



30th Annual **INCOSE**
international symposium

Virtual Event
July 20 - 22, 2020

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When to Constrain the Design?

Application of Design Standards on a New Development Program

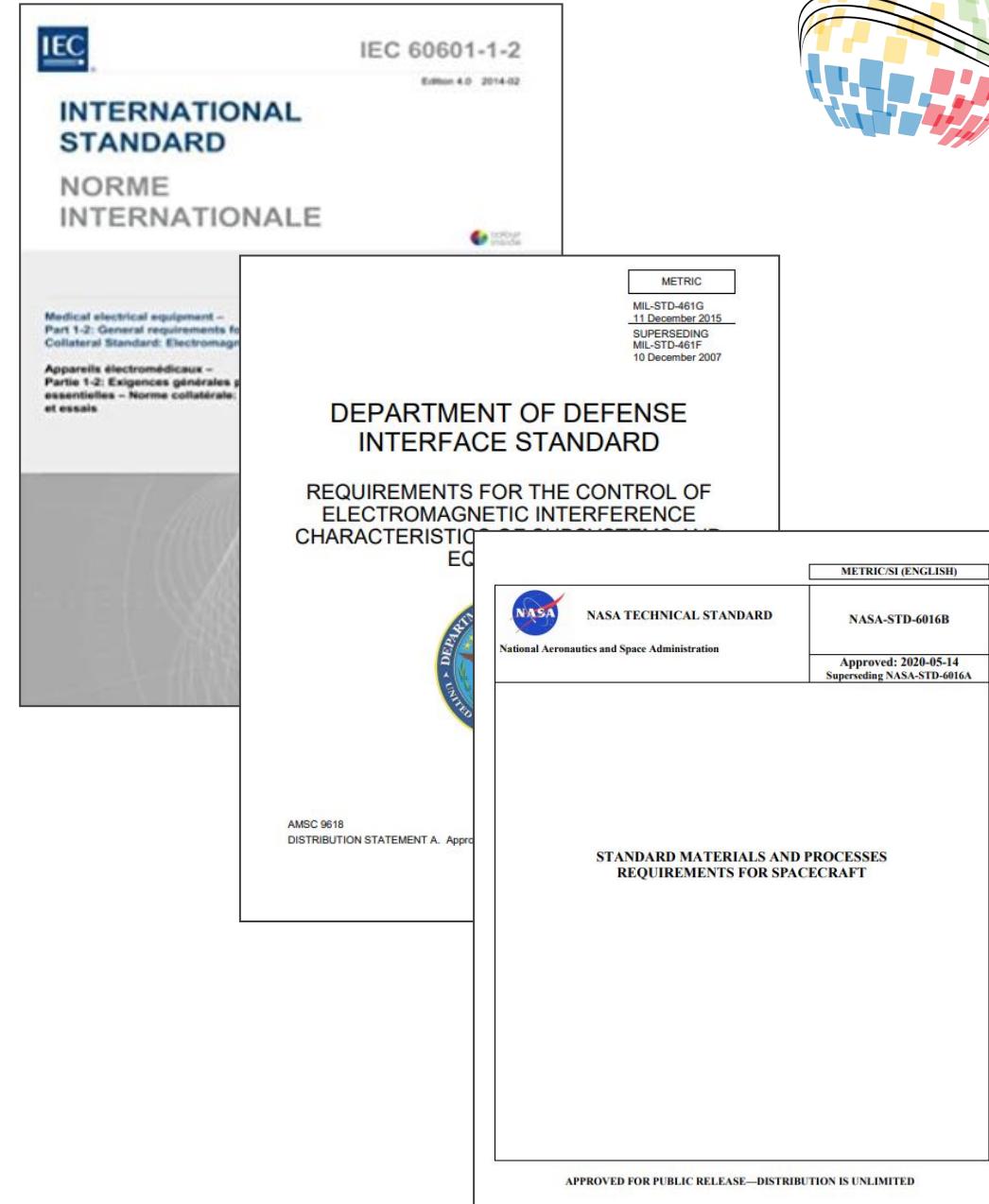
Overview



- What are Design and Construction Standards?
- Examples of Application of Use
- Usage Cost Impact Evaluation
- Alternate Strategy of Approach
- Considerations of When to Enforce Standards

Introduction

- Design and construction standards can appeal to organizations as they ensure consistency and robustness of a product.
- However, mandatory usage has the ability to increase cost during the product development if not applied thoughtfully.
- Considerations of when to enforce application of standards on a new development program are provided, as well as alternate strategies to enable cost effective, innovative designs.



What are Design and Construction Standards??



- Standardization documents are developed and used for products, materials, and processes to promote commonality and interoperability.
- Multiple organizations develop standards to address products and services associated with their scope of effort:
 - Military “MIL” standards are used to help achieve standardization objectives by the U.S. Department of Defense.
 - International Electrotechnical Commission (IEC) standards enable global trade, increase the efficiency of design, manufacturing, operation, testing and conformity assessment of electrotechnical devices and systems.
 - The Federal Aviation Administration (FAA) publishes guidelines and standards that regulate civil aviation safety to ensure uniform development, evaluation and certification for airspace systems, procedures and equipment.

Types of Design and Construction Standards



Aerospace Field

Organization	Source	Addresses
National Aerospace and Space Administration (NASA)	https://standards.nasa.gov/	NASA technical standards provide the means of standardization used to achieve and maintain desired levels of compatibility, interchangeability, or commonality within NASA and with industry practices. Ex: NASA-STD-6016 provides acceptable material and process controls for spacecraft.
International Electrotechnical Commission (IEC)	http://www.iec.ch/index.htm	IEC is a non-governmental org that publishes international standards for electrical, electronic and related technologies, thousands of experts in industry. Ex: IEC-61000 addresses Electro Mechanical Compatibility (EMC) of electrical equipment.
IPC, Association Connecting Electronics Industries	http://www.ipc.org/ContentPage.aspx?pageid=Standards	IPC has published standards for many steps of the printed circuit manufacturing and assembly process, building from a foundation of solid design up to final. Ex: IPC-2220 provides the design standards for electronic printed boards.
ASTM Aerospace Standards	https://www.astm.org/Standards/aerospace-material-standards.html	ASTM's aerospace material standards are instrumental in evaluating materials, components, and devices primarily used in aerospace and aircraft industries. Ex: ASTM E595 - 15 provides the standard test method for measuring total mass loss due to outgassing in a vacuum environment.
"MIL-STD", "MIL-SPEC",	https://www.dsp.dla.mil/Specs-Standards/	MIL Specification and Standardization documents are developed and used for products, materials, and processes that have multiple applications to promote commonality and interoperability among the U.S. Military Departments .Ex: MIL-STD-464 establishes electromagnetic environmental effects (E3) interface requirements and verification criteria for airborne, sea, space, and ground systems.

Medical Device Field

Organization	Source	Addresses
International Organization for Standardization (ISO)	http://www.iso.org/iso/home/standards.htm	ISO is a non-governmental org that develops and publishes international standards on many subjects, ensures that products and services are safe, reliable and of good quality. Ex: ISO 13485 specifies quality management system for design and manufacture of medical devices.
International Electrotechnical Commission (IEC)	http://www.iec.ch/index.htm	IEC is a non-governmental org that publishes international standards for electrical, electronic and related technologies. Ex: IEC-60601 are standards for safety and effectiveness of medical electrical equipment.
ASTM International (formerly known as American Society for Testing and Materials)	http://www.astm.org/index.shtml	ASTM International is a global leader in development and delivery of international voluntary consensus standards. thousands of industry professionals contribute. Ex: ASTM F2739-08 establishes standard for quantitating cell viability within biomaterial scaffolds.

Examples of Standards



MIL-STD-461G

FOREWORD

1. This standard is approved for use by all Departments and Agencies of the Department of Defense.
2. The stated interface requirements are considered necessary to provide reasonable confidence that a particular subsystem or equipment complying with these requirements will function within their designated design tolerances when operating in their intended electromagnetic environment (EME). The procuring activity should consider tailoring the individual requirements to be more or less severe based on the design features of the intended platform and its mission in concert with personnel knowledgeable about electromagnetic compatibility (EMC) issues affecting platform integration.
3. An appendix is included with the verification section.
4. A committee consisting of representatives from government, industry, and industry prepare
5. Comments, suggestions, or changes, you may want to verify Online database at <http://quick>

MIL-STD-461G

4.3.2 Shielded enclosures.

To prevent interaction between the EUT and the outside environment, shielded enclosures will usually be required for testing. These enclosures prevent external environment signals from contaminating emission measurements and susceptibility test signals from interfering with electrical and electronic items in the vicinity of the test facility. Shielded enclosures shall have adequate attenuation such that the ambient requirements of 4.3.4 are satisfied. The enclosures shall be sufficiently large such that the EUT arrangement requirements of 4.3.8 and antenna positioning requirements described in the individual test procedures are satisfied.

4.3.2.1 Radio frequency (RF) absorber material.

RF absorber material (carbon impregnated foam pyramids, ferrite tiles, and so forth) shall be used when performing electric field radiated emissions or radiated susceptibility testing inside a shielded enclosure to reduce reflections of electromagnetic energy and to improve accuracy and repeatability. The RF absorber shall be placed above, behind, and on both sides of the EUT, and behind the radiating or receiving antenna as shown on Figure 1. Minimum performance of the material shall be as specified in Table I. The manufacturer's certification of their RF absorber material (basic material only, not installed) is acceptable.

TABLE I. Absorption at normal incidence.

Frequency	Minimum absorption
80 MHz - 250 MHz	6 dB
above 250 MHz	10 dB

4.3.3 Other test sites.

If other test sites are used, the ambient requirements of 4.3.4 shall be met.

NASA-STD-6016B

FOREWORD

This NASA Technical Standard is published by the National Aeronautics and Space Administration (NASA) to provide uniform engineering and technical requirements for processes, procedures, practices, and methods that have been endorsed as standard for NASA programs and projects, including requirements for selection, application, and design criteria of an item.

This NASA Technical Standard is approved for use by NASA Headquarters and NASA Centers and Facilities and may be cited in contract, program, and other Agency documents as a technical requirement. It may also apply to the Jet Propulsion Laboratory and other contractors only to the extent specified or referenced in applicable contracts.

This NASA Technical Standard (M&P) and provides a general concept for hardware procurements and technical

Requests for information should Requests for changes to this NASA 4657, Change Request for a NASA

NASA-STD-6016B

4.1.8.1 Requirements for Design Values

- a. [MPR 33] A, B, or S-basis statistical values for mechanical properties of materials shall be utilized for the design and analysis of hardware for all applications where structural analysis is required.

Statistical design values are needed for any hardware where structural analysis is required in order to demonstrate positive margins of safety for the design loads and environments in combination with the factor of safety requirements.

Each distinct form of a material should be assumed to have unique design values unless testing and statistical analysis shows that design values are combinable. For example, rolled bar may have different design values than the same alloy in plate, forging, spin forming, extrusion, or casting. Different layups affect the properties of composite structures. Manufacturing methods, like welding, brazing, swaging, forming, diffusion bonding, adhesive bonding, and co-curing of sandwich alter the properties of the original materials. Design features, such as joints, ply-drops, and tapered ramps affect the design values of composites.

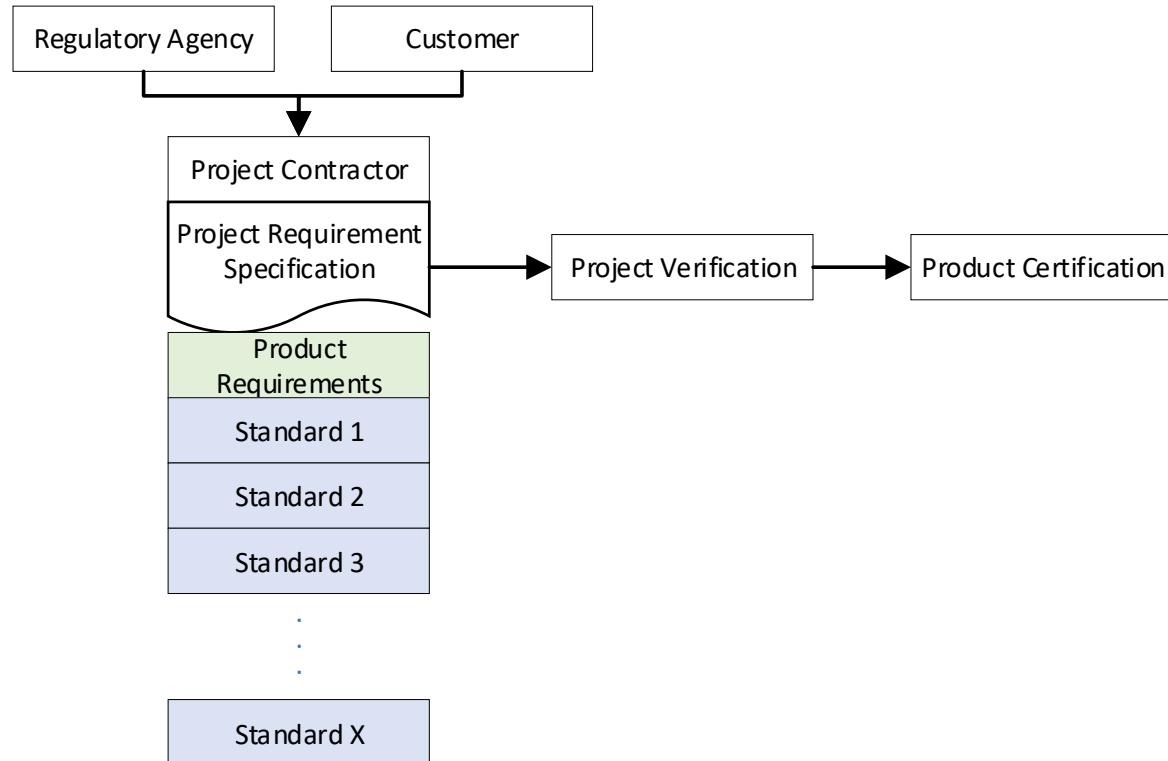
Design values are also required for other mechanical properties, such as dynamic properties like fatigue and fracture. The basis for these properties is not necessarily statistical, but the sampling is expected to be representative of the material, product form, and state used in the design. Some applications require lower bound, and others require typical properties. The specific requirement can be found in the governing specifications for the design, such as NASA-STD-5019, Fracture Control Requirements for Spaceflight Hardware, or NASA-STD-5012, Strength and Life Assessment Requirements for Liquid-Fueled Space Propulsion System Engines.

- b. [MPR 34] The sampling for other mechanical properties, such as dynamic properties like fatigue and fracture, and verification of design values shall be representative of the material, product form, and state used in the design.

Application of Standards



- Projects develop their requirements to address their customer needs as well as applicable regulatory requirements.
- Design and construction standards are a form of quality requirement which can be incorporated with the overall requirements.
- While standards are often self applied by a product supplier to enable development, another common application of technical standards is by inclusion in a requirements specification; the net result is an expanded set of requirements that need to be verified to achieve product certification.



Application of standards can lead to multiple documents of requirements.



Assessing Various Usage of Standards

- Three industries were assessed for how they apply standards, and if there was an associated cost impact or lesson learned associated with this approach.
- Industry and projects assessed included:
 - A Medical Device project (a small project in a highly regulated field)
 - The NASA Constellation project (a large project in a lightly regulated field)
 - Regulation Change in the Aviation industry (a large project in a highly regulated field)



Medical Device Case Study

- New development of medical device products, like the infusion pump shown, are subject to strict controls and procedural regulations.
- In the United States, the Code of Federal Regulations (Title 21 Part 800) addresses development of medical devices.
 - Product developers will need to consider comparable regulations in other countries where they plan to market their product.
- Standards are used to specify requirements for performance characteristics, characterization and testing methodologies, manufacturing practices, product evaluation.



Medical Device Case Study – Application of Standards



- Some regulations require specific standards, while others specify a performance-based approach where standards are allowed to be used by a product supplier to show it meets the regulatory requirements.
- The design and certification approach of medical devices resembles the flow shown, where the product developer assesses regulatory requirements and standards, and then ensures they are imbedded within the design and manufacturing processes of the product.
- Compliance is shown through the product documentation (drawings, test reports, as-built records) as part of the regulation process.

§ 898.12 Performance standard.

(a) Any connector in a cable or electrode lead wire having a conductive connection to a patient shall be constructed in such a manner as to comply with subclause 56.3(c) of the following standard:

International Electrotechnical Commission (IEC)

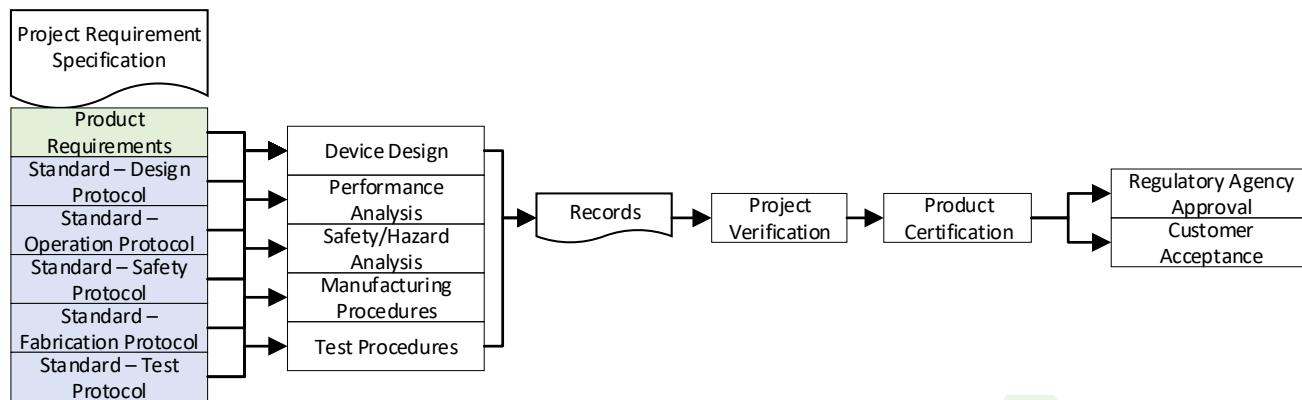
601-1: Medical Electrical Equipment

601-1 (1988) Part 1: General requirements for safety

Amendment No. 1 (1991)

Amendment No. 2 (1995).

(b) Compliance with the standard shall be determined by inspection and by applying the test requirements and test methods of subclause 56.3(c) of the standard set forth in paragraph (a) of this section.



Medical Device Case Study – Application of Design Controls



- Literature research shows that the medical device field supports the use of design controls in product development.
- Standards are a means of design controls, along with application of Good Manufacturing Practice (GMP) to assure quality control that aligns with regulatory requirements.
- The preferred approach is to establish a framework of design controls with a design process that incorporates standards but with approaches that support supplier processes.
- Considering that a paradigm of medical device providers is to generate product towards a market, they are driven by addressing regulations and their shareholders, and usage of design and manufacturing controls is part of the approach to enable their products to be sold.



Medical Device Case Study – Cost Impacts



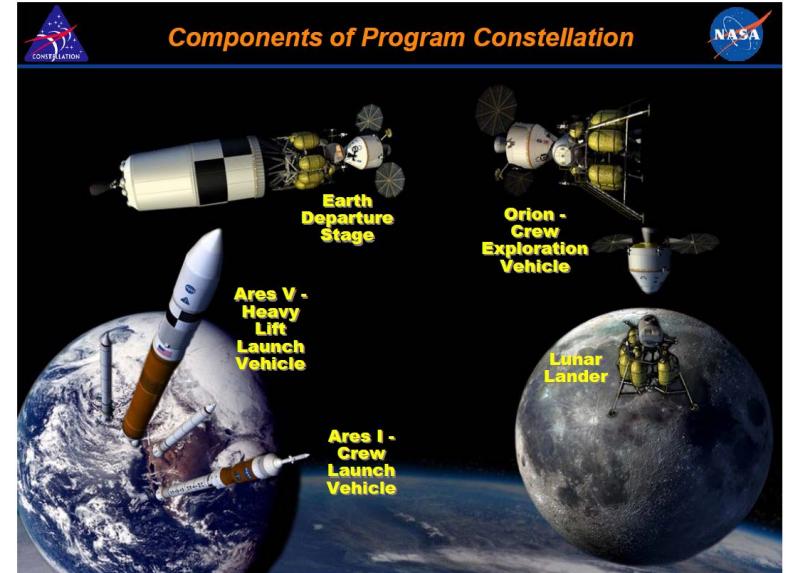
- For an entire industry that regularly complies with regulations and standards, it appears that usage of design and construction standards is factored into the effort of development and production of the products.
- For these products, the cost drivers are the establishment of the initial protocols for the design, analyses, manufacturing and test processes, and in providing the records of compliance required for certification.
- For this type of industry there is very little option to not having processes aligned with the standards, but the regulations do allow for ability to show equivalent safety with established processes to be leveraged in place of specific standard requirements.

Application of standards is prevalent and factored into cost of product development.



Space System Case Study

- Another case study is the NASA Constellation Program, a U.S. program to develop a space system from 2005-2011.
 - Consisted of a crew vehicle, two launch vehicle designs, a lunar lander, all developed by different contractors.
 - While cancelled in 2011, several elements are still being developed under a new program and set of requirements.
- In the United States, federal regulations for space products consist of launch safety regulations, communication frequency regulations, orbital debris regulations – however spacecraft product development is not regulated in the same way aviation and medical devices are.
- Standards for aerospace are often levied by the customer organization to provide requirements for quality control, safety conformance, testing methodologies, and manufacturing practices.
 - For manufacturing processes many suppliers certify to the standards common in the industry.
 - Most space product suppliers do not follow a single set of design standards as there are a number of them in effect (Aerospace Corporation, MIL standards, NASA standards, Europe standards, etc.).



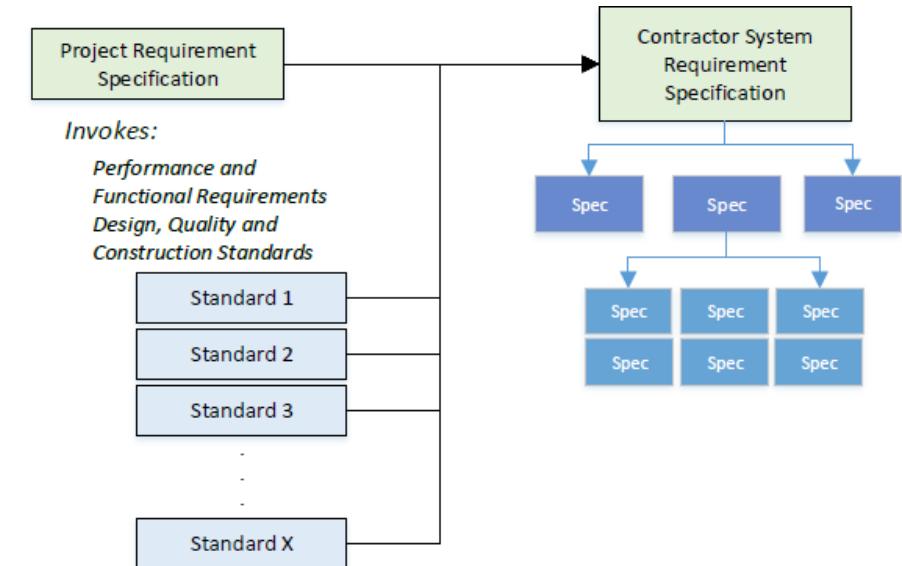
Space System Case Study – Application of Standards



- NASA decided to utilize standards on Constellation as a method to apply best practices from the space shuttle program and ensure safe approaches by the contractors; about 70 various standards addressing design techniques, analysis approaches, test approaches, and project management were levied.
- These standards were typically invoked in the contract or within a contractor's requirement specification.
- Suppliers were allowed to tailor the standards with NASA approval via a waiver.

[CA3005-PO] The Constellation Architecture shall comply with NASA-STD-(I)-6016, Standard Materials and Processes Requirements for Spacecraft.

Rationale: This document defines the minimum requirements for manned spacecraft Materials and Processes (M&P) and provides a general control specification for incorporation into NASA program/project hardware procurements and technical programs.

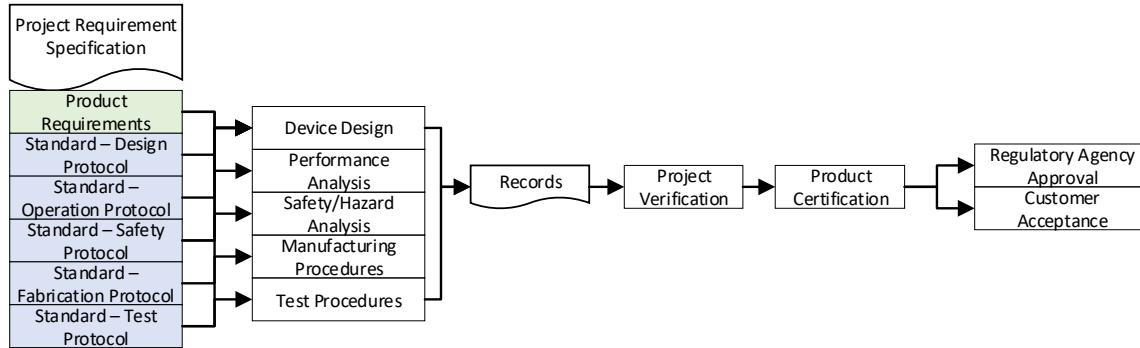


Space System Case Study – Application of Standards

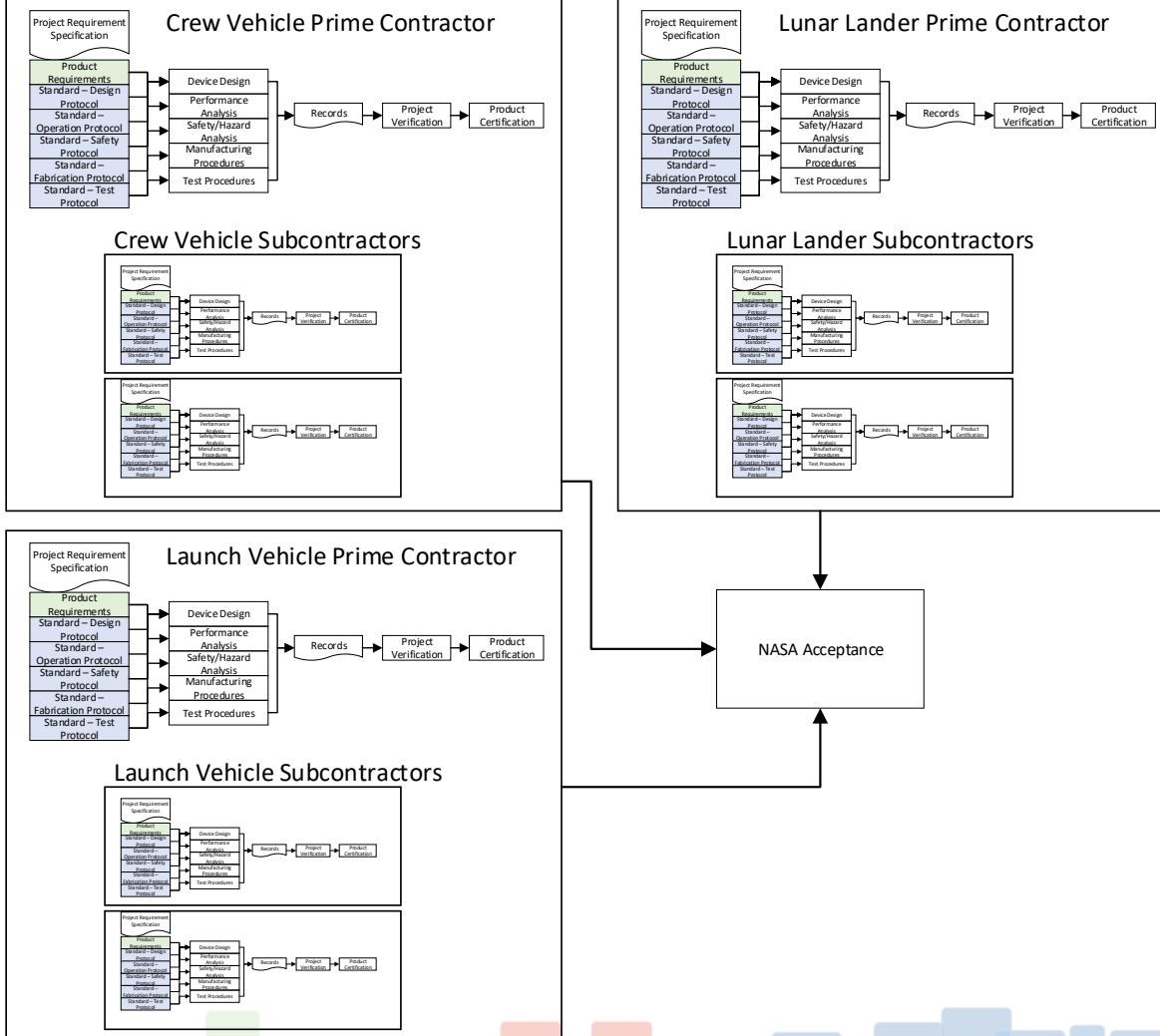


- The design and certification approach of the Constellation elements resembled the flow shown on the right, where NASA mandates a set of standards that the product developer ensures are imbedded within the design and manufacturing processes of the product, as well as all of the associated subsystems and components.
- For Constellation this led to the flow of standards across many levels of effort (compared to the more simple medical device effort below).
- Compliance is shown using the contractor documentation (drawings, test reports, analysis reports, etc.) as part of the contractor's verification process with NASA.

Medical Device Approach



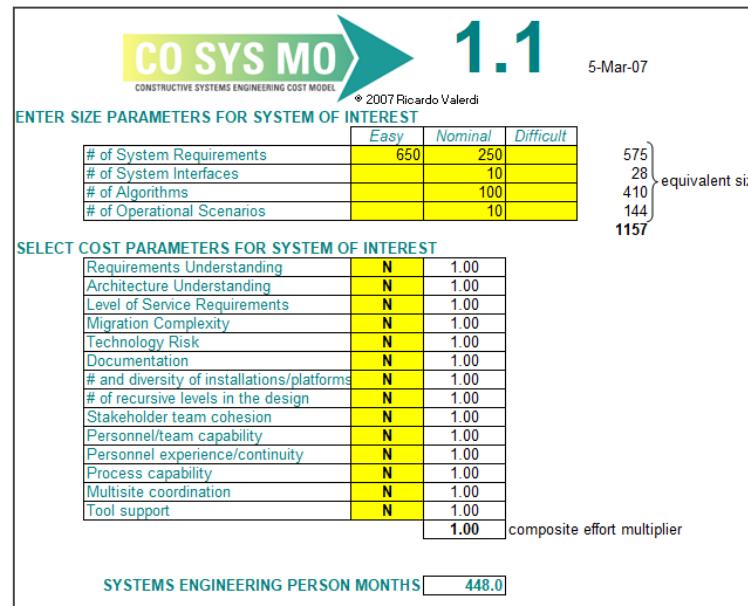
Constellation Approach



Space System Case Study – Cost Impacts



Number of requirements	Applied Requirements	Labor Months
~250	Crew Vehicle Specification	316
~ 900 (250 + 650)	Crew Vehicle Specification + Design and Construction Standards	448
Added Cost of Design and Construction Standards:		132



- Space product providers vary in their approaches for product development, the usage of NASA standards essentially become a set of additional requirement to follow.
- Calculating a potential cost impact for these requirements using COSYSMO:
 - Mandatory requirement to use 70 standards leads to approximately 650 additional requirements on a Constellation contractor.
 - Assessing the additional requirements for that effort using the COSYSMO cost model shows this can increase the labor costs by 40%
- Additionally, the time to assess each standard and address contractor tailoring with NASA can take up to six months per standard (based on observational experience)



Mandate of standards can be a hidden source of cost.

Space System Case Study – Lessons Learned



- *NASA's Constellation Program: The Final Word*, by Thomas, Hanley, Rhatigan, and Neubek, provided the following observations on how design and construction standards were applied on Constellation:

The mismatch of design and construction standards among centers...threatened contractors' ability to meet schedule milestones and cost thresholds.

The involvement of 10 NASA Centers, along with the overabundance and overprescriptive nature of design and construction (D&C) standards, led to an avalanche of "shall" requirements on the Constellation contracts. While Constellation was allowed broad latitude to tailor requirements, tailoring required rationale and negotiation with the requirement "holder." The sheer number of direct and embedded requirements made the task of tailoring intractable.

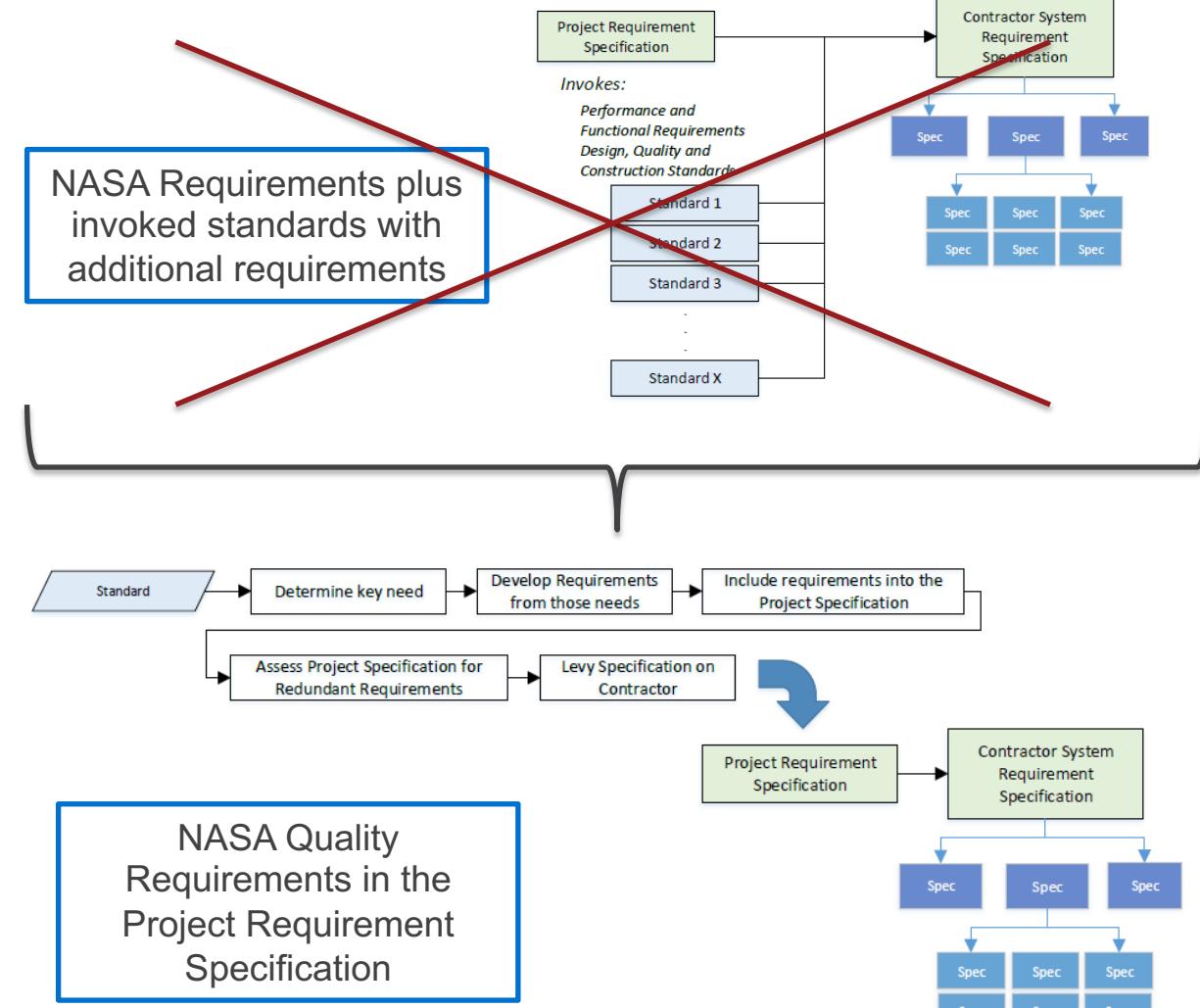
All of the major aerospace contractors, who build systems for multiple government customers (DoD, NSA, NASA, etc.), have certified internal processes and suppliers that meet national and international standards. The set of NASA requirements included in D&C standards are often redundant to this.

The quantity of NASA D&C standards defies tailoring for even a large program like Constellation. Major aerospace contractors have sufficient processes such that NASA D&C standards are of questionable value. This is a significant driver of program fixed costs.

Space System Case Study – Alternate Approach



- The COSYSMO calculation, as well as observation from the Constellation Lessons Learned, led to an evaluation for another option on levying quality control requirements.
- Considering the entire Constellation program as a system, another option could be to generate the specific requirements needed to be met for quality as discrete requirements, compared to levying NASA documents on how to design and build space products.
- Providing the standards as reference documents (containing approaches based on NASA experience), allows the communication of good approaches, yet the contractor can respond to the specific “shall” requirement using their own approaches as verification methodology.





Aviation Case Study

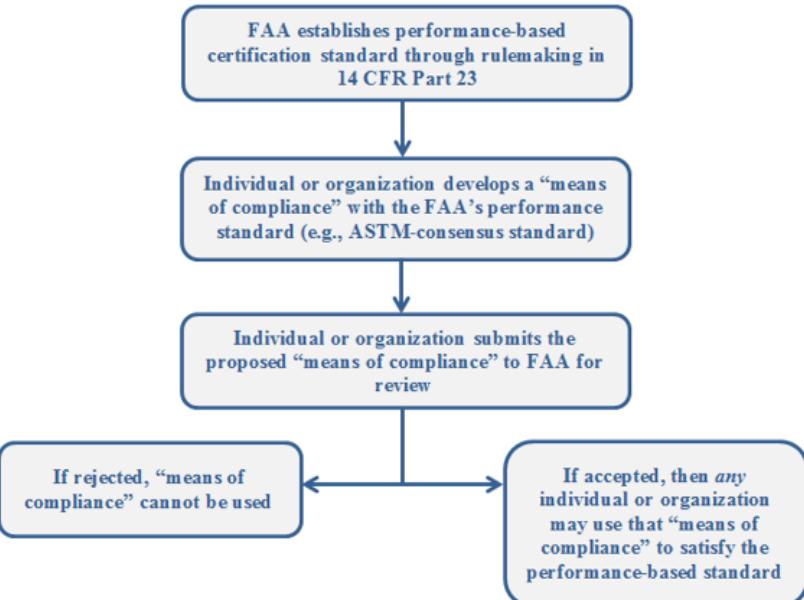
- The third case study looked at an industry which recently changed approaches in levying design and construction standards, looking at the resulting impact to the overall industry.
- In 2013 the US Government passed the Small Airplane Revitalization Act of 2013 (SARA), a bill that requires the FAA to adopt new certification regulations to reduce the cost of aircraft and avionics upgrades. This bill required the FAA to:
 - Create a regulatory regime to improve safety and decrease certification costs;
 - Set safety objectives to spur innovation and technology adoption;
 - Replace prescriptive rules with performance-based regulations; and
 - Use consensus standards to clarify how safety objectives may be met by specific designs and technologies.





Aviation Case Study – Application of Standards

- In 2015, the FAA provided a set of revisions to 14 CFR Part 23, which reduced the specific set of design requirements (and imposed design standards) into "performance-based" standards.
- What is a performance-based standard? A performance-based standard establishes a level of performance that must be achieved through the airplane's design, rather than dictating how a manufacturer should arrive at a particular level of performance.



Aviation Case Study – Application of Standards



Federal Aviation Administration, DOT	§ 23.729
	(1) 2.25 times the drop height prescribed in § 23.725(a); or
	(2) Sufficient to develop 1.5 times the limit load factor.
	(b) The critical landing condition for each of the design conditions specified in §§ 23.479 through 23.483 must be used for proof of strength.
	[Amdt. 23-7, 34 FR 13091, Aug. 13, 1969]
§ 23.727 Reserve energy absorption drop test.	
	(a) If compliance with the reserve energy absorption requirement in § 23.723(b) is shown by free drop tests, the drop height may not be less than 1.44 times that specified in § 23.725.
	(b) If the effect of wing lift is provided for, the tests must be dropped with an effective mass equal to $W_e/W_h(h-d)$, when the symbols and other details are the same as in § 23.725.
	[Doc. No. 4080, 29 FR 17955, Dec. 18, 1964, as amended by Amdt. 23-7, 34 FR 13091, Aug. 13, 1969]
§ 23.729 Landing gear extension and retraction system.	
	(a) <i>General.</i> For airplanes with retractable landing gear, the following apply:
	(i) Each landing gear retracting mechanism and its supporting structure must be designed for maximum flight load factors with the gear retracted and must be designed for the combination of friction, inertia, brake torque, and air loads, occurring during retraction at any airspeed up to 1.6 V_{SI} with flaps retracted, and for any load factor up to those specified in § 23.345 for the flaps-extended condition.
	(2) The landing gear and retracting mechanism, including the wheel well doors, must withstand flight loads, including loads resulting from all yawing conditions specified in § 23.351, with the landing gear extended at any speed up to at least 1.6 V_{SI} with the flaps retracted.
	(b) <i>Landing gear lock.</i> There must be positive means (other than the use of hydraulic pressure) to keep the landing gear extended.
	(c) <i>Emergency operation.</i> For a landing plane having retractable landing gear that cannot be extended manually, there must be means to extend the landing gear in the event of either—
	(1) Any reasonably probable failure in the normal landing gear operation system; or
	(2) Any reasonably probable failure in a power source that would prevent the operation of the normal landing gear operation system.
	(d) <i>Operation test.</i> The proper functioning of the retracting mechanism must be shown by operation tests.
	(e) <i>Position indicator.</i> If a retractable landing gear is used, there must be a landing gear position indicator (as well as necessary switches to actuate the indicator) or other means to inform the pilot that each gear is secured in the extended (or retracted) position. If switches are used, they must be located and coupled to the landing gear mechanical system in a manner that prevents an erroneous indication of either "down and locked" if each gear is not in the fully extended position, or "up and locked" if each landing gear is not in the fully retracted position.
	(f) <i>Landing gear warning.</i> For landplanes, the following aural or equally effective landing gear warning devices must be provided:
	(1) A device that functions continuously when one or more throttles are closed beyond the power settings normally used for landing approach if the landing gear is not fully extended and locked. A throttle stop may not be used in place of an aural device. If there is a manual shutoff for the warning device prescribed in this paragraph, the warning system must be designed so that when the warning has been suspended after one or more throttles are closed, subsequent retardation of any throttle to, or beyond, the position for normal landing approach will activate the warning device.
	(2) A device that functions continuously when the wing flaps are extended beyond the maximum approach flap position, using a normal landing procedure, if the landing gear is not fully extended and locked. There may not be a manual shutoff for this warning device. The flap position sensing unit may be installed at any suitable location. The system for this device may use any part of the system (including the aural warning device) for the device required in paragraph (f)(1) of this section.



§ 23.2305 Landing gear systems.

- (a) The landing gear must be designed to -
 - (1) Provide stable support and control to the *airplane* during surface operation; and
 - (2) Account for likely system failures and likely operation environments (including anticipated limitation exceedances and emergency procedures).
- (b) All *airplanes* must have a reliable means of stopping the *airplane* with sufficient kinetic energy absorption to account for landing. *Airplanes* that are required to demonstrate aborted takeoff capability must account for this additional kinetic energy.
- (c) For *airplanes* that have a system that actuates the landing gear, there is -
 - (1) A positive means to keep the landing gear in the landing position; and
 - (2) An alternative means available to bring the landing gear in the landing position when a non-deployed system position would be a hazard.

Example of change to a performance-based standard for the landing gear system.



Aviation Case Study – Cost Impacts

- Upon release of the 14 CFR Part 23 updates, industry and news media responded with the expectation of improvement of aircraft development within the industry, with the National Business Aviation Association noting:
 - The new small airplane certification standards contained in the Part 23 final rule usher in a new approach to regulation by the FAA, they will enhance the production and marketability of aircraft made in the United States, and will add industry jobs.
 - The intent of this is to create a regulatory architecture for Part 23 that is agile enough to keep up with innovation.
- In 2018, the FAA issued 63 means of compliance (MOCs) for Part 23 which they indicated "will foster faster installation of innovative, safety-enhancing technologies into small airplanes, while reducing costs for the aviation industry." [FAA, 2018].

Aviation regulations are moving away from mandating specific design and construction standards.

Why Use Standards??



- While there was a lot of focus on impacts of standards in this presentation, there is something to be said about the benefits (there are many).
- Standards are created from industry experts on a best practice – these are based on lessons learned and sound principles.
- While not a one size fits all, they can address many different topics for various industries and provide great starting points for developing solutions.
- Standardization enables open systems and allows reuse.
- The key to avoid hidden costs is to evaluate the mandatory use of standards within a product development effort, it may not always yield the benefits expected.



Impact to Innovation

- The cost impacts of mandating design and construction standards was assessed, but what is the impact on product development innovation?
- It is observed that when prescriptive methods are imposed the responding developers are often constrained into approaches that meet those methods.
- Per the INCOSE Guide to Writing Requirements:
 - A requirement statement is the result of a formal transformation of one or more needs or parent requirements into an agreed-to obligation for an entity to perform some function or possess some quality (within specified constraints with acceptable risk).
 - Common mistakes made when documenting needs and the resulting requirements include using design output level requirements as design input requirements.
 - Design input requirements must not be any more detailed or specific than is necessary for the level at which they are stated. The design input requirements avoid placing unnecessary constraints on the design at the given level.
 - The goal for design input requirements is to be implementation-independent.
- In requirement development, it is best practice to specify the functions, not the implementation. As the very intent of standardization documentation is to promote commonality and interoperability, usage can be a constraint against product innovation.



Observations

- Usage of design and construction standards appears to be evolving in the U.S. regulations from prescriptive to performance based.
- Companies use standards to support their development efforts, yet in industries where there is no common single set of standards mandating usage can yield hidden costs.
- Parameters that factor into impacts associated with application of design and construction standards include:
 - Expectation of a regulatory certification process
 - Ability to utilize of multiple, equivalent approaches
 - Cost budgets associated with the project
 - Need for innovation compared to need to assure design consistency or outcome
- It is proposed that an optimized system is realized by implementing an evaluation on whether to levy design and construction standards directly, or to levy requirements for specific quality attributes (or performance-based standards), and provide design and construction standards as reference material.

Complexity	Budget	Regulated Field	Need for Design Outcome Consistency	Multiple Approaches Acceptable	Need for Innovation	Recommended Approach
Low	Limited-Moderate	Yes	Yes	No	Moderate	Design Standards
High	Unlimited	Yes	Yes	Yes	Moderate	Design Standards
High	Limited /Fixed Price	No	No	Yes	High	Quality Requirements, Design Standards are References



Conclusions

- There is an appeal to the usage of design and construction standards, levying processes can mitigate risk related to safety and quality of the product, and ensure commonality of design, test, operation and verification practices.
- However, as shown in this paper, there are hidden costs associated with levying design and construction standards as formal requirements.
- It is recommended that projects consider the context when making the determination to mandate the use of design and construction standards for their project.
- To avoid the hidden costs associated with levying design and construction standards, as well as to allow for innovation, projects should consider whether they are addressing a product in a highly regulated field, or one that is not as regulated and where a variety of equivalent approaches may be sufficient, when requiring standards to their suppliers.
- The benefit of usage of standards may be diminished if applied without thinking of the context and purpose of application.



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