NIST Handbook 150-872

2021 Edition

NVLAP Federal Warfare System(s)

Jeannine A. Abiva, PhD Jesse I. Angle, PhD John H. Avera David C. Dobosh Phillip J. Hanes, PhD John D. Matyjas, PhD Raymond G. Tierney, Major, USAF Bradley Moore

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July 2021



U.S. Department of Commerce *Gina M. Raimondo, Secretary*

National Institute of Standards and Technology James K. Olthoff, Performing the Non-Exclusive Functions and Duties of the Under Secretary of Commerce for Standards and Technology & Director, National Institute of Standards and Technology Certain commercial entities, equipment, or materials may be identified in this document in order to describe an experimental procedure or concept adequately. Such identification is not intended to imply recommendation or endorsement by the National Institute of Standards and Technology, nor is it intended to imply that the entities, materials, or equipment are necessarily the best available for the purpose.

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Foreword

The National Institute of Standards and Technology (NIST) Handbook (HB) 150 publication series sets forth the procedures, requirements, and guidance for the accreditation of testing and calibration laboratories by the National Voluntary Laboratory Accreditation Program (NVLAP). The series compromises the following publications:

- NIST HB 150, *NVLAP Procedures and General Requirements*, which contains the general procedures and requirements under which NVLAP operates as an unbiased third-party accreditation body;
- NIST HB 150-xx program-specific handbooks, which supplement NIST HB 150 by providing additional requirements, guidance, and interpretive information applicable to specific NVLAP Laboratory Accreditation Programs (LAPs).

The program-specific handbooks are not stand-alone documents, but rather are companion documents to NIST HB 150. They tailor the general criteria found in NIST HB 150 to the specific tests, calibrations, or types of tests or calibrations covered by a LAP.

NIST HB 150-872, *NVLAP Federal Warfare System(s)*, presents the technical requirements and guidance for the accreditation of laboratories under the NVLAP Federal Warfare Systems (FWS) LAP.

This Laboratory Accreditation Program is not intended to support the testing of any specific technology. Rather, it is a process accreditation to ensure the competence, impartiality, and operational consistency of laboratories supporting the Federal Warfare Systems by means of System Integration Testing (SIT) and Operational/User Acceptance Testing (O/UAT).

The handbook is intended for information and use by accredited laboratories, assessor(s) conducting onsite assessments, laboratories seeking accreditation, users of laboratory services, and others needing information on the requirements for accreditation under this program. All statements in this handbook are supplemental to and do not contradict ISO/IEC 17025 and NIST HB 150. If ambiguity unintentionally arises, the ISO/IEC 17025 and NIST HB 150 requirements take precedence.

The 2021 Edition of NIST HB 150-872 is the initial edition of this handbook.

The handbook was created with the participation of technical experts from the Air Combat Command (ACC) Federal Laboratory – Beale, formerly known as the U-2 Federal Laboratory (Beale Air Force Base; California) and the United States Air Force (USAF) Air Combat Command (ACC) Science and Technology Directorate (Office of the Chief Scientist; Joint Base Langley-Eustis, Virginia). The requirements of ISO/IEC 17025, NIST HB 150, and NIST HB 150-872 combine to produce the criteria for accreditation in the NVLAP Federal Warfare Systems LAP. Laboratories who successfully pass FWS LAP assessment will join a community of more than 700 laboratories with active NVLAP accreditations.

It is important to note that a Laboratory Management System is a foundational component to meeting the aforementioned requirements.

This handbook is available on the NVLAP website (<u>https://www.nist.gov/nvlap/publications-and-forms/nvlap-handbooks-and-lab-bulletins</u>) and at the NIST Research Library (<u>https://doi.org/10.6028/NIST.HB.150-872-2021</u>).

Questions or comments concerning this handbook should be submitted to NVLAP, National Institute of Standards and Technology, 100 Bureau Drive, Stop 2140, Gaithersburg, MD, 20899-2140; phone: 301-975-4016; fax: 301-926-2884; e-mail: nvlap@nist.gov.

Acknowledgements

This Federal Warfare Systems Laboratory Accreditation Program was developed by NVLAP (NIST; Department of Commerce) at the request of the ACC Federal Laboratory – Beale. The program was created under the support and affirmation of the USAF ACC Science and Technology Directorate – led by the ACC Chief Scientist, Dr. John Matyjas. Since the Laboratory's inception, the following individuals have meaningfully and graciously provided support by means of their wisdom, guidance, and professional expertise: Lt. Gen. (Ret.) Robert P. "Bob" Otto, Ms. Jessica R. Todd, Lt. Col. Matthew E. Nussbaum, Mr. Hung D. Nguyen, CAPT. (Ret.) Al Pollard, and Mr. Brian Ark. Additionally, the authors would like to thank the uniformed service members, scientists, and NIST colleagues for their unwavering sacrifices in support and defense of the United States of America.

Introduction

In 2019, at the request of the ACC Federal Laboratory - Beale, NVLAP initiated the process to establish this program to address the needs of Federal Major Weapons systems. The Federal Warfare Systems(s) (FWS) Laboratory Accreditation Program (LAP) establishes the 20th laboratory accreditation program in NVLAP. It standardizes the traceability, competence, impartiality, and operational consistency of all laboratories of this type in the Department of Defense (DoD). Importantly, this LAP specifically affords FWS Laboratories within the DoD a standardized means to address the findings of The Report of the Committee on Armed Services, House of Representatives, on H.R. 5515 (National Defense Authorization Act (NDAA) for FY 2019) as well as 2018 National Defense Strategy mandates.

Background¹

Provenance of the Need

The Report of the Committee on Armed Services, House of Representatives, in H.R. 5515 (National Defense Authorization Act (NDAA) for FY 2019), states, "The committee has continuing interest in the Department of Defense laboratories and engineering centers, their responsiveness to Department of Defense requirements, and maximizing their expertise and reach. The Department's laboratories are integral to the Department's ability to retain capability in areas where the private sector has no commercial interest, and ensuring that commercial solutions are adapted for warfighter needs in a timely manner so that the United States remains dominant in the land, air, sea, space, and cyber domains. The committee recommends that the Department better enable laboratories and centers to embrace an open and innovative posture, while simultaneously becoming more active in the Department's requirements process."

The 2018 National Defense Strategy (NDS; p.11), furthers this thought by directing that, "prototyping and experimentation should be used prior to defining requirements." Such prototyping and experimenting are intended as a method to streamline rapid, iterative approaches from development to fielding. The NDS (Page 10; Organize for Innovation) directs Department leaders to "adapt their organizational structures to best support the Joint Force."

The Congressionally mandated response to the 2018 NDS (Providing for the Common Defense: The Assessment and Recommendations of the National Defense Strategy Commission; Page 65), Recommendation No. 7, states that "The Secretary of Defense should... make maximum use of...government R&D labs."

In accordance with the Chairman of the Joint Chiefs of Staff Instruction (CJCSI) 3170.01(2)(a)(1) (Joint Capabilities Integration and Development System; JCIDS), "Prior to entering the JCIDS Process...assess capability requirements and associated capability gaps and risks." Warfare System stakeholders are responsible for assessing capability gaps and risks, and generating requirements germane to that weapon system. To meet 2018 NDS intent, Warfare System stakeholders now require a capability to prototype and experiment prior to requirement generation.

¹ Major Tierney, Raymond G. (Newt), ACC Federal Laboratory – Beale, "<u>The Federal Warfare Systems Laboratory</u> <u>Executive Summary</u>" (unpublished manuscript - November 5, 2020 - now available on FWS LAP webpage - <u>https://www.nist.gov/document/basis-lap-original-white-paper</u>) and reproduced, in part, here.

In response to the aforementioned criteria, the ACC Federal Laboratory-Beale was established in accordance with Title 15 U.S.C. § 3710 and 10 U.S.C § 2500 with a mission to "Fast-field advanced technologies at a speed relevant to the warfighter," in accordance with the 2018 National Defense Strategy (p.10) – accomplished through a vision to affect the "Confluence of Warfighter, Developer, and Acquirer," vertically integrated under the same operational roof.

The Imperative

"Discover the Future."

-Lt. Col. Matthew 'Chaos' Nussbaum

"Delivering performance means we will shed outdated management practices and structures while integrating insights from business innovation...If current structures hinder substantial increases in lethality or performance, it is expected that Service Secretaries and Agency heads will consolidate, eliminate, or restructure as needed."² Change is not optional – it is expected. What if we fail to change? How much time is left?

A Primer on Federal Laboratories

The What

"Our competitive military advantage has been eroding. We are facing increased global disorder, characterized by a decline in the long-standing rules-based international order."

-2018 National Defense Strategy

This global shift ushers in a high-stakes epoch. Without commensurate change, the Department of Defense (DoD) cannot achieve the pivot velocities required to stay ahead of our adversaries.

The So What

"The current bureaucratic approach, centered on exacting thoroughness and minimizing risk above all else, is proving to be increasingly unresponsive."

-2018 National Defense Strategy

<u>Why this matters</u>: From 1945 to 1974, the mean time to develop a new aircraft from program start to Initial Operational Capability (IOC) was five years. In 1975, the DoD Directive 5000.01 (*The Defense Acquisition System*) was first published. Since then, time-to-IOC has increased at rate of approximately five years per decade. *Exempli gratia*: The F-18 achieved IOC in 11 years (1985), the B-2 in 16 years (1996), and the F-22 and F-35 in 19 years (2005) and 21 years (2016) respectively.

What Right Looks Like

"Prototyping and experimentation should be used prior to defining requirements."

-2018 National Defense Strategy

<u>No amount of policy modification will correct this problem</u>. The boundaries of the known marketplace (Defense Acquisition System, Joint Capabilities Integration and Development System, and Planning, Programming, Budgeting, & Execution process) are well defined and unilaterally accepted. This yields limited freedom of maneuver to reconcile inefficiency – a domain best characterized as a "Red Ocean."

² 2018 National Defense Strategy

It is possible, however, to approach the issue externally – from the vantage of an unknown, uncontested marketplace which exists 'pre-requirement.' In this space, "cumbersome approval chains, wasteful applications of resources in uncompetitive space, or overly risk-averse thinking that impedes change"³ can be eliminated by virtue of the unregulated nature of the space. Touch-points to acquisition milestones are reduced. Access and knowledge (e.g., Science, Technology, Engineering, and Math (STEM), Acquisitions, Contracting, & Financial) at the warfighter level are raised. And new Federal Laboratories and associated accreditation programs are created. This, domain is best characterized as a "Blue Ocean."

<u>Tierney's Philosophical Razor</u>: "To change a system, a requirement cannot exist that the system must change." The value of this model is that it does not demand any modification to existing Defense Acquisition System, JCIDS, and/or planning, programming, budgeting, and execution (PPBE) systems. Implementation is external and seamless.

<u>Why this works – direct Warfighter integration</u>. FWS Federal Laboratories bring development and acquisitions in-house with operations. Through this, the Warfighter is empowered with the access and knowledge required to rigorously mature requirements to well-vetted, high-Technology Readiness Level (TRL) solutions – reducing risk, compressing milestones to field, and front-loading the system to mitigate unknown-unknowns. This embedded model is faster and more accurately delivers capabilities that the Warfighter needs. Through this model, development costs are offset via (1) a vertically-integrated, embedded developer model and (2) by leveraging local training (fielded weapon systems, operated by Warfighter personnel – neither of which are generally used test operations).

<u>Differentiation from current approaches</u>. AFWERX, Defense Innovation Unit, and similar programs are inspiring efforts designed to kindle emerging businesses with Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) resources to mature technologies with promising defense application. Although these companies may be involved with the warfighter as part of the process, they are not organizationally integrated. <u>Access</u> (to Authorization Officials, operators, weapon systems, program engineers, cyber security expertise, industry partners, etc.) <u>and knowledge</u> (of requirements, Tactics/Techniques/Procedures, government acquisitions, program management, contracting, STEM, etc.) <u>remains limited</u>. For this reason, the burden to shepherd these technologies from concept to field remains with the warfighter – who often lack the time, contacts, and acquisition/finance/contracting knowledge to successfully guide these new companies to field their technologies. Additionally, they must compete with incumbent efforts (backed by a robust industrial base) for funding and sustainment.

The How

"Individuals and interactions over processes and tools. Working systems over comprehensive documentation... [and] as a primary measure of success."

-agilemanifesto.org

<u>Old World</u>. Warfighters are, by nature, imperfect at capturing physical or functional needs in writing. This is attributed to (1) Problems of Scope, (2) Problems of Understanding, and/or (3) Problems of Requirement Volatility. In response, the Defense Acquisition System and Joint Capabilities Integration and Development System (JCIDS) were created to ensure exacting thoroughness and abate risk. As seen, the results came at cost.

³ 2018 National Defense Strategy

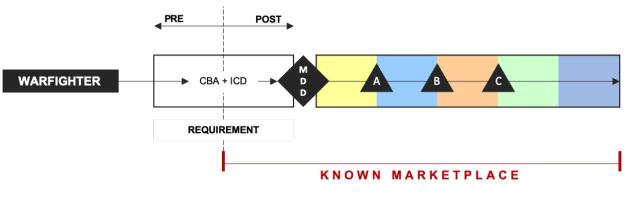




Figure 1. Mated diagram showing the Defense Acquisition System and JCIDS timeline of Capabilities Based Assessment (CBA), Initial Capabilities Document (ICD), Materiel Development Decision (MDD), and Milestones A, B and C as related to official warfighter Requirements. While the traditional acquisition process is post-Requirement, a FWS Federal Laboratory operates pre-Requirement.

<u>New World</u>. New Federal Warfare Systems laboratories are introduced. The FWS laboratory construct exploits an unregulated space that exists left of "Requirement," as defined by the DoD Directive 5000.01. Business would characterize this environment as an uncontested market space – as mentioned, a true "Blue Ocean." Under this framework, advanced technologies can be developed or integrated to determine technical feasibility ("Is it possible?"). Embedded developers then hand the technology to the Warfighter to determine operational utility ("Is it useful?"). This process continuously cycles between development and operations, with a fluidity impossible to realize by current DoD processes.

End-state is achieved when the technology has evolved to a TRL, Warfighter-useful solution. At this point, the technology graduates normally into the Joint Capabilities Integration and Development System and Defense Acquisition System (DoD Directive 5000.01 and DoD Instruction 5000.02) as a vetted, mature requirement. In this way, the acquisitions process is compressed, and cost offsets realized, by (a) front-loading development with the end-user, and (b) abatement of the problems of scope, understanding, and volatility associated with the requirements process. Additionally, the Chairman of the Joint Chiefs of Staff Instruction (CJCSI) 5123.01H(1)(d)(4) states, "Once proven at the appropriate technology level an S&T [Science & Technology] effort, prototype, and/or other innovative approach must align with existing capability requirements or be supported by an analysis that makes a defendable case for a new capability."

As Title 15 U.S.C. § 3710a Federal Research Laboratories, technology endeavors within FWS laboratories constitute as S&T efforts (and potentially as prototypes and/or innovative approaches). As such, the CJCSI 5123.01H(1)(d)(4)(c)(1) provision stating, "For evolutionary technologies that support an expeditious deployment of successful weapon system component or technology prototypes IAW [In Accordance With] reference m, JCIDS is flexible enough to consider entry at Milestone B with a new or updated CDD [Career Development Document] provided there is traceability to a validated capability requirement (JUON, JEON, DoD component UON, and ICD) [Joint Urgent Operational Need, Joint Emergent Operational Need, DoD Component Urgent Operation Need, and Initial Capabilities Document]" may be reasonably applied.

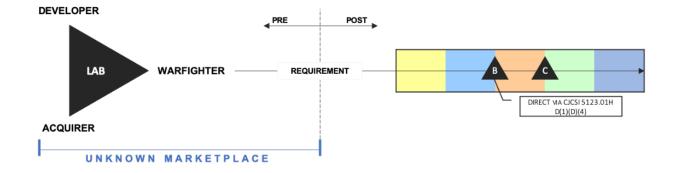


Figure 2. Diagram illustrating how the FWS laboratory integrates with the existing acquisition system.

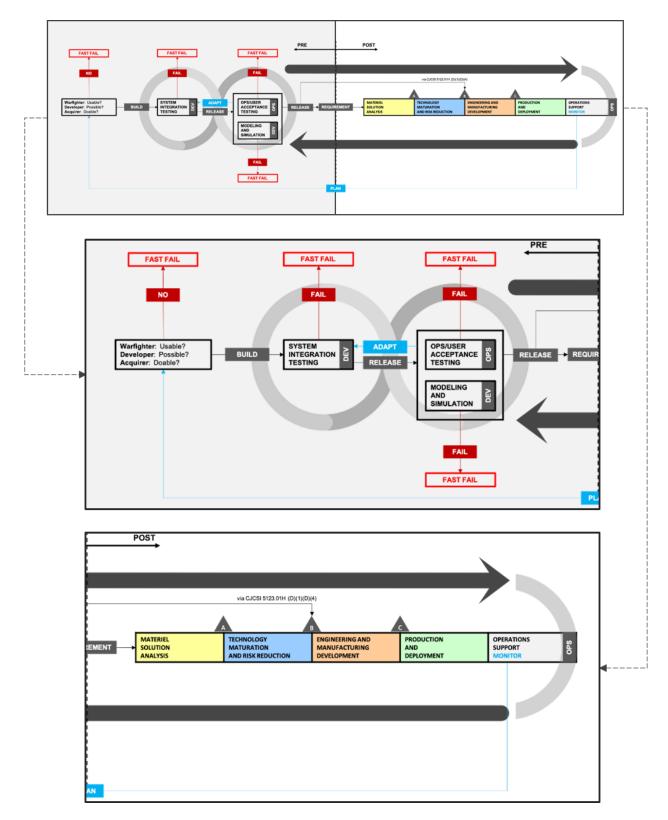


Figure 3. Federal Warfare Systems laboratory – Process View, Full Zoom (top), Pre-requirement, Left Half zoom of Process View (middle), Post-requirement, Right Half zoom of Process View (bottom)

Evidence this is Real

The ACC Federal Laboratory-Beale developed the Advanced Virtualized Enterprise Reconfigurable Architecture (AVERA+; First Flight: 2019NOV13) as a 100% government-owned Open Software Architecture to enable rapid edge development and the delivery of advanced capabilities to fielded Major Weapon Systems (MWS). The Lab went from first line of code to first flight in six months. With this locally-developed capability, a team of six achieved:

- First in DoD⁴: In-flight utilization of Kubernetes on a fielded Major Weapon System (First Flight: 2020SEP22). Container orchestration & processing distribution across four singleboard computers onboard a U-2 in-flight. Allows non-materiel aggregation of legacy computers onboard fielded MWS to run advanced AI/ML algorithms with higher-performance processing requirements. Work start to first-flight: 24 days.
- First in DoD⁵⁶: <u>In-flight Software Update</u> (First Flight: 2020OCT16). Uploaded and deployed Auto Target Recognition algorithms to a U-2 in-flight. End-end data transfer leveraged operationally-representative U-2 ground-air link architecture. Dr. Roper challenged the Lab in-person (13 OCT 20) to achieve this milestone. Challenge to response: 2 days, 22 hours.
- First in DoD⁷⁸: <u>In-flight Pilot-AI teaming</u> (First Flight: 2020DEC15). The Lab deconstructed/modified a learning algorithm to demonstrate two onboard workers (Pilot & artificial intelligence identified as 'ARTUµ') each with individual, competing missions, a shared common resource, and with human actions unknown to the AI. Dr. Roper challenged the Lab on 10 NOV 20. Challenge to response: 35 days.
- <u>First in DoD</u>²: <u>In-flight Utilization of PlatformONE on a fielded Major Weapon System</u> (First Flight: 2021MAR23). Partnered with PlatformONE engineering staff to integrate relevant selections from the "BigBang" product line (a portion of PlatformONE's cybersecurity and Zero Trust offerings) to enhance the security posture of laboratory software in alignment with DoD Chief Information Officer direction. Work start to first-flight: 13 days.

Pathway to the FWS LAP Development

Types of Laboratories

There are several types of laboratories in the U.S. Government – all derive from different statutory authorities. First are Federally Funded Research & Development Centers (FFRDCs) – also called National Laboratories (48 U.S.C. § 35.017). These are Public-Private Partnerships with the U.S. Government. The second are University Affiliated Research Centers (UARCs; 10 U.S.C. § 2304). These are established by the Under Secretary of Defense (R&E) and are DoD research centers affiliated with universities. Finally, there are Federal Research Laboratories (Title 15 U.S.C. § 3710 & 10 U.S.C § 2500). These are established by Federal Agencies, and must be "a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering

⁴ https://www.af.mil/News/Article-Display/Article/2375297/u-2-federal-lab-achieves-flight-with-kubernetes

⁵ https://www.thedrive.com/the-war-zone/37131/u-2-spy-plane-got-new-target-recognition-capabilities-in-first-ever-in-flight-software-update

⁶ https://www.c4isrnet.com/air/2020/10/09/the-air-force-updated-the-software-on-one-of-its-oldest-aircraft-while-it-was-in-the-air/

⁷ https://www.washingtonpost.com/business/2020/12/16/air-force-artificial-intelligence/

⁸ https://www.popularmechanics.com/military/aviation/a34978872/artificial-intelligence-controls-u2-spy-plane-air-force-exclusive

⁹ https://www.acc.af.mil/News/Article-Display/Article/2557413/accs-u-2-federal-laboratory-rapidly-integrates-platform-one-in-first-weapons-sy/

by employees of the Federal Government." The ACC Federal Laboratory-Beale is an example of a Federal Research Laboratory.

Understanding Accreditation

LAPs are necessary for laboratories to develop the management and technical schema required to govern testing operations. LAPs also set requirements to standardize the competence, impartiality, and operational consistency of laboratories. In the U.S., NVLAP exists under NIST to provide unbiased, third-party evaluation to accredit laboratories (in their respective fields) in accordance with the International Organization for Standardization (ISO) 17025 standard (Testing and Calibration Laboratories).

Value of Accreditation

Grounded on universally recognized standards (e.g., NIST, NVLAP, ISO/IEC, etc.), accreditation provides FWS Laboratories with the requisite bona fides (credibility) necessary to interact with Government (e.g., System Program Offices supporting defense systems, Services Laboratories, etc.), Industry, Academia, and/or Federally-Funded Research and Development Centers (FFRDCs – also known as National Laboratories; e.g., Sandia National Laboratories).

1 General information

1.1 Scope

1.1.1 This handbook specifies the technical requirements and provides guidance for the accreditation of laboratories under the NVLAP Federal Warfare Systems Laboratories Accreditation Program (FWS LAP). It supplements the NVLAP procedures and general requirements found in NIST HB 150, *NVLAP Procedures and General Requirements*, by tailoring the general criteria found in NIST HB 150 to the specific types of testing covered by the FWS LAP.

1.1.2 NIST HB 150, this handbook, and ISO/IEC 17205, and their respective checklists constitute the collective body of requirements that must be met by a laboratory seeking NVLAP accreditation for this LAP.

1.1.3 This handbook is intended as informational and for use by accredited FWS laboratories, assessors conducting onsite assessments, laboratories seeking accreditation, users of laboratory services, and others needing information on the requirements for accreditation under the FWS LAP.

1.1.4 The goal for this document, in conjunction with ISO/IEC 17025 and NIST HB 150, is to provide the technical requirements and guidance necessary to attain NVLAP accreditation of FWS laboratories capable of performing System Integration Testing (SIT) and Operational/User Acceptance Testing (O/UAT), such that each testing method ensures reproducible, decision-quality results. NVLAP recognizes that FWS encompass a wide spectrum of technologies and associated user requirements.

1.1.5 The scope of testing activities covered under this LAP include SIT and O/UAT.

1.2 Organization of handbook

1.2.1 The numbering and titles of clauses four through eight of this handbook intentionally match those of ISO/IEC 17025. The primary subclauses in clauses four through eight (e.g., 4.1, 4.2, etc.) are also numbered and titled to correspond with ISO/IEC 17025, even when there are no additional requirements. For sections denoted with the text "*there are no requirements additional to those set forth in....*", refer to ISO/IEC 17025 or NIST HB 150

1.3 Program description

1.3.1 The FWS Program accredits testing laboratories to ensure that they are competent to define and conduct SIT and O/UAT testing activities.

1.3.2 A laboratory may request to have parameters, calibrations, or other features added to the scope of the FWS LAP. Any additions or deletions will be handled in accordance with NVLAP procedures for adding to or modifying an established LAP (see NIST Handbook 150, clause 2).

1.4 References

The following documents are referenced in this handbook. For undated references, the latest revision applies. When a specific clause(s) of a document is cited, the date of the referenced document is included.

- ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories
- NIST HB 150, NVLAP Procedures and General Requirements (<u>https://doi.org/10.6028/NIST.HB.150-2020</u>)
- DoD Directive 5000.01, *The Defense Acquisition System* (https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/500001p.pdf?ver=2020-09-09-160307-310)
- DoD Instruction 5000.02, *Operation of the Adaptive Acquisition Framework* (<u>https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/500002p.pdf</u>)
- Chairman of the Joint Chiefs of Staff Instruction (CJCSI) 5123.01H, *Charter of the Joint Requirements Oversight Council (JROC) and Implementation of the JCIDS*" (<u>https://www.jcs.mil/Portals/36/Documents/Library/Instructions/CJCSI%205123.01H.pdf?ver=2018-10-26-163922-137</u>)
- 2019 NDAA, Report of the Committee on Armed Services, House of Representatives, on H.R. 5515 (National Defense Authorization Act for FY 2019 (https://www.congress.gov/115/bills/hr5515/BILLS-115hr5515enr.pdf)
- 2018 NDS, Summary of the 2018 National Defense Strategy (https://dod.defense.gov/Portals/1/Documents/pubs/2018-National-Defense-Strategy-Summary.pdf)
- Providing for the Common Defense, The Assessment and Recommendations of the National Defense Strategy Commission (<u>https://www.usip.org/sites/default/files/2018-11/providing-for-the-common-defense.pdf</u>)

1.5 Terms and Definitions

For the purposes of this handbook, the terms and definitions given in NIST HB 150, ISO/IEC 17025, and the following apply.

1.5.1 Federal Laboratory

Title 10 U.S.C § 2500(5) references the definition in Title 15 U.S.C. § 3710a(d)(1)(2)(A) as "a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government."

1.5.2 Warfare System (WS)

A generalized term originating from the 48 C.F.R. § 234.70 (Federal Acquisition Regulation) definition for a "Major Weapon System," defined as "*a weapon system acquired pursuant to a major defense acquisition program.*" The term "Warfare Systems" is defined in this handbook as an agnostic category of defense technologies derived from government, academic, or industry sources which provide support to all warfighting domains (e.g., sea, land, air, space, and cyberspace). The use of this broad definition is deliberate and is not confined to those technologies which are formally titled "Weapon System," "Major Weapon System," or similar. Additionally, the definition is not meant to exclude technologies developed in support of Federal, State, Municipal, and/or other uniformed services as defined by 10 U.S. Code § 101(a)(5).

1.5.3 System Integration Testing (SIT)

The testing of a system as the aggregate of many subsystem components and/or elements. The system(s) tested may be composed of hardware, software, and/or hardware with embedded software. SIT methods may adopt a continuous integration, continuous delivery model with established configuration controls.

NOTE SIT is the assessment of a system against set technical criteria to determine whether it functions as expected (i.e., "Does it work?").

1.5.4 Operational/User Acceptance Testing (O/UAT)

The testing of systems post-SIT in collaboration with the end-user (e.g., airplane pilot, etc.). O/UAT test cases will include operational logic evaluations and representative environmental conditions. End-users will be the primary stakeholders of these tests.

NOTE *O/UAT is the assessment of a system against set user-defined criteria to determine operational suitability (i.e., "Is it useful?").*

1.6 Program documentation

1.6.1 General

NVLAP assessors use NVLAP checklists to ensure that each laboratory receives an assessment comparable to that received by others. Checklists assist assessors in documenting the assessment to the NVLAP requirements found in ISO/IEC 17025, NIST HB 150, and this handbook. Checklists contain definitive statements or questions about all aspects of the NVLAP criteria for accreditation and form part of the onsite assessment report (see NIST Handbook 150).

1.6.2 NVLAP General Criteria Checklist

All NVLAP programs use the NVLAP General Criteria Checklist, which contains the requirements published in ISO/IEC 17025 and NIST HB 150. The checklist items are numbered to correspond to clauses four through eight of ISO/IEC 17025 and Annexes A, B, and E of NIST HB 150.

1.6.3 NIST Handbook 150-872 Checklist

The NIST HB 150-872 Checklist addresses the requirements specific to this LAP. The current version of the checklist is available from the NVLAP website at https://www.nist.gov/nvlap.

1.6.4 NVLAP Lab Bulletins

NVLAP Lab Bulletins are issued to laboratories and assessors, when needed, to clarify program-specific requirements and to provide information about program additions and changes.

2 LAP establishment, development, and implementation

There are no requirements additional to those set forth in NIST HB 150.

3 Accreditation process

3.1 General

3.1.1 An overview of the laboratory accreditation process is provided in NIST HB 150, clause 3, and includes information pertaining to: application for accreditation, onsite assessment, proficiency testing, accreditation decision, granting accreditation, renewal of accreditation, changes to scope of accreditation, monitoring visits, suspension, denial, revocation, and voluntary termination of accreditation.

3.1.2 The assessment process consists of a NVLAP review of the laboratory's application and management system documentation as well as an onsite assessment visit.

3.1.3 The applicant laboratory or NVLAP may consider a pre-assessment onsite visit to better define a laboratory's requested scope of accreditation. In such cases, the pre-assessment costs will be charged to the laboratory in addition to the actual onsite assessment fee.

3.2 Initial capability demonstration

3.2.1 In order to receive NVLAP accreditation, the laboratory shall demonstrate its competence to conduct SIT and O/UAT evaluations. The NVLAP decision will be based upon information drawn from the management system review, onsite visit(s), and evaluation of historical SIT and O/UAT activity, as required.

3.2.2 It is important to note that the laboratory cannot be granted accreditation unless:

- the laboratory has provided documentation of previously demonstrated SIT and O/UAT activity, as required;
- the laboratory staff has demonstrated an understanding of, and competence to, perform SIT and O/UAT during the initial evaluation;
- the laboratory has demonstrated that it has exercised its management system and has produced appropriate records to verify as such.

3.3 Management system review

3.3.1 Prior to applying to NVLAP for accreditation, a laboratory should have a fully implemented management system. If the management system of the laboratory uses different numbering than that of ISO/IEC 17025, the laboratory shall create a cross-reference document allowing both the laboratory and a NVLAP assessor to readily verify that all requirements of clauses four through eight of ISO/IEC 17025, as well as other applicable general NVLAP requirements, are met by the management system. It should be noted that the NVLAP General Criteria Checklist contains a column for the location of specific requirements within a laboratory's management system and, when completed, may serve as a core part of a cross-reference document. The checklist associated with this handbook may be similarly used.

3.3.2 Prior to the onsite assessment, the NVLAP assessor will review laboratory documents to ensure they cover all aspects of the management system and, if followed, satisfy the requirements in ISO/IEC 17025, NIST HB 150, this handbook, and applicable test methods for which the laboratory seeks accreditation. The NVLAP assessor may also request additional technical documents for review prior to arriving onsite. During the review, the NVLAP assessor may identify nonconformities and require changes to the management system so that it meets requirements.

3.4 Onsite assessment

3.4.1 The purpose of the onsite assessment is to determine whether the laboratory is following its documented management system and to assess the competence of the laboratory's delivery of its testing services.

3.4.2 Onsite assessments will take place at the laboratory site. Prior to the visit, the NVLAP assessor will provide a preliminary agenda. Efforts will be made to minimize disruption to normal working routines during the assessment. The assessor will need time and private workspace to complete assessment documentation during their time at the laboratory site.

3.4.3 The assessor may be accompanied by SMEs from other FWS laboratories to help in assessing competence, proficiency, and suitability of candidate laboratory. To minimize conflicts of interest, these SMEs should not be FWS laboratory members who have provided mentoring during the early establishment period of candidate laboratories.

3.4.4 All laboratory equipment required to perform accredited testing shall be available for assessment and in good working order. Although all test methods on the scope or proposed scope of accreditation need not be set up during the onsite assessment, the laboratory shall be prepared to demonstrate selected test methods as requested by the assessor. For those cases where a demonstration is not requested, the laboratory shall be prepared to describe the test method and procedures it would follow and show the actual equipment, fixtures, and arrangements that would be used. The assessment will cover the requirements identified in this handbook, NIST HB 150, ISO/IEC 17025, the laboratory's management system documentation, and the laboratory's written detailed test and/or evaluation instructions.

3.4.5 The laboratory shall make available all supporting technical information in a format that is conducive to a detailed review. The assessor may request additional information to clarify issues regarding nonconformities or to delve more deeply into technical issues.

3.4.6 The activities covered during a typical onsite assessment are described below:

a) Opening meeting: The NVLAP assessor will meet with laboratory management, supervisory personnel, and other appropriate staff members as determined by the laboratory to explain the purpose of the onsite assessment and to discuss the schedule for assessment activities. Information provided by the laboratory on its application form may be discussed during this meeting.

b) Staff interviews: The assessor will ask the laboratory director or technical director to assist in arranging times for individual interviews with laboratory staff members. The assessor will interview staff members filling key positions (e.g., laboratory director, technical director, quality manager, authorized representative, approved signatories, etc.) and staff members who conduct, or otherwise have an effect on, the outcome of testing or the operation of the laboratory. The assessor does not need to talk to all staff members; however, the assessor will select a representative sample of staff members representing all areas of the laboratory. These interviews are conducted to determine whether the staff members are properly trained, assigned, and supervised, and are technically competent to perform tasks assigned to them, and are implementing the assigned aspects of the management system and are in compliance.

c) Records review: The assessor will review laboratory documentation, including the management system policies and procedures, equipment and maintenance records, record-keeping procedures, testing procedures, laboratory test records and reports, personnel competency records, personnel training plans and records, and safeguards for the protection of classified, sensitive, and proprietary information. Laboratory staff should be available to answer questions pertaining to the accreditation review; however, the assessor may wish to review documents and records in private.

d) Internal audit and management review: The assessor will review and discuss with the laboratory staff the laboratory's internal audit and management review activities, which are viewed as separate and distinct activities. The discussion will include all aspects of those activities including management system procedures, audit findings, cause determination, actions taken to resolve problems identified, actions taken to prevent recurrence, and results of the management review.

e) Equipment and software: The assessor will examine and determine the suitability of all equipment and facilities required to perform the standard test methods for which the laboratory is accredited (or is seeking accreditation). The appropriate environmental conditions required for testing will be assessed. The assessor will observe the demonstration of selected procedures by appropriate personnel assigned to conduct the tests and will interview those personnel. The assessor will review test data, examine hardware and software for function and appropriateness, and review software validation and verification procedures, records, and proper-use authorizations (e.g., licenses, etc.).

f) Demonstrations: Based on the scope of accreditation, the assessor will observe demonstrations of selected testing procedures conducted by technical personnel assigned to conduct the testing and will discuss the testing to assure the staff understanding of the procedures. The assessor may select and trace the history of one or more samples from receipt to final issuance of the test reports.

g) Quality control: The assessor will discuss all aspects of quality control results (see Section 7.7 of ISO/IEC 17025; Ensuring the validity of results) with appropriate staff. Test methodology and records documenting the laboratory's execution of testing will be reviewed and discussed. Any unusual trends or outlying results will be discussed.

h) Onsite assessment report: The assessor will complete an onsite assessment report, which summarizes the findings and clearly lists nonconformities and comments (both positive and/or negative). This report normally consists of the Onsite Assessment Narrative Summary, the NVLAP General Criteria Checklist, and the NIST HB 150-872 Checklist.

i) Closing meeting: The assessor will conduct a closing meeting with the laboratory director, technical director, and other appropriate staff members to discuss the findings. During the visit the assessor will have identified all nonconformities and comments. These will be discussed at the closing meeting. The assessor will specifically note items that have been corrected during the onsite assessment along with any identified during the onsite assessment for other action(s). The process for resolving nonconformities identified during the onsite assessment is documented in NIST HB 150. Disagreements between the laboratory and the assessor shall be referred to NVLAP for arbitration and final resolution. The first page of the onsite assessment report is signed by the assessor and the laboratory's Authorized Representative to acknowledge the discussion but does denote agreement on the part of the laboratory. A copy of the report is given to the Authorized Representative for retention. The assessor sends the original document to NVLAP.

3.4.7 The laboratory's response to all nonconformities shall be clearly documented, providing a reference to applicable sections in the management system, the assessor's onsite assessment report, and any other technical supporting information. If found to be incomplete, NVLAP may reject the laboratory's response submission and request that the laboratory resubmit and provide the necessary documentation in order to facilitate a complete review of the resolved nonconformities.

3.4.8 The laboratory should review all comments for potential improvements to its processes and/or operations. It is not required that actions be taken in response to comments; nor is there a requirement to notify NVLAP of any response or non-response to comments.

3.5 **Proficiency testing**

3.5.1 The laboratory management system shall define the procedures, forms, and/or tools used to implement proficiency testing (PT) activities, including planning and reporting. The Director and Technical Director shall bear the overall responsibility for the efficacy of the PT program.

3.5.2 PT plans and schedules shall be developed by each laboratory and updated as required. Each laboratory shall review PT plans to determine if the frequency and scope is appropriate and adequate.

3.5.3 Minimum requirements: Each laboratory staff member shall participate in one PT activity per major sub-area of their accredited scope between recurring NVLAP assessments. It is recommended that laboratories participate in PT activities for both SIT and O/UAT independently as part of an ongoing process assurance program. Failure of a laboratory to demonstrate regularly exercised PT programs will negatively impact accreditation, as PT is seen as integral to ensuring the fitness and validity of the results of SIT and O/UAT.

NOTE: When more than one FWS laboratory is available, it is recommended that cross-laboratory PT should be affected to the maximum extent possible.

4 General requirements

4.1 Impartiality

There are no requirements additional to those set forth in ISO/IEC 17025.

4.2 Confidentiality

There are no requirements additional to those set forth in ISO/IEC 17025.

5 Structural requirements

5.1 Laboratories compliant with the definition of a Federal Laboratory in Subsection 1.5.1 of this handbook meet structural requirements as defined by ISO/IEC 17025, Subsection 5.1 and associated note.

5.2 To ensure compliance with ISO/IEC 17025, Subsection 5.3, the laboratory shall define SIT and O/UAT in the documented range of laboratory activities.

6 **Resource requirements**

6.1 General

There are no requirements additional to those set forth in ISO/IEC 17025.

6.2 Personnel

6.2.1 All personnel shall hold security clearances and meet access requirements commensurate with the level of work being performed or as determined by facility, system, and/or data requirements.

6.2.2 Key personnel: Certain skilled management and/or technical personnel (hereafter, "key personnel") are essential for accomplishing this LAP and as such, are substantively tied to laboratory accreditation (NIST HB 150, para. 3.3.1.3). Key personnel shall be identified by name, qualification, and title/job classification. Key personnel shall not be removed, replaced, or added without a justified reason. A laboratory shall report to NVLAP within 30 days any significant changes relevant to its accreditation, in any aspect of its status or operation relating to: organization, top management, or key personnel, including Authorized Representative and Approved Signatories. Laboratory staff may simultaneously hold one or more key personnel positions provided that risks to impartiality are eliminated or minimized. The laboratory shall maintain records of personnel designated to fulfill NVLAP key personnel requirements. At a minimum, key personnel fulfilling this LAP shall include:

- Director
- Technical director
- NVLAP authorized representative
- NVLAP approved signatory

NOTE 1: *FWS laboratories achieve diversity of thought through the confluence of warfighters, developers, and acquirers, vertically integrated under the same operational roof. FWS laboratories are encouraged to hire technical and acquisition staff from outside the Department of Defense to further increase the spectrum of perspective.*

NOTE 2: Regular participation in technical meetings, conferences, and other forums is encouraged to provide laboratory staff exposure to contemporary industry, academia, and national laboratory research, development, testing methods, and novel thought.

6.2.3 Director: The laboratory shall be led by a director with demonstrated, practical experience in the areas of leadership and program management commensurate with the work being performed.

NOTE: Knowledge and/or proficiency in areas of federal finance, acquisitions, and contracting are highly desired. It is recommended that the Director attain and/or maintain federal competencies requirements in supported warfare system(s).

6.2.4 Technical director: The technical operations of the laboratory shall be led by a technical director with demonstrated, practical experience leading and managing research, testing, development, and evaluation activities. The technical director shall possess a post-graduate degree in a STEM field.

NOTE: Knowledge and/or or proficiency in areas of federal finance, acquisitions, and contracting are highly desired.

6.2.5 Laboratory staff holding leadership positions shall demonstrate general knowledge of all supported warfare systems. "General Knowledge" means, for example, a working understanding of capabilities, limiting factors, concepts of operation, underlying technologies, development history, upgrade plans, sustainment information, and/or other relevant information of the supported warfare system(s).

6.3 Facilities and environmental conditions

6.3.1 The laboratory shall have adequate facilities to conduct SIT and O/UAT. The laboratory shall have direct access to the warfare system(s) to perform SIT and O/UAT unencumbered. If testing is conducted outside the primary laboratory location, the environment shall conform, as appropriate, to the requirements established by the ISO/IEC 17025, NIST HB 150, and this handbook.

6.3.2 If the laboratory is unable to be co-located with the supported warfare system, the laboratory shall have unencumbered access to the supported MWS and its associated systems, operators, maintenance, leadership, support personnel, program offices, and other related entities.

6.3.3 SIT should, and O/UAT, shall, to the maximum extent possible, include testing in an operationally relevant environment.

NOTE: An operationally relevant environment is one that closely or precisely emulates what a FWS would experience during a conflict. While virtual environments and system integration lab (SIL) setups are useful, testing onboard the FWS itself is ideal for reducing risk and increasing technology readiness levels (TRLs).

6.3.4 A process shall be in place to safeguard customer proprietary equipment, data, records, and other materials from unauthorized personnel.

6.3.5 The laboratory shall demonstrate the means to protect digital systems from unauthorized, external entities and shall not adversely affect the validity of results. If testing is conducted outside of the main laboratory location, these additional locations shall meet requirements established by ISO/IEC 17025, NIST HB 150 and this handbook.

6.4 Equipment

6.4.1 The laboratory shall maintain all equipment required to support SIT and O/UAT.

6.4.2 The laboratory shall maintain a configuration management system to establish and maintain consistency of a system's performance, functional, and physical attributes with its requirements, design, and operational information throughout its life.

6.4.3 All equipment used for SIT and O/UAT shall be maintained in accordance with the manufacturer's recommendations and/or in accordance with internally documented laboratory procedures.

6.4.4 The laboratory shall ensure that required equipment is properly calibrated in accordance with ISO/IEC 17025, clause 6.4, as required. The laboratory shall maintain all calibration records.

6.5 Traceability

6.5.1 Testing traceability: The laboratory shall ensure testing activities are traceable to underlying, established technical criteria (SIT) and/or user-defined criteria (O/UAT). As such, the laboratory shall ensure equipment and methods used for SIT and O/UAT yield reproducible, decision-quality results that directly assess a system against its underlying requirements.

6.5.2 Calibration: For all test equipment that requires calibration, the laboratory shall meet the requirements in ISO/IEC 17025 Section 6.5 and NIST HB 150 Annex B.

6.5.3 Cybersecurity traceability: The laboratory shall ensure testing activities are traceable to specific security controls. This means the ability of the laboratory to trace security requirements from their origin (e.g., regulations, IA frameworks, etc.) to their low-level implementation allows organizations to readily demonstrate compliance to one or more Information Assurance (IA) compliance frameworks.

6.6 Externally provided products and services

There are no requirements additional to those set forth in ISO/IEC 17025.

7 **Process requirements**

7.1 Review of requests, tenders and contracts

There are no requirements additional to those set forth in ISO/IEC 17025.

7.2 Selection and verification of methods

7.2.1 The laboratory shall prioritize technologies proposed for testing induction and evaluate proposed technologies, ideas, concepts, and/or capabilities and compare to current national security and defense strategies.

7.2.2 The laboratory shall develop, perform, and continuously evolve SIT methods and capabilities commensurate with supported warfare system(s). In performance of SIT, a laboratory shall:

- Verify that the system(s) under test meet established technical criteria as defined by expected system functionality;
- Validate that the system(s) under test performs in accordance with pre-defined use-cases;
- Establish defined entry/exit criteria;
- If at any point, a technology fails to meet SIT exit criteria, ensure an immediate "fast fail" determination and discontinuance of further testing activity related to that technology; and
- Develop and deliver SIT exit reports detailing test activity results.

NOTE 1: Following SIT, passing systems are forwarded to O/UAT.

NOTE 2: SIT-exited technologies should be evaluated through Department of Defense-established Modeling and Simulation (M&S) means and methods (<u>https://www.msco.mil/</u>). Laboratory M&S activities may run concurrent with O/UAT. If at any point, a technology fails to show tactical, operational, or strategic value, ensure an immediate "fast fail" determination and discontinuance of further M&S activity related to that technology.

7.2.3 The laboratory shall develop, assist end-users in the execution of, and continuously evolve O/UAT capabilities commensurate with supported warfare system(s). In performance of O/UAT, the laboratory shall:

• Verify that the system under test meets acceptance criteria as defined by the end-user in common end-user language;

• Verify that the system under test meets operational acceptance criteria as generally defined by nonfunctional requirements. These requirements cover attributes including, but not limited to: usability, functional stability, portability, and reliability;

- Establish defined entry/exit criteria;
- If at any point, a technology fails to meet O/UAT exit criteria, ensure an immediate "fast fail" determination and discontinuance of further testing activity related to that technology; and
- Develop and deliver O/UAT exit reports detailing test activity results.

NOTE: Concurrent to O/UAT, systems should be evaluated via modeling and simulation, or other means, to further derive objective value. Passing systems are exited in accordance with current acquisition directives.

7.2.4 The laboratory shall monitor and/or surveille technologies that have exited O/UAT and have been deployed, fielded, and/or otherwise currently in operation to ensure a Continuous Integration and

Continuous Delivery (CI/CD) rhythm is achieved. The laboratory shall ensure continuous and collaborative technology planning, adaption, testing, and release cycles.

7.2.5 The laboratory shall ensure the end-to-end integration of information/infrastructure (cyber) security throughout the lifecycle of laboratory processes. The laboratory shall employ automation as appropriate. The laboratory shall ensure laboratory systems are compliant with all Federal, DoD, and uniformed service directives, policy, and written guidance relating to cyber security. The laboratory shall ensure Risk Management Framework and Security Impact Assessment compliance, as required. The laboratory shall attain Interim Authorizations to Test, Authorizations to Operate/Connect, and other authorizations, as required. The laboratory shall ensure all laboratory cyber security activities are compliant with any established CI/CD schema.

7.2.6 As required, the laboratory shall develop, perform, and continuously evolve laboratory Independent Verification and Validation (IV&V) capabilities. The laboratory shall evaluate whether products, services, and/or systems tested are capable and/or appropriate to fulfill their intended purpose and/or established requirements. As required, the laboratory shall develop and deliver reports resultant to each specific IV&V activity.

7.2.7 As required, the laboratory shall develop and deliver technology transfer/release reports. For systems that have successfully graduated O/UAT, and as required, the laboratory shall ensure seamless technology transfer via the DoD 5000-series and Chairman of the Joint Chiefs of Staff Instruction (CJCSI) 5123.01H (Joint Capabilities Integration and Development System [JCIDS]) processes.

7.3 Sampling

There are no requirements additional to those set forth in ISO/IEC 17025.

7.4 Handling of test or calibration items

There are no requirements additional to those set forth in ISO/IEC 17025.

7.5 Technical records

There are no requirements additional to those set forth in ISO/IEC 17025.

7.6 Evaluation of measurement uncertainty

There are no requirements additional to those set forth in ISO/IEC 17025.

7.7 Ensuring the validity of results

In addition to PT, the FWS laboratory shall have quality control procedures for monitoring the validity of tests undertaken. Quality control (QC) is a continuous process. All QC measures shall be assessed and evaluated on an ongoing basis. There are many acceptable QC practices or methods available to demonstrate that testing is under control and trends are detectable. Monitoring methods shall regularly be planned, reviewed, and updated. Derived from GLP 1 (*Good Laboratory Practice for the Quality Assurance of Laboratory Measurement Results*; NIST), monitoring methods shall include, where appropriate, but are not limited to:

- a. Regular use of reference materials or quality control materials.
- b. Use of alternative instrumentation that has been calibrated to provide traceable results
- c. Functional checks of measuring and testing equipment
- d. Use of check or working standards with control charts, where applicable
- e. Periodic intermediate checks on measuring equipment
- f. Replicate tests or calibrations using the same or different methods, with the use of standard deviation charts or range charts where applicable
- g. Retesting or recalibration of retained items (e.g., customer items that are not immediately returned)
- h. Correlation of results for different characteristics of an item
- i. Review of reported data by competent laboratory personnel
- j. Inter- and intra-laboratory comparisons
- k. Blind tests.

To abate risk of error, the following is recommended to be incorporated into laboratory functions:

- a. Training staff and evaluating effectiveness and proficiency
- b. Monitoring the laboratory environment to minimize potential errors or excess variation
- c. Maintaining suitable equipment (including installation, monitoring, approvals, and integrated software)
- d. Selecting and calibrating standards
- e. Ensuring suitable suppliers for materials and/or calibrations
- f. Selecting and validating procedures with evaluation of accuracy/bias and precision

g. Ensuring proper care and handling of laboratory standards, equipment, and items submitted for calibration

h. Accurately and effectively calculating, evaluating, and reporting measurement uncertainty, where applicable

i. Participating in inter- and intra-laboratory comparisons

j. Creating and reviewing calibration certificates to ensure accuracy of measurement results and the effective communication of results

k. Controlling data – information management (including software and information technology controls).

7.8 Reporting of results

There are no requirements additional to those set forth in ISO/IEC 17025.

7.9 Complaints

There are no requirements additional to those set forth in ISO/IEC 17025.

7.10 Nonconforming work

There are no requirements additional to those set forth in ISO/IEC 17025.

7.11 Control of data and information management

All classified data shall be handled, stored, and transmitted in accordance with governing policies, procedures, and guidelines.

8 Management system requirements

8.1 **Options**

There are no requirements additional to those set forth in ISO/IEC 17025.

8.2 Management system documentation

If the laboratory documentation does not follow the outline of ISO/IEC 17025:2017, a cross-reference document shall be developed to both verify that the laboratory meets the requirements and to facilitate review by the assessor.

8.3 Control of management system documents

There are no requirements additional to those set forth in ISO/IEC 17025.

8.4 Control of records

Unless otherwise specified, records shall be kept, at a minimum, between recurring NVLAP assessments.

8.5 Actions to address risks and opportunities

There are no requirements additional to those set forth in ISO/IEC 17025.

8.6 Improvement

There are no requirements additional to those set forth in ISO/IEC 17025.

8.7 Corrective actions

There are no requirements additional to those set forth in ISO/IEC 17025.

8.8 Internal audits

There are no requirements additional to those set forth in ISO/IEC 17025.

8.9 Management reviews

There are no requirements additional to those set forth in ISO/IEC 17025.