TRANSATLANTIC REGULATORY HARMONIZATION AND GLOBAL STANDARDS

21st Century Challenges and Opportunities for Regulatory Policy Cooperation, Cross-Border Competition and Global Market Governance in North America and Europe

The George Washington University
School of Business and Public Management
In cooperation with The Katholieke Universieteit Leuven
The University of Toronto
National School of Public Administration – ENAP
Pembroke College – Oxford University

and

The German Marshall Fund of the United States
Pfizer
The Ford Motor Company
Daimler-Chrysler Corporation
America Online (AOL)
Barclays Bank (UK)
Deutsche Telekom
The National Institute of
Standards and Technology (NIST)

January 2001

Conformity Assessment in the North American Market: 21st Century Challenges and Opportunities

Belinda Collins
Technical Standards, Certification and Conformity
NIST
Gaithersburg, Maryland

It is a pleasure to be here and to have a chance to talk to you about conformity assessment, this time from a North American, and in fact, a US perspective. I am Belinda Collins from NIST, the Director of the Office of Standard Services at NIST. I will focus a bit more on the voluntary sector than the regulatory sector.

I think it is fair to say that everyone has seen conformity assessment as a major challenge for trade facilitation. Let me explain very briefly, although I suspect that I am preaching to the choir. Conformity assessment refers to the process of determining that a product, service, or system conforms to standards or regulations. This process can be the most expensive and complex part of applying a standard or regulation. Very often, we find a great deal of problems with overlapping, duplicative and conflicting conformity assessment requirements, particularly as we try to coordinate across the Atlantic, or even north and south within North America. There is certainly growing concern that some of these requirements increase the cost of doing business without adding much in the way of value.

On the other side, if there were coherence in the requirements, either regulations or standards or both, and acceptance of the results, then free trade would be facilitated. So our challenge as we go into the 21st century is to find effective and cost-effective pathways to support both trade, regulatory cooperation and consumer protection. As Philippe Meyer from the EU Commission has pointed out, there are a number of pathways to support trade, such as government-to-government agreements, and mutual recognition agreements such as US-EU MRAs. Likewise, there is an emerging MRA in the telecom sector in APEC -- the Asia Pacific Economic Cooperation regional framework.

At this point I will describe conformity assessment arrangements that exist between a variety of national and international bodies and agencies. These arrangement are voluntary, but can be used to facilitate trade. Obviously, there may be direct recognition of tests and certificates, and we have heard a great deal about suppliers' declarations of conformity. However, the confidence of the regulatory and procurement authorities is critical because they have to believe in it if conformity assessment and MRAs are going to be implemented. "What are we talking about when we refer to conformity assessment?" We are talking first about certification, in which we do many type evaluations. For example, we evaluate a product, and then verify that the rest of the line conforms through sampling and inspection. All of these things are done to make sure that the product conforms to applicable standard. As Philippe Meyer noted, on both sides of the Atlantic the standards and regulations often differ making life extremely complicated.

Although this probably will not be talked about much this week, we do certify personnel for a variety of activities, ranging from qualifications for being a medical doctor on down. NIST conducts registration of management systems on this side of the Atlantic, we also do certification. We register both quality and environmental management systems, e.g., ISO 9000, to ensure that a process is reliable, and that the system produces the same kind of product every time. At a higher level, we conduct laboratory accreditation whereby there is oversight of a testing or calibration laboratory by an accreditation body, as well as accreditation of providers of certification, and of registration at the product level for the management system. While there are various ways to instill confidence in different types of conformity assessment, the user typically decides what he or she needs to meet his requirements. That choice complicates our lives as we try to facilitate free trade.

In the US, we have thought a great deal about different types of conformity assessment systems. In the first part of the supplier's declaration, the supplier tells you that the product conforms to the standard. But, I will show you some ways of relating this to both risk and cost as a means of facilitating the decision you might make. For second party insurance, the customer directly assesses a supplier's product or systems. This is very common in government procurement arrangements, especially large volume purchases, where the Department of Defense, for example, might go in and audit a particular supplier. Finally, in "third party" arrangements, an independent assessment is made in a similar way when a certifier evaluates a product for conformance to a standard, or someone evaluates a firm for its ability to follow ISO 9000 or 14000 standards.

Each of these certification options obviously differs in value and significantly in cost, however choice has been driven in what might appear to be a slightly haphazard fashion. If you are dealing with an explosive environment, you are far more concerned about risks, than if you evaluate the quality of pencils and paper. Nevertheless, cost is obviously a very important thing: industry doesn't wish to be audited 15 different times for the same type of product. Therefore the supplier/customer relationship must be viewed with respect to whether the customer has dealt with supplier X for a long time. You may already have a certain degree of confidence in that supplier, and you may even have established your own audit procedures. Furthermore, there are also different types of regulatory requirements at the federal, and state levels, at least in the United States.

Consequently, if governments and industries are going to adopt a conformity assessment system, from the very beginning, we have to evaluate the cost, benefit, and value. While, the first party supplier's declaration of conformance is clearly appropriate for low-risk products, we have to determine what those products are. Second party situations rely on a direct relationship between the customer and supplier, particularly for procurement, and much less obvious, for regulatory relationships. Third party assurance is appropriate for both regulators and industrial customers for products and services that are high-risk. While this is an easy thing to say, it is much harder to implement at the national, regional, and global levels.

I am indebted to my colleagues at the American National Standards Institute, Company Member Council for their input on this issue. There are several types of conformity assessment: first party, second party, third party, along with the relative cost and value. This is certainly true for medical devices and drugs, and I think it is clear that the consumer, producer, and indeed everyone is extremely concerned that these products comply with standards. Therefore, customers and suppliers are willing to tolerate extensive third party assessment, because although the cost is high, the value is at least equally high. You can imagine though, with my paper and pencil example--you really don't want to go into third party evaluation because the benefit isn't that high. But this is an attempt to put some perspective on conformity assessment. Ideally, as we go forward in time, we would be far better off if we were able to fit examples and procedures to these various risks and costs.

Still another major player in conformity assessment, once you've defined what you're talking about and thought about the level of risk and value, is who is going to accept it? In some cases, it depends directly on the customer. In other cases, government resorts to regulation and procurement. Often, as noted earlier in high-risk cases and sometimes in not so high-risk cases, you rely on the assurance of a third party, an accredited body through agreed upon arrangements. I will talk about some activities that I am personally aware of in laboratory accreditation and with foreign governments through the MRA's that Philippe spoke about.

Since Philippe has described this in great detail, let me just cite the US-EU MRA, which I know we'll be talking about as we go through today, tomorrow, and the next day. Again, the point of all of this is mutual recognition of the results of conformity assessment procedures performed in one country to meet the requirements of the other country. Critical in all of this is that, very often, national standards and regulations differ. This whole process will be a lot simpler if we can achieve the TABD goal of one standard, one test, but we are not there yet. Nevertheless, there are large numbers of people involved: regulatory authorities on both sides of the Atlantic, designating authorities, accreditors, conformity assessment bodies (known as CAB's) and, of course, manufacturers. All of this requires an evaluation of competence to meet governmental requirements in the US and in the EU.

NIST is actively involved in all of this. While the Department of Commerce and NIST participated in the negotiations for the MRU, NIST is in fact a designating authority under the MRA. As a result, we are busy trying to identify qualified US conforming assessment bodies to ensure initial and continuing competence to meet the European regulatory requirements under the MRA. As part of this role, we assist various federal agencies, including the Food and Drug Administration, the Federal Communications Commission and the Coast Guard. Since NIST is a technical agency, we look at the technical competence of an applicant laboratory to meet the EU requirements. This means that we have to know, and make sure that they know the European requirements, and then we conduct a technical assessment.

We are making definite progress in implementing the medical devices annex, but we are not moving as rapidly as in other areas. The key factors in all sectors include full understanding of requirements by all affected parties. The Conformity Assessment Bodies (CABs) on both sides of the Atlantic must know and understand all procedures, regulations, rules, etc.

Let me move now to an area with which I am much more familiar, namely laboratory accreditation. You may ask why I am going to spend so much time on this, but I think that this can be a building block toward greater confidence across the Atlantic. NIST focuses on the quality of the laboratory data, both within a country and across borders. Laboratory accreditation is a process of evaluating a laboratory to make sure that staff know the appropriate test procedures for the product and can be expected to apply those procedures correctly every time they do it. This process also ensures that a laboratory has a quality system in place. In this respect, laboratory accreditation is an extension of regulatory programs. In fact, what we do at NIST in this arena is largely in response to regulatory requirements from agencies ranging from the Nuclear Regulatory Commission, the Federal Communications Commission, and EPA for asbestos testing. In this context, you incorporate the regulatory concerns into the evaluation and regulatory criteria for the laboratory.

Laboratory accreditation is also an aid for procurement purposes. To use some NIST example, trivial ones perhaps, but we've evaluated the testing of carpets for conformance to requirements for the Housing and Urban Development Department and electric motors for the Department of Energy. Such programs can support inter-governmental agreements. While this is slow to materialize, it is certainly an opportunity for the future. Most recently, this concept is being used in the APEC region.

For many years the International Laboratory Accreditation Cooperation (ILAC), has tried to bring together the accreditation bodies of 40 or more economies around the world. While most economies though not the United States, usually have a single national body. ILAC promoted the use of international guides and standards by all accreditation bodies. As a result, there is now a uniform approach to accreditation. These guides and standards are sometimes incorporated into regulation. This uniform approach to laboratory accreditation ensures consistency, and will facilitate a regulatory authority and consumer confidence.
ILAC uses the term MRA, but the A here is "arrangement" - this MRA is not an intergovernmental assessment. But again, it facilitates acceptance of test and collaboration data across borders and helps to increase confidence. ILAC provides important guidance and information, and has accomplished a great deal for a 20 years. It was actually started as an initiative of the US Department of Commerce to provide some guidance and information on what laboratory accreditation is, extend outreach to developing nations and anyone in need of information, and promote widespread compliance with the internationally agreed criteria. Typically, these are ISO standards and guide lines agreed upon for the laboratory accreditation process. This obviously includes,

appropriate traceability and statements of uncertainty so that you can be confident that the measurements are reasonably correct. It also provides a means of being sure that the members who have been recognized are indeed competent. In the long run, this can lead to international recognition and diminished barriers to trade.

ILAC is in the process of developing an international arrangement to recognize laboratory accreditation bodies across the world. We have emerging efforts in Europe and Asia, but there are also active programs in North America, South Africa, and in South and Central America. So, if this works as intended, it will provide a level of confidence that regulators can use. At the same time, in the United States, we have a complicated system, because we estimate that there are about 150 accrediting bodies in this country. Many of these bodies are very, very narrow and sector specific, but they support both government and industry. For example, car manufacturers in the United States use laboratory accreditation as one of their way of establishing confidence in the suppliers.

NIST, the American Council of Independent Laboratories (ACIL), and the American National Standards Institution, several years ago decided to attack some of the duplication and overlap in domestic laboratory accreditation. We developed the National Cooperation for Laboratory Accreditation, NACLA, which is designed to do for the United States some of the things that ILAC does at the international level ie, coordination information training, and more importantly, recognition of competent accreditors. At the end you'd be able to say that a NACLA-recognized accreditor is a valid entity for you to consider for your procurement or for your regulations. In response to North America throughout the whole evolution of NACLA, we had regular observers from both Canada and Mexico because there are issues relative to cross-border data acceptance. Likewise as well as the desire to make what we do work throughout North America and, in fact across the rest of the world is important.

Our intent is to coordinate the multiple US programs, reduce duplication, reach agreement on the standards, ISO Guides 25 and 58 and 43 for example, so that you can be assured that appropriate proficiency testing has been used, etc. The bottom line is assurance that the accreditor is competent, and that you can believe in the data from accredited labs. The US Government has been heavily involved in NACLA along with a variety of federal regulators and procurement agencies. More important is the fact that accreditation is still evolving.

In conclusion, as we think about the 21st century, we see a huge number of challenges. Obviously, we need to be sure that we can achieve recognition of North American and US conformity assessment results in both the regulatory and voluntary spheres without adding large additional costs or new regulations. In all of this, protection of health, safety and the environment is critical, and serves to reinforce consumer needs. At the end of the day, we'd like to know that we can ensure and support the free flow of certified goods and services across borders and throughout the world. Thank you very much.

These slides 1-17 are from Belinda Collins's slide show presentation.

1

Conformity Assessment in North America

Belinda L. Collins, Ph.D.
Office of Standards Services
National Institute of Standards and Technology

2

Challenges for Trade Facilitation

- Overlapping, duplicative, and conflicting conformity assessment requirements can raise the cost of doing business with no added value
- Coherence in requirements and acceptance of results can facilitate trade
- Challenge: to find effective, cost-effective pathways to support trade and regulatory needs

3

Pathways to Support Trade

- Government to Government Agreements
- Cooperative arrangements by conformity assessment bodies, including accreditation as basis for acceptance of results
- Direct recognition of tests, certificates, etc
- Suppliers Declaration of Conformance
- Confidence of regulatory authorities critical

4

Types of Conformity Assessment

- Certification
  - Products (Type evaluation/sampling, inspection)
  - Personnel qualifications
- Registration
  - Quality/environmental management systems
- Accreditation
  - Testing and Calibration Laboratories
  - Providers of certification and registration

5

Conformity Assessment Systems

- Systems applied to each type
  - First party - Supplier's declaration
  - Second party - Customer assesses supplier
  - Third party - Independent assessment
- Each differs in value and cost
- Choice of system driven by
  - Hazard, cost, supplier/customer relationship, and possible regulatory requirements

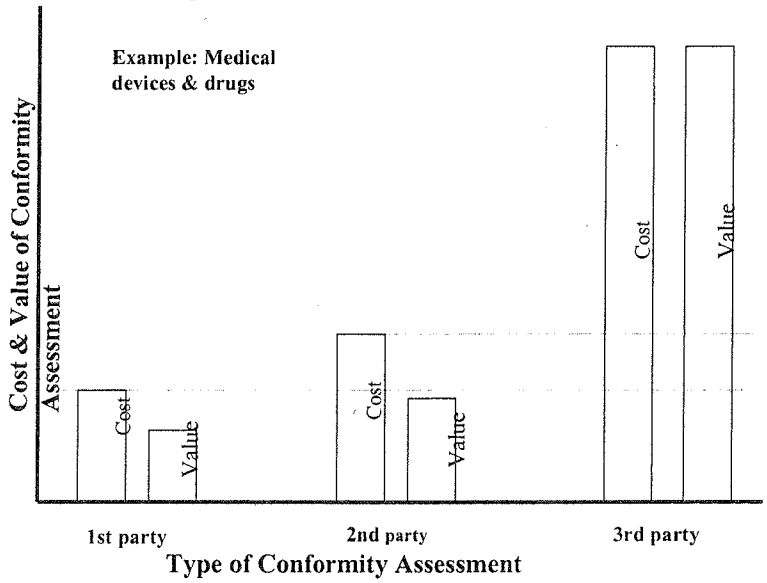
6

Application of Conformity Assessment Systems

- Evaluate cost and benefit/value
  - First party appropriate for low risk
  - Second party appropriate for direct relationship between customer and supplier (e.g., procurement)
  - Third party appropriate for regulatory or industrial customers for products/services that are high risk

7

Cost & Value of Conformity Assessment High Risk Products & Services



8

Acceptance of Conformity Assessment Processes

- Direct by customer
- Government
  - Regulation
  - Procurement
- Rely on assurance of third-party
  - Accrediting body - through arrangements
  - Foreign Government - through MRAs

9

U.S./EU Mutual Recognition Agreement (MRA)

- Mutual recognition of results of conformity assessment procedures performed in the exporting country to meet regulatory requirements of the importing country
- Actors: regulatory authorities, designating authorities, accreditors, conformity assessment bodies (CABs), manufacturers
  - requires evaluation of competence to meet governmental requirements

10

NIST As Designating Authority

- Identifies qualified CABs and assures their continued competence to meet European regulatory requirements under the MRA; assisting Federal Agencies
- Assesses the technical competence of applicant CABs to meet EU requirements
- Acts primarily at the recognition level by assessing the competence of accreditors of laboratories, certifiers or quality system registrars

11

Status of MRA Implementation

- Test reports are beginning to flow between the U.S. and EU, under the provisions of the EMC and telecom annexes
- Significant disagreements continue over implementation of the electrical safety annex - no movement in this area
- Implementation of the medical devices annex is on a slower track than the others

12

Arrangements for Laboratory Accreditation

- Confidence in laboratory data across borders
- Extension to regulatory programs
  - Incorporate regulatory concerns into evaluation and recognition criteria
- Aid for procurements
- Support for inter-governmental agreements

13

International Laboratory Accreditation Cooperation - ILAC

- Recognized laboratory accreditation bodies in many economies
- International guides and standards - basis
  - Provides uniform approach
  - Ensures consistency
  - Facilitates user/stakeholder confidence
- Mutual Recognition Arrangements to enable acceptance of test/calibration data

14

ILAC PROVIDES

- Guidance and information on laboratory accreditation; outreach
- Compliance with internationally agreed criteria, including appropriate traceability and uncertainty
- Confidence in competence of members
- International recognition and diminished technical barriers to trade

15

U.S. Laboratory Accreditation

- 150 accrediting bodies
  - largely sector specific
  - both government and industry
- National Cooperation for Laboratory Accreditation - (NACLA)
  - Coordination
  - Information and training
  - Recognition of competent accreditors

16

NACLA

- Coordination of multiple U.S. programs and sectoral approaches and needs
  - Reduced duplication
- Agreement on standards and cross-cutting requirements
- Assurance that accreditor is competent and that data from accredited labs are sound
- Government use and participation
  - Leverage resources

17

The 21st Century

- Achieve recognition of U.S. and North American conformity assessment results without adding significant cost or regulation
- Continue to protect health, safety, and the environment effectively
- Ensure and support the free flow of goods and services globally