet Guide 58. Any accreditation body interested in meeting Guide 58 and using Guide 25 can be party to the cooperation. Accreditation bodies who seek mutual recognition must be willing to be assessed by knowledgeable assessors from other MRA members. Current members will vote on the acceptance of an applicant accrediting body based on the assessor reports and responses to the reports. This is, again, what is happening right now in EAL.

What about the membership of this U.S. Laboratory Accreditation Cooperation (USLAC), which is what I've called it? The membership would include states and federal agencies with regulatory responsibilities, as well as accreditation bodies. Membership in the MOU doesn't commit anybody to use anything; it simply says "We are interested and willing to be involved in the process and we are either users of laboratory accreditation systems or operate laboratory accreditation systems." That's a little different than EAL, but it seemed to me we have to get the aerospace industry and the automotive manufacturers and the people who are using laboratory accreditation involved. We have to have them identify the fact that they assess laboratories--that's the first problem--and then second, they must have the right for a voting membership. And private sector bodies which specify the use of accredited laboratories, laboratory accreditation systems willing to seek cooperation, and such other members and observers as shall be invited by the committee, shall comprise the USLAC MOU.

The members shall elect a chairman and secretary from among its members with a maximum term of 3 years.

There are 15 objectives defined, and these are principles that come right out of this ILAC MOU document. So these aren't things that we have just dreamed up. Let's use what exists.

Each member shall have certain opportunities to obtain data about other members, et cetera. You can read those, I think, on the slides attached.

Each member body commits itself to the use of operational laboratory accreditation systems in accordance with standards and guidelines established by USLAC, make available documents, et cetera. So, we have obligations that each member body to the MOU would take on by signing the MOU.

I sent this proposal out to the participants at the December 8 meeting and to everybody that was on the mail list that we had. I framed the MOU so that they could sign it and become members, and I said when we had five members, we would start something called USLAC. I think I said four members originally, but we ended up with five.

We have five organizations that signed this MOU at this point. We suggested that NVLAP might want to sign. But we don't have any users. We have presented this to the Laboratory Accreditation Working Group which concluded that it was premature because all of you would not have had a chance to interact with it. As far as I was concerned, a model was there and we needed to demonstrate what could be done, and so we ended up with five organizations signing this mutual recognition agreement.

So, what happens next? Now we have an MOU committee or group formed of interested parties. These are organizations that have made no firm commitments to be assessed. They have made a commitment to supply personnel to perform assessments on assessment teams, and they get a vote as to who should be accepted as an MOU partner. This is very much as it happens in EAL. When EAL started they had five organizations who had agreements, but they let all 17 MOU members vote. So that the people who were not far enough along didn't feel disenfranchised about the acceptance of these systems. It worked very well.

So, the next thing for USLAC was to establish a Mutual Recognition Agreement Committee and send out the Mutual Recognition Agreement document for review, comment and possible adoption, with revision as necessary, for the U.S. scene. That document was sent out at the first part of September. We were hoping to have a meeting to discuss it yesterday but we weren't able to get everybody here yesterday.

What is a Mutual Recognition Agreement? Well, it's the structure of the guidelines, an evaluation of the accreditation systems. The major steps in the Mutual Recognition Agreement process are: evaluation, preparation of agreements, and a process for maintaining the agreements. These are all spelled out in great detail.

The accreditation bodies will use Guides 25 and 43. This is another part of that ILAC-developed document. They must have an operational system. They must be in at least their first surveillance rounds. That means they can't have just accredited somebody; they should have gone back for a second look. They must have a full-time secretariat. They must have granted some accreditations and must have relied on appropriate measurement systems to provide traceable testing. It is here that we get into the discussions we were having with EAL. All major documentation must be submitted to the evaluation team so there aren't any secrets.

The next step is the initial appraisal of the accreditation system to Guide 58 requirements. The on-site evaluation also includes the implementation of the policies and procedures of the system. Finally, the assessment team witnesses an assessment performed by the accreditation body.

What does all that mean in practice? If, for example, we have 10 or 12 bodies who have agreed to sign this MOU, they would identify someone from their system who has experience in assessment. A Mutual Recognition Agreement Committee would be developed, and these people would be on that committee. An applicant who wanted to have their system recognized would then submit an application and an assessment team would be identified and the assessment would be conducted. The assessment team generally takes about four people. We've done these kinds of assessments in Europe and in Asia, and so it's not something that's new. Members of the MRA Committee would vote on acceptance of each assessed system into the MRA.

The procedures now are all spelled out in the ILAC MRA Guidelines, so there are about 24 pages of details on how this is all worked out.

What does this cost and how is it put together? As far as I understand, when EAL started, the accreditation bodies basically funded their own participation. There was a volunteer secretariat and a chairman that was not a funded position. Now I think it's become a little more formal. Bill Henderson may want to comment on that. There are committees, and these are committees of a similar nature to what ELAC was talking about. These are committees for particular fields of testing, for particular issues. The whole operation really is not very bureaucratic, seems to be very, very effective, and has, I think, a good track record. It's being adopted now by the Asia Pacific Laboratory Accreditation Cooperation (APLAC) with the same kind of approach. It's a model that has been demonstrated and can be implemented effectively.

These procedures have been implemented in other parts of the world. They can be readily adopted in the United States by accreditation bodies and their users who are committed to cooperation on behalf of the U.S. industry and Government.

I would be happy to share with you the details of the procedures. Anyone who is interested, just leave me your card and I'll be happy to provide that to you.

MR. MAZZA: Thank you, John.

The next speaker is Steve Baldwin.

MR. BALDWIN: Did that microphone just walk away?

MR. LOCKE: It just walked away.

MR. BALDWIN: Okay. Thank you, once again. This talk is a little more conceptual than it is very specific in terms of where we want to go with our next steps. There is one part of the survey that Lou Dixon didn't share, another conclusion that came out of there. "The total intelligence on Earth is constant, but the population, however, continues to grow."

(Laughter.)

MR. BALDWIN: Where do I go from there? I think that the situation with these comments here, really, I want to say that I appreciate the comments from Joe, from Maryland, as far as what he had to deal with. I think, to me, that gave a whole new appreciation of what we have to put up with or what we have to manage. And I think I can see some of your specific points, not all of them, here in this list of acceptable solutions we developed. And up here more of the one-step evaluation here, efficiency, flexibility, focus to a single source, and impartiality. These seem to be some of the elements that maybe summarize these bullets.

And what is it that's going to help us put together a system like this? I think some of the things that we need to consider is the context, and that's why I've said that already it's important, if we look at laboratory accreditation, to see it in the context of overall conformity assessment. And it's only from that overall context that we can come up with a solution that really will work in the real world, that takes into account that reality.

I think the most fundamental thing that needs to be put in place though is--Are those letters big enough--a U.S. Conformity Assessment System. There are dozens and hundreds of conformity assessment systems out there, but there is no universal U.S. or national model for that, and we think that one needs to be established, identified, and recognized.

You may ask, "What does that mean to have a model that we can work from?" At least conceptually, we use in our business a word you can understand, "conformity demonstration," and that's this model here, which you start out with compartments at one end and come out with conformity being demonstrated at the other. That can be a product, a material, a process. You can either go through your own test house, or a third party. This "capability confirmed" is really accreditation. And this is sort of a generic conceptual model. It doesn't answer some of the questions, but it does show some of the ways of getting from Point A to Point B.

I think we can characterize many, if not all, aspects of all systems that are out there in one way or another through this model.

The point is, as was said earlier, that we need a model which gives flexibility. Spire's Declaration has an appropriate place, but it isn't always appropriate, nor is mandatory third-party test and certification always appropriate either. But this gives us the beginning of an opportunity to really understand that there are options, and I think that's something we need to do when we look at any given agency, or program, is to look at it and say, "Which path are they following,

and is that the best path?" There may be another route that would be more appropriate, or at least would give us equivalent results, if done properly.

As we look at the model of the U.S. system, that really can't be done in isolation. I know I'm just reiterating some points that have already been made, and that is that the U.S. system, as we develop something, we define, and accept and recognize, we need to understand that in terms of the entire world and the systems that are out there. That doesn't necessarily mean that our system looks like their system, but at the point of interface there is an ability to connect with a global market.

This concern of the global marketplace, in addition to the national marketplace is, in our company, you know, half of our work is done outside the United States, and so we see ourselves also as an importer to the United States as well as an exporter from the United States, and so we, I think, in this country, sometimes we see ourselves as-- The requirements here aren't so bad, but wait until you go outside and go into Europe, or go into some other countries. Really, the United States looks pretty complicated from outside the United States.

The characteristics for a U.S. conformity assessment system. It should be characterized by international standards and clearly defined options or paths, and that the options and the paths are determined between the buyer and the seller.

The strategy. U.S. industry must work together with Government. That's how we have to go about doing it. And I think we have just an excellent example in what Sergio has done with the Memorandum of Understanding with NIST and ANSI. It's just a model for what we need to do as industry as a whole with various government agencies at the Federal, state, and local levels.

I think within our own industries we found, in our Task Group, we have such a wide range of interests, from the different kinds of industries that dealt with consumer markets, Federal procurement issue, those that are regulated, those that are non-regulated, large markets, small markets, international markets. We had so many different kinds of people in that room that I think we found that we have a lot of things that are in common, but there are a lot of things that are different, and we need to understand those differences. You don't have an homogenous industry out there. And that industry doesn't always know that either.

The industry's knowledge of the whole issues of conformity assessment. You know, I guess I was surprised myself with some of the strategic directions I think we ought to take, and that is that industry itself needs to be educated. Now, before I even had all the numbers from Lou Dixon, we had this idea of the need to educate U.S. industry as to what conformity assessment and laboratory accreditation, et cetera, was all about. We found more people, 5 or 6 to 1, were choosing inappropriate standards to evaluate the fitness of the laboratory for being able to produce data, so actually it shows really a gross misunderstanding of standards and conformity assessment.

We need to work with the agencies directly as well and understand what it is that they are up against, instead of just demanding a change. We need to understand what they're up against and imaginatively try to understand what could be in their interest in meeting their needs. So I think we want to move in the direction of the items we've indicated. And that's, I think,

why I appreciated this talk from the Maryland Health Department as to what they have to face. It helps us to understand how we need to look at this.

Now, I guess, instead of just-- We hear all this about internationalization and trying to use international standards. You know, it's a two-way street. I'll just give you one story since I have about another 30 minutes.

(Laughter.)

MR. BALDWIN: No. I mean, I've been involved in the standards world for many, many years and in the conformity assessment world really not quite so long, but we used to lose a lot of face at the international level when they saw Americans coming to the international table with proposals and actually influencing the international standards and then going home and doing something entirely different. Over a period of time Americans started to have a pretty bad reputation for telling us what to do outside the United States and going back and doing their own thing, which was completely different. So, when we talk about adopting international standards, we're not adopting standards that are foreign to us in the sense you might think. There was a lot of work that was done with Americans that were involved in the development of those international standards, and there are a number of people in this room involved with conformity assessment standards at the international level, ISO 9000, 14,000, the CASCO Guides, ISO Guide 25, and so these aren't necessarily as foreign as you might imagine. There is U.S. input on those. And I think there is a real need for us to be actively involved in those if we're asking ourselves to accept those.

So, those are just some of the elements of the direction I think we ought to take and some of the things we have to consider. What I haven't presented is what, exactly, what kind of organization this is going to take and that sort of thing. I don't have those answers, and that's why they're not on my presentation. But there are some clearly overriding themes and strategies that I think we ought to take as we move forward from here.

MR. MAZZA: Thank you, Steve.

Our last speaker is Belinda Collins. She will then manage the Q&A to cover this section and then, between Belinda, George and Joe, they will do the wrap, since I have to go. Thank you.

OPTIONS

DR. COLLINS: Given that my voice is definitely fading, this will be a short presentation.

We've heard a number of different proposals for ways to try to put the pieces involved in laboratory accreditation together, and I think it's very important that we continue to work towards a system that we all can live with. We need to note that there are users of laboratory accreditation and that these really are the Federal agencies that require it, the state agencies, and the manufacturers. Each of these uses the products of laboratory accreditation. Other parties include the laboratories, accreditors, and standards developers. The labs themselves have to suffer being accredited. The accreditors are involved in doing that accreditation, while the standards developers are involved in making the standards by which accreditation is done, and also determining the form in which accreditation is done. And finally, the associations are involved, and as we've heard from a lot of people today, the legal profession, among others. So there are many people involved in laboratory accreditation. And we have created, thus far, an unassembled puzzle. Our challenge is to put that puzzle together.

One possible system for doing this is a system which has a coordinating entity which I think should be a public/private body so that we can get the input that we desperately need from the regulators at all levels; so that we can cooperate with the existing conferences on laboratory accreditation--NELAC, the National Conference on Weights and Measures, the National Conference of Standards Laboratories; and so that all parties have input into the coordinating entity.

The participants in much of this are the users, the laboratories, the accreditors. Central to all of this is a requirement that they use common procedures, at least at the starting point. And we've mentioned ISO Guides 25 and 58, and there are other ISO Guides coming down the pike on recognition. If we could agree on procedures that we use as a starting point in individual sector areas, we will be closer to reaching our goal of one-stop shopping. We then solve the problems mentioned in Maryland with 15 different Federal agencies telling Mr. Bober what to do. Once we agree on procedures, then we can begin some implementation and coordination.

I'd like to see us at the Federal level seriously consider what sorts of procedures we think are needed. Perhaps we could consider an implementation of specific procedure on a test case basis to examine what might work to fit our needs.

I also think that the model that John Locke described of mutual recognition among accreditors fits in here in this public/private model. That is one way of solving these problems, to be sure that the accreditors are using common procedures, that they understand how to do the accreditation, again always to ensure that we have the best data that we can get.

So this is another possible system for laboratory accreditation and I encourage all of you here to think about models and to provide your ideas to us on the steering committee so that they can be included in the proceedings, because I think there is more than one way to skin a cat, and I think this cat is best skinned--to use an awful analogy--by the input from all of us, so that we build a system that works together so that when other countries come to us about products we can say, "Here is a point of contact, and you need to follow this particular path, that particular

path, or some other path, to get the answer that you want." I think that will help to build a workable system for the United States.

Thank you.

I think at this stage of the game, in the interests of my voice, Sergio, I will turn it over to Joe.

MR. MAZZA: Fine. Joe, do you want to--

MR. O'NEIL: Take questions?

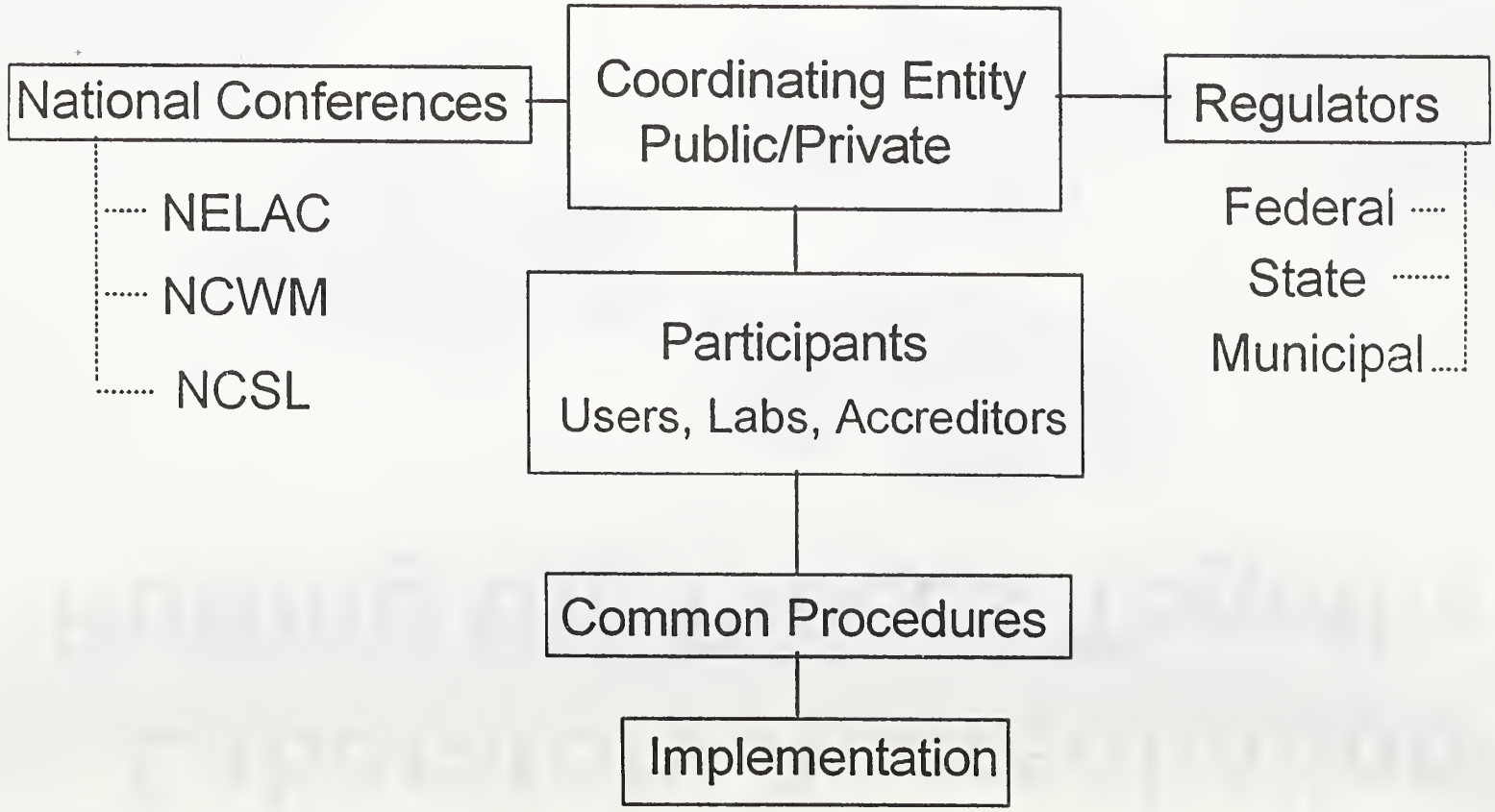
MR. MAZZA: Yes. Sure.

Laboratory Accreditation - Putting the Pieces Together!!

A System for Laboratory Accreditation in the U.S.

Goal

Minimize redundant accreditations and provide a system to ensure the quality of laboratory data



DISCUSSION

MR. O'NEIL: You've heard a couple of different possible models for a system of laboratory accreditation. We'd welcome your comments about those models as suggested.

Jim?

MR. JOHNSON: Jim Johnson, TV Product Services. I would like to do a follow-on to Dr. Collins' recommendation on common procedures. And the piece that I would like to introduce today is a piece about technology. Now, I don't know how many of you had an opportunity to read the recent "Business Week" cover article on productivity. That cover article talked about American competitiveness, and one of the things that it brought forth was the idea, with the personal computer, with Internet, what we were able to accomplish. The analysis I'm going to give you is not mine, but it's by a fellow by the name of Ong, O-N-G. He's a Canadian. And he said, "With the introduction of the printing press, we basically went out of a situation of tribal unity, sitting around in a cave talking about things around a fire, to disunity." And he figures, and I think it's a good analysis, that with such things as the World Wide Web, we're going to get back to the cave, as it were, with being able to communicate about the issue of accreditation.

Now, we have not heard about technology today. Here we are entering into the 21st Century and we have a tool, the World Wide Web, with Home Pages, with downloading every which thing you could imagine, and still we have been talking about procedures that have been going on for decades, people getting in planes, landing, renting a car, going out, spending four days at a lab, getting back on a plane, writing a report. The technology piece has got to be put into the model. Technology is available. Here we are, we are a technological industry, and we have to use these tools. And, as we're looking at that letter again, and I seem to be hung up on this letter by Al Gore, "We can all succeed by working together to make laboratory accreditation effective." We can do this by working together. I don't know of a better way to do that than by using technology through the World Wide Web.

Thank you, Joe.

MR. O'NEIL: Yes?

MS. WARD: Marlene Ward. I'm the Chairman of the Accreditation Committee of IA, and you may have said this earlier and I may have forgotten, but can you remind us all who we send our comments in to for additional comments? Now that we've seen the visions and the principles, now maybe some of us who hadn't been privy to this in advance could then get some comments in to you.

DR. COLLINS: I think probably the sensible thing to do is to send them care of me at NIST and we'll make sure they get into the proceedings. You're certainly welcome to go ahead and send them to the other cosponsors, but we're going to be working with the gentleman who is putting together the proceedings.

MS. WARD: How long will it take you to get these out? We always need a time frame.

DR. COLLINS: Right. Thanksgiving?

MS. WARD: Thanksgiving?

DR. COLLINS: The U.S. Thanksgiving, in deference to our Canadian members.

MR. O'NEIL: If they don't get into the proceedings, we'll take them for forever.

DR. COLLINS: Yes. Obviously, we'll continue to take input forever, but I'd really like to have them before 2005, when we do the next one of these things, as Charlie has predicted. I hope by that time we can have a party to celebrate that we've actually gotten somewhere.

MS. WARD: Okay. So definitely by Thanksgiving then?

DR. COLLINS: Please.

MR. Freedman: David Freedman. I guess what concerns me is the gentleman put up the principles that were worked up by the working group, but I didn't see the options addressing those principles. A couple of them, especially, where you need to have, for this to succeed, a comprehensive, rigorous system of testing and accrediting bodies so that everybody can have absolute confidence, recognition of accreditation by the Government, and also oversight by the Government. In both the proposal that ACIL put forth, the other proposals, none of those addressed those critical factors. Even the one that you put together, that third one, didn't really get to that.

DR. COLLINS: I think some of it got lost on the editing floor yesterday. The common procedures would be for accreditation and for recognition and somewhere in here we provide for governmental oversight or recognition in the coordinating body as appropriate. I think that has to be part of this picture that it be there. Also, I think it needs to be a system that includes all of the players that we've heard from earlier and this is why simply I think a Memorandum of Understanding among accreditors is not going to be sufficient, because that doesn't give you, necessarily, the governmental recognition or oversight that you might need.

MR. Freedman: My point is oversight and recognition are not the same. If you have oversight, you probably will get recognition. If you don't have oversight I'm not sure that the Government is going to be willing to give recognition that you can use the Federal Government seal, as the gentleman from England suggested.

DR. COLLINS: I agree. And I believe that the Government must be a strong participant in this coordinating entity and that whatever program is developed must satisfy Federal regulatory, as well as everything else. But I also think regulators and those of us in the Federal Government need to be aware that we don't have unlimited resources. When we see budgets dwindling, this may be one way of accomplishing our objective of ensuring the health and safety and welfare of our citizens for whom we are their public servants, by developing a credible, honorable system with good rules, and I think that's why we all need to work together to get into these common procedures that we can agree to.

MR. O'NEIL: John?

MR. LOCKE: Yes. I kind of disagree with that. The concept that Government somehow can bless this multifaceted function which includes mechanical testing and all kinds of testing which includes testing for corporations and big business and little business is just not in parlance. There isn't any Government agency. There was talk of using the NELAC Model, for example, or the Weights and Measures Model. Who, at the state level, is going to be in a position to accredit laboratories doing mechanical testing for some automobile manufacturer? Sorry, it's not in the cards. What we're talking about here is a cooperation among the people who are supplying the service and the people who are requiring the service, the users, in the process so that even the users of the service and the regulators can be part of the evaluation of these laboratory accreditation systems in that process and can gain confidence in the depth and the veracity of the analysis being done at that level so that they can accept those findings on that basis, which is the very thing that has been done in Europe where, in fact, the Government in the U.K. now accepts findings of EAL because of the actual involvement of the Government in the process. And so why do we always have to have, "a government oversight" in some sort of another bureaucratic process which does all kinds of evaluation? It's not the purpose. The purpose is to cooperate in a system that gives confidence to all the participants who are cooperating.

MR. O'NEIL: Thanks, John. Bob?

DR. STEPHENS: I think the strength in the system that Belinda has put up on her slide is that, if you look at this, the central body is a coordinating entity, and it is coordinating various actual accreditation systems, like NELAC and Weights and Measures, et cetera, which all may be very different from one another, and some require Government oversight and some do not--it's totally inappropriate--but, as I read this, and what I like about this, is that this coordinating body, which is a public/private partnership, focuses at common procedures related to the process and related to issues such as reciprocity. They don't develop specific standards which would be developed by each one of the areas of accreditation, some of which would be maybe largely Government-run, some of which would be largely or exclusively private sector-run. Their job as this coordinating entity is to try to canonize the procedures and look for opportunities whereby in one type of accreditation that it has sufficient overlap with--and similarity--with other types of coordination that you ought to be able to have reciprocity between maybe what NELAC will do and what some other component assessment program would do.

So this body really is, as I think Belinda rightfully says, is a coordinating entity. They're not setting the standards for NELAC, or Weights and Measures, or anything else, and they are trying to coordinate all these so they all go by the same sort of processes as to the degree possible. And I think that's the strength in this proposal.

MR. O'NEIL: Thank you. Walter?

MR. LEIGHT: I'd like to second what Bob just said and go a little bit further. If you remember--and if you don't remember, you can look it up--the ninth of the 10 commandments that we had, and somehow or other we lost the 10th commandment, and I think that was the one that said that adultery is still in-- That's a joke, and that's the punch line.

(Laughter.)

MR. LEIGHT: The point that I would make is that ninth point talked to the fact that we may need different councils, different boards, or something like that, because there are different activities that require different degrees of sophistication. In the same sense as I talked about shoe laces and prescription drugs before, we have licensing procedures now where the licensing process is similar, but the degree of stringency varies considerably from a cobbler up to a neurosurgeon. And certainly we're not going to want, and we're not going to have--Congress certainly won't let us have--Government oversight over everything. Nobody wants that. We can't afford it. There are some things that are unregulated and will take care of themselves, either by the marketplace taking care of it, or by people getting together and agreeing in trade associations on what they do. There are some things that require Government oversight in protecting the health, safety, and the environment and, in some cases, for getting the regulated products that are to be sold abroad.

The process, as Bob said, has to be similar, and the notion of doing it through a coordinating body and then applying the stringency as required is, I think, part of the principles that we had. Thank you.

MR. O'NEIL: Thanks, Walter. Les?

MR. BREDEN: I'd like to support John Locke's proposal. I feel that sometimes too much of a good thing is not really acceptable. If you'll notice in the program there isn't any speaker from any U.S. Government regulatory agency. And one of the things that we think everybody agrees to in the Federal agencies is a need to use the ISO Guide 25. We don't think any single agency has a monopoly on brains, and that every organization should be able to have access to ISO Guide 25. So, the point we're trying to make is that that's the only thing that we seem to agree about between the public and the private sectors. Whether we need this coordinating function, I don't know. I don't think so. But, as far as HUD goes, we feel John Locke's model is probably closer to reality than anything we've seen so far.

MR. O'NEIL: Thank you. I'm going to jump to the private sector and then right down to the public. Pete?

MR. UNGER: Pete Unger. I'm speaking on behalf of ASTM E-36. We have, what used to be known as E-36, on laboratory accreditation and is now going to be E-36 on conformity assessment. We have a dozen standards, standard guides, standard practices, but it basically adopted the international guides, Guide 25, Guide 58, and Guide 43 on proficiency testing. And, in addition, we're suggesting several issues with regard to commonality of procedures and processes that accrediting bodies should use. And I offer E-36 as a form to help adopt and develop those common procedures that are being suggested by this coordinating body. We already have a process for standardizing procedures of laboratory accreditation run through ASTM as one model. Thank you.

MR. DONALDSON: I have to say I have a problem with what John Locke is saying, and I think it goes back to something that Keith Mowry picked up earlier, and none of us responded. Keith had heard what I said about what's the incentive for the accreditation bodies to get involved, to join a group, and without that incentive I'm not sure it will develop. And I realize subsequently Walter Leight, when he was picking up on something I said, caused me

to realize I lied in my presentation. Actually I do have a more or less humorous remark, but it's very seriously humorous, about accreditation.

A couple of years ago we had a workshop in Geneva at ISO having to do with accreditation and certification, and the person from Israel who was responsible for operating their certification program asked the audience if they knew the difference between God and an accreditor. And the answer to the question that she gave was that God doesn't think he's an accreditor.

(Laughter.)

MR. DONALDSON: I changed it, by the way. I told her she should have said that God doesn't think "she's" an accreditor, but that was too sophisticated and so it didn't go over.

But, in any case, that was a remark made at an international meeting by a certifier, a perception of the accreditor, and that that is a perception and, if that has any validity, then what's going to make accreditors come to a table where they cooperate?

MR. O'NEIL: We're running short and I want everybody who is standing to get a chance to say his piece. I'd like you to try to say it in a minute, if you can.

Lou, you're next?

MR. DIXON: A key ingredient to a proposal like Belinda put forward was the public/private sector cooperation in oversight, and again a second layer down was the reliance on common procedures, and I read that as "common standards." Now, to back up what Pete just said, there are several fora for development of common standards, and I would like to see, rather than a separation of the standards that are needed by the regulators and the standards that are needed by private sector, I would like to see private sector and regulators work through common standards and everybody work for those common agreed standards.

MR. O'NEIL: Thank you. Larry?

MR. GALOWIN: I just simply want to say the goal of a public official--I'm not necessarily as the expert--but as part of a cooperative team with the private sector, cannot be dropped, in my opinion. Just look around this audience. There is not a single public sector/private sector representative here to speak about needs of the public, their protection, the use of accreditation in purchase of goods and how to balance this whole system. So I have to take a position that it must be a governmental role in strong cooperation with the private sector and there is truly a role for Government.

MR. O'NEIL: Thanks, Larry. Now, we're rapidly losing a quorum, and let me assure those of you who are wondering whether to stay or leave, we're not going to take much longer. I'm going to hear these two gentlemen and then I'm going to wrap up, and that's it. Correct? And so, if you can hang on for five minutes, we'll conclude.

Yes, sir?

SPEAKER: I would tend to agree with John Locke's interpretation of this, and that is that the cooperation amongst the accreditors, which I believe could be induced by working together with the product liability insurance industry to try to develop some financial incentives for either the laboratories themselves or their customers to participate in this accreditation process, recognizing all the various accreditors, that that could bring all these diverse interests together without a public agency. I think we're in an environment where we're decreasing regulation, rather than increasing it; we're also decreasing the activities of Government and the amount of monies that we allocate towards that. And since the implementation of this is going to require some funding, and since we're all concerned about that, I think that perhaps looking towards getting these financial incentives by some industrial group is worthwhile.

MR. O'NEIL: Thank you.

We've got a minute so, Pete, if you can do it in 30 seconds, that will leave John 30.

MR. UNGER: I was just going to respond to John Nelson. What is the motivation for accreditors? We have customers. They pay fees to us. They would like to see their accreditation have value. They would like to see a reduction in multiplicity of accreditation. So, our customers are looking for us to cooperate to reduce that duplication.

MR. O'NEIL: Thank you. John? You've got the last word.

MR. LOCKE: I feel like my model has been discordant. As you recall, I said that the accreditors would be members of the agreement, the MOU, but also the users, and a user could be a member of the MOU, including regulatory officials and buyers. And so, in that sense, if that committee becomes truly what it's intended to be, it becomes identical to what Belinda has shown. The only difference is that people who want to be involved become involved; not someone defining who gets involved and structuring a committee somehow through some Government action.

Thank you.

WRAP UP AND CONCLUSIONS

MR. O'NEIL: Thank you, John. Well, we're right on time. You may find that hard to believe, but we are right on time, and it is time to wrap up.

First of all, on behalf of the sponsoring groups--NIST, and ANSI and ACIL--I want to thank you very much for coming, and even more so for staying the course. It has been a long day. And I guess the good news is that you have the next two days off and you can recover.

What I heard are some consensus points. I think I'm correct in saying this, that these are some of the points on which there seem to be almost universal agreement:

1. That the status quo in laboratory accreditation in this country is not acceptable.

2. That we need a system.

3. That some type of public/private partnership seems appropriate.

4. That all stakeholders must have a role in this system.

5. And that our system must fit into the international framework.

Some, you might say, housekeeping points about what's going to happen now. Having agreed on those points, what will be the process by which we come to some method for putting those agreement points into real life?

First of all, let me comment on the last subject that was the source of some pretty lively discussion, about the models that have been proposed. These are simply strawmen that are put forward for your consideration and to stimulate your input. We're very anxious to have your comments. Not all of you had a chance to speak, and I know you've got your ideas about this subject. You wouldn't be here if you weren't interested. So, we welcome all your input. I think Belinda, you said if they get their input in by Thanksgiving then your thoughts will be incorporated in the proceedings. The proceedings will be published for all to see and the availability of the proceedings, I assume, will be announced in *The Federal Register*, so the whole country will know about what happened today and they'll be able to read all the words that were said, and so we not only invite, but strongly encourage, your input. As I say, the proceedings will be available.

Belinda mentioned that--and I guess this is where, Charlie, we did listen to you and anticipated the fact that another conference, the 10-year anniversary conference, to be followed by another one in 2005 probably wouldn't cut it--and so we're thinking of having something early in 1996 that won't repeat all that we've said today, but will build upon what we've come to agree upon today--at least I think I'm fair in stating those points of agreement--that will try to build upon where we've come today and the additional input that you'll be providing us and take it from there toward bringing us closer to this system.

In the meantime, the steering committee will be meeting to try to sift through all the comments and further prepare the way for this next public meeting.

The spirit of the group is to be all inclusive and to operate in the open so that everybody who is interested will have a full chance to participate. And may I say, for instance, that any of you who would like to be more active in the working groups that operate in between this conference and the next one, please indicate that. If you want to get more involved than simply getting the proceedings and coming to the next general gathering, then please indicate that in your comments to NIST.

In conclusion, our goal is to work toward consensus, that LAWG activities should continue after today, and that we can, and should, continue to bring together all affected parties to work toward a solution. We sense we have a wide consensus for an over-arching system of some sort that will streamline and make more efficient our present terribly convoluted, duplicative, and costly make-shift system so that we can strengthen the economic position of the United States both domestically and internationally.

And I think, to go back to Jim Johnson's favorite letter, I think the fact that the Vice President has written this is important and that what he has to say is a good note on which to conclude. And he said, as you'll note, "As you proceed in your deliberations, I urge you to seize upon this superb opportunity to make an historical contribution to American competitiveness. We can all succeed by working together to make laboratory accreditation effective in ensuring public health and well being without hampering competitiveness." And the Vice President asks that he be advised of the results of our deliberations, particularly with regard to efforts which should be addressed by this office and, certainly, we will want to be looking to his office to help us as we go forward.

So, again, thank you very much for coming. And I have a comment from Walter.

MR. LEIGHT: I would like to make a suggestion. Besides sending in comments, if you've heard anything you liked, or didn't like, you saw a bunch of people sitting up there who were the heads of the various task groups and, if one of them appeals to you, get in touch with that person and get on that task group.

MR. O'NEIL: You all heard that, and so we do want participation from all the sectors and, as Walter said, choose the one you want and notify that party that you want to get involved.

Thank you.

(Whereupon, at 4:35 p.m., on October 13, 1995, the meeting adjourned.)

APPENDICES

APPENDIX A

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National Institute of Standards and Technology, Gaithersburg, Md.
October 13, 1995

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APPENDIX B

DEFINITIONS

Definitions Paraphrased from ISO Guide 2
(see NIST Handbook 150)

Accreditation (of a laboratory): A formal recognition that a laboratory is competent to carry out specific tests or calibrations or types of tests or calibrations.

Accreditation criteria: A set of requirements used by an accrediting body which a laboratory must meet in order to be accredited.

Assessment (of a laboratory): The on-site examination of a testing or calibration laboratory to evaluate its compliance with the conditions and criteria for accreditation.

Calibration: A set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or system, or values represented by a material measure, and the corresponding known values of a measurand.

NOTES:

(a) The result of a calibration permits the estimation of errors of indication of the measuring instrument, measuring system, or the assignment of values to marks on arbitrary scales.

(b) A calibration may also determine other metrological properties.

(c) The result of a calibration may be recorded in a document, sometimes called a calibration certificate or a calibration report.

(d) The result of a calibration is sometimes expressed as a calibration factor, or as a series of calibration factors in the form of a calibration curve.

Calibration certificate or report: Document that presents calibration results and other information relevant to a calibration.

Calibration method: A defined technical procedure for performing a calibration.

Client: Any person or organization that engages the services of a testing or calibration laboratory.

Competence: The ability of a laboratory to meet the conditions and to conform to the criteria in publications for specific calibration and test methods.

Deficiency: The non-fulfillment of conditions and/or criteria for accreditation.

Error: The difference between the true and measured value of a quantity.

Interlaboratory comparisons: Organization, performance and evaluation of calibrations or tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions.

Scope of accreditation: A document issued by NVLAP which lists the test methods or services, or calibration services for which the laboratory is accredited.

Stability: The ability of a measuring instrument to maintain constant its metrological characteristics.

NOTE: It is usual to consider stability with respect to time. Where stability with respect to another quantity is considered, this should be stated explicitly.

Standard, international (measurement): A standard recognized by an international agreement to serve internationally as the basis for assigning values to other standards of the quantity concerned.

Standard, measurement: A material measure, measuring instrument, reference material or measuring system intended to define, realize, conserve or reproduce a unit or one or more values of a quantity to serve as a reference.

Standard, mutual consent: An artifact or process that is used as a de facto standard by mutual consent of the supplier and customer when no recognized U.S. national or international standard is available.

Standard, national (measurement): A standard, recognized by a national decision, to serve in a country as the basis for assigning values to standards of the quantity concerned.

Standard, primary: A standard that is designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity.

Standard, reference: (See definition of *Reference standard*.)

Standard, secondary: A standard whose value is assigned by comparison with a primary standard of the same quantity.

Standard, transport (or transfer): A standard used as an intermediary to compare standards.

Standard, working: A standard usually calibrated against a reference standard that is used routinely to calibrate or check material measures, measuring instruments or reference materials.

Statistical Process Control (SPC): A systematic process for monitoring the validity of a calibration or the value of a laboratory standard using statistical tools as a basis for decision.

Sub-facility: A laboratory operating under the technical direction and quality system of a main facility that is accredited.

Suspension: Suspension is a temporary removal of the accredited status of a laboratory when it is found to be out of compliance with the terms of its accreditation.

Test: A technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

Test method: A defined technical procedure for performing a test.

Person: Associations, companies, corporations, educational institutions, firms, government agencies at the federal, state and local level, partnerships, and societies—as well as divisions thereof—and individuals.

- **Precision:** The repeatability of measurement data; the similarity of successive independent measurements of a single magnitude generated by repeated applications of a process under specified conditions.

Product: A type or a category of manufactured goods, constructions, installations, and natural and processed materials, or those associated services whose characterization, classification, or functional performance is specified by standards or test methods.

Proficiency testing: The determination of laboratory performance by means of comparing and evaluating calibrations or tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions.

Quality audit: A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

NOTE: The quality audit typically applies, but is not limited, to a quality system or elements thereof, to processes, to products, or to services. Such audits are often called "quality system audit," "process quality audit," "product quality audit," or "service quality audit."

Quality manual: A document stating the quality policy, quality system, and quality practices of an organization. The quality manual may reference other laboratory documentation.

Quality system: The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Quality system review: A formal evaluation by management of the status and adequacy of the quality system in relation to quality policy and new objectives resulting from changing circumstances.

Reference material: A material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, for the assessment of a measurement method, or for assigning values to materials. A "certified reference material" means that one or more of the property values of the reference material are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.

Reference standard: A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

Requirement: A translation of the needs into a set of individual quantified or descriptive specifications for the characteristics of an entity in order to enable its realization and examination.

- **Resolution:** The smallest discrete or discernible change in a value that can be measured.

Revocation: Revocation is the removal of the accredited status of a laboratory when it is found to have violated the terms of its accreditation.

Influence quantity: A quantity which is not the subject of the measurement but which influences the value of the measurand or the indication of the measuring instrument. Examples: ambient temperature; frequency of a measured alternating voltage.

Laboratory: An organization that performs calibrations and/or tests. When a laboratory is part of an organization that carries out activities additional to calibration and testing, the term "laboratory" refers only to those parts of that organization that are involved in the calibration and testing process. The laboratory activities may be carried out at or from a permanent location, at or from a temporary facility, or in or from a mobile facility.

NOTE: NIST further defines "laboratory" as being a physical entity; that is, a testing or calibration facility that is separate and apart physically from any other laboratory whether or not sharing common ownership, management, or quality systems with any other laboratory(s).

Laboratory accreditation body: Body that conducts and administers a laboratory accreditation system and grants accreditation.

Laboratory accreditation system: System that has its own rules of procedure and management for carrying out laboratory accreditation.

Limits of permissible error (of a measuring instrument): The extreme values of an error permitted by specifications, regulations, etc., for a given measuring instrument.

NOTE: This term is frequently referred to as "tolerance" in the United States.

Measurement: The set of operations having the object of determining the value of a measurand.

Measurement assurance: A process to ensure adequate measurement results that may include, but is not limited to: 1) use of good experimental design principles so that the entire measurement process, its components, and relevant influence factors can be well characterized, monitored, and controlled; 2) complete experimental characterization of the measurement process uncertainty including statistical variations, contributions from all known or suspected influence factors, imported uncertainties, and the propagation of uncertainties throughout the measurement process; and 3) continuously monitoring the performance and state of statistical control of the measurement process with proven statistical process control techniques including the measurement of well-characterized check standards along with the normal workload and the use of appropriate control charts.

Measuring and test equipment: All of the measuring instruments, measurement standards, reference materials, auxiliary apparatus and instructions that are necessary to perform a measurement. This term includes measuring equipment used in the course of testing and inspection, as well as that used in calibration.

Measuring instrument: A device intended to make a measurement, alone or in conjunction with supplementary equipment.

NIST: The National Institute of Standards and Technology.

NVLAP: The National Voluntary Laboratory Accreditation Program. NVLAP is an Office within the National Institute of Standards and Technology.

Testing **laboratory:** A laboratory which measures, examines, tests, calibrates or otherwise determines the characteristics or performance of products or materials.

- **Traceability:** Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

Traceability of the accuracy of measuring instruments: A documented chain of comparison connecting the accuracy of a measuring instrument to other measuring instruments of higher accuracy and ultimately to a primary standard.

Uncertainty of measurement: Parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand.

Uncertainty, Type A (evaluation of): Method of evaluation of uncertainty by the statistical analysis of series of observations.

Uncertainty, Type B (evaluation of): Method of evaluation of uncertainty by means other than the statistical analysis of series of observations.

Verification: Confirmation by examination and provision of evidence that specified requirements have been met.

APPENDIX C

ACIL STATEMENT ON ESSENTIAL CHARACTERISTICS

ESSENTIAL CHARACTERISTICS OF A U.S. LABORATORY ACCREDITATION SYSTEM

ACIL (formerly the American Council of Independent Laboratories) believes that the United States needs an efficient and effective laboratory accreditation system that incorporates the following characteristics.

1. **Reciprocity and common standards.** Qualified accreditors operating in the same field must recognize each other's accreditations, within the limits of the special needs of an industry or a government program. Common use of generally accepted international accreditation standards will make this reciprocity possible

2. **Shared governance.** Within a given accreditation program, all stakeholders - laboratories, users, government, and accreditors, among others - should share in the decisions and the policy-making process.

3. **Principally private sector.** There is nothing inherently governmental about laboratory accreditation. And there is ample expertise in the private sector to conduct accreditations of all types.

4. **Government oversight.** The spirit of the National Research Council's recommendation should be honored: namely, that the National Institute of Science and Technology (NIST) be given authority to "organize" the U.S. accreditation system so that all are treated fairly and duplication is eliminated. (Cf., "Standards, Conformity Assessment, and Trade into the 21st Century," copyright 1995, The National Academy of Sciences) The government role is to coordinate the accreditation system and ensure international recognition of U.S. accreditations.

5. **Adequate funding.** It is important that there be sufficient funds to enable accreditors to meet high standards for thoroughness and quality. One essential component is a cadre of well-qualified and well-trained assessors. Ideally, the costs of accreditation should be shared among laboratories, accreditors and users.

ACIL represents approximately 2000 U.S. laboratories.

October 13, 1995

APPENDIX D

A STAKEHOLDER'S VIEW OF ACCREDITATION

OPEN FORUM ON LABORATORY ACCREDITATION

A STAKEHOLDER'S VIEW OF ACCREDITATION

MARYLAND DEPARTMENT OF HEALTH & MENTAL HYGIENE

OCTOBER 13, 1995
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QUALITY, RELIABLE DATA

SIMPLIFICATION

ONE STOP SHOPPING

RECIPROCITY

UNIFORMITY

EFFICIENCY

Accreditation Responsibilities: Environmental

Safe Drinking Water Act (Primacy) Certification of laboratories testing (Maryland) drinking water.

Accreditation/Certification Required: Environmental

Safe Drinking Water Act (Primacy) Certified by EPA Region III.

National Water Quality Reviewed by US Dept. of the Interior, Geological Survey.

Fluoridated Drinking Water Monitored by US Dept. of Health& Human Services, Centers for Disease Control, Dental Disease Prevention Activity.

Bulk Asbestos Fiber Accredited by US Dept. of Commerce, NIST, NVLAP.

PCB Analysis Validation by EPA, Office of Enforcement, National Enforcement Investigations Center.

Federal Water Pollution Control Act - Chesapeake Bay Program Nutrients, etc. Monitored by EPA Consortium.

National Radon Measurement Program Reviewed by EPA Radon Division, Office of Radiation Programs.

Radiochemistry Program Certified by EPA EMSL, Las Vegas, NV.

Proficiency Analytical Testing Program Certified CDC, NIOSH, Administered by AIHA.

Environmental Lead Laboratory Accreditation (ELPAT) Accredited By AIHA Through EPA & NIOSH.

Milk Program (Phosphatase) Monitored by Dept. of HHS, Food and Drug Administration.

Fish Tissues & Sediments Round Robin Sponsored by Dept. of Commerce, National Oceanic and Atmospheric Administration, National Status and Trends Program For Marine Environment Quality.

Accreditation Responsibilities: Public Health

Clinical Laboratory Act of 1988 Regulates all medical laboratory testing despite location of testing.

HCFA delegates responsibility for inspection, enforcement of regulation and recommendation for licensure to the State Health Department.

HCFA also reimburses the State for licensure activity. When the State has its own laboratory licensure of medical laboratories, then HCFA reimburses the State at 50% of cost.

Maryland Medical Laboratory Licensure Law This Law is consistent with CLIA-88 Act. The State of Maryland is not permitted to have laws/regulations more stringent than federal laws/regulations in this arena.

Maryland Blood and Tissue Banks Licensure Laws These Banks include all body tissues and human sperm. These regulations are used to protect individuals from infectious disease transmission through human tissues and to prevent serious reactions resulting from transplant of tissues that are not adequately tested for incompatibilities.

Forensic Chemistry Laboratory Oversight Certify chemist/analyst and approve procedures used in crime laboratories of police departments in cities, counties and State for the analyses of controlled dangerous substances (CDS).

Newborn Screening for Hereditary Disorders Any laboratory that screens newborns for these disorders must be licensed, specifically, for this purpose.

APPENDIX E

U.S. INDUSTRY TASK WORKING GROUP REPORT SUMMARY

U.S. Industry Report Summary

October 13, 1995

The U.S. Industry Working Group on laboratory accreditation is composed of manufacturers and service providers with ties to national industry associations. A broad spectrum of U.S. industry is represented:

- automotive
- chemical
- computer
- cosmetics
- electronic
- furniture
- heavy equipment
- medical
- petroleum
- pharmaceutical
- plastics
- primary metals
- telecommunications
- textiles
- and others...

The Working Group was formed to identify laboratory accreditation problems facing the industry and to articulate the elements of an acceptable solution. This summary focuses on the key elements of that solution.

CONTEXT: It is the view of this Working Group that laboratory accreditation must be considered within the larger context of conformity assessment. To that end, we articulate U.S. Industry's vision as follows.

VISION: Worldwide acceptance of products, processes and services based on a supplier's declaration of conformance to **one** standard based on **one** assessment.

VALUE: Laboratory accreditation has value to the industry when and only when it satisfies a market need. This need may take two forms; either a customer demand or a legal requirement. *Superior* value is demonstrated when data is accepted worldwide from a laboratory having **one**, low cost, accreditation.

THE NEED: An internationally credible architecture supporting laboratory accreditation as part of a unified U.S. conformity assessment system which:

- Gains both domestic and international acceptance of test results
- Eliminates duplication of Federal, State and Local systems
- Utilizes private sector resources
- Recognizes the validity of a supplier's declaration
- Identifies a single US government entity for recognizing accreditors
- Gives equal standing to manufacturers' labs and independent test labs
- Takes a non-sectoral approach.

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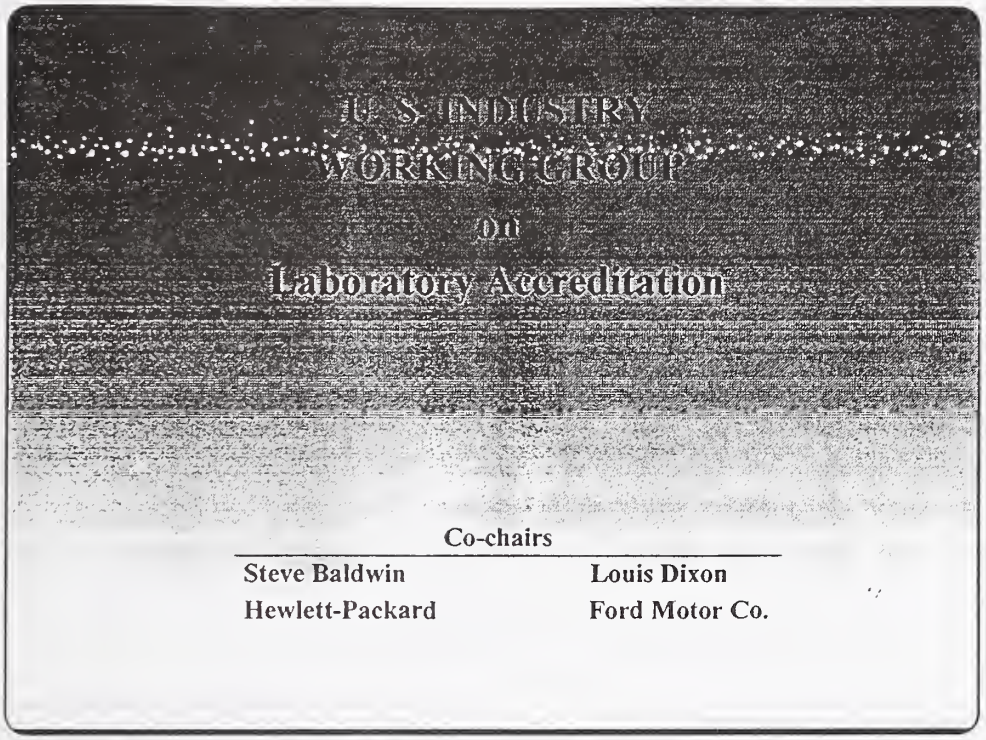

U. S. Industry Working Group

A Common Vision:

Our reputation is the basis for *customer acceptance* of our products and services

Third parties are used at *our* discretion

U. S. Industry Working Group

Our Vision:

WORLDWIDE acceptance of:

- ***Products, Processes and Services*** based on ***Supplier's Declaration*** of conformance
- to ***One Standard***
- based on ***One Assessment***

U. S. Industry Working Group

Value:

Laboratory Accreditation has *Value* to the Industry when, ***and only when***, it satisfies a market need*:*

- *Customer Demand* or
- *Legal Requirement*

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U.S. Industry Working Group

Superior Value Demonstrated:

WORLDWIDE acceptance of ***TEST DATA***:

from any Laboratory having

a Single, Low Cost, **accreditation**

s baldwin, i:\data\pre\awg.pre, rev: 5 October 1995

U.S. Industry Working Group

The Need:

An *Internationally credible architecture* supporting ***lab accreditation*** as part of a unified ***U.S. Conformity Assessment System*** which:

- Gains Domestic & International Acceptance of Test Results
- Eliminates duplication of Federal, State and Local systems
- Utilizes private sector resources
- Recognizes the validity of Supplier's Declaration
- Identifies a single U.S. entity for recognizing accreditors
- Gives equal standing to manufacturer's & independent labs
- Takes a Non-Sectoral approach

s baldwin, i:\data\pre\awg.pre, rev: 5 October 1995

U. S. Industry Working Group

The Need:

An *Internationally credible architecture* supporting *lab accreditation* as part of a unified *U.S. Conformity Assessment System* which:

- Gains Domestic & International Acceptance of Test Results
- Eliminates duplication of Federal, State and Local systems
- Utilizes private sector resources
- Recognizes the validity of Supplier's Declaration
- Identifies a single U.S. entity for recognizing accreditors
- Gives equal standing to manufacturer's & independent labs
- Takes a Non-Sectoral approach

s baldwin, I:\data\prev\awg.pre, rev: 5 October 1995

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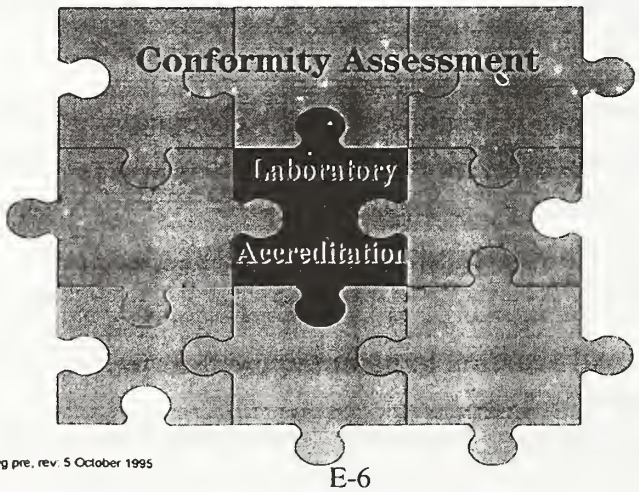
Context:

Laboratory Accreditation must be considered within the larger context of Conformity Assessment



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We Need:

A Defined and Recognized

U.S. Conformity Assessment System

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Characteristics:

U.S. Conformity Assessment to be characterized by:

- International Standards
- Clearly defined options (paths)
- Options/Paths determined by Buyer & seller

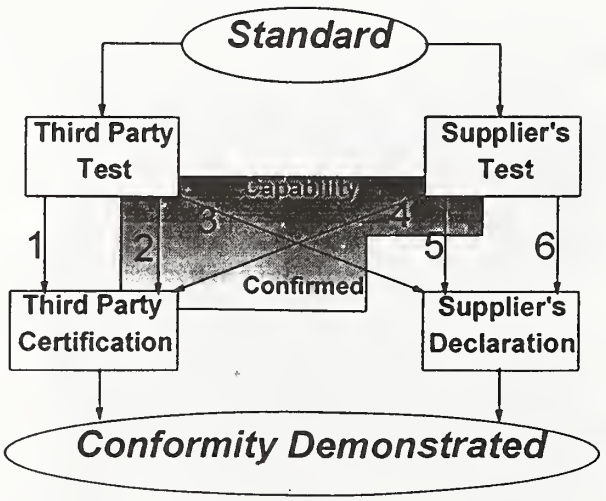
s baldwin, i:\data\pre\awg.pre, rev: 5 October 1995

Conformity Assessment

There is **no single solution**, but...

there *may* be a **single architecture**

Six Routes to Conformity Demonstration:



APPENDIX F

A CONCEPT FOR ESTABLISHING MUTUAL RECOGNITION

U.S. LABORATORY ACCREDITATION COOPERATION

A CONCEPT FOR ESTABLISHING MUTUAL RECOGNITION OF COMPETENT LABORATORIES IN THE UNITED STATES

BY

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OPEN FORUM

NIST
GAITHERSBURG, MARYLAND
OCTOBER 13, 1995

USLAC BASED ON AN INTERNATIONAL MODEL

ILAC DRAFT GUIDELINES FOR ESTABLISHMENT AND
REVIEW OF MUTUAL RECOGNITION AGREEMENTS (MRAs)

- FIRST DRAFT, ILAC 88
- FOURTH DRAFT, ILAC 94

BASIS FOR THE WECC AND WELAC MRAs
NOW IMPLEMENTED BY EAL
NOW BEING IMPLEMENTED BY APLAC
NOW BEING IMPLEMENTED WITH MODIFICATION BY IAF

BASIC CONCEPTS:

- ALL ACCREDITATION BODIES USE ISO/IEC GUIDE 25 TO ASSESS AND ACCREDIT LABORATORIES
- ALL ACCREDITATION BODIES MEET ISO/IEC GUIDE 58 AND HAVE A DOCUMENTED QUALITY SYSTEM
- ANY ACCREDITATION BODY AND/OR USER OF ACCREDITATION BODIES WILLING TO COOPERATE CAN SIGN THE MEMORANDUM OF UNDERSTANDING (MOU)
- ACCREDITATION BODIES SEEKING MUTUAL RECOGNITION MUST BE WILLING TO BE ASSESSED BY KNOWLEDGEABLE ASSESSORS FROM MOU MEMBERS
- MOU MEMBERS VOTE ON ACCEPTANCE OF ASSESSED BODIES BASED ON ASSESSOR REPORTS AND ASSESSED BODY RESPONSES

USLAC MOU MEMBERS

FIVE US LABORATORY ACCREDITATION SYSTEMS HAVE SIGNED THE U.S. MOU

- AIR MOVEMENT AND CONTROL ASSOCIATION, INC. (AMCA)
- AMERICAN ASSOCIATION FOR LABORATORY ACCREDITATION (A2LA)
- AMERICAN INDUSTRIAL HYGIENE ASSOCIATION (AIHA)
- INTERNATIONAL SAFE TRANSIT ASSOCIATION (ISTA)
- NATIONAL EVALUATION SERVICE (NES)

A MUTUAL RECOGNITION AGREEMENT COMMITTEE HAS BEEN FORMED AND THE ILAC MRA REQUIREMENTS DISTRIBUTED FOR REVIEW AND ADOPTION.

ASSESSMENTS OF WILLING APPLICANTS CAN BEGIN AS SOON AS THE MRA REQUIREMENTS ARE AGREED

THE U.S. MOU -- USLAC

MEMBERSHIP

- STATES AND FEDERAL AGENCIES WITH REGULATORY RESPONSIBILITIES
- PRIVATE SECTOR BODIES WHICH SPECIFY THE USE OF ACCREDITED LABORATORIES
- LABORATORY ACCREDITATION SYSTEMS WILLING TO SEEK COOPERATION
- SUCH OTHER MEMBERS AND OBSERVERS AS SHALL BE INVITED BY THE COMMITTEE

USLAC MEMBERS SHALL ELECT A CHAIRMAN AND SECRETARY FROM AMONG ITS MEMBERS -- MAXIMUM TERM OF THREE YEARS

15 OBJECTIVES DEFINED: FROM IMPROVING THE QUALITY OF TESTING TO IMPROVING HARMONIZATION IN LABORATORY REQUIREMENTS TO ESTABLISHING THE BASIS FOR RECOGNITION IN OTHER PARTS OF THE WORLD

* U.S. GOVERNMENT PRINTING OFFICE: 1996-404-525/57927

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