3rd Party Testing Laboratories
July 25, 2000

UL	How firm is NIOSH thinking on the format, are they open to suggestions? Yes we are open to suggestions
UL	How is NIOSH draft rule related to NIST Part 15 (15 CFR 277 or 278?)? NIOSH following same process, NIST encourages government agencies to use ISO accredited labs.
UL	How is NIOSH draft rule related to international QA requirements? Rich–NIOSH is looking for feedback on how to best handle this. Products would have to meet Part 84 requirements for performance and QA.
UL	Industry seems to favor both 3rd party labs that can perform both NIOSH and international testing as well as process approvals. Rich-NIOSH is not proposing to allow approval bodies to issue NIOSH approvals.
Matt	How do labs feel about NIOSH or other accredited bodies auditing 3rd party labs?
ICS	You need both ISO or A2LA accredited lab reviews as well as technical reviews by NIOSH to cover both administration and technical requirements.
UL	NIOSH should also consider design controls when looking at QA requirements
Matt/Rich	This is inherent to NIOSH requirements, just not spelled out in overheads. Part 84 does list QA requirements as does ISO 9000.
UL	Technical experts should be included in QA audits to make sure testing/technical requirements are met as well as just checking on QA requirements.
ICS	Lead assessor should be certified by NIOSH in knowing product. Perhaps 1 accredited auditor and 1 technical expert per team.
UL/ICS	We can mandate that they know industry specific requirements and have technical competence.
Roland	Part 84 has performance, QA, and inspection requirements now. Manufacturers have some flexibility to do "equivalent" tests. How would 3rd party labs handle this.

UL Could either subcontract some testing? 1. Pre-market approval process (NIOSH approval/verification activities) 2. Post-market surveillance (continued manufacturer conformance) and 3. Product or lot sampling (storage and field)

A2LA Does NIOSH look at contracted labs or vendors?

Matt-Rich Currently no our regulations only cover the approval holder.

Does NIOSH have any test outlined for the proposed contracted labs?

Matt/Roland Looking at pilot program using labs for testing, taking accredited labs and allowing them to use our STP's, NIOSH requires pretest prior to submission

Roland We are not looking to certify 3rd party labs. We are looking to incorporate the use of 3rd party labs and auditors into the NIOSH approval process.

ICS 3rd party labs has to keep a distinction between pre-submission testing and approval testing if the same lab is used.

UL We have to prevent lab shopping. Going to lab after lab until they get passing test results.

ICS When a submission is made for certification, not pretest data, NIOSH should be notified of failures.

ICS NIOSH should consider requiring any manufacturer that uses 3rd party labs for pre-test data to notify NIOSH of test results pass or fail. That way NIOSH is aware of any failures and can handle them accordingly. This data should be maintained in a database that all interested parties would have access to.

Roland Has concerns about confidentiality and sharing of test data especially failures among all test labs.

ICS In order for this system to work, all parties would have to operate under a confidentiality clause, therefore all parties must protect data not misuse it.

UL International approvals do not require the confidentiality concerns that ICS is proposing

UL Discussion on European approval process–Mike Savarin points out this model is not relevant since NIOSH is not looking for 3rd parties to issue approvals.

Sandy Need clarification on who picks the test lab for certification testing. Is it NIOSH or the Manufacturer?

Rich This decision is not yet made and we are still considering input from stake holders. This is not yet a closed model. We haven't made any final decisions on how this process would work.

Discussion on correlation testing at NIOSH–What is it?

Also discussion on what CE (European) process does.

Matt Some manufactures have their own labs. How does this fit into proposed process?

UL In CE process as well as some other domestic approval programs, UL witnesses every test to ensure technical competence. This includes a full assessment and audit prior to witnessing testing (is equipment calibrated, ability, personnel)

Discussion...it is important to be technically competent in order to witness testing.

Matt Lab accreditation issues

A2LA Everyone must conform to same requirements. A2LA has 1300 accredited labs. They have agreements with European and pacific RIM countries.

A2AL Guide 25 and now 17025

A2LA Discussion on accreditation process

UL UL does accredit others but is somewhat cynical about what value accreditation gives to companies and manufactures.

It will be important for NIOSH to identify technical requirements and give them to the accrediting body. 17025 is an acceptable baseline.

UL Strongly considers NIOSH uses RAB system?

ICS Points out that NIOSH will either have to be the expert or identify experts for the accrediting body.

UL Discussion on NIOSH/Joint accreditation process. UL stated this is not a "self-accreditation" process but is controlled by NIST and is used in medical products and other parties. However IAFF, Rich Duffy and others have expressed concerns over NFPA approval process which is truly "self-accreditation" Also FDA process was not very effective in dealing with recent O2 fires/ignitions in O2 resuscitators

used by fire departments. The FDA appro al process allowed "Self-certification" of a bad design.

Final discussion on related topics

Need for NIOSH to "train" auditors/laboratories (via training or assessments)

Limited flexibility to approval "types" of respirators outside Part 84 Guidelines

Handling extensions of approvals

End product auditing by manufacturers of all their approved products as a complete assembly.

Product audits should come from end–users or distributors and not from manufacturer inventory since it is too easy to"stage" a product. (ICS)

Possibility of conducting pilot projects before implementing new regulations

May want to consider market bearing price instead of a set amount. Currently running from $700 to 1500 a day depending upon the type of tests.

3rd Party Auditors
July 26, 2000

Matt — Description of NIOSH Concept/Criteria for Auditor

- NIOSH would develop audit checklist with NIOSH requirements
- NIOSH would provide training on NIOSH requirements
- NIOSH could accompany auditor on first audit
- NIOSH would accompany ISO auditor on spot checks thereafter
- RAB recognized in ISO 9000

Discussion on whether NIOSH should have periodic re-certification or refresher for auditors

- UL — Definitely
- UL — May be a problem keeping ISO auditors accredited in order to keep this program viable
- ICS — NIOSH (+) audits would count toward re-accreditation
- ICS — Recommends having a small population of trained auditors to do NIOSH (+) audits.

ICS — Could choose between RAB accredited auditors and ASQ Certified Lead Auditors.

UL — There are problems with having NIOSH require a lead auditor be "accredited" by NIOSH since small number of respirator manufacturers mean it would be difficult to maintain RAB accreditation.

UL — The problem is that the accrediting body would accredit the respirator manufacturer to ISO requirements. In order to recognize the "NIOSH-plus" audit results the accrediting body would have to re-accredit the respirator manufacturer to "NIOSH-plus" requirements and since there are only 65 manufacturers, this would quickly work itself out of business.

UL — Better to require the auditor be registered with an accredited body without being specific on who they are registered with.

Roland — Is this a viable program?

UL — In general this proposal would keep 2-4 auditors busy full time there may not be any qualified auditors in the world so program would have to develop them. Speaking for UL, UL would be interested in participating.

Tim Are there any similar programs out there?

UL Yes-FDA and Coast Guard
FDA has 3rd party for pre-market testing

ICS Automotive but it is not a federal government program. Private sector

Currently Coast Guard maintains approval program for flotation devices. UL does testing and auditing. Coast Guard issues approvals UL will identify contacts in the Coast Guard.

Comments/Discussion
How much will NIOSH maintain and how much would NIOSH shop out to private sector? i.e. would NIOSH require manufacturer to go to one accrediting body for audits, product audits, and testing, or could manufacturer splinter to 3 different bodies. NIOSH needs to identify the role of quality (up-front certification, site audits, post audit testing)

How would NIOSH balance QA auditor requirements with technical requirements specific to respirator performance and safety product requirements?

Are most foreign manufacturers ISO certified?

ICS Europe-yes; Japan-yes; Mexico and South America-no; Taiwan-probably yes

UL FDA website may have some info.

Discussion NIOSH will probably retain oversight on accrediting auditors. NIOSH probably would not allow ICS or UL to accredit auditors. DRDS B-reader certification program.

ICS QA module needs to contain specific language on what the technical requirements are. May want to write a quality system in our regulations similar to 21 CFR 820.

ICS Is there a training fee or will government pay for training to train the auditors?
NIOSH will probably provide training similar to B-reader training.

ICS Has anyone ever challenged NIOSH on providing drawing, QA, etc. in English?
No, NIOSH has already required this

Getting auditors who speak the local dialect will be a problem on foreign audits.

ICS NIOSH will need to allow an integration phrase for the new requirements.

Summary–Matt

1. Audit team must have technical presence

2. Should consider FDA model for QA requirements (quality system and inspection techniques)

3. Should look at FDA and Coast Guard approval process (UL will give us Coast Guard contacts)

4. (UL concern) should consider internal audit confidentiality and issue of self-incrimination. Third party auditors circumvents this concern.

5. Third party audit results (findings) must consider impact on respirator performance. NIOSH must be involved in the findings of the audit.

6. NIOSH would be the keeper of all audit/test records and the supporting documentation.

7. NIOSH needs to define what information we want in reports from the labs and auditors.

Potential Problems

1. NIOSH can be accused of favoring one test house over another. Would have to develop rotating schedule

2. Fee structure could restrict development of new companies (respirator manufacturers) as well as new labs. Agency should set the fees so that there are not "discount pricing" test labs.

3. Each potential program puts different resource requirements on NIOSH as well as different issues for manufacturer and end-user.

4. Should set up pilot program

5. Should NIOSH maintain current program for any manufacturer who wants to continue doing things status quo.

6. NIOSH will always be the gold standard and should retain the right to test in-house to verify test competency of the 3rd party labs.

7. Different persons serving as technical experts for labs vs audits result in different perspectives.

LABORATORY PROGRAMS

DEFINITIONS:

ACCREDITATION: A FORMAL RECOGNITION THAT A TESTING LABORATORY IS COMPETENT TO CARRY OUT A SPECIFIC TEST OR TYPES OF TESTS.

CERTIFICATION: A FORMAL RECOGNITION THAT A LABORATORY HAS THE RESPONSIBILITY FOR ALL ASPECTS OF THE CERTIFICATION PROCESS. THIS INCLUDES THE ASPECTS OF PRODUCT TESTING, INSPECTION, AUDITING, AND CONTROL OF ITS REGISTERED MARK OR LOGO.

EXAMPLES:	ACCREDITATION	CERTIFICATION
GOVERNMENT	NVLAP	NRTL
PRIVATE	A2LA	ANSI SEI

EUROPEAN SCHEME

NOTIFIED BODY: A BODY APPROVED BY THE SECRETARY OF STATE (DESIGNATING AUTHORITY) AND NOTIFIED TO THE COMMISSION AND ALL OTHER MEMBER STATES TO ACCREDIT AND/OR CERTIFY.

THE LABORATORY MUST BE ACCREDITED BY A NOTIFIED BODY AGAINST EN45001 (ISO GUIDE 25) AND/OR EN45011 (ISO GUIDE 28). THE EC CATAGORY WILL DETERMINE THE ACCREDITATION CRITERIA. THE EC CATAGORIES ARE:

TYPE-EXAMINATION
QUALITY CONTROL FOR FINAL PRODUCTION
QUALITY OF PRODUCTION BY MEANS OF MONITORING

A LAB CAN BE ACCREDITED AS A TEST HOUSE AND/OR NOTIFIED BODY AND MAY BE AFFILIATED WITH A MANUFACTURE.

SUMMARY OF U.S. LABORATORY PROGRAMS

NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM (NVLAP) - THIS IS AN ACCREDITATION PROGRAM. NIOSH WOULD HAVE TO REQUEST A LABORATORY ACCREDITATION PROGRAM (LAP) BE DEVELOPED AND THIS WOULD BE ANNOUNCED IN THE FEDERAL REGISTER FOR 60 DAYS TO DETERMINE INTEREST AND NEED. THE DIRECTOR OF NIST MAKES THE LAP DEVELOPMENT DECISION. NVLAP WITH NIOSH WILL DEVELOP A LAP WHICH WILL INVOLVE COLLECTING ADVISE FROM TECHNICAL EXPERTS OBTAINED THROUGH INFORMAL PUBLIC WORKSHOPS. ONCE A LAP IS

DEVELOPED AND A SCHEDULE OF FEES FOR ACCREDITATION IS DETERMINED IT WILL BE PUBLISHED IN THE FEDERAL REGISTER.
A LAB THEN APPLIES FOR ACCREDITATION AND PAYS THE ESTABLISHED FEES. THE LAB IS EVALUATED TO THE LAP AND ISO GUIDE 25. ONCE ACCEPTED THE LAB IS AUDITED WHICH INCLUDES AN ON-SITE ASSESSMENT AND PROFICIENCY TESTING EVERY TWO YEARS. EACH TIME A FEE IS PAYED.

AMERICAN ASSOCIATION FOR LABORATORY ACCREDITATION (A2LA) - THIS IS AN ACCREDITATION PROGRAM. A2LA ACCREDITS THE LAB TO BE COMPETENT TO PERFORM SPECIFIC TESTS OR TYPES OF TESTS; THE LAB's QA SYSTEM ADDRESSES AND CONFORMS TO ALL ELEMENTS OF ISO GUIDE 25 ; CONFORMS TO ANY ADDITIONAL REQUIREMENTS OF A2LA OR SPECIFIC FIELDS OF TESTING OR PROGRAMS NECESSARY TO MEET PARTICULAR USER NEEDS.

ACCREDITATION PROCESS: ONCE THE APPLICATION INFORMATION IS COMPLETED AND FEE IS PAYED. A2LA CONTRACTS ASSESSORS WITH SPECIFIC EXPERTISE TO CONDUCT AN ON-SITE ASSESSMENT. PROFICIENCY TESTING IS ALSO CONDUCTED. ACCREDITATION IS GRANTED FOR 2 YEARS. HOWEVER, AFTER THE FIRST YEAR OF ACCREDITATION THE LAB MUST PAY ANNUAL FEES AND SUBMIT UPDATED INFORMATION. A2LA CONDUCTS A FULL ON-SITE REASSESSMENT AT LEAST EVERY TWO YEARS.

NOTE: IN THE ABOVE TWO PROGRAMS THE LABS AFFILIATED WITH A MANUFACTURER ARE ELIGIBLE TO APPLY.

NATIONALLY RECOGNIZED TESTING LABORATORIES (NRTL) - THIS IS A CERTIFICATION PROGRAM. NRTLS ARE RECOGNIZED UNDER AN OSHA PROGRAM, HOWEVER AUDITS ARE CONDUCTED BY MSHA AUDITORS (THIS APPLIES TO LABS APPLYING TO CONDUCT MSHA TESTING AND EVALUATION OTHERWISE THIS COULD BE CONTRACTED OUT). NRTLS MUST BE INDEPENDENT AND FREE OF INFLUENCE FROM MANUFACTURERS. APPLICANTS UNDERGO A COMPREHENSIVE ON-SITE ASSESSMENT COVERING NUMEROUS IEC APPROVAL STANDARDS, AND/OR SOME OTHER APPROVAL REQUIREMENTS. EACH CERTIFICATION LAST FOR 5 YEARS.

SAFETY EQUIPMENT INSTITUTE (SEI) - THIS IS A CERTIFICATION PROGRAM. THE APPLICANT IS CERTIFIED TO STANDARDS PERTANENT TO THE PRODUCTS BEING TESTED (I.E. FOR SCBAs TO NFPA 1981). AN APPLICANT PAYS AN ADDITIONAL ANNAUAL PARTICIPATION FEE WHICH IS DERIVED FROM TOTAL SALES. AUDITS ARE CONDUCTED BY A THIRD-PARTY AUDITING COMPANY AT THE RATE OF $50/HR PLUS EXPENSES. APPLICANTS ARE AUDITED TWICE A YEAR. CERTIFICATIONS ARE FOR 5 YEARS UNLESS IT IS AN IDLH PRODUCT THEN IT'S YEARLY. SEI HAS APPLIED TO BECOME CERTIFIED UNDER ANSIs
PROGRAM Z34.1.

AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI) - THIS A CERTIFICATION PROGRAM. THIS PROGRAM IS SIMILAR TO THE EUROPEAN SCHEME WHICH USES THE EUROPEAN STANDARD, EN 10011-13 (ISO GUIDE 28).AFTER CERTIFICATION THE APPLICANT IS AUDITED ANNUALLY.

CONCERNS:

THAT ADEQUATE EQUIPMENT AND STAFF BE MAINTAINED BY TEST LAB.

APPLICANT'S COSTS INCREASE DUE TO GOING TO INDEPENDENT LABS.

INDEPENDENT LABS PROVIDE SAME CONFIDENTIALITY AND SECURITY.

THAT INDEPENDENT LABS MAYBE AFFILIATED WITH OR BIAS TOWARDS A MANUFACTURER.

SHOULD MANUFACTURER'S BE FREE TO CHOOSE WHICH APPROVED TEST LAB TO USE?

INTERESTS:

AN ACCREDITATION PROGRAM (NIOSH REVIEWS TEST REPORTS AND ISSUES APPROVALS).

PRE-AUDIT ASSESSMENT BY NIOSH TEAM (TEAM COULD INCLUDE THIRD-PARTY ISO 25 AUDITORS).

ISO GUIDE 25 CERTIFICATION MAINTAINED BY TEST LAB.

BI-ANNUAL AUDITS (BY THIRD-PARTRY WITH REPORT GOING TO NIOSH OR BY NIOSH TEAM).

FEES PAID TO COVER PROGRAM COSTS.

TEST LABS TRUELY INDEPENDENT NOT AFFILIATED WITH MANUFACTURER.

NIOSH SELECTS TEST TO BE RAN.

PROGRAMS

NIOSH	NVLAP	A2LA	NRTL	SEI	ANSI
Pre-Assessment	X	X	X	X	X
ISO 25 Cert.	X	X			
Bi-Ann. Audits				X	
Non-Affil. Test labs			X		
No Subcon. Of Tests			X		
Fees to cover costs	X	X	X	X	X
NIOSH Approval (acc. Pgm)	x	X			
Re-Accred.(yrs)	2	2	5	1*/5	

* one year for IDLH (SCBA) products.

STANDARDS SERVICES

OFFICE OF STANDARDS SERVICES

The Office of Standards Services (OSS) is the focal point for the Commerce Department's standards and conformity assessment activities. The office formulates and implements standards-related policies and procedures to enhance domestic commerce and international trade. The office provides representation to domestic and international organizations and federal agencies concerned with standardization, product testing, certification, laboratory accreditation, and other forms of conformity assessment. It chairs the Interagency Committee on Standards Policy to implement the Office of Management and Budget Circular No. 119, "Federal Participation in the Development and Use of Voluntary Standards," which is aimed at harmonizing standards and related programs of federal agencies. OSS also implements the National Technology Transfer and Advancement Act by coordinating standards and conformity assessment activities of federal, state, and local government agencies and with the private sector.

Contact: Belinda L. Collins

LABORATORY ACCREDITATION PROGRAM

The National Voluntary Laboratory Accreditation Program (NVLAP) provides third-party accreditation of testing and calibration laboratories. Accreditation programs are established in response to mandates or administrative action by the federal government or requests from private-sector organizations.

Accredited laboratories are listed in a published directory and at http://ts.nist.gov/nvlap. NVLAP is in full conformance with the standards of the International Organization for Standardization (ISO) and the International Electrotechnical Commission, including ISO Guides 25 and 58. Accreditation provides confidence that a laboratory can provide the technical services claimed and has the quality system to maintain high levels of proficiency.

NVLAP accredits laboratories in the following fields of testing: acoustics, asbestos fiber, carpet, commercial products, computer applications, construction products, electromagnetic compatibility and telecommunications, energy efficient products, ionizing radiation dosimetry, and thermal insulation. NVLAP also accredits laboratories in these calibration areas: dimensional, electromagnetic-dc/low frequency, electromagnetic-rf/microwave, ionizing radiation, mechanical, optical radiation, thermodynamics, and time and frequency.

Contact: James L. Cigler

TECHNICAL STANDARDS ACTIVITIES PROGRAM

The Technical Standards Activities Program (TSAP) provides technical support for public- and private-sector standardization and standards-related activities. TSAP manages U.S. representation and participation in the International Organization of Legal Metrology (OIML). OIML is a treaty organization of the international measurement community that promotes global trade through harmonization of performance requirements (regulations) for measuring instruments used to ensure equity in commerce, ensure public and worker health and safety, and monitor environment protection.

TSAP also manages technical support for domestic and international standardization activities and coordination for U.S. standards advisers posted abroad. The program serves as the Commerce Department's (DOC's) technical contact point to investigate non-tariff trade barriers for non-

agricultural products under the Agreement on Technical Barriers to Trade of the World Trade Organization. It administers the DOC Voluntary Standards Program, providing a mechanism for private-sector sponsors to develop standards in the public interest with significant domestic and international trade impact. Current standards pertain to construction and industrial plywood, wood-based structural-use panels, and softwood lumber. The program provides the executive secretariat for the Interagency Committee on Standards Policy and coordinates NIST participation in the annual U.S. observance of World Standards Day.

Contact: Samuel E. Chappell

GLOBAL STANDARDS PROGRAM

The Global Standards Program (GSP) provides technical information and support to federal agencies and industry to assist them in resolving trade issues related to standards and conformity assessment. GSP monitors developments in standards and conformity assessment activities in the Western Hemisphere, the European Union, Russia and the Newly Independent States (NIS), Central Europe, the Middle East, and the Asia-Pacific Region. It supports programs of the Commerce Department's (DOC's) International Trade Administration, such as the Special American Business Intern Training (SABIT) program for technical experts from Russia and the NIS and conducts standards related economic and policy analyses.

GSP staff participate in the activities of interagency groups to establish U.S. government positions on standards-related aspects of major international agreements, such as the North American Free Trade Agreement. The program also supports work in the Asia Pacific Economic Cooperation and Free Trade Area of the Americas. Staff participate in international and regional organizations covering standards and conformity assessment, and also chair or participate in bilateral standards working groups.

GSP recruits and assigns standards experts to posts at key U.S. embassies and missions. Standards experts are currently in place in Mexico City, Mexico; Buenos Aires, Argentina; Brussels, Belgium (U.S. Mission to the European Union); Riyadh, Saudi Arabia; and New Delhi, India. These experts work with DOC commercial officers, other U.S. government agencies, U.S. business, and foreign organizations to identify and remove technical barriers to trade. GSP staff also organize and conduct workshops at NIST on U.S. standards and conformity assessment practices for foreign standards officials.

Contact: Mary H. Saunders

STANDARDS INFORMATION PROGRAM

The Standards Information Program (SIP) operates the National Center for Standards and Certification Information (NCSCI), a central repository for standards-related information in the United States. NCSCI provides access to standards, technical regulations, and related documents published by U.S. and foreign governments as well as by domestic, foreign, and international private-sector standards organizations. SIP responds to domestic and foreign requests for information on U.S. standards, technical regulations, and conformity assessment procedures and to requests for information about foreign standards and technical regulations through its access to the network of information centers (ISONET) of the International Organization for Standardization.

SIP serves as the U.S. inquiry point under the Agreement on Technical Barriers to Trade of the World Trade Organization (WTO) to inform the WTO secretariat in Geneva of proposed U.S. government regulations that might affect trade, receives corresponding proposed foreign regulations, and disseminates them to U.S. industry and cognizant government agencies. SIP operates the U.S. North American Free Trade Agreement (NAFTA) inquiry point, which provides information about standards and technical regulations of the NAFTA countries. SIP also operates two telephone

hotlines. One, (301) 921-4164, offers weekly updates on draft European standards and reports on draft standards of the European Committee for Standardization and the European Committee for Electrotechnical Standardization. The other, (301) 975-4041, offers weekly updates on proposed foreign regulations for those concerned about regulations and standards that might create technical barriers to trade.

Contact: JoAnne R. Overman

STANDARDS CONFORMITY PROGRAM

The Standards Conformity Program (SCP) has responsibilities under the Fastener Quality Act (FQA) (Public Law 101-592 as amended by Public Law 104-113), and the National Technology Transfer and Advancement Act (NTTAA). The SCP also provides operational support for the National Voluntary Conformity Assessment Systems Evaluation (NVCASE) program.

SCP issues final implementing regulations for the FQA; approves laboratory accreditation bodies to accredit fastener testing laboratories under the act and its implementing regulations; and provides technical advice and assistance to the Bureau of Export Administration, which is responsible for enforcement, and to the Patent and Trademark Office, which is responsible for recording insignia. For more information on the Fastener Quality Act, see www.nist.gov/fqa.

Under the NTTAA, SCP coordinates conformity assessment activities of federal, state, and local government agencies and with the private sector, aiming to eliminate unnecessary duplication and complexity in the development and promulgation of conformity requirements.

The NVCASE program recognizes competent accreditors of laboratories, certifiers, or registrars of quality assessors in order to provide assurances to other governments regarding the conformity of U.S. products that are exported to regulated markets in their countries.

Contact: Subhas G. Malghan