

American Council of Independent Laboratories (ACIL)

THE US TESTING INFRASTRUCTURE



presented at:

**NIST Standards in Trade Conference for
Association of Southeast Asian Nations (ASEAN) Economies
Conformity Assessment in the Electric and Electronics Sector**

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American Council of Independent Laboratories

Presentation Overview

- US Testing Infrastructure
 - ACIL Background
 - Types of Labs in the U.S.
 - Capacity
 - Management
 - Finance Issues
 - Quality

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ACIL Background

- Founded in 1937 in New York City
- 120+ Members
 - Testing laboratories
 - Product certifiers
 - Manufacturer's labs
 - R&D firms
 - Consultants and suppliers



ACIL Mission

- To Enhance Members Success by:
 - Providing advocacy, education, service and mutual support
 - Promoting quality, ethics, independence, objectivity and free enterprise

Sections

- Conformity Assessment Section(CAS)
- Environmental Sciences Section (ESS)
- Food Sciences Section (FCC)
- Construction Materials, Engineering and Testing (CMET)

Public Policy

- Laboratory Accreditation
- Unfair Competition

Federal Activities

- Commerce/NIST
- FDA
- FCC and TCB Council
- DOL/OSHA
- DOD
- EPA
- CPSC
- DHS

NIST

FDA

OSHA[®]



FCC



Consumer Product Safety Commission

- ACIL Member Laboratories – Resource
- Accreditation (Mattress Standard)
- Consumer Product Safety Reform Act

CAS Projects

- China Conformity Assessment System
 - TBT
 - Policies and Practices
 - Position statement
- Smart Grid Interoperability
- Proficiency Testing Program
- Third Party Certifier Activities
- DOJ Offender Tracking Program



Made in USA



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Lab Infrastructure in the US

- Public Sector Labs (US Government)
- Private Sector Labs



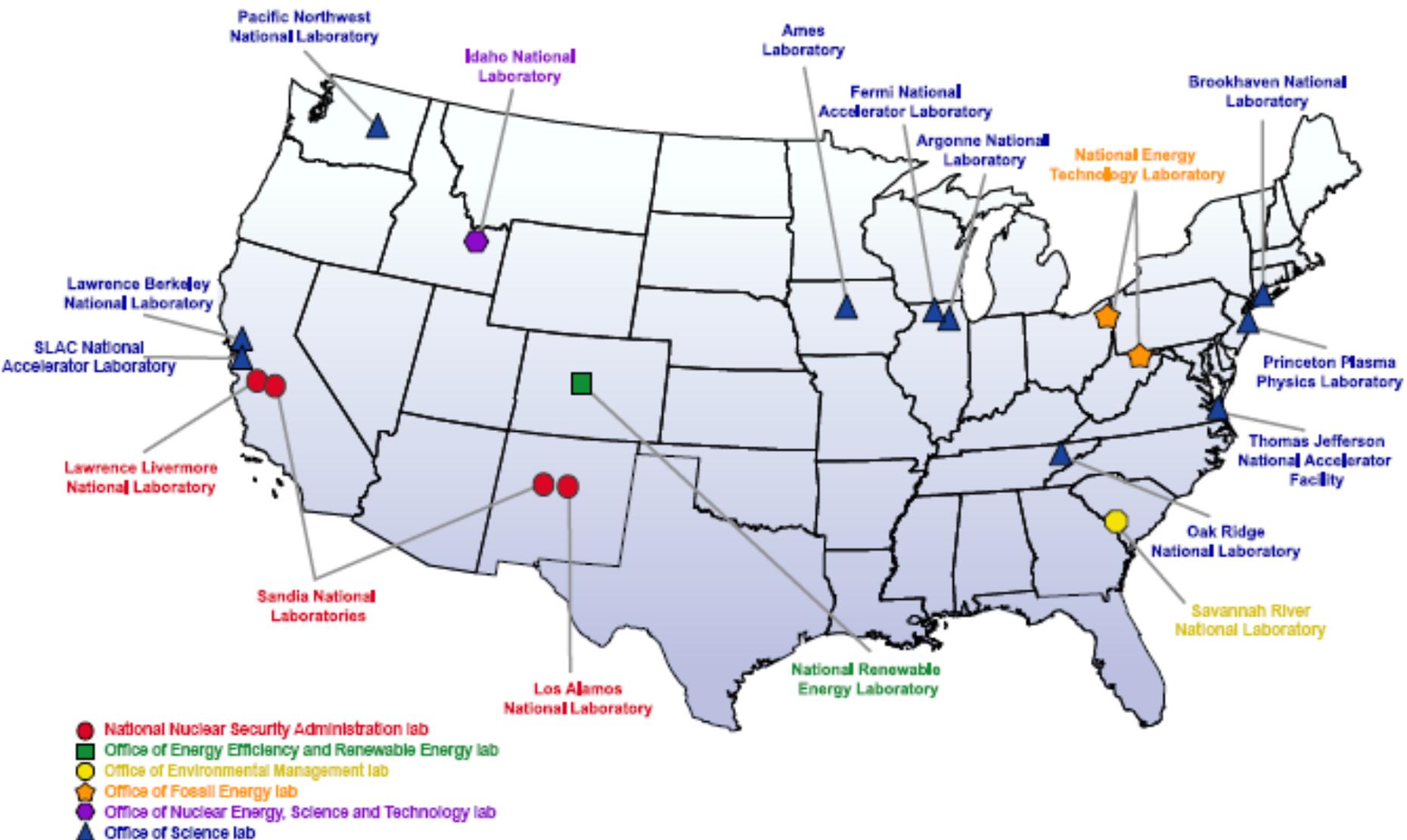
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Public Sector Labs

- **NASA**
National Institutes of Health
National Science Foundation
 - **National Institute of Standards and Technology**
 - **Naval Research Laboratory**
Biometric Consortium
 - **National Energy Research Scientific Computing (NERSC)**
Army Research Lab
 - **Topographic Engineering Center (Tec)**
Environmental Measurements Laboratory
 - ***National Renewable Energy Laboratory (NREL)**
***Oak Ridge National Laboratory**
***Lawrence Berkeley Laboratory**
***Los Alamos National Laboratory**
***Sandia National Laboratories**
 - ***Brookhaven National Laboratory**
***Lawrence Livermore National Laboratory**
***Argonne National Laboratory**
 - ***Fermi National Accelerator Laboratory**
***Pacific Northwest National Laboratory**
- } *Dept of Energy
\$4.9B in Research



DEPARTMENT OF ENERGY NATIONAL LABORATORIES



Public Sector (non-research) Labs

- Environmental Monitoring and Compliance Labs

- EPA

- Virginia

- Division of Consolidated Laboratories Services

- Analytical Sampling for local governments, federal agencies

- 6 million tests per year

- Accredits other laboratories



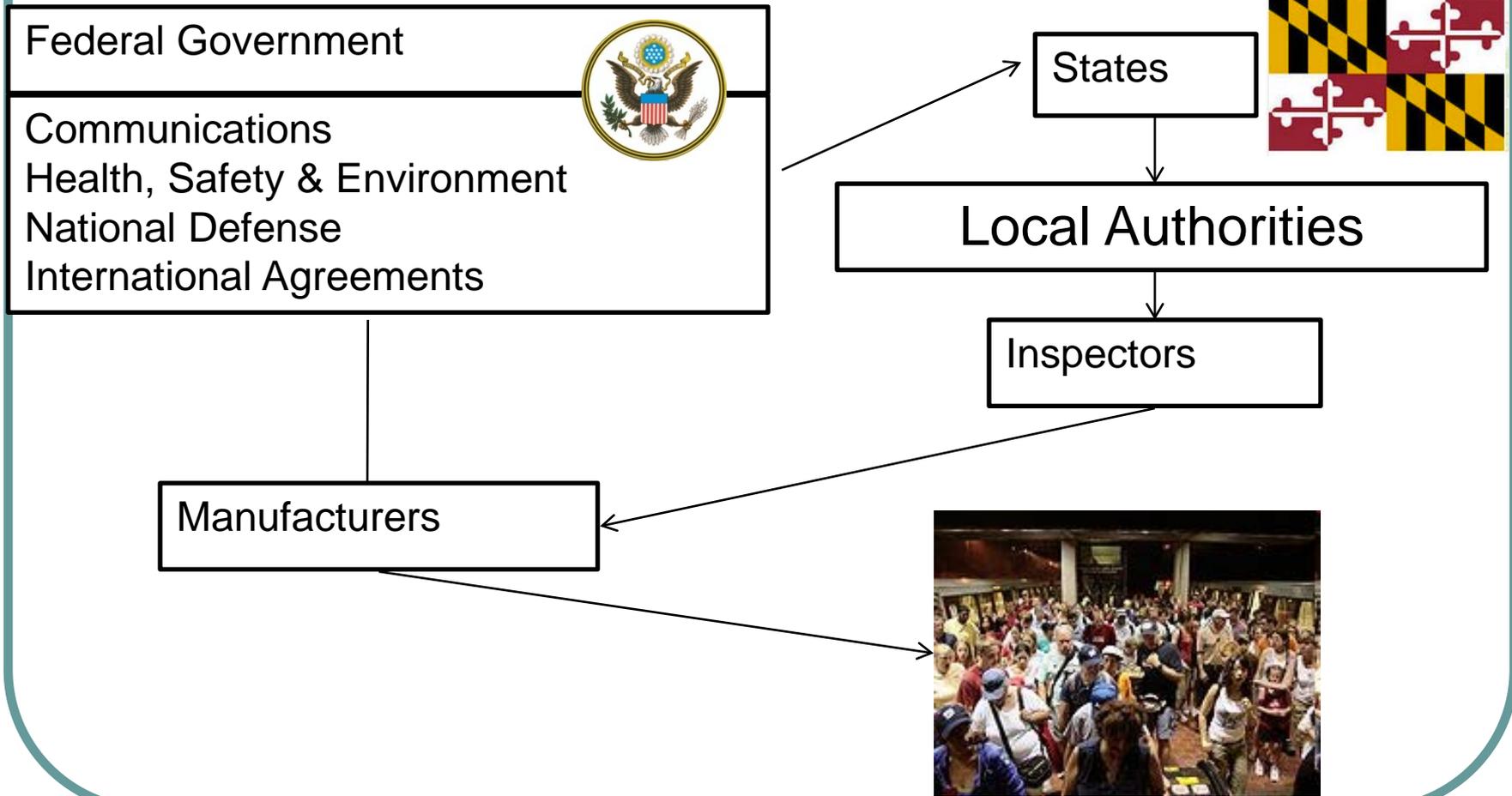
Private Sector Labs

- Mostly deal with compliance to regulatory requirements
- Protection of People and Services
- Health and Safety
 - Electrical and Mechanical
- Spectrum & Communications
- Environmental Protection
 - Air & Water

Laboratory Business

- Many private labs are started as small businesses, engineers, chemists
- Develop niche capability
- Regional markets
- Many labs build capacity through acquisition
- Most labs generate \$120,000 per employee

Simplified Regulatory Structure in US



U.S. Regulatory Authorities

- U.S. Department of Agriculture (USDA)
 - Domestic and Imported
 - Meat
 - Poultry
 - Eggs
 - Establish Ingredient Standards and Approve Recipes and Labels for Processed Meat and Poultry Products



U.S. Regulatory Authorities

- Environmental Protection Agency
 - Water and Air Quality
 - Pesticide Approval and Registration
 - Establish Tolerances for Pesticides
 - FDA and USDA Enforces Pesticide Tolerances

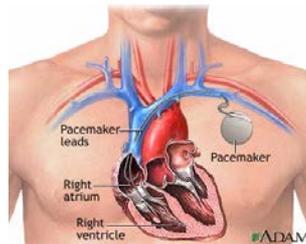


U.S. Regulatory Authorities

● Food and Drug Administration



- Foods
- Drugs
- Cosmetics
- Medical Devices
- Veterinary Drugs and Feeds
- Biological Products
- Radiation Devices



Food Safety Concerns



U.S. Regulatory Authorities

- Federal Communications Commission (FCC)



- Control use and protection of Radio Frequency Services for Public



U.S. Regulatory Authorities

- Occupational Health & Safety Administration (OSHA)
 - Workplace Safety
 - NRTL Program



UNITED STATES
DEPARTMENT OF LABOR

Code of Federal Regulations (50 titles from Food to Nuclear Power)

- <http://www.gpoaccess.gov/CFR/>

Code of Federal Regulations: Main Page - Mozilla Firefox

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ACIL EBI's Environmental Market ... U.S. Accreditation Bodies Di... ILAC - ILAC MRA and

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Home Page > Executive Branch > Code of Federal Regulations

Code of Federal Regulations (CFR): Main Page

The Code of Federal Regulations (CFR) is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government. It is divided into 50 titles that represent broad areas subject to Federal regulation. Each volume of the CFR is updated once each calendar year and is issued on a quarterly basis. [More](#).

Most Current 50 Titles (2009-2010)

- Quick Search: (ex: 20CFR404, prescriptions AND "drug enforcement administration")
 Submit [Search Tips](#)
- [Browse and/or search the CFR](#)

1996 through current year

Based on CFR update schedule

- [Browse and/or search the CFR](#)
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- CFR Main Page
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- [e-CFR](#)
- [Federal Register](#)

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Spending: Department of Energy

- 17 Government Labs providing basic research in physics, chemistry and material sciences
- Budget: \$4.9B (40% of total is R&D)
- National Spending: \$12B

Market Size: Product Testing (not foods)

- 600+ (mostly) private providing testing services for equipment manufacturers
- Estimated market size: \$1.8B

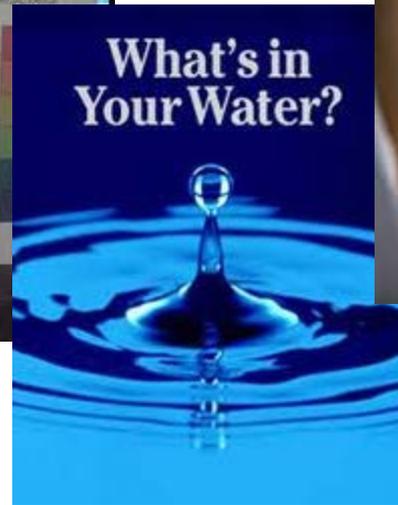


Market Size: Conformity Assessment Labs

- 114 Accredited Labs on FCC Website
 - 31 in California
 - 6 in Massachusetts & Minnesota
 - 5 in New York
 - 4 in Maryland, Texas, Washington State & Illinois
- Regionally distributed

Market Size: Environmental

- 1600 labs providing environmental analytical services
- Market size \$2.4B



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Processes

- Lab Management: Quality Systems
 - Accreditation requirements drive processes
- Quality Systems: 17025 and related

Accreditation

- ISO 17025 for Laboratory Operations
- Accreditation by third-party accreditors



Accreditation Bodies

- International Laboratory Accreditation Program (ILAC)
 - Chartered in 1996 to develop international cooperation and mutual acceptance criteria
 - 66 Accreditation Bodies have signed the ILAC Mutual Recognition Agreement

Accreditation Process

- Audit
 - Management System
 - Records
 - Calibration
 - Incoming sample control
 - Reports
 - Methods
 - Complaints and Corrective Actions

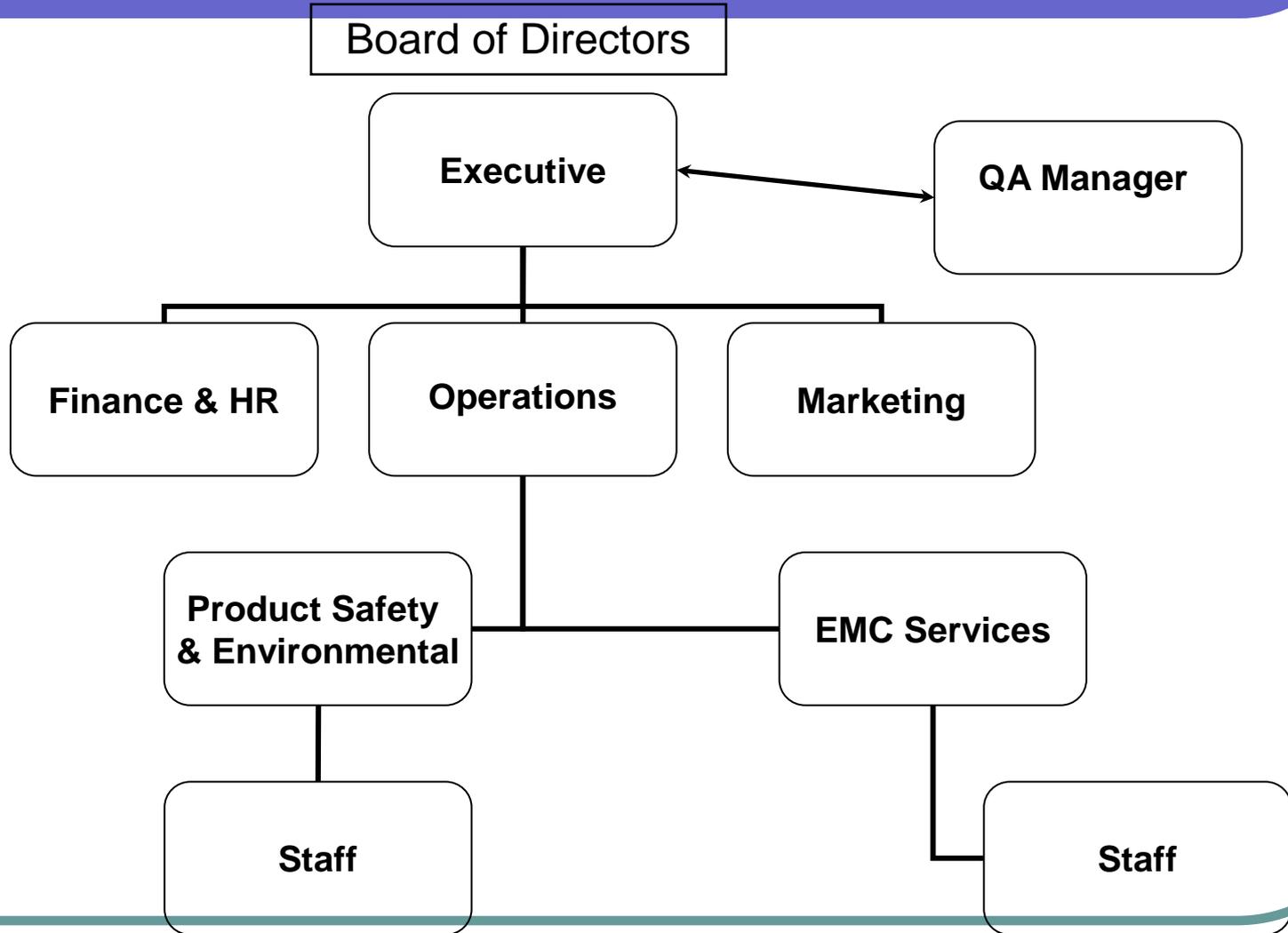
Laboratory Management Structure

- Most management structures are dictated by Quality Systems

ISO/IEC/EN 17025

General Requirements for the Competence of Calibration and Testing Laboratories

Management Structures



ISO 17025 Elements

- Requirements
 - Legal Entity
 - Responsibility
 - Facilities
 - Conflicts of Interest
 - Staff Responsibility
 - Customer Confidentiality
 - Conflicting Activities

ISO 17025

Duties and Responsibilities

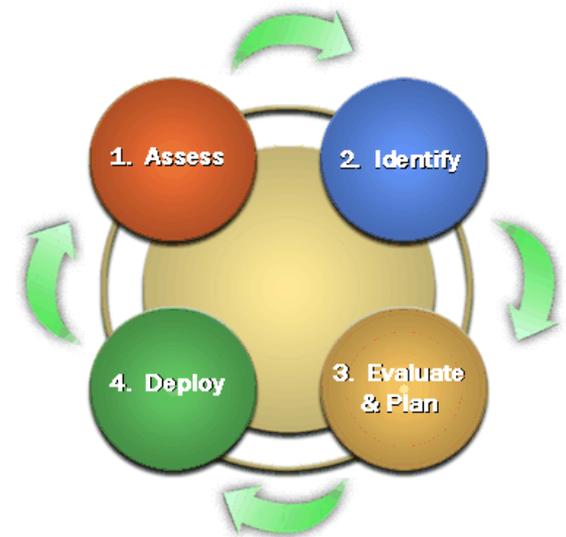
- Quality Manager
- Supervision is Clear
- Personnel Involvement is Encouraged
- Management System Communications
 - Transparent and frequent

ISO 17025 Management System

- **Statement of Policy**
 - ...meet or exceed Customer Expectations and Industry Standards in a Timely and Consistent manner
 - Continuous Improvement

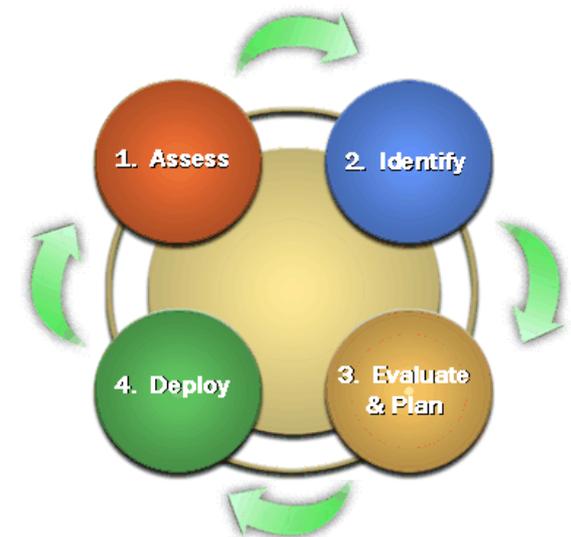
Procedures for all processes

- Testing Procedures
- Internal Equipment Calibration Procedures
- Administrative Procedures
- Quality Procedures
- Engineering Procedures
- Documentation Procedures
- Business Procedures



Procedures (continued)

- Training Procedures
- Technical File Procedures
- Purchasing Procedures
- Documentation Control
- Review of Contracts
- Subcontracting
- Purchasing



Complaints

- External (customers)
- Internal (anyone)
- Generate Corrective Action Report (CAR)
 - Must address ROOT CAUSE and corrective action
 - Change in procedure/
 - Change in behavior?
- *Preventative Action*



Processes

- Internal audits
- Periodic management reviews
 - Anything to do with Quality Management System
- Personnel Qualifications
 - Competency
 - Training
- Uncertainty
- Traceability
- Equipment handling

Records

- For most records (reports, customer correspondence, etc) must keep on file for 10 years
- For work in the Nuclear Power Industry, must keep records for 30 years
- Data backup, physical and electronic security is required



Certificate and Scopes



CERTIFICATE OF ACCREDITATION

ANSI-ASQ National Accreditation Board/AClass
500 Montgomery Street, Suite 625, Alexandria, VA 22314, 877-344-3044

This is to certify that

Washington Laboratories, Ltd.
7560 Lindbergh Drive
Gaithersburg, MD 20879

has been assessed by AClass
and meets the requirements of international standard

ISO/IEC 17025:2005

while demonstrating technical competence in the field(s) of

TESTING

Refer to the accompanying Scope(s) of Accreditation for information regarding the types of tests to which this accreditation applies.

AT-1448

Certificate Number

AClass Approval

Certificate Valid: 04/01/2012-06/30/2014
Version No. 004 Issued: 01/31/2013

1. This organization maintains satellite organization(s) where no key activities are performed other than calibration and/or testing. Please refer to the accompanying scope of accreditation for more information.

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated January 2009).



Washington Laboratories, Ltd.¹

7560 Lindbergh Drive
Gaithersburg, Maryland 20879
John Repella Phone: 301-216-1500

TESTING

Valid to: June 30, 2014

Certificate Number: AT-1448

I. Electrical

FIELD OF TEST	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED
Emissions Standards	Radiated and Conducted Emissions (40 Hz to 30 GHz)	FCC Part 15 B/C/D/E using ANSI C63.4 (2003) & ANSI C63.17; FCC Part 18 using FCC OST/MP-05 (1986); FCC Report and Order ET Docket 98-153 (FCC 02-48); Procedures IDB 20040420-001; Procedures in IDB 20021108-001 with FCC Method 47 CFR Part 15, Subpart F: DA 00-705 (March 30, 2000) and KDB Pub. No.558074, KDB Pub. No. 200433; DA 02-2138; CISPR 16-1-4 2007 +A1 2007; CISPR 22 (1997)+A1, (2000)+A2, (2002), CISPR 22 (2005); EN 55022 (1998)+A1, (2000)+A2, (2003), EN 55022 (2006),+A1 (2007); AS/NZS CISPR 22; CAN/CSA-CEI/IEC CISPR 22; CNS 13438(up to 6GHz); KN 22 with (RRA Announcement 2010-5, Dec 24, 2010); CISPR 11 (1997)+A1, (1999)+A2, (2002); CISPR 11: 2004-06 CISPR 11:2009/A1:2010 EN 55011 (1998)+A1, (1999)+A2, (2002); EN 55011:2009/A1:2010 AS/NZS CISPR 11; CNS 13803KN 11 with RRA Announcement 2010-5, (Dec 24, 2010); Technical Requirements for Electromagnetic Interference (RRA Public Notification 2011-18, Jul 5, 2011)

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Financial Measurements

- Private sectors labs are mix of publicly-traded and privately held laboratories
 - Publicly-traded (stock corporation) labs must report details to the public
 - Private labs may have boards of directors and private investors to account to

Profit And Loss Statement: The Key Indicator

- Revenue - Cost of Good Sold = Gross Profit
- Gross Profit - Overhead = **Earnings***
- Earnings - Interest, Taxes & Deprec = **NET PROFIT**

Private Lab Profitability

	1 Month Ended <u>Jun. 30, 2009</u>	%	
REVENUE	\$ 263,203.50	100.00	
DIRECT COSTS	<u>122,817.60</u>	<u>46.66</u>	Labor
GROSS PROFIT	<u>140,385.90</u>	<u>53.34</u>	
OPERATING EXPENSES			
General and Administrative	55,759.95	21.19	
Marketing	<u>12,427.91</u>	<u>4.72</u>	
TOTAL OPERATING EXPENSE	<u>68,187.86</u>	<u>25.91</u>	
INCOME FROM OPERATIONS	<u>72,198.04</u>	<u>27.43</u>	Gross Margins
OTHER INCOME AND EXPENSES			
Interest Income	219.10	0.08	
Interest Expense	(2,872.17)	(1.09)	
Other Income	1,000.00	0.38	
Depreciation	<u>(14,183.40)</u>	<u>(5.39)</u>	
TOTAL OTHER INCOME AND EXPENSES	<u>(15,836.47)</u>	<u>(6.02)</u>	Net
NET INCOME	<u>\$ 56,361.57</u>	<u>21.41</u>	

NATIONAL TECHNICAL SYSTEMS, INC. AND SUBSIDIARIES

Unaudited Consolidated Statements of Income
for Nine Months Ended October 31, 2009 and 2008

	2009	2008
Net revenues	\$ 90,229,000	\$ 89,576,000
Cost of sales	65,357,000	64,829,000
Gross profit	24,872,000	24,747,000
Selling, general and administrative expense	19,546,000	18,318,000
Equity loss (income) from non-consolidated subsidiary	51,000	(7,000)
Operating income	5,275,000	6,436,000
Other income (expense):		
Interest expense, net	(1,020,000)	(1,671,000)
Other income, net	156,000	51,000
Total other expense, net	(864,000)	(1,620,000)
Income before income taxes and noncontrolling interests	4,411,000	4,816,000
Income taxes	1,796,000	2,004,000
Income before noncontrolling interests	2,615,000	2,812,000
Net income attributable to noncontrolling interests	(98,000)	(50,000)
Income from continuing operations	2,517,000	2,762,000
Income from discontinued operations, net of tax	-	271,000
Net income	\$ 2,517,000	\$ 3,033,000
Basic earnings per common share		
Income from continuing operations	\$ 0.27	\$ 0.30
Income from discontinued operations	-	0.03
Net income	\$ 0.27	\$ 0.33
Diluted earnings per common share		
Income from continuing operations	\$ 0.26	\$ 0.29
Income from discontinued operations	-	0.03
Net income	\$ 0.26	\$ 0.32
Weighted average common shares outstanding	9,207,000	9,086,000
Dilutive effect of stock options and nonvested shares	387,000	480,000
Weighted average common shares outstanding, assuming dilution	9,694,000	9,566,000
Cash dividends per common share	\$ 0.06	\$ 0.02

Critical Financial Factors

- Labor is biggest cost (~50%)
 - Engineers average salary \$75K
- Health insurance is second-biggest
- Equipment, repair & calibration
- Marketing
- Rent
- Debt service

WL: ~50 Expense Categories

Marketing

- **Competitive environment**
- Constant marketing effort required
- Mix of media
 - Electronic/Email
 - Web-based
 - Print advertisement
 - Video
 - Personal
 - Trade Show

Summary

- Independent Labs are critical part of Testing Infrastructure
- Competitive environment
- Regionally-served market
- Accreditation and Quality Systems are a necessary part of operations

Questions?

- Questions?
- Contact:
 - Mike Violette
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 - +1 240 401 1388