Needs and Requirements Manual

Verification and Validation Across the Lifecycle

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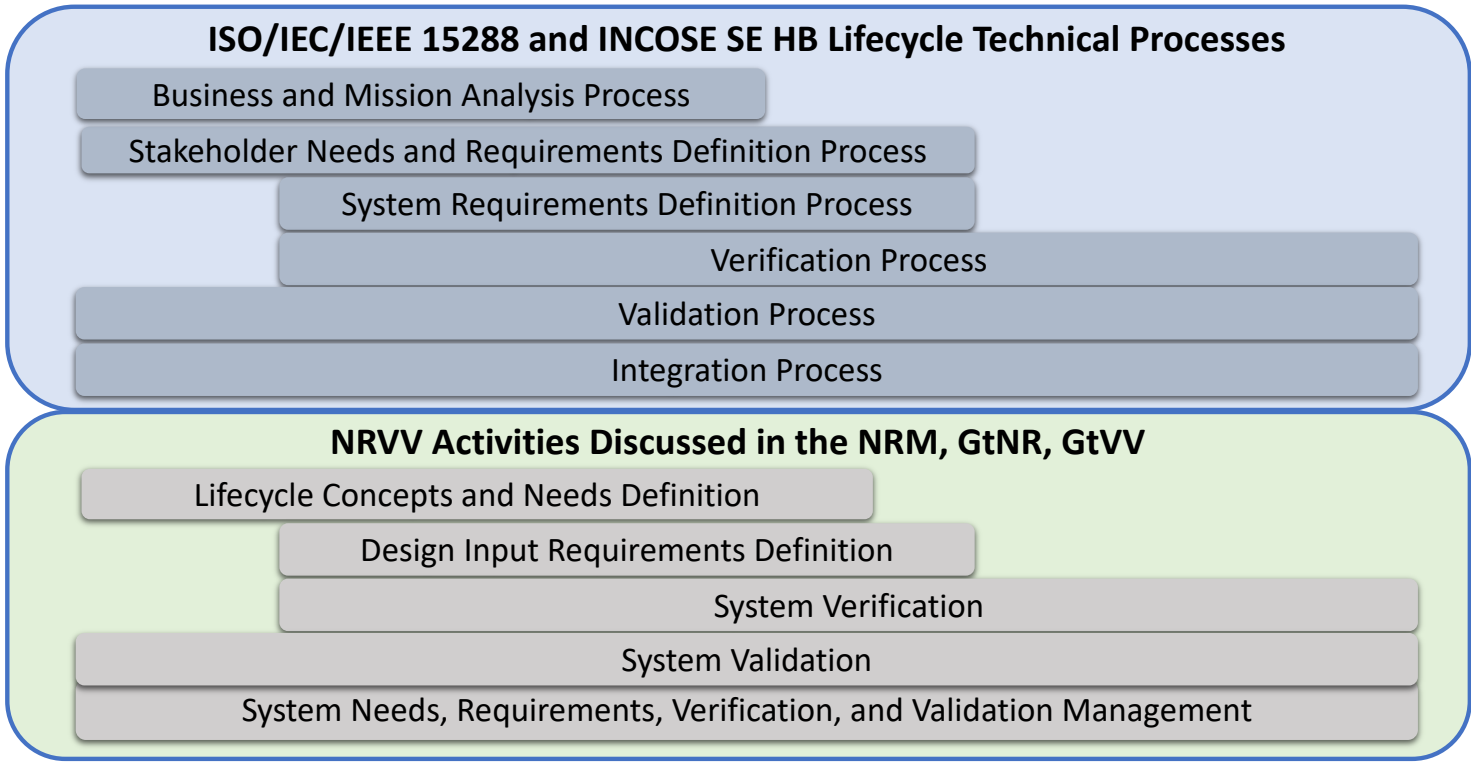
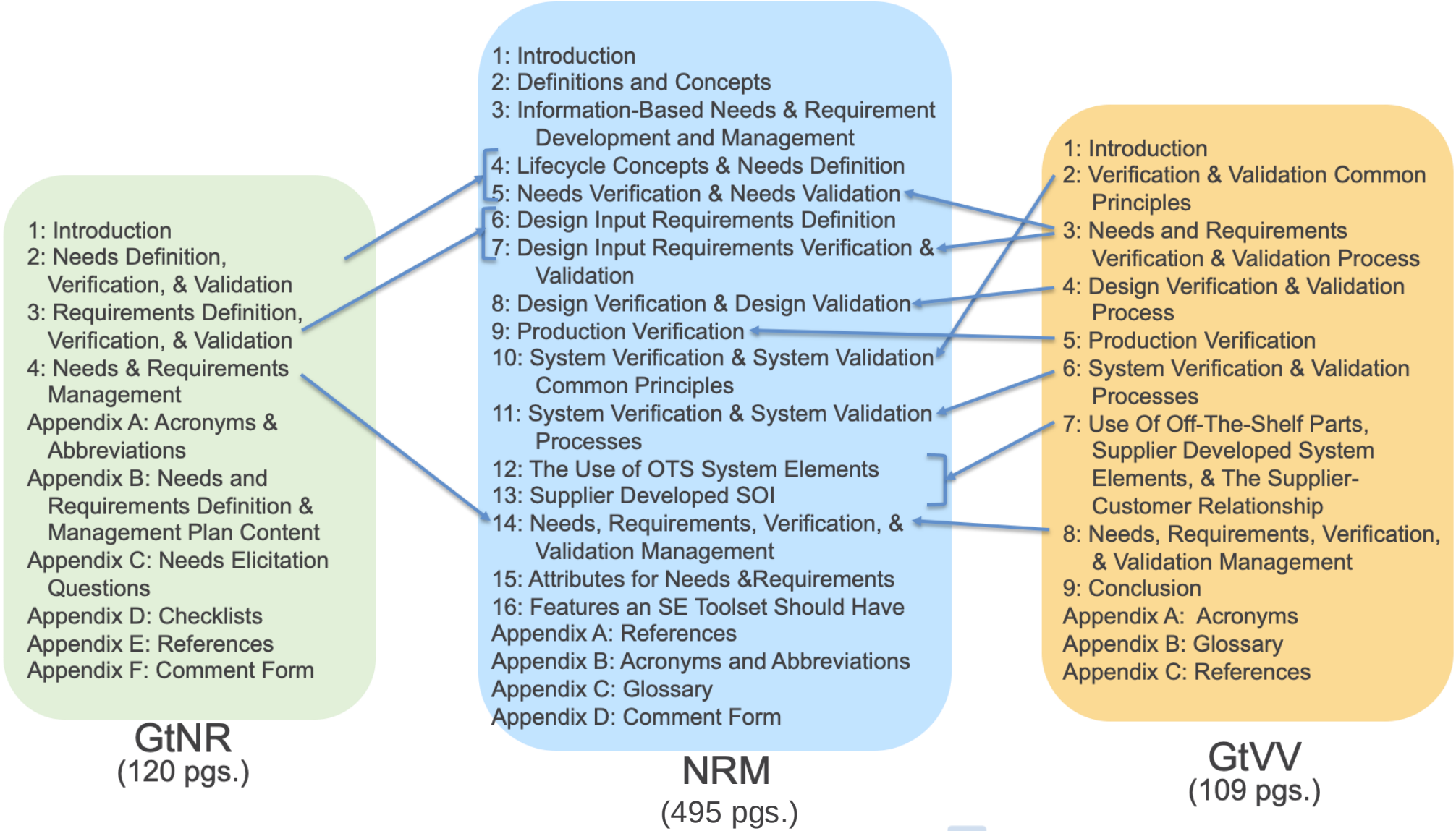
Context of the RWG Products

- The Needs and Requirements Manual (NRM), Guide to Needs and Requirements (GtNR),& Guide to Verification and Validation (GtVV) supplements and elaborates on the INCOSE SE HB
  - Provide more detailed guidance on the what, how, and why concerning needs and requirement definition and management, verification, and validation across the lifecycle.
  - Address ambiguities and inconsistencies in ontology concerning needs and requirements definition and management, verification, and validation.



Focus is on activities performed as part of the SE HB technical processes.

NRM & Guides Relationships



Verification and Validation Common Principles

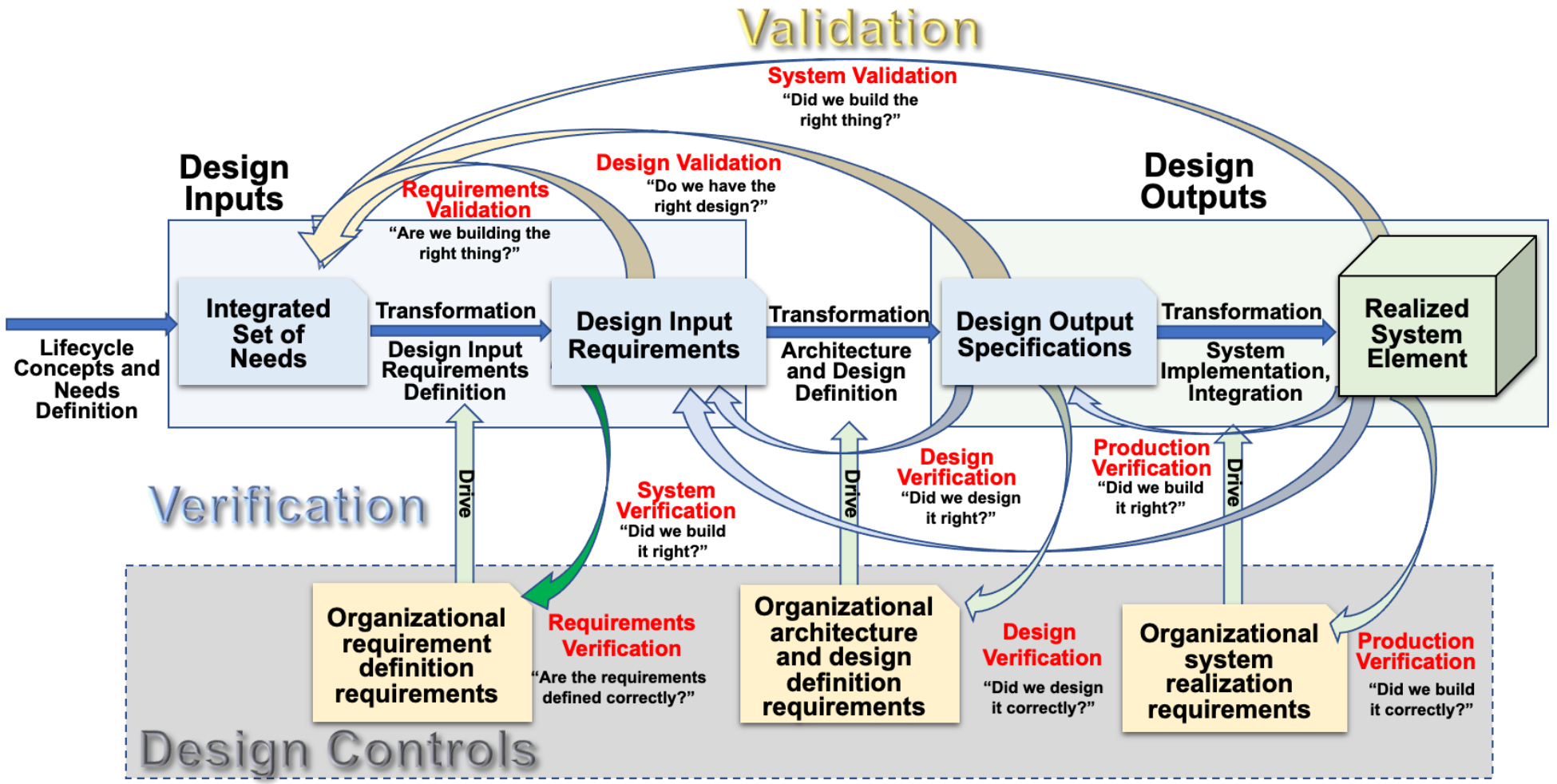
Verification and Validation in Context

- The concepts associated with the terms verification and validation are distinctly different depending on the context.
- The intended meaning of the concepts represented by each term is often misunderstood and the terms are often used interchangeably without making clear the context in which they are used, resulting in ambiguity and a failure to communicate.
- To avoid this ambiguity, each of these terms should be preceded by a modifier (i.e., the subject) which clearly denotes the proper intended context in which the term is being used.
  - *Needs verification* or *needs validation* for verification and validation of the needs.
  - *Requirements verification* or *requirements validation* for verification and validation of the design input requirements.
  - *Design verification* or *design validation* for verification and validation of the design and associated design output specifications.
  - *System verification*, *system validation*, or *production verification* for verification and validation of the realized SOI.

General Nature of Verification and Validation

- For both verification and validation, the entity involved is being verified or validated **against** something.
  - Needs are validated **against** their source or lifecycle concepts from which they were transformed (needs validation).
  - Needs are verified **against** the organizational requirements for defining well-formed needs (needs verification).
  - Requirements are verified **against** the organizational requirements for defining well-formed requirements (requirements verification).
  - Requirements, design, and realized system are validated **against** the integrated set of needs (requirements, design, and system validation).
  - Design and realized system are verified **against** their design input requirements (design and system verification).
  - The built or coded system is verified **against** its design output specifications (production verification).

Verification and Validation in Context



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

Distinctions Between the Concepts of Verification and Validation

- The **focus of verification** is more on form.
  - Do the integrated sets of needs and sets of design input requirements have the characteristics as defined in the GtWR (or similar guide)?
  - Will the design result in a system that can be verified to meet its set of design input requirements?
  - Is the SOI made correctly in accordance with its set of design output specifications?
  - Are the internal relationships, like traceability and dependencies, recorded properly within the subsystems, system elements, and integrated system?
  - Are the interactions between the system and external entities recorded properly?
- **Verification** addresses the questions, “Are we designing and building the system in the right way?” (i.e., in accordance with its requirements), and “Are we designing and building the system correctly?”, (i.e., in accordance with the design controls).
  - For systems developed by a supplier, verification is part of acceptance.

Distinctions Between the Concepts of Verification and Validation

- The **focus of validation** is more on content and intent concerning what is being communicated.
  - Do the integrated set of needs or set of design input requirements communicate the right thing?
  - Do the need or requirement statements clearly communicate the correct intent of the parent or source from which it was derived?
  - Is the integrated set of needs or set of design input requirements correct, complete, consistent, and feasible?
  - Will the resulting system be able to be used as intended in the operational environment when operated by the intended users and will not enable unintended users to negatively impact the intended use of the system?
- **Validation** addresses the question "Are we asking for, designing, and building the right system?"
  - In EIA-632, Processes for Engineering a System, there is guidance that states: "*Validation in a system lifecycle context is the set of actions ensuring and gaining confidence that a system is able to accomplish its intended use, goals, and objectives*".
  - Validation is critical because it addresses the risk that the final system will not satisfy the customers, users, and operational and system level stakeholder real-world *expectations*.
  - Validation includes concepts of certification, qualification, acceptance, & approval for use.

Test Phase?

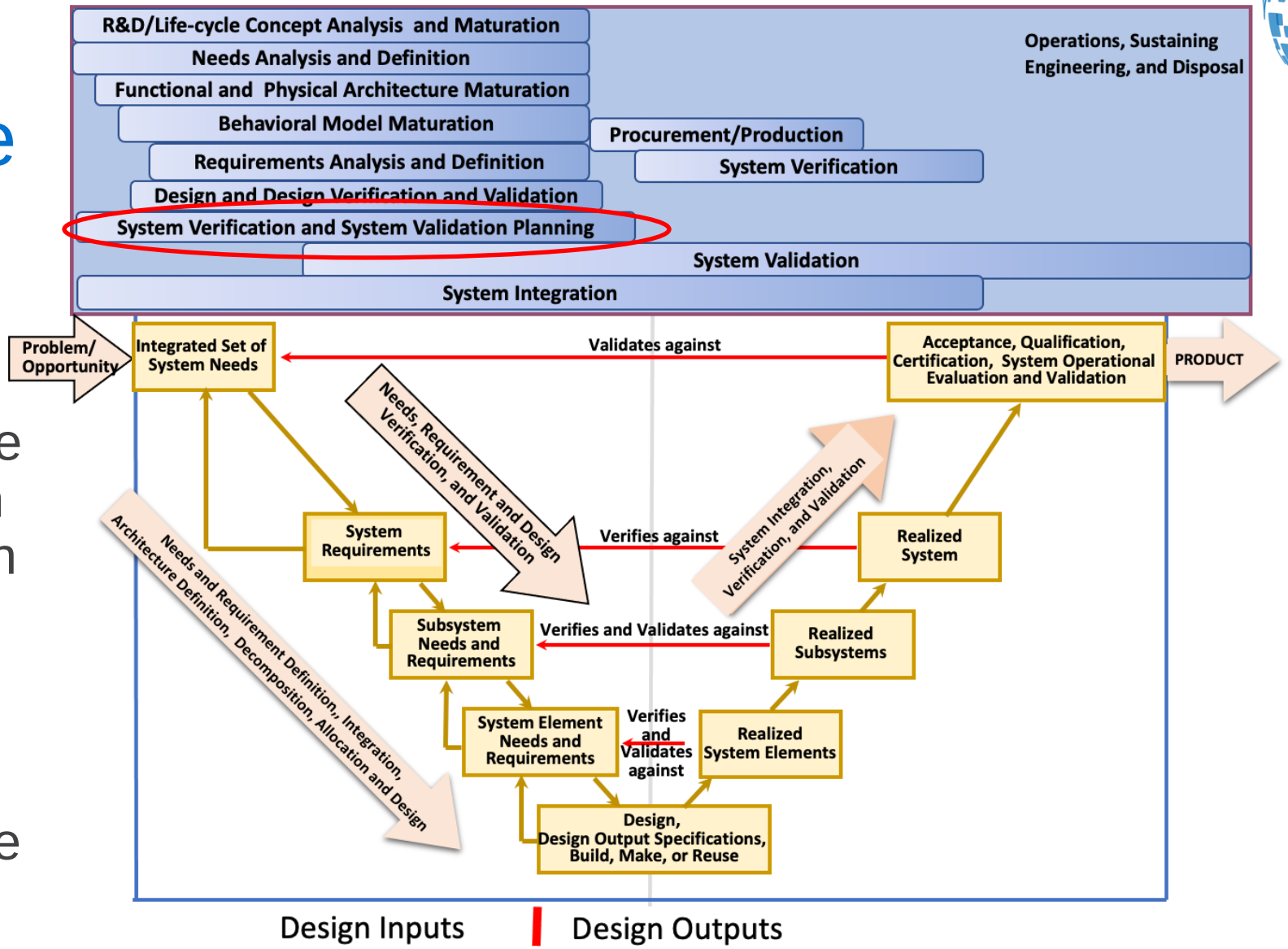
- Are these activities part of system verification or system validation?
  - If part of system verification and validation, Test is a Method, as are Analysis, Inspection, or Demonstration.
  - Acceptance testing, qualification testing, certification testing are often done as part of system validation.
  - Functional testing, environmental testing, EMI testing, load testing, thermal testing, as examples, may be a subset of system verification or validation or may be standalone tests.

- Or are these activities part of design maturation?
  - Part of a design cycle, maturing the design, or doing design verification or validation.
  - Testing that is not necessarily tests in support of system verification or validation – discover faults and design defects.
  - Part of “early system verification or validation”.

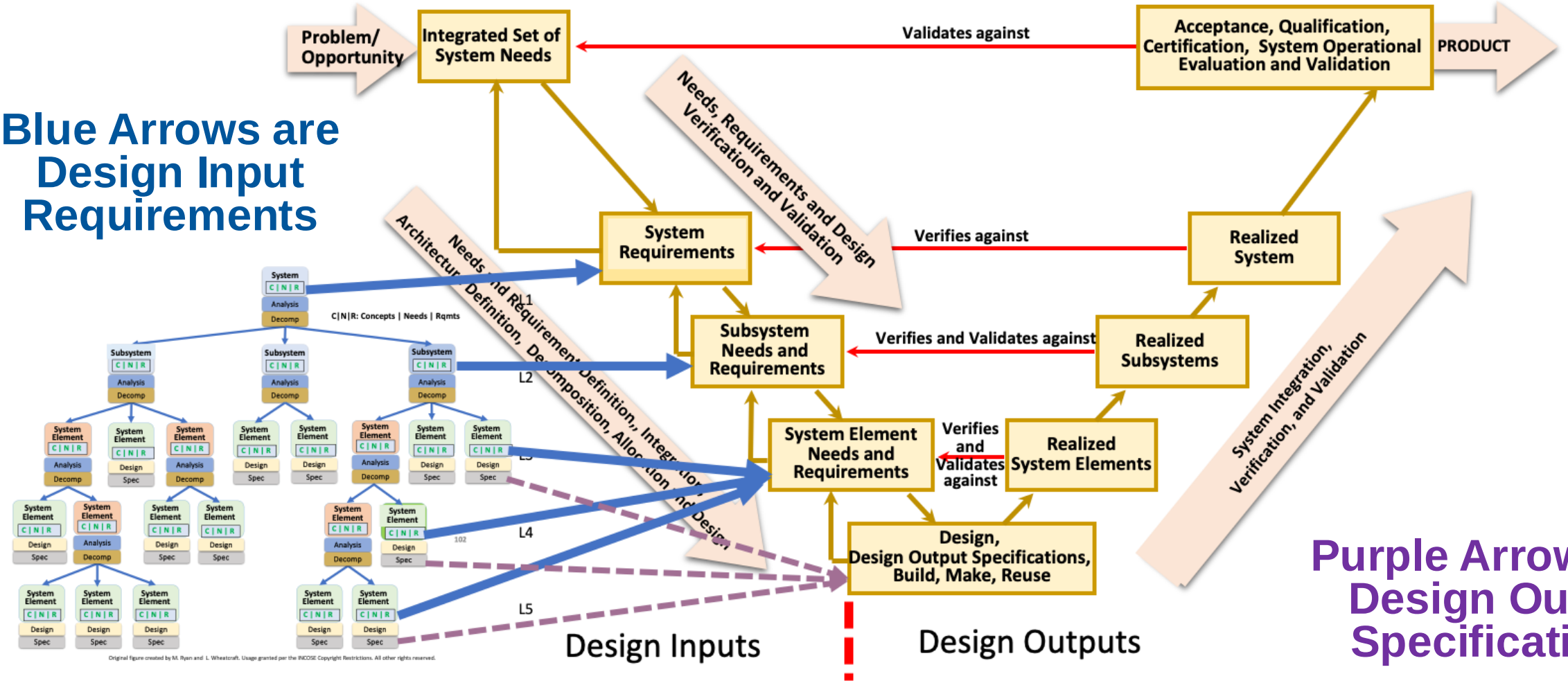
Verification and Validation and the SE Vee

A key activity when defining needs and requirements concerns the planning and preparation for and system verification and validation activities across the lifecycle.

The overall approach for IVV must be defined in the project's SEMP, MIVV Plan, and SIVV Plans.



Verification and Validation and the SE Vee

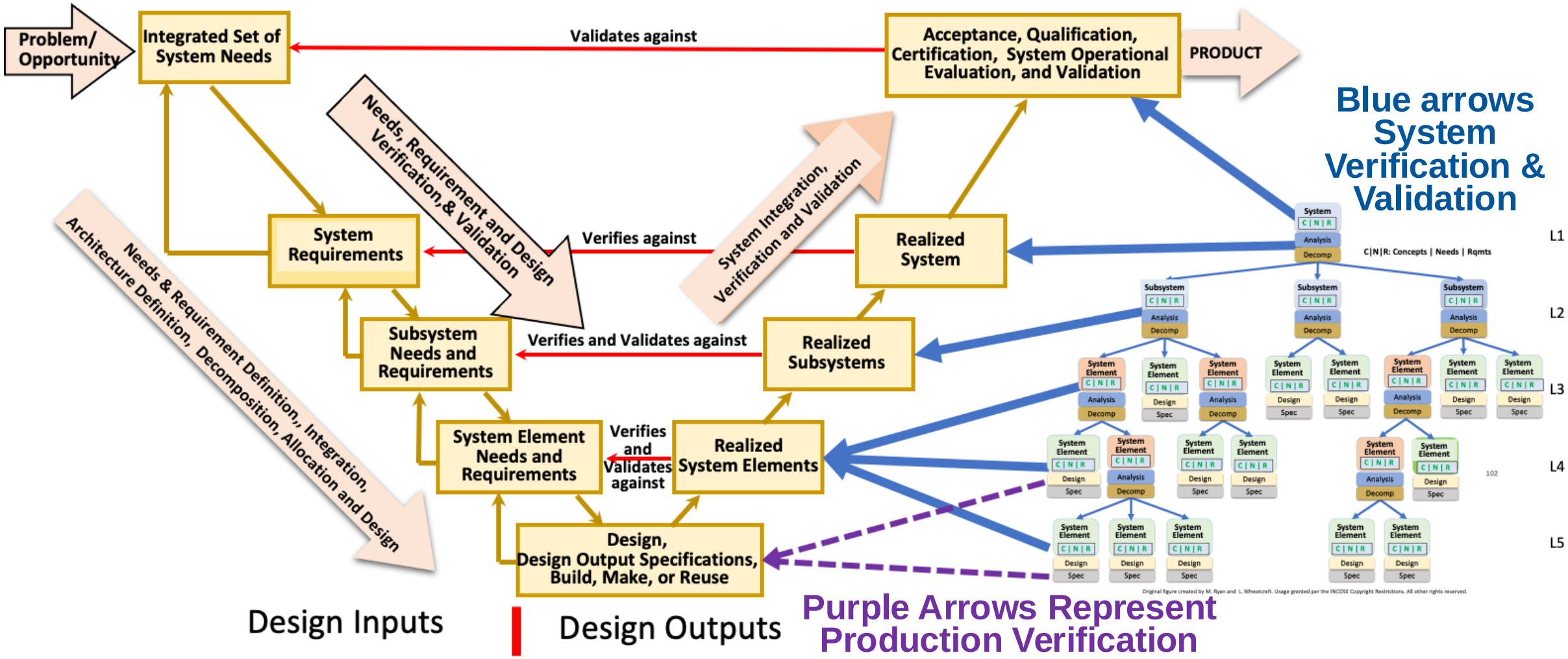


Blue Arrows are Design Input Requirements

Purple Arrows are Design Output Specifications

Adapted from M. Ryan, L. Wheatcraft, L.S., "On the Use of the Terms Verification and Validation", February 2017 and INCOSE SE HB, Version 4, Figures 4.15 & 4.19

Verification and Validation and the SE Vee



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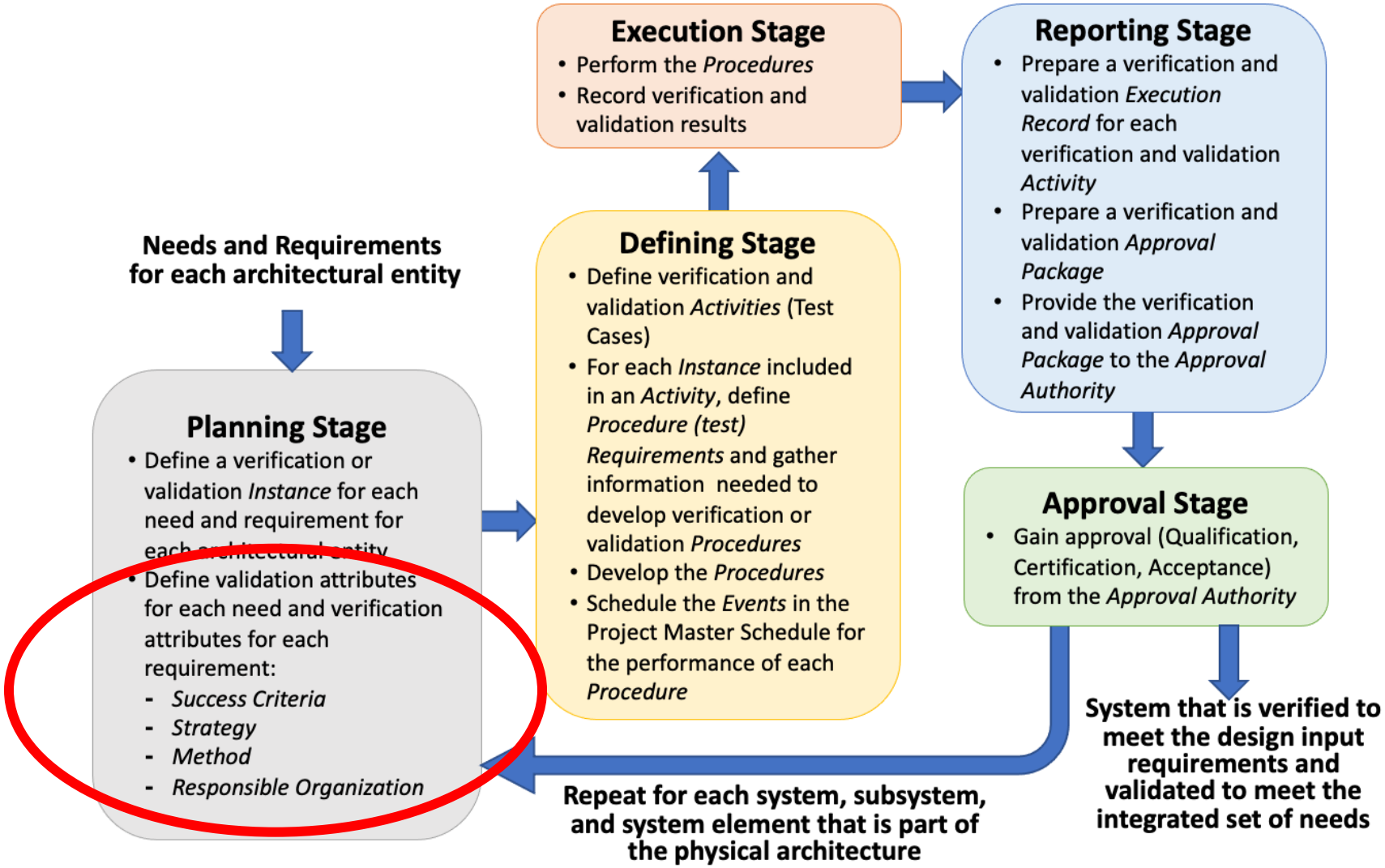
System Verification and Validation Stages



Attributes Associated with Verification and Validation

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

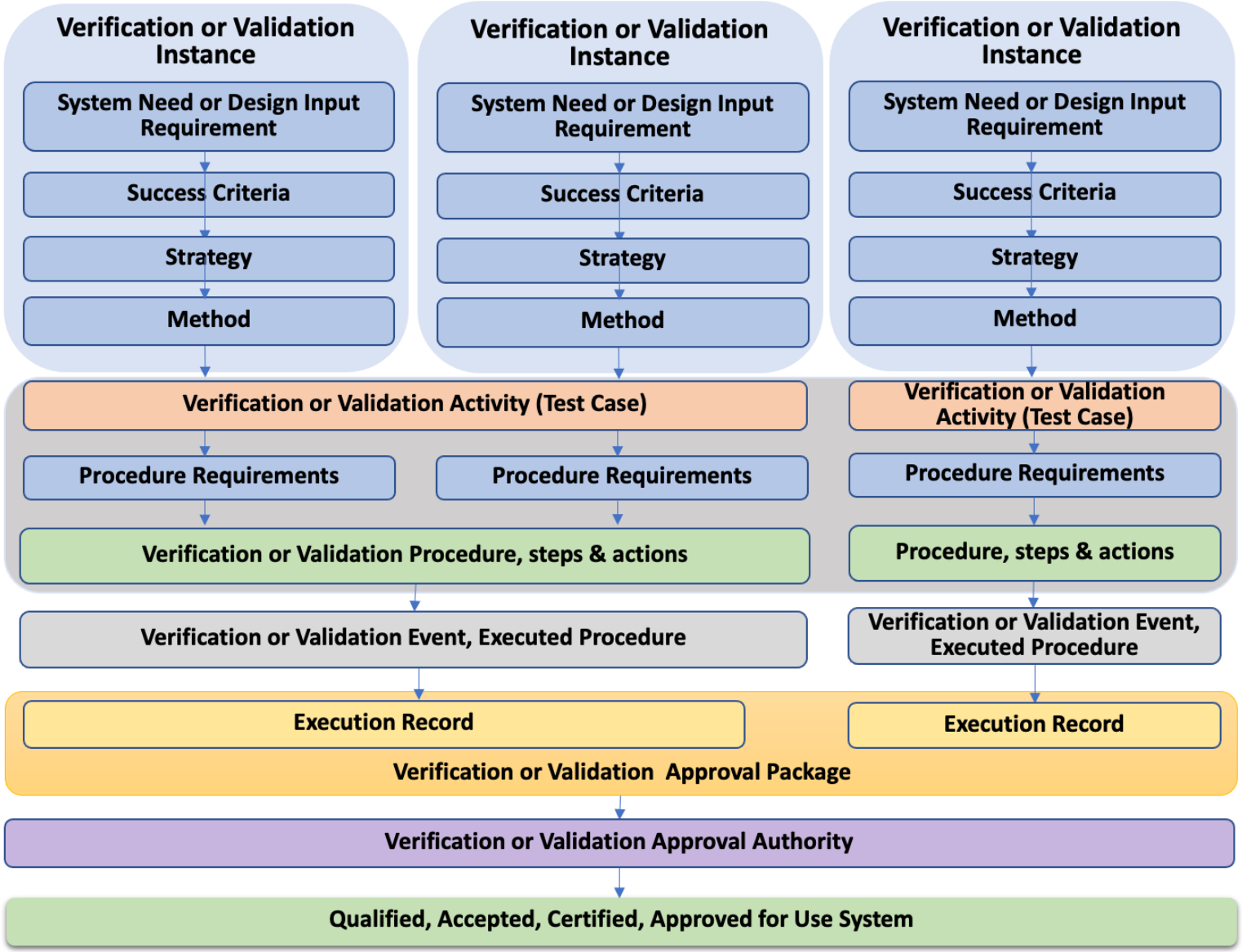
Attributes to Aid in Product Line Management
- A47 – Product Line
- A48 - Product Line Common Needs and Requirements
- A49 - Product Line Variant Needs and Requirements

(Refer to the NRM for a detailed discussion on Attributes)

Test Case

- A “Test Case” is analogous to a Verification or Validation “Activity”.
- Test case is a structured format used in software testing to:
  - **Verify** whether a specific application or system **meets its requirements.**
  - **Validate** whether a specific application or system meets **user needs as communicated within a use case**.
  - **Determine** whether the specific application or system **functions correctly (bug free?)**
    - Can the specific application or system be used as intended, by its intended users, in its intended operational environment.
- Each test case must be clearly defined in terms of each verification and validation instance:
  - The specific condition(s) to be checked during the test.
  - Success criteria.
  - What must be done by the test.
  - Data needed as inputs to the test.
  - Detailed steps to be performed as part of the test (test procedure – manual or automated).
  - Data to be collected as part of the test that provides objective evidence the success criteria was achieved.

System Verification and Validation Common Principles



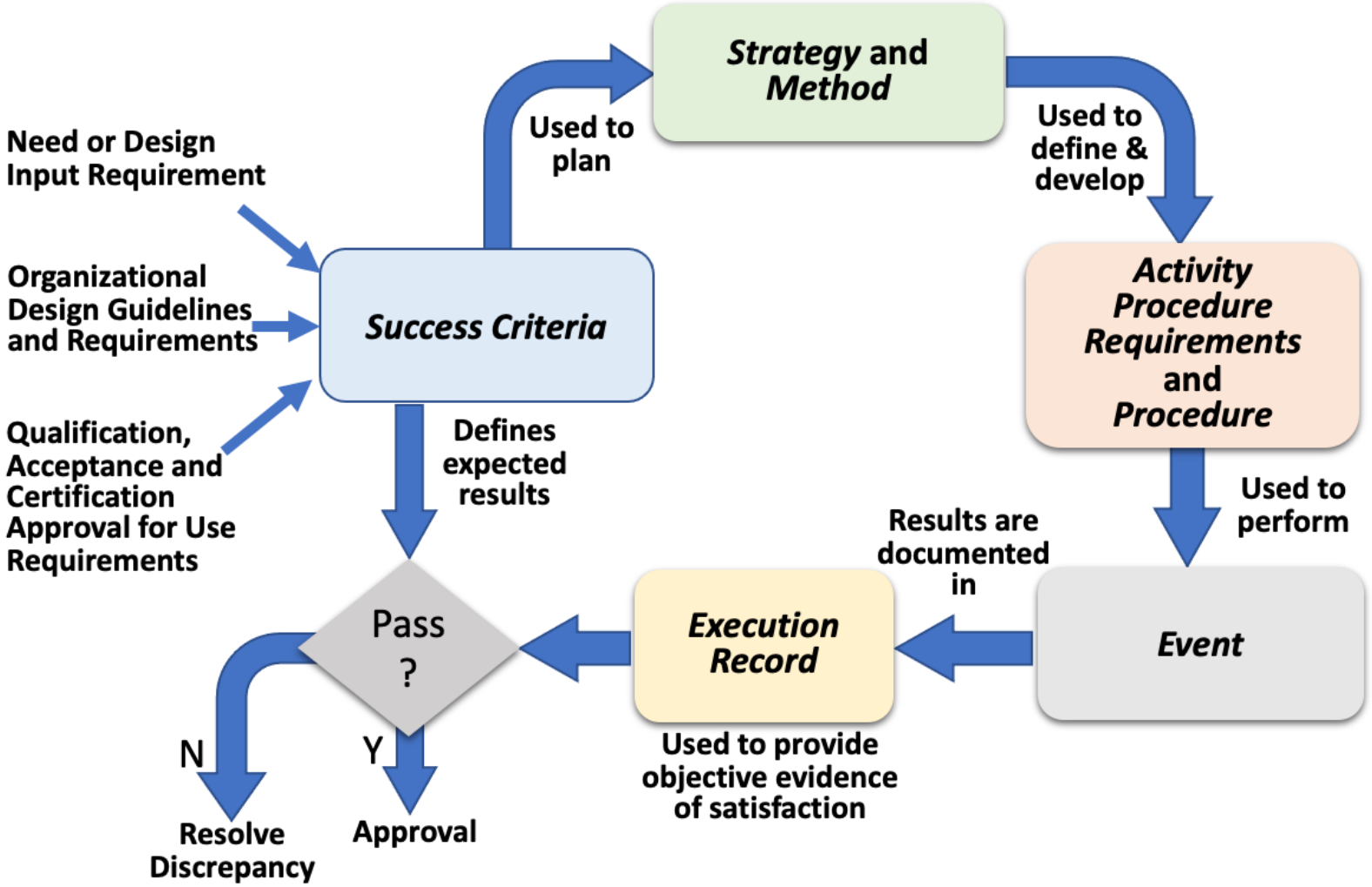
When there is a customer/supplier relationship, responsibility for system verification and validation activities and deliverables must be clearly defined in a SOW.

See NRM Section 13 for a more detailed discussion on supplier developed SOIs

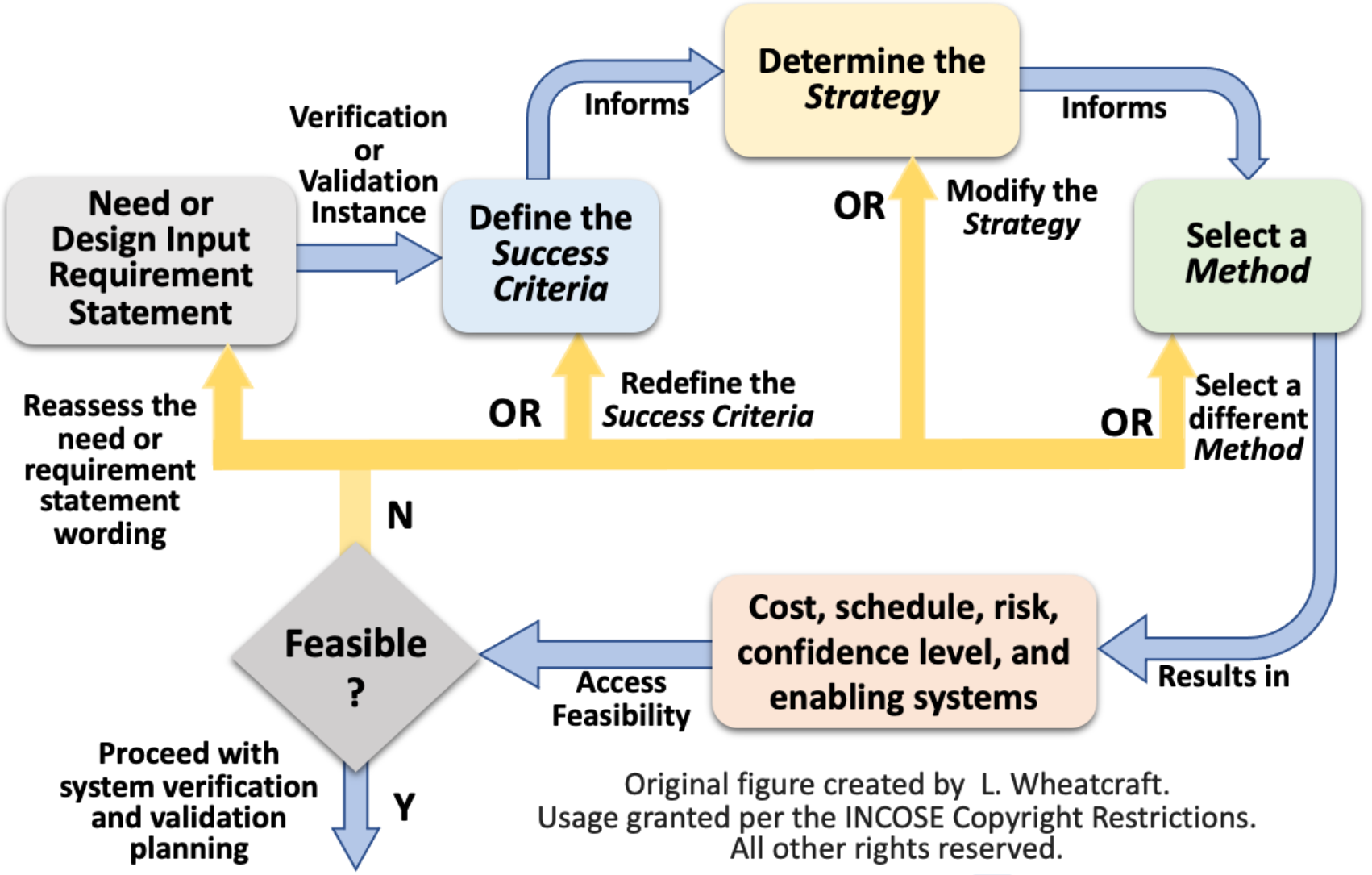
See NRM Section 10 for a more detailed discussion on verification and validation common principles.

System Verification and Validation Attributes Defined When the Needs and Requirements are Defined.

Attributes concerning Success Criteria, Strategy, Method, and Responsible Organization must be defined as the needs and requirements are defined.

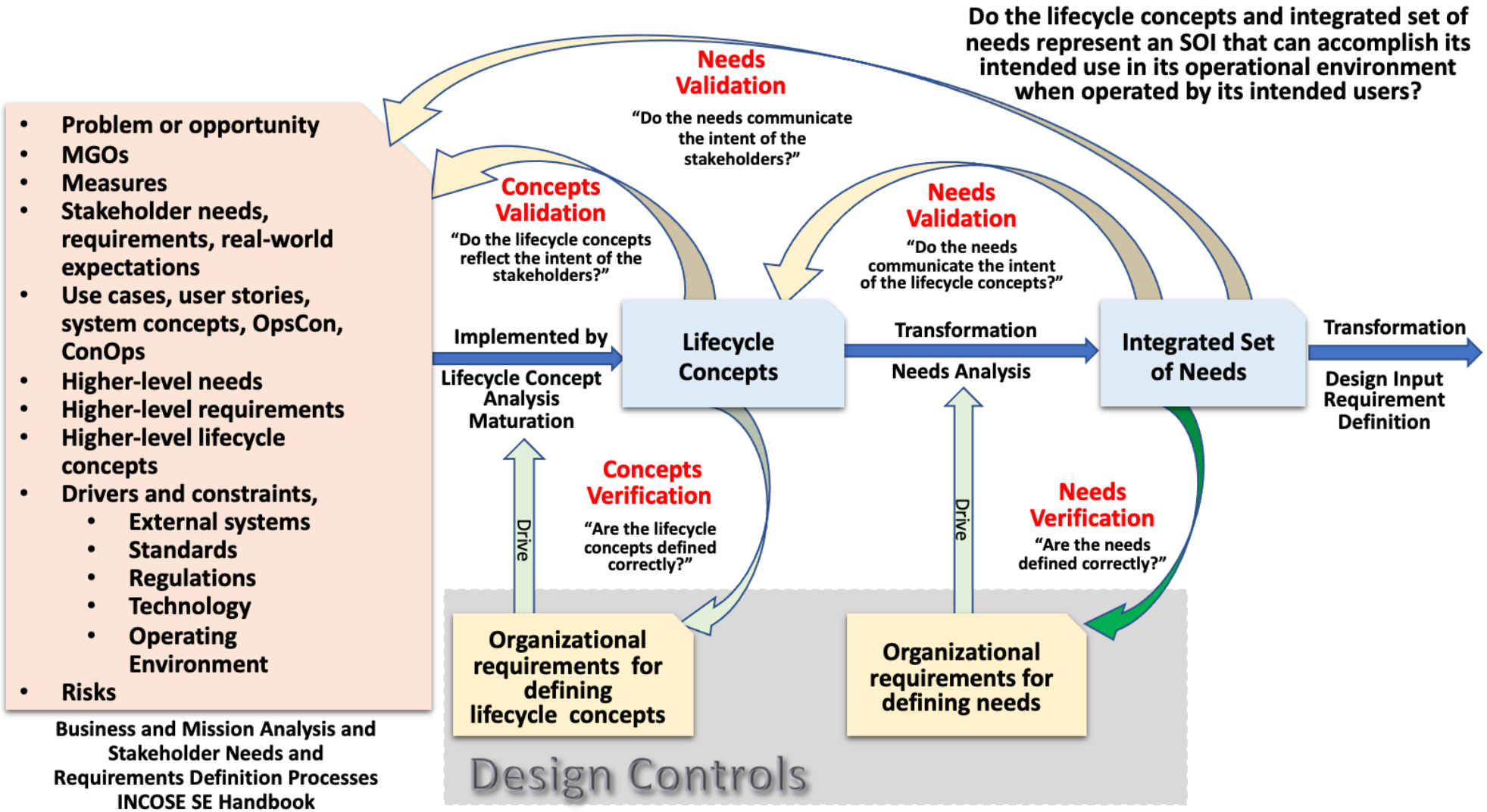


Success Criteria, Strategy, and Method are Cost, Schedule, and Risk Decisions



Verification and Validation Across the Lifecycle

Needs Verification and Needs Validation



Needs Verification

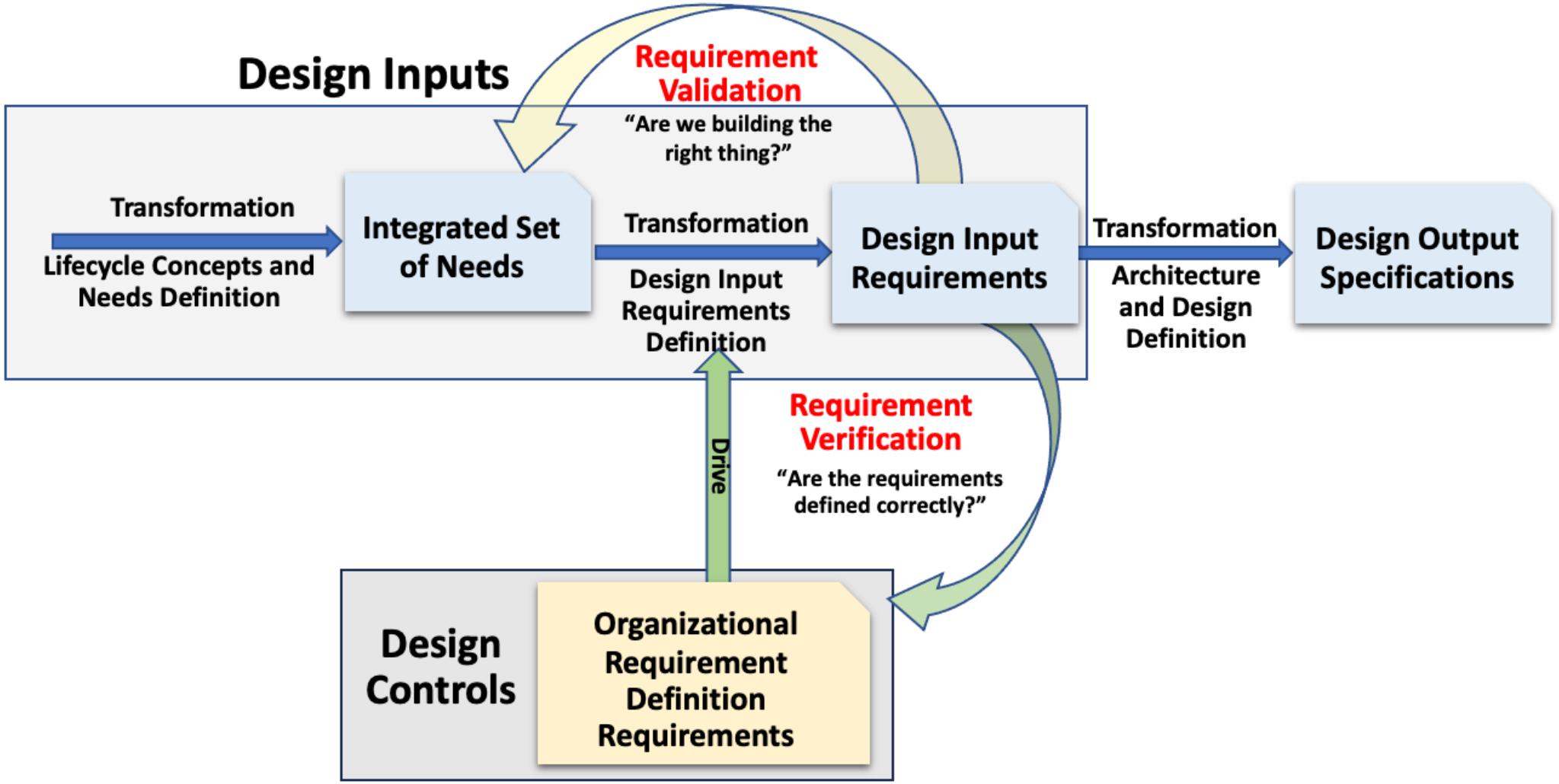
- Confirmation that the need statements and set of needs are well-formed.
- The focus is on the wording and form.
  - Are individual need statements worded or structured correctly in accordance with the organization's requirements, rules, and checklists?
    - Do the needs have the characteristics of well-formed needs and sets of needs?
  - Are the attributes for each need statement defined?
  - Is the set of needs complete, containing needs dealing with form, fit, function, quality, and compliance?
  - Does each need statement trace to a source?
  - Does each source have a corresponding need statement?

Needs Validation

- Confirmation that the needs clearly communicate the intent of the agreed-to lifecycle concepts, constraints, risks, and stakeholder real-world expectations from which they were transformed in a language understood by the requirement writers.
- Confirmation that the set of needs correctly and completely captures what the stakeholders need and expect the system to do in context of its intended use in the operational environment when operated by its intended users.
- The focus is on the message being communicated.
  - Have all relevant stakeholders been consulted?
  - Are the needs the right needs, i.e., do they accurately represent the drivers and constraints, risks, and lifecycle concepts from which they were transformed?
  - Do the needs correctly and completely capture what the stakeholders need the SOI to do in the operational environment in terms of form, fit, function, compliance, and quality?
  - Will the set of needs, if met, adequately address the problem, opportunity, or threat?
  - Is the set of needs complete, correct, consistent, and feasible?

See NRM Section 5 and GtNR for a more detailed discussion on needs verification and validation.

Requirements Verification and Validation



Requirements Verification

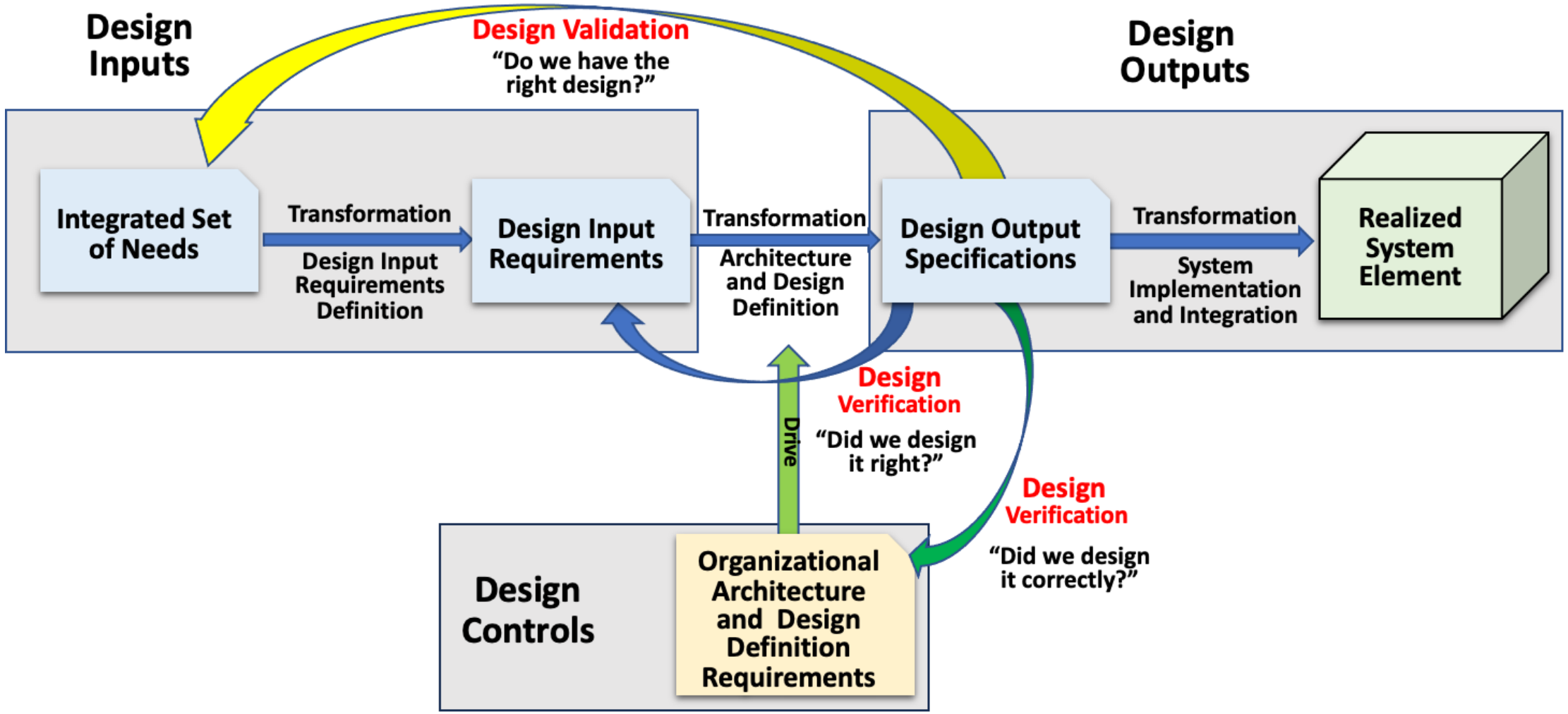
- Confirmation that the requirement statements and sets of requirements are well-formed.
- The focus is on the wording and form.
  - Are individual requirement statements worded and structured correctly in accordance with the organization's requirements, guidelines, rules, and checklists?
    - Do the requirements have the characteristics of well-formed requirements and sets of requirements?
    - Do the requirement statements adhere to the rules for writing well-formed requirements?
  - Are the attributes for each requirement statement defined?
  - Do the requirements trace to the need(s), parent requirement(s) or source requirement(s)?
  - If applicable, have the requirements been allocated to the next level of the architecture? Are there any gaps?

Requirements Validation

- Confirmation that the requirements clearly communicate the intent of the needs, parent requirements, and other sources from which they were transformed into a language understandable by the design and manufacturing/coding teams.
- The focus is on the message being communicated.
  - Are the requirements and sets of requirements the right requirements, i.e., do they accurately represent the intent of the needs, parent requirements, or source from which they were transformed?
  - Is the set of requirements correct, complete, consistent, and feasible?
  - Have the requirements been allocated correctly to the next level of the architecture?
  - For allocated requirements, do the resulting child requirements represent a necessary and sufficient set to meet the intent of the allocated parent?

See NRM Section 7 and GtNR for a more detailed discussion on requirements verification and validation.

Design Verification and Validation



Derived from Ryan, M. J.; Wheatcraft, L.S., "On the Use of the Terms Verification and Validation", February 2017

Design Verification

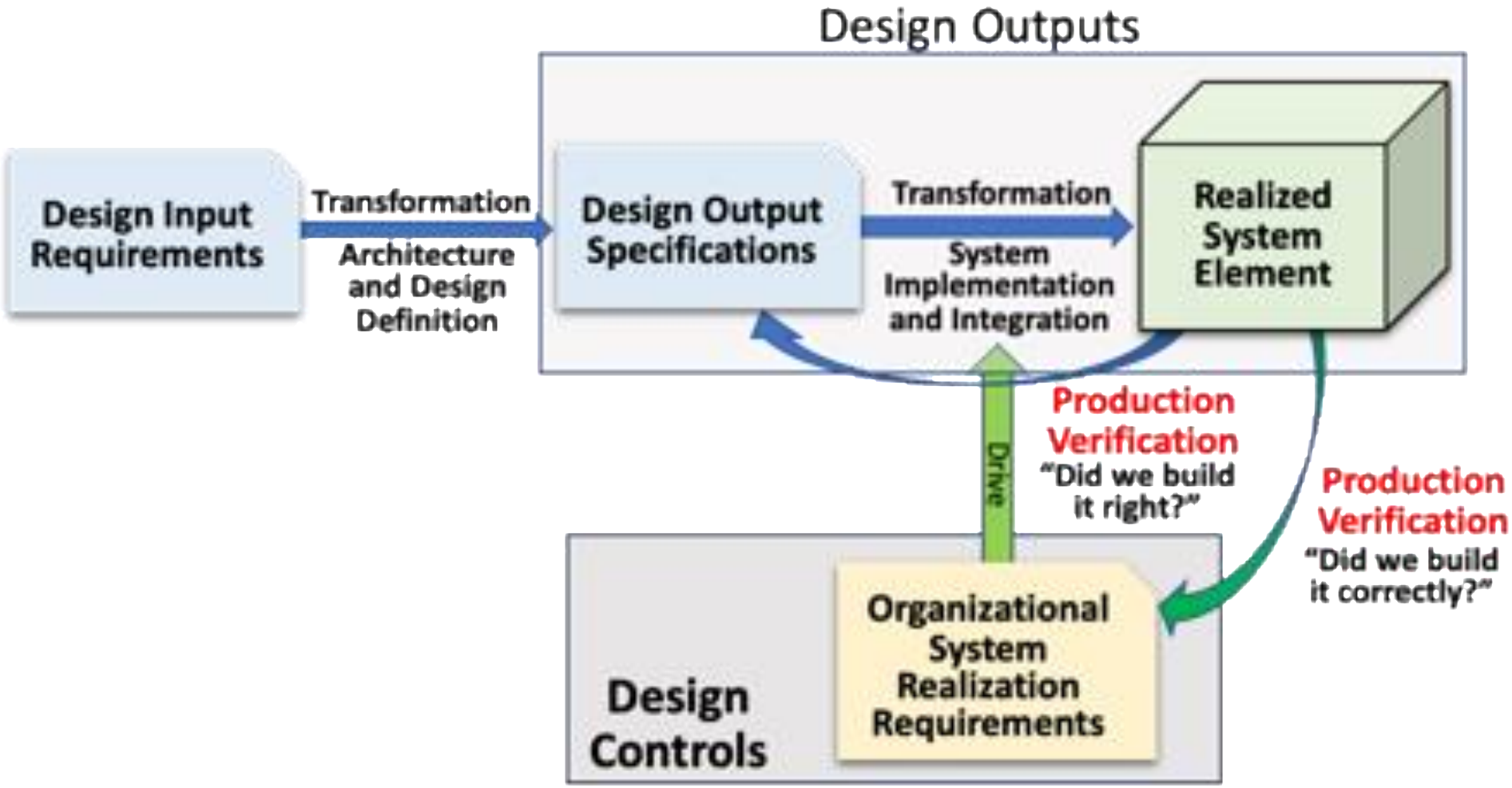
- Confirmation that the design and resulting design output specifications are well-formed.
- The focus is on the design.
  - Has an acceptable transformation of the set of design input requirements into design output specifications been applied?
  - Does the design satisfy the set of design input requirements?
  - Do the design output specifications clearly and accurately communicate the agreed-to design to the suppliers/builders/coders?
  - Can the system be built to the design output specifications?
  - Has traceability been established between the design artifacts and the design input requirements?
  - Did the design team follow the organization's requirements for the design activities?
  - Did we design the thing right?

Design Validation

- Confirmation that the design, as communicated in the set of design output specifications, will result in a system that:
  - Meets its intended purpose when operated by the intended users in its intended operational environment as defined by the set of needs.
  - Will not enable unintended users to negatively impact the intended use of the system nor use the system in unintended ways.
- The focus is on the message the design is communicating.
  - Do we have the right design (as defined by the design output specifications)?

See NRM Section 8 and GtVV for a more detailed discussion on design verification and validation.

Production Verification

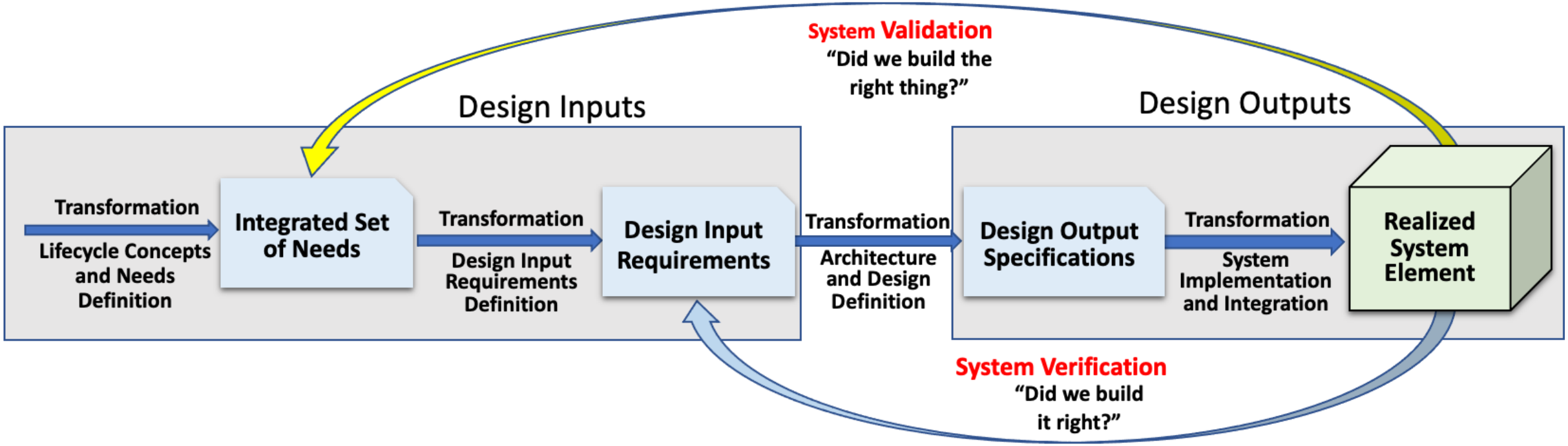


Production Verification

- Confirmation that:
  - The system was “built right” or “built to spec” as defined by the design output specifications.
  - The system was “built correctly” per the organizational guidelines, best practices, and requirements concerning the equipment and processes used to manufacture and code the system element.
  - The manufacturing system didn’t introduce defects or faults into the system.
  - A quality system can be made repeatedly.
    - For example, the FDA addresses the manufacturing process in Title 21, Part 820, defining [manufacturing] process validation as “establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications”.
- While system verification is performed once against the design input requirements, production verification is done continuously as a quality function for each system that is manufactured or coded.
- While production verification is normally performed by a quality organization and not the responsibility of systems engineers, those involved in manufacturing are key stakeholders that have needs and requirements concerning the system being built or coded.
- For supplier made systems, production verification and its results must be addressed in the Statement of Work (SOW).

See NRM Section 9 and GtVV for a more detailed discussion on production verification.

System Verification and System Validation



Derived from Ryan, M. J.; Wheatcraft, L.S., "On the Use of the Terms Verification and Validation", February 2017.

System Verification

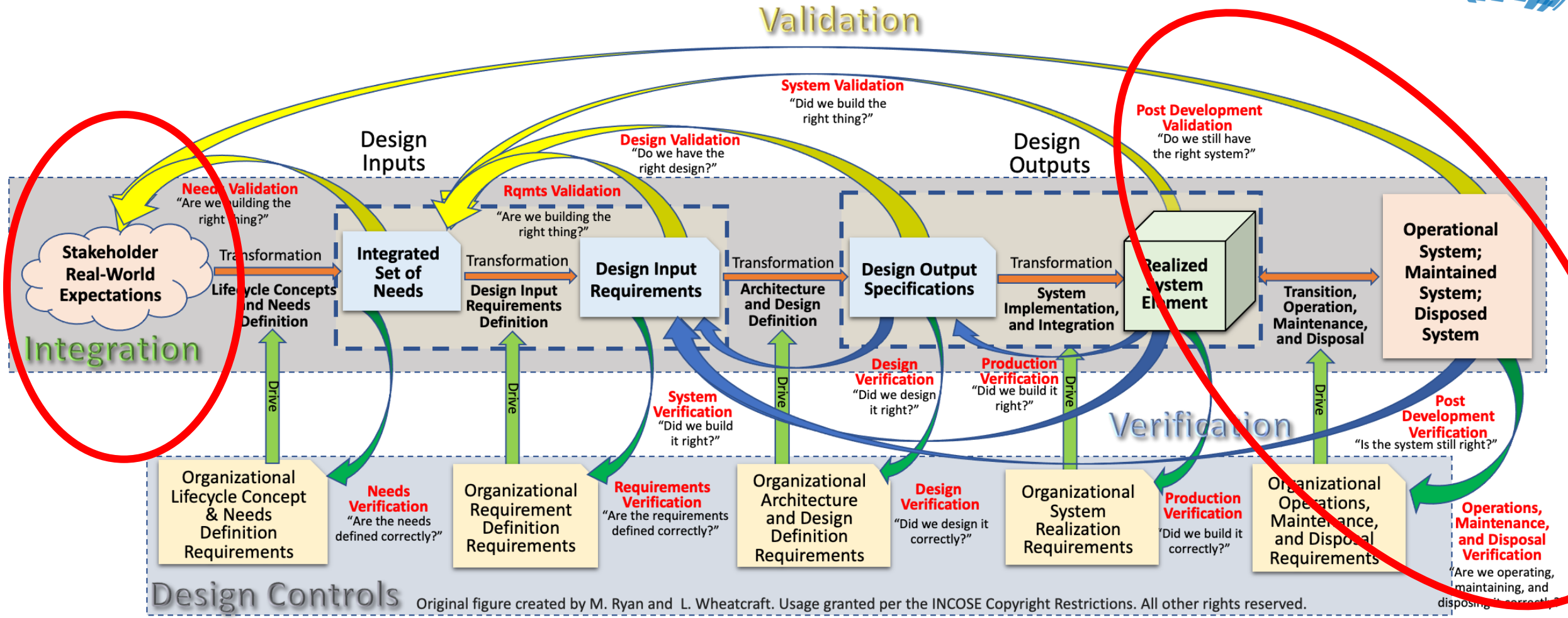
- Confirmation that the designed and built or coded SOI:
  - Has been produced by an acceptable transformation of design inputs into design outputs.
  - Meets its set of design input requirements.
  - No error/defect/fault has been introduced at the time of any transformation.
- The focus is on the built or coded SOI and how well it meets the agreed-to design input requirements.
  - Is there objective evidence the SOI satisfies the design input requirements and design output specifications with the required level of confidence?

System Validation

- Confirmation that the designed, built, and verified system will result or has resulted in an system that meets its intended purpose in its operational environment when operated by its intended users and does not enable unintended users to negatively impact the intended use of the system as defined by its integrated set of needs.
- The focus is on the completed system:
  - Does it address the problem, opportunity, or threat, MGOs, and stakeholder real-world expectations as defined within the agreed to integrated set of needs?
  - Does it successfully address the defined use cases, misuse cases, and loss scenarios, operational scenarios, and operational concepts?
  - It is able to successfully interact with the external systems that are part of the macro system it is a part?
  - Does it effectively address the risks it is intended to mitigate?

See NRM Sections 10 & 11 and the GtVV for a more detailed discussion on system verification and validation.

Post-Production Verification and Validation



Post-production Verification and Validation

- **Post-production validation** addresses the question: “Do we still have the right system?”, i.e., does the system still meet the stakeholders’ real-world expectations.
- **Post-production verification** addresses the question: “Is the system still right?”, i.e., does the system still meet its design input requirements.
- Both post-production verification and validation are a continuous set of activities performed across the system operational life.
- For some products, there may be post-production verification and validation performed on returned items (fault or root-cause analysis) or items in the field to gather data about operational performance over time (quality analysis).
  - Such efforts can identify defects in the released system that were missed during initial system verification and validation activities - or can detect aging (degradation over time) and end-of-life (EOL) defects before a catastrophic failure occurs.

Post-production Verification and Validation

- Additionally, depending on the system and qualities of its operational environment, emergent properties may be identified after an extended period of fielding which may not have been identified during system development and system validation.
- These post-production verification and validation activities are often part of an organization's post-release quality surveillance program required by regulatory agencies that feed the organization's warrantee and recall efforts.
  - For medical devices and pharmaceuticals post-production validation is required by law and defects and corrective actions must be reported to the FDA.
- This information can also be used when a new version of the system is being developed, enabling the project to take advantage of the lessons learned from the current system and incorporate them into the new version.

There is No Easy Button!!!

Questions and Discussion

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.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