Medical Device Needs and Requirements



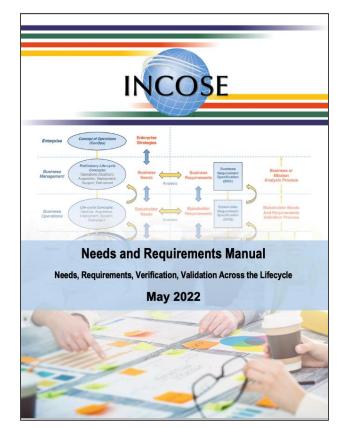
Lou Wheatcraft, Senior Consultant, Wheatland Consulting

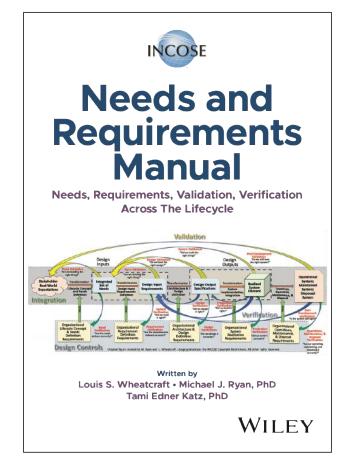
Wheatland.consulting@gmail.com

Needs and Requirements Manual (NRM)



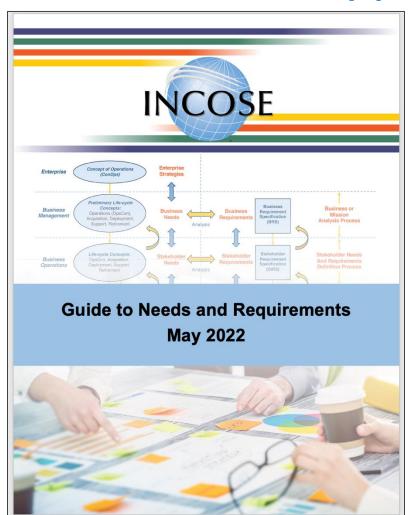
- The NRM is the RWG flagship product, V1 released in January 2022
- V1.1 minor updates in May 2022 to shorten title, add subtitle, and align with other RWG products
- Content aligns with, and expands, the INCOSE SE Handbook version 5 material.
- The NRM is being updated to Version 2, which is planned to be published by Wiley in November 2024

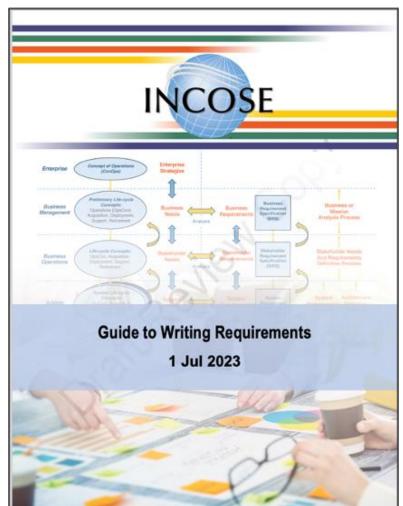


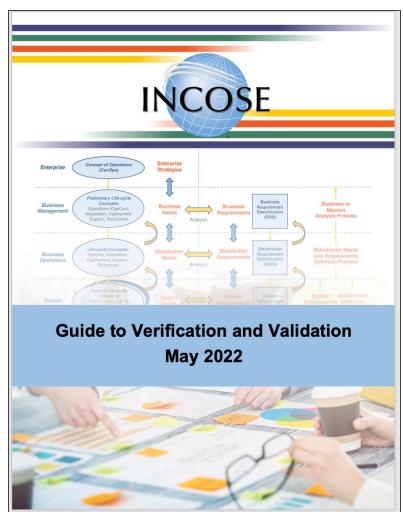


The RWG Guides Provide Practical Application of the NRM











INCOSE Product of the Year 2022 Award



CFR Title 21 Part 820 and ISO 13485

- CFR Title 21: Part 820, Quality System Regulation and ISO13485, Medical Device Quality Management Systems, contain a set of requirements for regulatory purposes that outline the current good manufacturing practice (CGMP) requirements for medical device manufacturers in the US and Europe.
- These regulations and standards cover the methods, facilities, and controls used for the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use.
- As the titles imply, the focus is more on quality as in a quality management system (QMS) than systems engineering as presented by INCOSE and the RWG products.

In this presentation the concepts, terminology, and requirements contained in CFR Title 21 Part 820 are integrated with the concepts, activities, and terminology contained in the INCOSE RWG Products.

Many of the concepts and terminology contained in CFR Title 21 Part 820 are reflected within the INCOSE RWG Products.

Definitions (Title21, Part 820)

- Component means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.
- Product result of a process components, manufacturing materials, in-process devices, finished devices, and returned devices.
- Finished device means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.
- Establish means define, document (in writing or electronically), and implement.
- Quality means the totality of features and characteristics that bear on the ability
 of a device to satisfy fitness-for-use, including safety and performance.
- Quality system means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.
- Specification means any requirement with which a product, process, service, or other activity must conform. (However as discussed later, they only use the term specification in relation to design outputs.)

What is not defined:



While Title 21 Part 820 uses the terms "needs" and "requirements"; they are not defined

Because of this we use the INCOSE definitions from the "Guide to Writing Requirements".

ISO 13485 does say that the word "shall" indicates the statement is a requirement and when a requirement is to be "documented", it is also required to be established, implemented, and maintained.

This applies to requirements on the organization as well as on the device being developed.

Definition of "Needs"



- A need statement is the result of a formal transformation of one or more sources or lifecycle concepts into an agreed-to expectation for an entity to perform some function or possess some quality within specified constraints with acceptable risk.
- A need set is a structured set of agreed-to need expressions for the entity (enterprise/business unit/system/subsystem/system element/process) and its external interfaces.
- An attribute is additional information associated with an entity which is used to aid in its definition, understanding, and management.
- A need expression includes a need statement and a set of associated attributes.

Definition of "Requirements"



- A requirement statement is the result of a formal transformation of one or more sources, needs, or higher-level requirements into an agreed-to obligation for an entity to perform some function or possess some quality within specified constraints with acceptable risk.
- A requirement set is a structured set of agreed-to requirement expressions for the entity (enterprise/business unit/system/subsystem/system element/process) and its external interfaces.
- A requirement expression includes a requirement statement and a set of associated attributes.

Define Attributes for each Need and Requirement Statement



To better manage projects, it is important that a set of attributes are defined that are combined with the requirement statements to form requirement expressions.

The inclusion of these attributes helps in understanding intent, contributes to the quality of the requirement statements, and provides management with important insight as to the health of a project.

Attributes to Help Define Needs & Requirement and Their Intent

- A1 Rationale*
- A2 Trace to Parent*
- A3 Trace to Source*
- A4 States and Modes
- A5 Allocation/Budgeting*

Attributes Associated with System Verification & System Validation

- A6 System Verification or System Validation Success Criteria*
- A7 System Verification or System Validation Strategy*
- A8 System Verification or System Validation Method*
- A9 System Verification or System Validation Responsible Organization*
- A10 System Verification or System Validation Level
- A11 System Verification or System Validation Phase
- A12 Condition of Use
- A13 -System Verification or System Validation Results
- A14 -System Verification or System Validation Status

Attributes to Help Maintain the Requirements

- A15 Unique Identifier*
- A16- Unique Name
- A17 Originator/Author*
- A18 Date Requirement Entered
- A19- Owner*
- A20 Stakeholders
- A21 Change Board
- A22 Change Proposed
- A23 Version Number

- A24 Approval Date
- A25 Date of Last Change
- A26 Stability/Volatility
- A27 Responsible Person
- A28 Need or Requirement Verification Status*
- A29 Need or Requirement Validation Status*
- A30 Status of the Need or Requirement
- A31 Status (of Implementation)
- A32 Trace to Interface Definition
- A33 Trace to Dependent Peer Requirements
- A34 Priority*
- A35 Criticality or Essentiality*
- A36 Risk (of Implementation) *
- A37 Risk (Mitigation)
- A38 Key Driving Need or Requirement (KDN/KDR)
- A39 Additional Comments
- A40 Type/Category

Attributes to Show Applicability and Allow Reuse

- A41- Applicability
- A42 Region
- A43 Country
- A44 State/Province
- A45 Market Segment
- A46 Business Unit

Attributes to Aid in Product Line Management

- A47 Product Line
- A48 Product Line Common Needs and Requirements
- A49 Product Line Variant Needs and Requirements

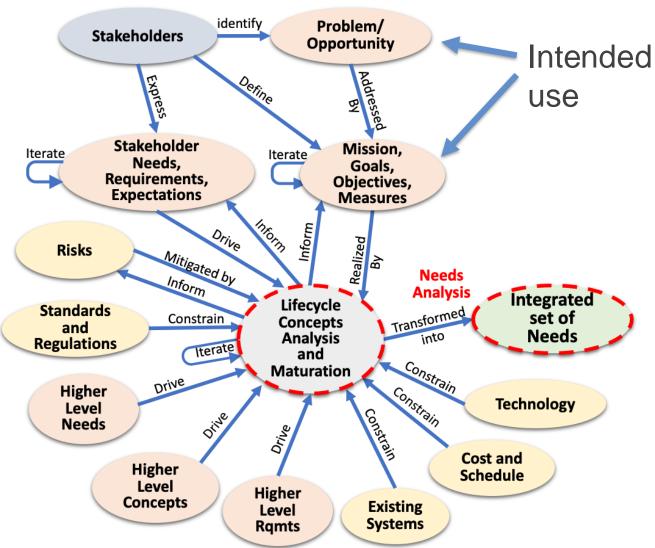
There is a lot of work to be done before requirements and before final design



An integrated, multidiscipline collaborative project team participates in the lifecycle concept analysis and maturation activities.

As a result, at least one feasible set of lifecycle concepts are identified, along with risk mitigation plans, plans for compliance with standards and regulations, plans for verification and validation, and preliminary architecture and design.

An integrated set of needs is baselined representing the agreed to scope of the project.



Original figure created by L. Wheatcraft. Usage granted per the INCOSE Copyright Restrictions. All other rights reserved.

Integrated Set of Needs

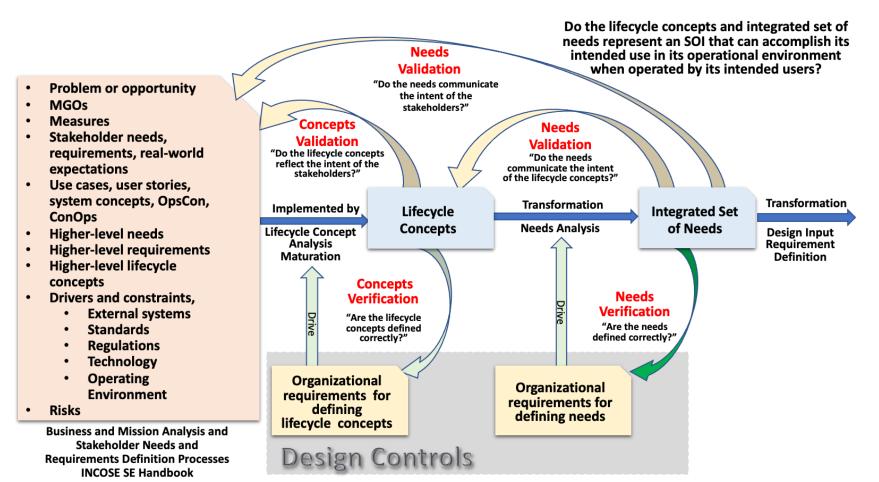


- The Integrated Set of Needs represent an integrated stakeholder, customer/acquirer view of the system of interest (SOI)
 - Communicates the perspective of the system as viewed externally (black/closed box).
 - Communicates the stakeholder real-world expectations for the end-state once the SOI is delivered.
 - In the end what will final acceptance be based on?
 - What is needed to show the delivered system is fit for use in its operational environment when used by its intended users?
 - The Integrated Set of Needs must be well-formed having the characterizes defined in the GtWR.
 - The baselined Integrated Set of Needs represents the agreed-to scope of the project.
 - The requirements, design, and SOI will be <u>validated</u> against its <u>Integrated Set of Needs.</u>

The quality of the needs is dependent on the quality of the lifecycle analysis and maturation activities from which they are transformed.

Defining an Integrated Set of Needs for an SOI





The FDA is concerned with the intended use of a product, a set of needs that address that intended use, along with risk identification and management.

The focus of requirements definition, architecting, and design is to be able to develop a product than can be validated to address these.

Original figure created by M. Ryan and L. Wheatcraft. Usage granted per the INCOSE Copyright Restrictions. All other rights reserved.

Planning for Product Realization (ISO 13485)



The organization shall determine the following:

- a) quality objectives and requirements for the product;
- b) the need to <u>establish processes</u> and documents and to provide resources specific to the product, including infrastructure and work environment;
- c) required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance;
- d) <u>records needed to provide evidence</u> that the realization processes and resulting product meet requirements.
- The output of this planning shall be documented in a form suitable for the organization's method of operations.

Design Input Requirements

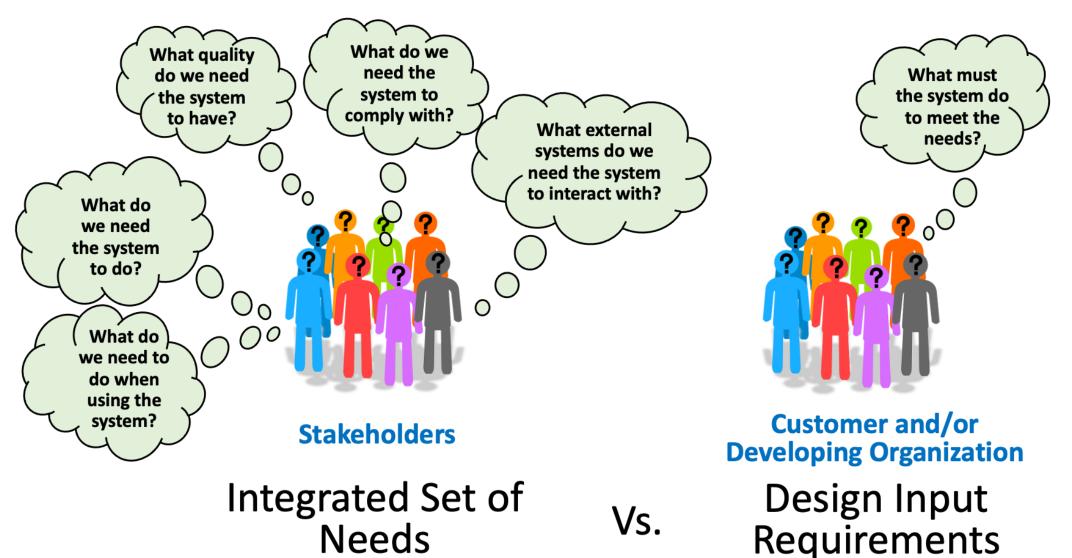
- Design input requirements represent the technical, developer view of the SOI referred to as "System Requirements".
 - Transformed from the Integrated Set of Needs.
 - Communicates the perspective of the system as viewed by the developers.
 - Expressed as "shall" statements,
 - "The SOI "shall" ..."
 - or for a goal, expressed as a "should" statement, "The SOI "should""
 - Inputs to the architecture and design definition processes.
 - The design input requirements are validated against the Integrated Set of Needs.
 - Both the design and realized SOI will be <u>verified</u> against its <u>design input</u> requirements.

The quality of the requirements is dependent on the quality of the needs from which they are transformed.

If the Integrated Set of Needs does not have the characteristics defined in the GtWR, neither will the resulting set of design input requirements.

Two Different Perspectives





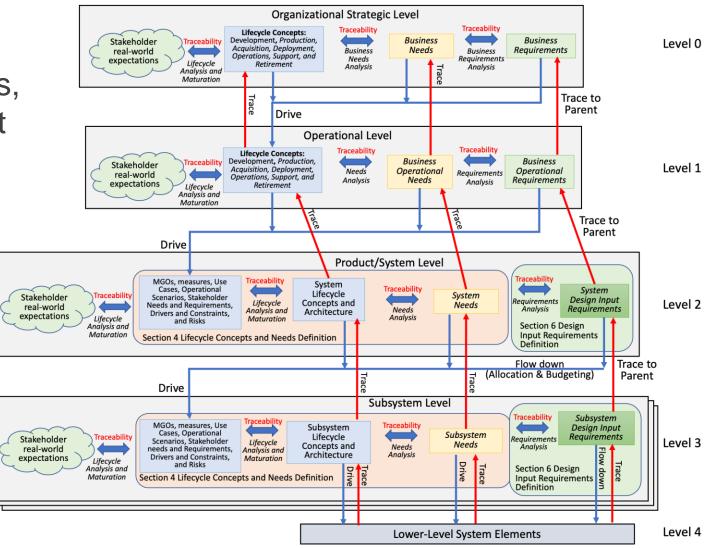
Original figure created by L. Wheatcraft. Usage granted per the INCOSE Copyright Restrictions. All other rights reserved.

Levels of lifecycle concepts, needs, and requirements



Stakeholder real-world expectations, lifecycle concepts, needs, and requirements exist at each level.

Stakeholders
communicate their
expectations in various
forms: needs,
requirements, use
cases, user stories,
operational scenarios.

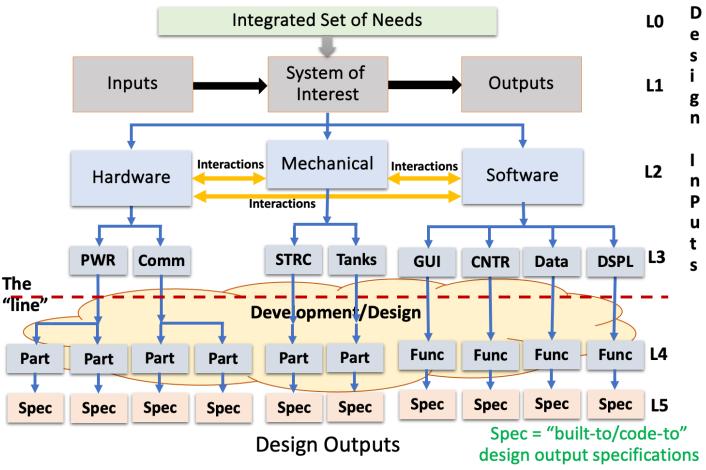


Levels of Architecture



Each element within the system architecture should have its own set of lifecycle concepts, integrated set of needs, and design input requirements that drive all design output activities.

Design outputs include design descriptions for each part or software functional module as well as design output specifications to which the product will be manufactured or coded.



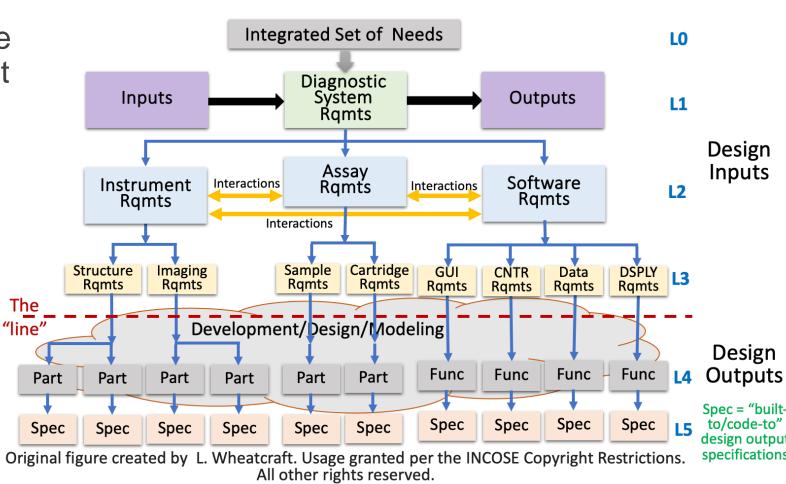
Original figure created by M. Ryan and L. Wheatcraft. Usage granted per the INCOSE Copyright Restrictions. All other rights reserved.

Levels of Architecture – Medical Device

The L1 Diagnostic System Requirements are allocated to the parts of the architecture at L2 that have a role in meeting those requirements.

Each part of the architecture then develops lifecycle concepts, needs, and requirements that will result in the higher-level requirements to be met.

Process continues until a make (build, code), buy, or reuse decision is made.



In systems with imbedded software, there will be many dependences and interactions with the other parts to which a requirement was allocated

Traceability



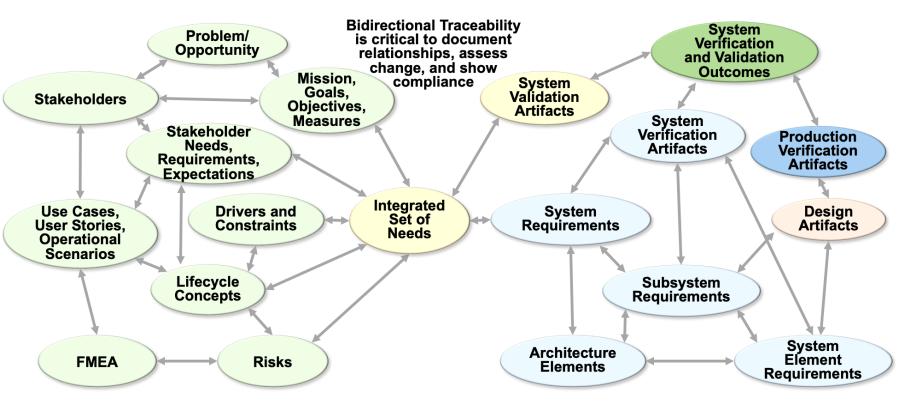
- USC Title 21 Part 820 requires developing organizations of medical devices to develop and maintain a Device History File (DHF) that "shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part." Traceability is a critical part of the DHF.
- Failure to show required traceability can lead to a product not being approved for its intended use in the marketplace.
- ISO 13485: The organization shall document procedures for traceability.
 - These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained

Without this traceability clearly communicated, the FDA will not approve the device for use.

Traceability



Given the importance of traceability to project success, many SE tools enable practitioners to define a traceability relationship metamodel within the tool and then enforce adherence to that model as data and information is entered into the tool, flagging discrepancies when the model is not followed



Original figure created by L. Wheatcraft. Usage granted per the INCOSE Copyright Restrictions. All other rights reserved.

Design Input Requirements Defined (Title 21, Part 820)

- The physical and performance requirements of a device that are used as <u>a basis</u> for device design.
 - Each manufacturer shall establish and maintain procedures to ensure that the <u>design [input]</u> requirements relating to a device are appropriate and address the <u>intended use</u> of the device, including the <u>needs</u> of the user and patient.
 - The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements.
 - Requirements shall be complete, unambiguous, able to be verified or validated, and are not in conflict with each other (ISO 13485)

Design Input Requirements = Design-to (what) requirements
The FDA does not use the term "specification" in association with design inputs.

FDA is concerned with the quality of the requirements (e.g., having the characteristics defined in the INCOSE Guide to Writing Requirements (GtWR)

Characteristics of Well-Formed Individual Requirement Expressions

Formal Transformation. Given the need and requirement is a result of a formal transformation, the following characteristics of a well-formed need or requirement have been derived:

- <u>C1 Necessary</u>: The need requirement statement defines capability, characteristic, constraint, or quality factor needed or required to satisfy a lifecycle concept, need, source, or higher-level requirement.
- C2 Appropriate: The specific intent and amount of detail of the need or requirement statement is appropriate to the level (the level of abstraction, organization, or system architecture) of the entity to which it refers.
- <u>C5 Singular</u>: The need or requirement statement should state a single capability, characteristic, constraint, or quality factor.
- <u>C8 Correct</u>: The need statement must be an accurate representation of the lifecycle concept or source from which it was transformed. The requirement statement must be an accurate representation of the need, source, or higher-level requirement from which it was transformed.
- C9 Conforming: Statements and expressions of individual needs and requirements should conform to an approved standard pattern and style guide or standard for writing and managing needs and requirements.

- **Agreed-to Obligation**. Since the need and requirement is to be a part of a fair agreement to meet an obligation, the following characteristics of a need or requirement have been derived.
- <u>C3 Unambiguous</u>: Need and requirement statements must be stated such that their intent is clear and can be interpreted in only one way by all intended audiences.
- <u>C4 Complete</u>: The need statement sufficiently describes the necessary capability, characteristic, constraint, conditions, or quality factor to meet the lifecycle concept or source from which it was transformed. The requirement statement sufficiently describes the necessary capability, characteristic, constraint, conditions, or quality factor to meet the need, source, or higher-level requirement from which it was transformed.
- <u>C6 Feasible:</u> The need or requirement can be realized within entity constraints (for example: cost, schedule, technical, legal, ethical, safety) with acceptable risk.
- C7 Verifiable: The need statement is structured and worded such that its realization can be validated to the approving authority's satisfaction. The requirement statement is structured and worded such that its realization can be verified to the approving authority's satisfaction.

Characteristics of Well-Formed Sets of Requirements

Formal Transformation. Given the set of needs and requirements Agreed-to Obligation. Since the set of need and is the result of a formal transformation, the following characteristics of the need and requirement set have been derived:

C10 - Complete: The set of needs and set of requirements for an entity should stand alone such that it sufficiently describes the capabilities. characteristics. functionality. necessary performance, drivers, constraints, conditions, interactions, standards, regulations, safety, security, resilience, and quality factors without requiring other sets of needs or sets of requirements at the appropriate level of abstraction.

C11 - Consistent: A set of needs and a set of requirements is consistent if contains individual needs or requirements that are:

- unique:
- do not conflict with or overlap with others in the set;
- makes use of homogeneous units and measurement systems; and
- are developed using a consistent language (that is, the same words are used throughout the set to mean the same thing); and use terms that are consistent with the architectural model, project glossary, and project data dictionary.
- C15 Correct: The set of needs must be an accurate representation of the lifecycle concepts or sources from which it was transformed. The set of requirements must be an accurate representation of the needs, sources, or higher-level requirements from which it was transformed.

requirements is to be a result of a fair agreement to meet an obligation, the following characteristics of the set have been derived:

- C12 Feasible: A set of needs and a set of requirements is feasible if it can be realized within entity constraints (such as cost, schedule, technical) with acceptable risk.
- C13 Comprehensible: The set of needs and the set of resulting requirements must each be written such that it is clear as to what is expected of the entity and its relation to the macro system of which it is a part.
- C14 Able to be validated: It must be possible to validate that the set of needs will lead to the achievement of the product goals and objectives, lifecycle stakeholder expectations, risks, and concepts within the constraints (such as cost, schedule, technical, legal and regulatory compliance) with acceptable risk.
- It must be possible to validate that the set of requirements will lead to the achievement of the set of needs and higher-level requirements within the constraints (such as cost, schedule, technical, and regulatory compliance) with acceptable risk.

Design Outputs Defined

- The results of a design effort at each design phase and at the end of the total design effort.
 - Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate <u>evaluation</u> of conformance to design input requirements.
 - Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are <u>essential</u> for the proper functioning of the device are identified.
 - Design output shall be documented, reviewed, and approved before release.
 - The total finished design output consists of the device, its packaging and labeling, and the Device Master Record (DMR).

Use of "essential" implies there are outputs that are "non-essential". Does this imply there could be essential needs and requirements?

From a design input perspective, we recommend that both the "priority" and "essentiality" attributes be defined for each need and requirement.

Requirements vs Specifications



- Device Master Record (DMR) is a compilation of records containing the procedures and specifications for a finished device.
- The DMR for each type of device shall include, or refer to the location of, the following information:
 - (a) Device <u>specifications</u> including appropriate drawings, composition, formulation, component <u>specifications</u>, and software <u>specifications</u>;
 - (b) Production process <u>specifications</u> including the appropriate equipment <u>specifications</u>, production methods, production procedures, and production environment <u>specifications</u>;
 - (c) Quality assurance procedures and <u>specifications</u> including acceptance criteria and the quality assurance equipment to be used;
 - (d) Packaging and labeling <u>specifications</u>, including methods and processes used; and
 - (e) Installation, maintenance, and servicing procedures and methods.

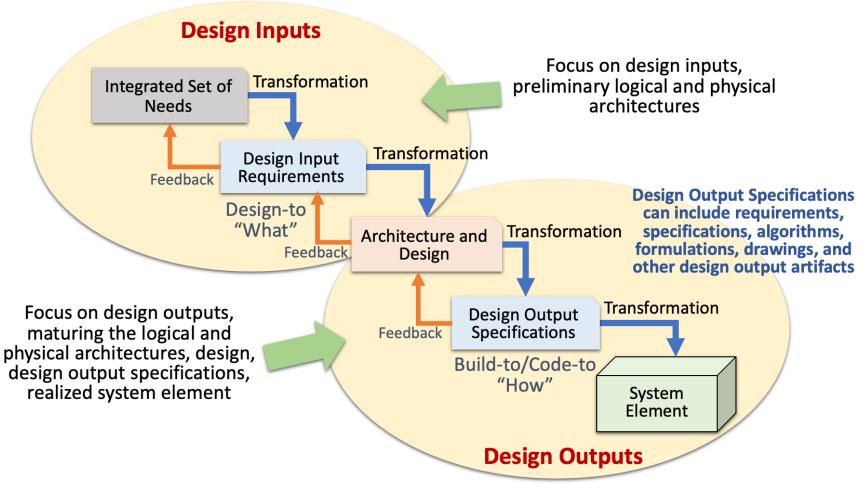
"Specification" is only used for design output artifacts

Putting It All Together - Design Inputs vs Outputs



The Integrated Set of Needs represents the needs of all stakeholders, not just the users

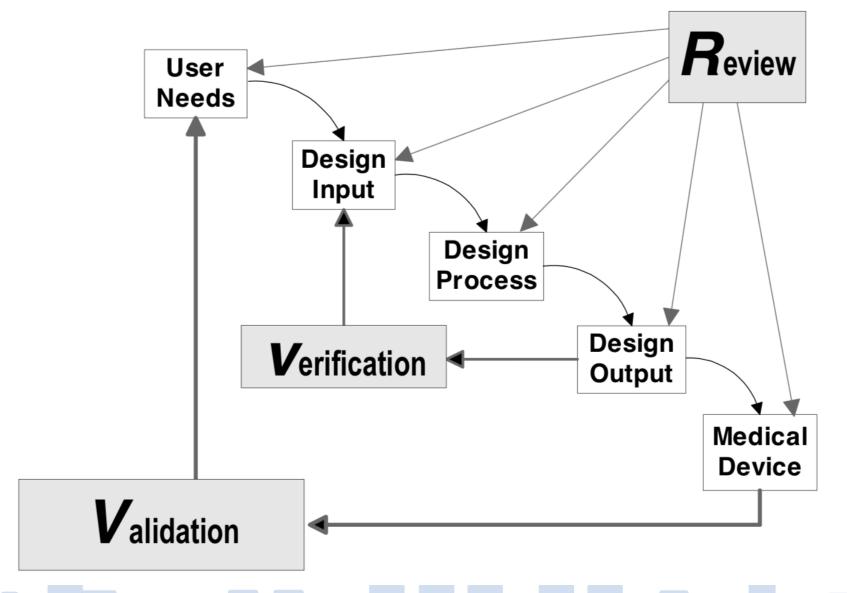
Design Inputs (needs and requirements) are implementation free



Original figure created by M. Ryan and L. Wheatcraft. Usage granted per the INCOSE Copyright Restrictions. All other rights reserved.

FDA Process Overview Diagram





the technical lifecycle stages defined in the INCOSE SE HB.

For example, the FDA does not differentiate between "architecture definition" and "design definition" processes as is done within INCOSE.

Design Reviews Defined

- A documented, comprehensive, systematic examination of a design to:
 - Evaluate the adequacy of the design [input] requirements,
 - Evaluate the capability of the design [outputs] to meet these requirements,
 - Identify problems.
 - Each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results [outputs?] are planned and conducted at appropriate stages of the device's design development.
 - The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed.

There are multiple design reviews across the lifecycle.

"Design" reviews are analogous to "Gate" reviews defined to occur at the end of each lifecycle stage (SR, SR, PDR, CDR, IRR, etc.)

Verification/Design Verification Defined



- Verification means confirmation by examination and provision of objective evidence that specified <u>requirements</u> have been fulfilled.
- Design [and development] verification.
 - Each manufacturer shall establish and maintain procedures for verifying the device design.
 - Design verification shall confirm that the <u>design output</u> meets the <u>design input</u> requirements.
 - The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the **Design History File (DHF)**.
- If the intended use requires that the medical device to be connected to, or interface with, other medical devices, verification (and validation) shall include confirmation that the design outputs meet the design inputs when so connected or interfaced. (ISO 13485).

Validation/Design Validation Defined

- Validation means confirmation by examination and provision of objective evidence that
 the particular requirements for a specific intended use can be consistently fulfilled.
- Design validation means establishing by objective evidence that device specifications conform with user needs and intended use(s).
 - Each manufacturer shall establish and maintain procedures for validating the device design.
 - Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents.
 - Design validation shall ensure that devices <u>conform to defined user needs and intended uses</u> and shall include testing of production units under <u>actual or simulated use conditions</u>.
 - Design validation shall include software validation and risk analysis, where appropriate.

"Particular requirements for a specific intended use" are what are referred to in the RWG products as the "Integrated Set of Needs".

"Users" include all stakeholders that "touch" or interact with the system or an output of the system in some way throughout the product life cycle.

Process Validation

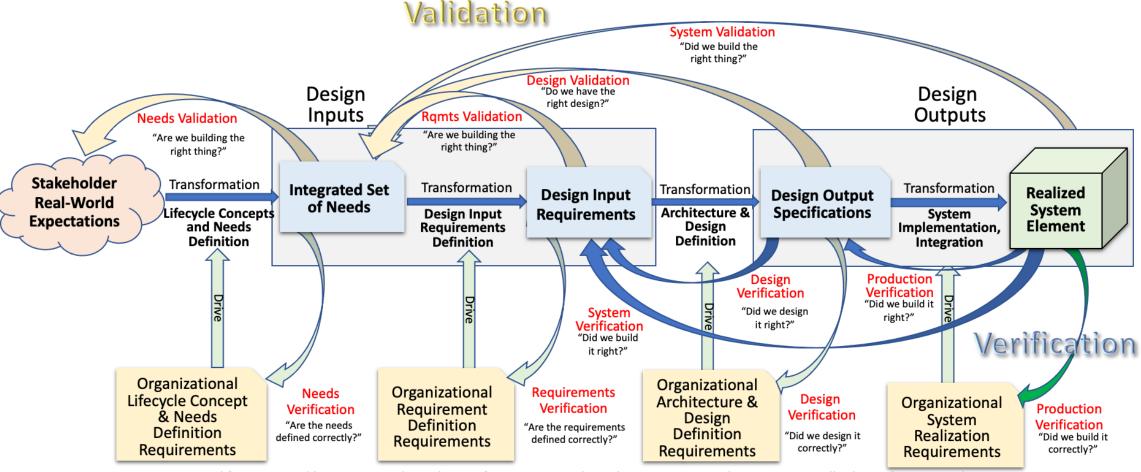


- Establishing by objective evidence that a process <u>consistently</u> produces a result or product meeting its predetermined specifications.
- Addresses different process types:
 - Use of a device,
 - Developing the device, and
 - Manufacturing of the device.

In the NRM, this is referred to as "Production Verification" where the made system is verified against its "design output specifications"

Verification and Validation – in context



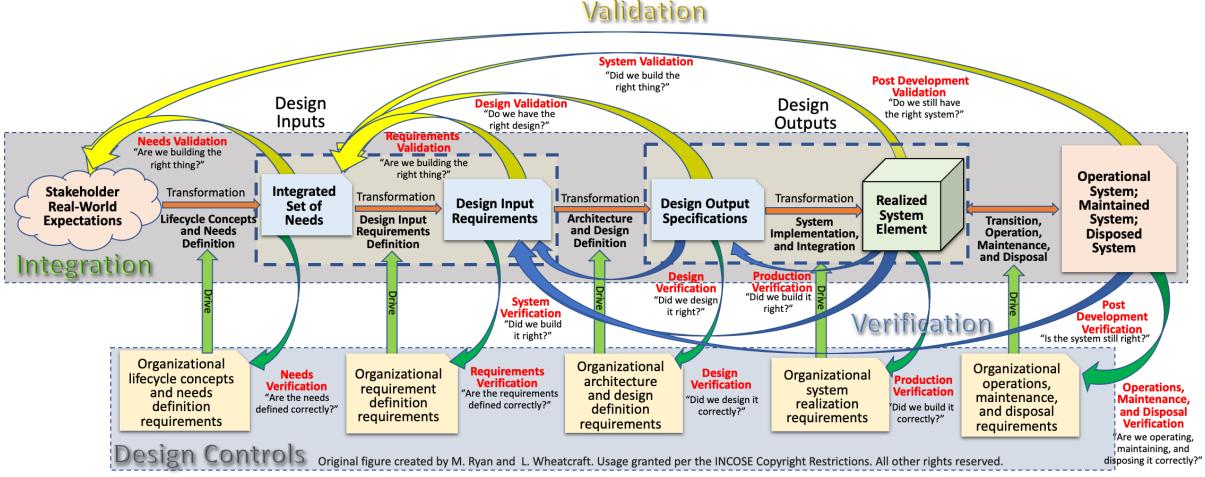


Original figure created by M. Ryan and L. Wheatcraft. Usage granted per the INCOSE Copyright Restrictions. All other rights reserved.

Needs, requirements, verification, & validation are the common threads that tie all SE lifecycle activities and artifacts together.

Post-Production Verification and Validation



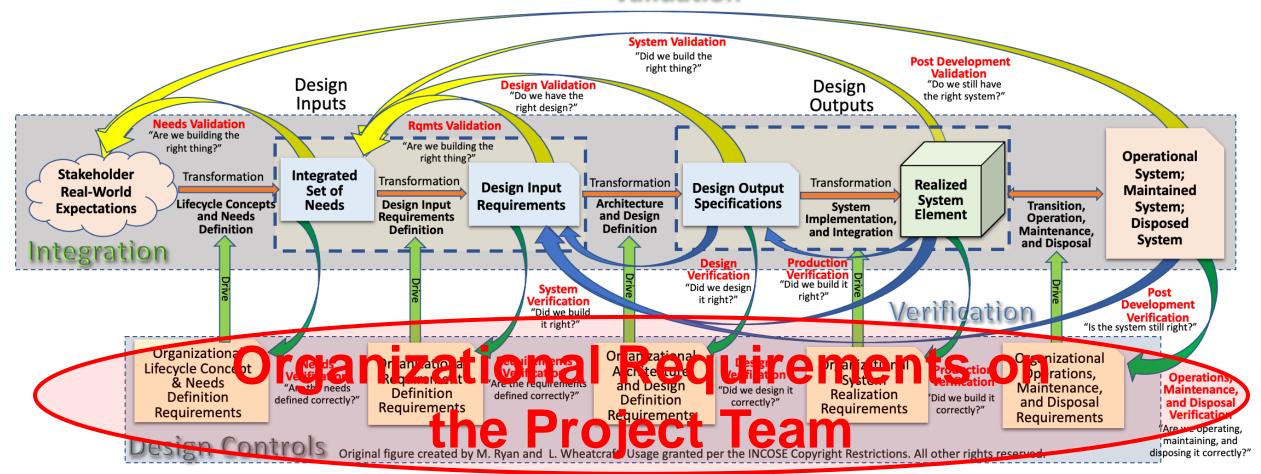


FDA requires organizations to do post-production verification and validation and keep records and report issues and corrective actions – CAPA: Corrective and Preventive Action, .

Design Controls



Validation



Design History File

- Design History File (DHF) is a compilation of records which describes the design history of a finished device.
 - Includes the design inputs including the set of needs and set of design input requirements.
 - Contains or references the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the design input requirements.
 - Traceability across the lifecycle is key to this demonstration.
 - Includes the results of the design verification and validation, including identification of the design, method(s), the date, and the individual(s) performing the verification and validation.

This information must be supplied to the FDA (Approving Authority) for the product to be accepted for its intended use.

Design History Record

- Device History Record (DHR) is a compilation of records containing the production history
 of a finished device.
 - Each manufacturer is required to maintain DHR's.
 - Each manufacturer is required to establish and maintain procedures to ensure that DHR's for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the DMR and the requirements of this part.
 - The DHR includes all the:
 - Records associated with production verification.
 - Design output specifications, which, via production verification, the medical device was manufactured and coded to.
 - Production procedures and processes used to manufacture and code the medical device.
 - Quality assurance processes and procedures used during production verification.
 - Packaging, labeling, instructions for use, installation, maintenance, and servicing procedures.

This information must be supplied to the FDA (Approving Authority) for the product to be accepted for its intended use.

Device Master Record



- Device Master Record (DMR) is a compilation of records containing the procedures and specifications for a finished device.
- The DMR for each type of device includes, or refers to the location of, the following information:
 - Device design output specifications including appropriate drawings, composition, formulation, component specifications, and software specifications.
 - Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications.
 - Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used.
 - Packaging and labeling specifications, including methods and processes used; and
 - Installation, maintenance, and servicing procedures and methods.
- The total finished design output consists of the device, its packaging and labeling, and the DMR.

This information must be supplied to the FDA (Approving Authority) for the product to be accepted for its intended use.



Discussion/Questions

Lou Wheatcraft

- Lou Wheatcraft is a senior consultant and managing member of Wheatland Consulting, LLC. Lou is an international expert in systems engineering with a focus on needs and requirements development, management, verification, and validation across the system lifecycle.
- Lou's goal is to help systems engineers practice better systems engineering from a needs and requirements perspective across all life cycle stages of system/product development. Getting the needs and requirements right upfront is key to a successful project.
- Lou has over 50 years' experience in systems engineering, including 22 years in the
 United States Air Force. Lou has taught over 200 requirement seminars over the last 23 years.
 Lou supports clients from government and industries involved in developing and managing systems and products including aerospace, defense, medical devices, consumer goods, transportation, and energy.
- Lou is very active in the INCOSE and is the current chair of the RWG. Lou is a principal author of several RWG manuals and guides including the Needs and Requirements Manual (NRM), Guide to Needs and Requirements GtNR), Guide to Verification and Validation (GtVV), and newly released version 4 of the Guide to Writing Requirements (GtWR).
- Lou has a BS degree in Electrical Engineering from Oklahoma State University; an MA degree in Computer Information Systems; an MS degree in Environmental Management; and has completed the course work for an MS degree in Studies of the Future from the University of Houston Clear Lake.







Requirements Working Group