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Need for Test Standards in Developmental Testing

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Why Do Developmental Testing?

- **Provide Information for informed decision making**
- **Verification and Validation of the Systems Engineering Process**
- **Provide confidence that the system design solution is on-track to satisfy the desired capabilities**

Reduce Technical Risk and increase probability of a successful program

Understanding the Capability

- **Use Developmental Testing to:**
  - **To stress the system and understand its limitations**
  - **To operate it for sufficient periods of time--in a relevant environment--to derive/predict future RAM**
  - **To prosecute it in a relevant environment to understand its survivability and safety in combat**
- **To know why it works/how it works**
- **To ensure the delivered performance can withstand scrutiny from challenges by Users/Industry**
- **To ensure that it can repeat its performance under operational conditions with actual operators**

Laboratory Tests

- Controlled environments
  - Temp, Humidity, Air Pressure, Concentrations, etc.
- Measured inputs, outputs
  - Linear and non-linear events in linear and non linear methodologies ?
- Methodology (Test Procedures, Test Data, and Test Tools) needs to be specific
  - Include calibration, identification of all parts and components, and detailed procedures for all steps
  - Functional and interoperable requirements
  - Referenced Standards
  - Derived test requirements based on the functional and interoperable requirements and referenced standards
  - Assumptions which may influence the selection of a specific test method or scope of testing

Demonstrate, Test, Evaluate and Introduce Technology

- **Potential solution is tested/evaluated to determine how well it addresses the intended functional requirement**
- **Introduction of solution into practice**
- **Develop performance standards and guides, as appropriate, to ensure safety and effectiveness**

Not all new solutions will require the publication of new standards and guides

Performance vs. Method Standards

- **Performance vs. Method Standards**
  - **Performance: Limit to be met**
  - **Methodology: Detailed description of how a test is to be conducted, under what conditions, calibration accuracy and interval, materials, etc.**

Methodology Development Needs

- **Development, validation, and application of new analytical methods**
- **Development of new analytical reference materials and operation of proficiency testing programs**
- **Full range of sophisticated measuring techniques and state-of-the-art laboratories**

Standards Organizations

- International Standards Organizations
  - ISO, IEC, ITU, etc.
  - ASTM International
- Regional Standards Organizations
  - CEN, ETSI, IRMM, PASC, etc.
- National Standards Bodies
  - ANSI, JISC, NFPA
- Standard Developing Organizations/Bodies:
  - IEEE, DoD
  - Peer Reviewed, Inclusive of all Stakeholders

DoD Policy: Use NGO STDs

DoD Policy on the Use of Non-Government Standards: DoD is committed to the adoption and use of voluntary consensus standards (defined in DoD 4120.24-M as "non-Government standards (NGS)"), where practical, instead of developing new or updating existing government specifications and standards. This policy is consistent with P.L. 104-113, the National Technology Transfer and Advancement Act of 1995 (NTTAA) and with Office of Management and Budget (OMB) Circular No. A-119 (Revised), "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities," dated February 10, 1998.

Repeatability, Reproducibility

- **Repeatability: Ability to repeat test in same laboratory, same tester**
- **Reproducibility: Ability to reproduce test in different laboratories, different testers**
- **Parameters to be included in future test reporting?**

Lab Management Practices

- **How Do We Ensure Quality Control in Processes?**
  - **ISO/IEC 17025: Industry standard, used also by facilities across the gov't**
    - **ISO 17025 is the leading international laboratory quality management system (QMS) standard. ISO 17025 is compatible with, but not equivalent to ISO 9001. ISO 17025 connects the laboratory quality management system to all other laboratory processes.**
    - **It specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling.**
    - **It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.**
    - **It is applicable to all organizations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification.**
    - **It is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities.**

ISO/IEC 17025

- There are many commonalities with the ISO 9000 standard, but ISO/IEC 17025 adds in the concept of competence.
- The contents of ISO/IEC 17025 - The ISO/IEC 17025 standard itself comprises five elements that are Scope, Normative References, Terms and Definitions, Management Requirements and Technical Requirements. The two main sections in ISO/IEC 17025 are Management Requirements and Technical Requirements. Management requirements are primarily related to the operation and effectiveness of the quality management system within the laboratory. Technical requirements includes factors which determines the correctness and reliability of the tests and calibrations performed in laboratory.

ISO/IEC 17025

- **Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to consistently produce valid results. It is also the basis for accreditation from an Accreditation Body. Since the standard is about competence, accreditation is simply formal recognition of a demonstration of that competence.**

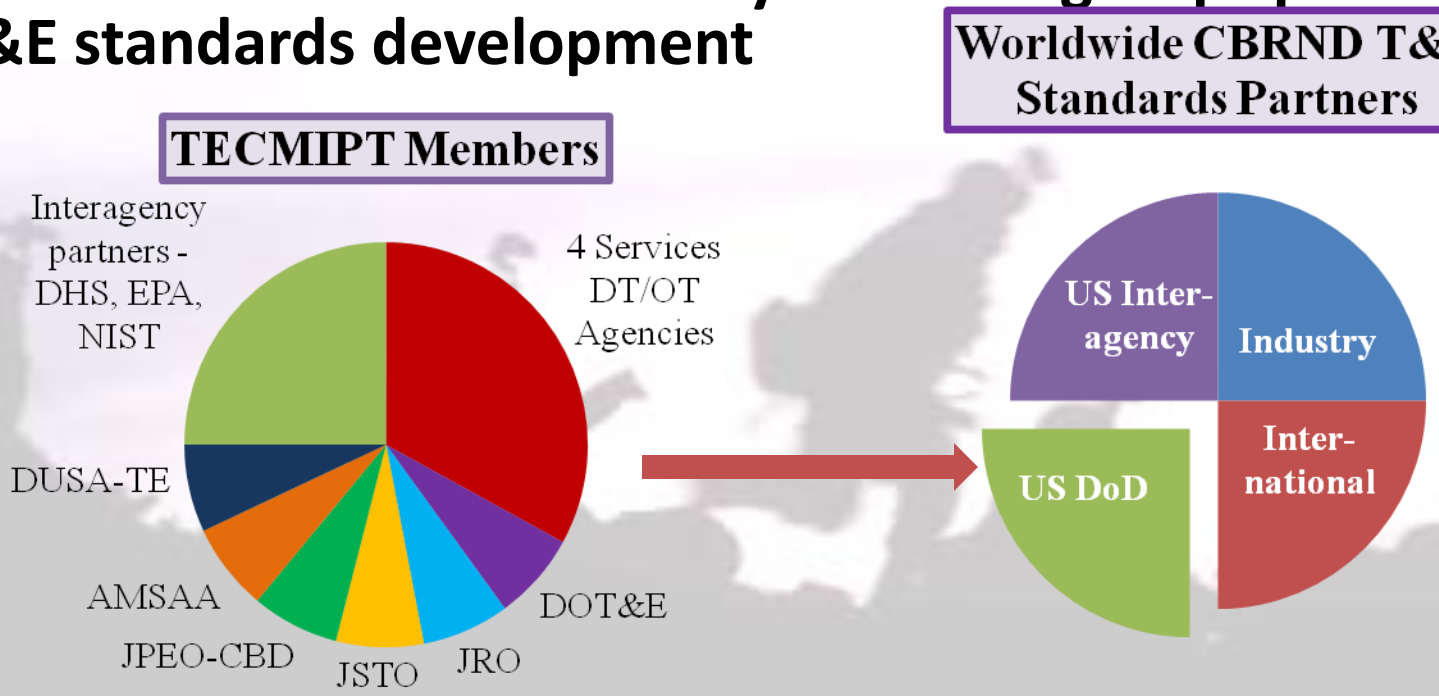
- **A prerequisite for a laboratory to become accredited is to have a documented quality management system. The usual contents of the quality manual follow the outline of the ISO/IEC 17025 standard.**

Need to Standardize Test Processes, Facility Mgmt

- It enhances credibility
- It enhances repeatability, reproducibility
- It defends against legal challenges
- It supports efficient use of resources and best data quality

DoD Process for Establishing T&E Standards

- **CBRND T&E Executive establishes DoD CBRND T&E standards through T&E Capabilities and Methodologies IPT (TECMIPT)**
- **SMEs in TECMIPT commodity area sub-groups provide rigor to T&E standards development**



How? TECMIPT Process

Provides joint, cross-community subject matter expertise and rigor to establish T&E Standards

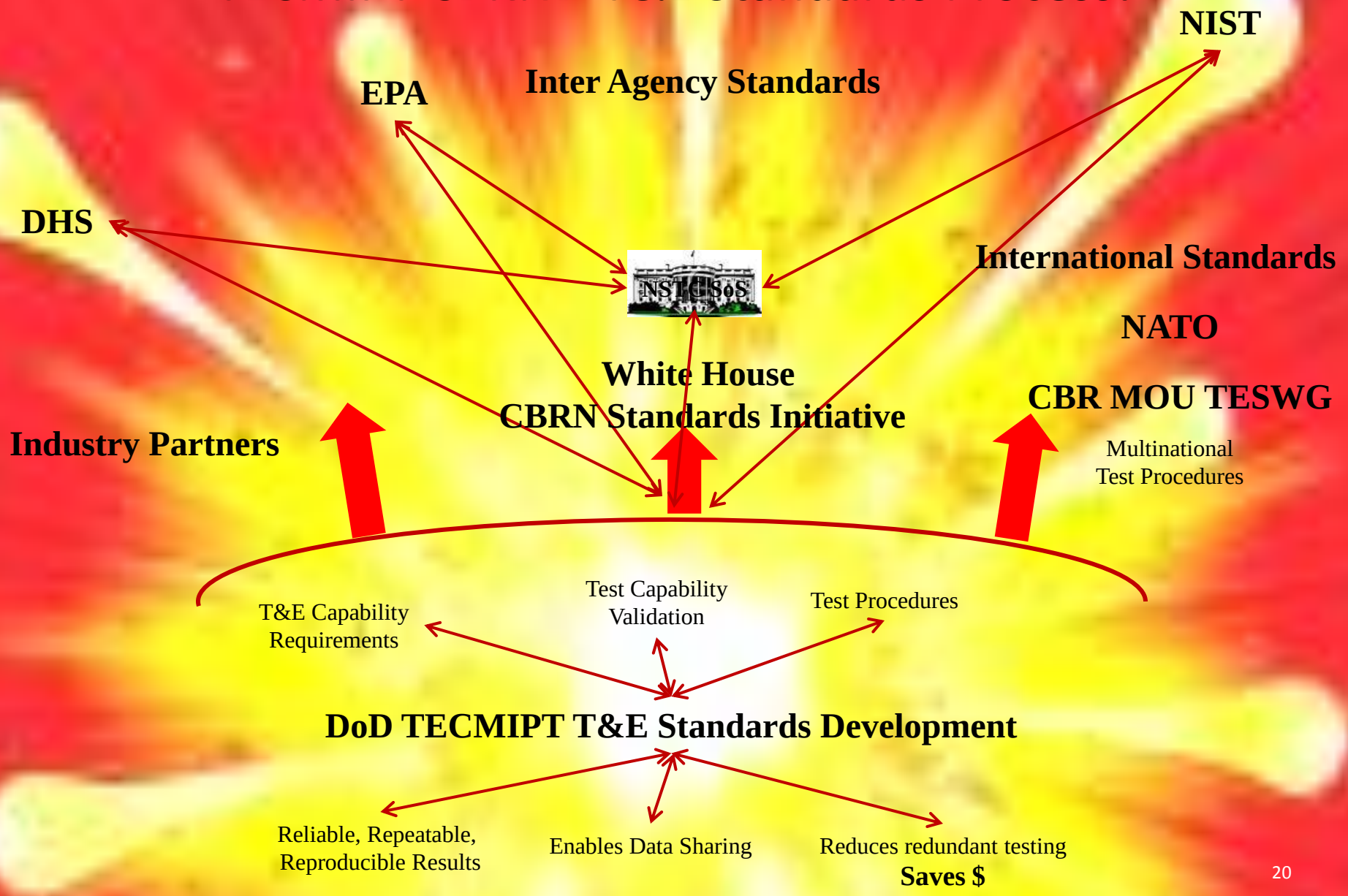
- **JPEO-CBD, JSTO, JRO, ATEC (AEC, OTC, DTC, DPG), MCOTEA, OPTEVFOR, AFOTEC, ECBC, DOT&E, NSWC-Dahlgren, AMSAA (serves as TECMIPT Chair for DUSA-TE), NIST, DHS, EPA**
- **Identifies T&E capability gaps for DUSA-TE's POM submission**
- **June 2009 – Instructions to the TECMIPT: Develop/review/recommend T&E standards documents for CBRND T&E Executive approval**
- **July 2010 – CBDP T&E Standards Development Plan signed into policy by CBRND T&E Executive**
  - **Includes plans for QA - obtain outside certification of all DoD CBDP test labs**

TECMIPT Mechanism for T&E Standards Development

- **Seven Capability Area Process Action Teams (CAPATs) develop/review/recommend T&E standards documents for CBRND T&E Executive approval**

- **CAPATs:**
  - **Chemical Detection**
  - **Biological Detection**
  - **Individual Protection**
  - **Collective Protection**
  - **Decontamination**
  - **Radiological/Nuclear (cross-commodity)**
  - **M&S (cross-commodity)**

Explosion of Interest in TECMIPT CBRND T&E Standards Process!



Principles and Key Actions

- **Rigorous Testing is Required to Ensure Vendor and System Compliance with Standards**
- **Standards and Conformity Assessment Processes Must be Identified and Adopted Across all Agencies to Ensure Full Interoperability**
- **Timely Adoption and Use of Appropriate Standards is Critical to Achieving Goals**


Questions?