



ACQUISITION INNOVATION  
RESEARCH CENTER

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# INNOVATION FOR DIGITAL TRANSFORMATION AND POLICY ANALYTICS

*An Innovative Probabilistic Approach to Risk-Based Validation*



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## EXECUTIVE SUMMARY

Current system, product, and service validation processes encompass a limited number of ad hoc system-level scenarios in which the system, process, or service is evaluated against the stakeholders' goals. However, budgetary and schedule constraints almost always limit validation scenarios, which reduces confidence in the validation process. In this study, we have developed a risk-based validation approach in which scenario selection is based on the importance and magnitude of the risk they can retire. We have presented an exemplar acquisition problem and attendant scenarios that can benefit from this approach. The exemplar problem is acquisition of a UAV-based forest fire detection system. This problem was selected because it is sufficiently rich in terms of scenario modifiers and sufficiently complex to demonstrate our innovative risk-based validation approach. In a potential Phase II, we will implement this methodology and demonstrate its efficacy and effectiveness on an acquisition problem of interest to AIRC and its customers. We intend to transition the software to Jet Propulsion Laboratory, a transition site, and any other AIRC-recommended transition sites.

The research team on this effort includes Professor Azad Madni (Principal Investigator), Professor Dan Erwin (Co-Principal Investigator), Dr. Michael Sievers (Risk and Technology Transition Expert), Dr. Ayesha Madni (Project Manager). All members of the research team are U.S. citizens. We have candidate transition sites already identified and will work with AIRC to finalize selections.

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## 1. INTRODUCTION

### 1.1 STUDY OBJECTIVES

Under the sponsorship of the Acquisition Innovation Research Center (AIRC), we conducted a study that led to the development of an innovative risk-based validation approach for acquisition processes. This report presents the accomplishments of this study. It first provides a background of traditional validation and its limitations. It offers an innovative approach to risk-based validation along with an exemplar acquisition problem that stands to benefit from a risk-based validation approach. It illustrates the use of the approach on the exemplar acquisition problem, i.e., the acquisition of a UAV-based Fire Detection System. The report concludes with a summary of the benefits of the innovative approach and presents an overview of a proposed follow-on effort concerned with developing, refining, and demonstrating the value proposition of the risk-based validation methodology for systems and processes of interest to the acquisition community. This work is specifically relevant to advancing AIRC's agile test and evaluation (T&E) research thrust.

### 1.2 BACKGROUND

System validation comprises methods that evaluate whether the system (or process or service) can perform its intended functions. The term validation is often used with verification. Verification is concerned with answering the question: "Was the system built right?" Validation, which follows verification, is concerned with answering the question: "Was the right system built." Unlike verification that consists of objective requirement tests that result in either pass or fail, validation demonstrates that a system meets stakeholders' goals by demonstrating goal satisfaction by exercising a limited, ad hoc set of system-level scenarios. Cost and schedule constraints invariably limit the quantity and quality of validation-cum-analyses demonstrations to understand indeterminate latent risk. Since we typically cannot demonstrate all facets of a use case given schedule and budgetary constraints, we instead demonstrate one or more scenarios applicable to a use case. For example, if a use case relates to detecting and reporting motion in a "watch-box," we cannot test all possible movements under all possible weather conditions and for all likely "movers." So, we demonstrate representative scenarios that cover a set of typical situations. The four terms that are relevant in this discussion are "test," "demonstration," "analysis" and "inspection." It is important to note that validation often comprises all four concepts. i.e., one or more scenarios may be demonstrated that require some form of analysis, or employ analysis for interpreting demonstration and test results performed at a lower level. Inspecting lower-level verification results is also a major part of validation. As with any aspect of validation, lower-level validations may be incomplete, late, or inconsistent, thereby impacting validation risk.

Against the preceding backdrop, our research is concerned with developing a systematic approach to selecting which validation scenarios are essential based on understanding the risk(s) retired by their execution. Conversely, latent risk can be estimated by evaluating the impact of not performing or reducing the scope of given validations. Conceptually, our proposed method computes risk probabilities in a manner analogous to failure analyses. However, it also focuses on evaluating the causal relationship between validations performed or not performed and system performance and functionality risk. Our proposed validation approach is an essential enabler of organizational efficiency. Simply stated, we are looking for a means to choose what is validated and how it is validated as determined by the latent risk incurred if corners are cut as they invariably are. The proposed approach can be used to select the most appropriate validation approach and informs specification of acceptance tests by acquisition organizations. It can also be used upfront to specify a set of operational constraints that the system must conform to within a risk-based approach.

### 1.3 CURRENT PRACTICE

Current practice encompasses methods for risk assessment and validation. These are discussed below.

#### 1.3.1 RISK ASSESSMENT

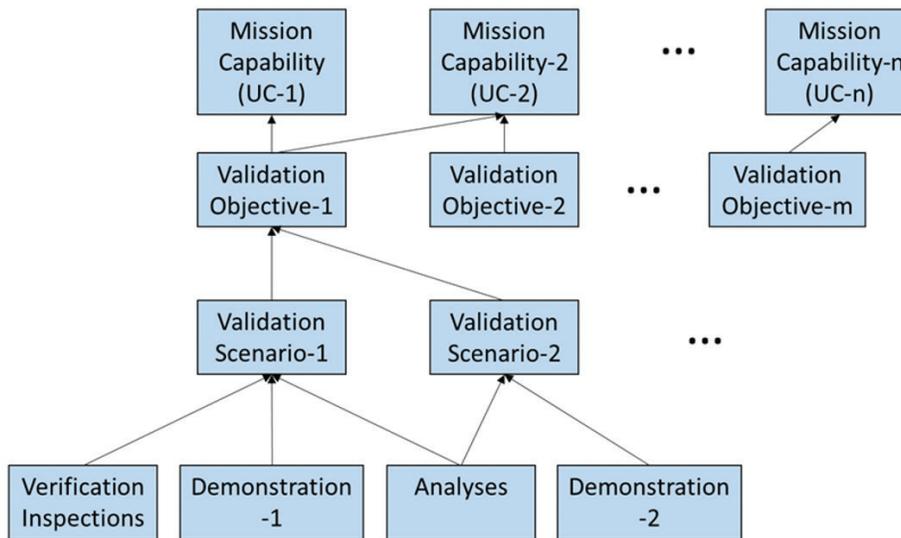
Traditional risk assessment comprises the following steps:

- Risk Identification and Analysis (“what could go wrong”)
- Risk Evaluation (“what is the likelihood of failure”)
- Risk Prioritization (“how severe are the consequences”)
- Risk Mitigation (“how to ameliorate the impact of consequences”)

*Risk identification* and analysis are concerned with answering two questions: what components/functions might fail in the system; what types of failures pose commercial, technical, or regulatory risks. *Risk evaluation* is concerned with calculating the basis of the severity of impact, the likelihood of occurrence, and detectability associated with the risk. *Risk prioritization* is concerned with ranking risk elements as “high,” “medium,” “low,” or “no risk” based on the results from risk evaluation. *Risk mitigation* is concerned with the decisions on the precautions to be employed to counter the risk. *Risk assessment* may produce a quantitative risk assessment (i.e., a risk score) depending on the risk evaluation methodology or a qualitative description of a risk range using qualitative descriptors such as high, medium, low, or no risk.

#### 1.3.2 VALIDATION

Today validation relies on the *intuition* of system engineers and the *experience* of stakeholders. Rarely, if ever, does this approach produce complete systematic assessments of what use case scenarios are critical and what aspects of a system those scenarios cover. One consequence of this approach is unknown validation gaps that only surface after the system is deployed, compromising system availability and/or safety when most needed. Moreover, the cost of fixing/mitigating holes found in an operational system is inevitably high. Ideally, system and test engineers develop validation plans from the use cases defined by mission capability statements and validation objectives (Figure 1).



**Figure 1. Ideal Validation Scenario**

Unfortunately, validation today does not follow the rigor in Fig.1. Generally, validation scenarios are based on what is affordable or what there is time for rather than risk retirement.

In Figure 1, the arrows represent associations in which the arrow points to the parent dependency. For example, validation objective-1 depends on use case 1 (UC-1). As schedule and budget tighten, validation plans are whittled down by reducing scope, watering down objectives, descoping or eliminating demonstrations, or accepting questionable test-like-you-fly (TLYF) exceptions. Although risk assessments are sometimes performed, these assessments tend to be simple, subjective, not based on causality, and invariably incorrect. Lacking solid, objective risk assessments, cost and schedule pressures end up driving validation.

Moreover, current practices assume that if a given scenario is successfully performed, then a given system feature is validated. While this may be true in some cases, it is not generally valid because a scenario is only a single instance of the conditions and functionality implied by a use case. Validation requires multiple scenarios executed under a range of conditions to obtain sufficient evidence for claiming success. A single execution of a use case scenario may demonstrate expected system behavior, but there are latent risks associated with system usage in circumstances that do not match the conditions in which the scenario was executed. Today there is limited understanding of this effect and its impact on latent system risks.

### 1.4 STUDY ACCOMPLISHMENTS

This study resulted in the development of a risk-based validation methodology that maximizes high-risk coverage with a finite set of scenarios associated with stakeholder use cases. We defined the concept of risk within the context of system acquisition and defined an initial validation metamodel (which we hope to refine in Phase II). We created a demonstration of the approach for acquisition of a UAV-based fire detection system. We defined the concept of validation success tree and described validation risk analysis. We developed the details of the V&V process and developed a Phase II concept and high-level plan for implementing, demonstrating, and successfully transitioning the Phase II prototype and attendant documentation to our transition sites. The latter includes JPL, and an AIRC-designated FFRDC or some other organization working in the acquisition space.

### 1.5 SUMMARY

This white paper presents the objectives, approach, and accomplishments of the three-month AIRC-sponsored study on risk-based validation. We present the key elements of the approach and provide a specific real-world example to convey the key innovations and scope of the overall approach.

## 2. RISK-BASED VALIDATION APPROACH

### 2.1 RISK ASSESSMENT

Risk assessments are conducted to determine the risk levels associated with system requirements in the case of adverse events related to the requirements. The risk levels help determine the scale of testing needed for a function. Risk determination requires evaluating the required mission capabilities identifying the broader risks and the specific risks associated with low-level dependencies. The key idea is to start with mission capabilities and then create a tree structure (Figure 1) that shows the elements needed to validate each capability.

### 2.2 RISK BASED VALIDATION

Risk-based validation, commonly heard expression in the pharmaceutical industry, does not have a clearly defined implementation process even in this industry. Similarly, other sectors also notionally recognize the value of risk-based validation but, as with the pharmaceutical industry, have no formal definition, methodology, or metrics. The general lack of risk-based formalisms is the impetus for our research.

Risk-based validation is a validation methodology in which qualification and validation processes are informed by an assessment of the risks to system quality (e.g., safety) or performance posed by an acquisition decision, equipment feature, process step, or capability. For example, a widely used commercial application with the requisite functionality in support of the needed mission capabilities is less likely to contain unknown defects than a custom application upon initial installation. In this case, risk-based validation could be used to provide a formal framework to demonstrate that the commercial application was deemed less risky than a custom application. A risk analysis could imply that the commercial application requires a relatively light validation program as contrasted with that needed for a custom application. While this example makes the point, it has aspects of both verification and validation. While validation can find defects, it does so at the integrated system level. If a system-level defect is found, then work is needed to dig into the implementation to find out what caused the anomalous system behavior.

The direct benefit of risk-based validation is that it provides the methods to make informed decisions about where and why to emphasize validation activities. Furthermore, it provides the rationale and attendant documentation that justifies decisions to acquisition and regulatory bodies.

### 2.3 CONCEPT OF RISK AND EXAMPLES

Acquisition organizations have to continually optimize operations, reduce operating costs, and increase efficiencies in today's environment. An appropriately developed risk-based validation approach can save both time and effort spent on validation and can assist organizations in achieving their optimization goals.

We can adapt FDA's definition of validation for our purposes. Validation is "establishing documented evidence that provides a high degree of assurance that a specific system, process or capability will consistently produce an outcome or result that meets predefined specifications and quality aspects." DoD and others define validation using similar language. High degree of assurance enables organizations to specify the appropriate level of evaluation for any system of interest.

It is important to note that traditional validation is not systematic and depends on demonstration (i.e., scenarios) because it is not possible to fully test a capability (use case). All functions are demonstrated, which may result in testing of positive and negative scenarios to ensure all oversight points are equally and demonstrated. This approach ensures that every requirement is thoroughly verified, but experience has shown that it causes unnecessary delays in the system validation process, invariably produces a large number of documents to review, and inevitably further delays the release of critical systems. Risk-based validation eliminates the production of these documents while reducing the overall validation effort.

Although risk is usually associated with event likelihood and the impact if the event happens, what we are doing is a bit different. We do not depend on determining a likelihood but rather focus on the impact of reducing or eliminating aspects of a validation program.

Therefore, the essential starting place for our work (Figure 1) is understanding the use cases or mission threads defined for a system and any constraints placed on those. Use cases come from mission capability statements (MCS), i.e., high-level

descriptions of what a system must do. A simple example of a MCS might be, “the system detects forest fires and sends real-time reports to the local fire command center.” The MCS might have mission threads for day and nighttime detection, UAV and fixed position monitoring stations, real-time processing, real-time reporting, and so forth.

Each MCS is also associated with one or more validation objectives. An MCS is satisfied when all of its subordinate objectives are addressed. Each objective is linked to one or more mission threads, which depend on several functional demonstrations, inspections of lower-level validations and requirement verifications, and analyses. Moreover, there are differences in the strength or importance of mission threads and lower-level compliances to objective satisfaction.

The above discussion defines an ontological description of validation and is central to our work. Defining terms and relationships enable reasoning about the contributions needed for defining MCS success criteria. Additionally, rigorously structuring validation components clarifies potential redundancies and overlaps that lead to unnecessary test replication.

The metamodel in Figure 2 shows a general relationship between Mission Capability and Stakeholders. Validation Objectives refine Mission Capabilities, i.e., provide more detail. Each Validation Objective has an associated Validation Method that explains the validation approach and needed resources. Lastly, a Validation Method aggregates one or more lower-level Requirement Verifications and 0 or more Function Validations. An aggregation relationship allows sharing Requirement Verifications and Functional Validations with other Validation Methods.

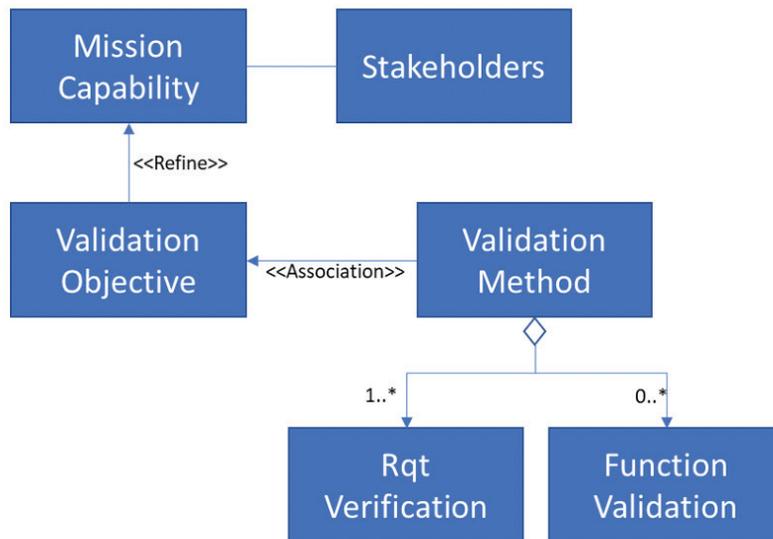


Figure 2. Validation Metamodel

## 2.4 VALIDATION MODEL

This section describes an instantiation of the above metamodel. The construct follows a Bayesian analysis in which we define the “strength” of relationships between lower-level and higher-level validation components. Rather than a physics-based determination of likelihood, we include an evaluation of how likely a given validation component will be removed or reduced in scope based on stakeholder preferences and cost and schedule constraints.

## 3. RESULTS OF THE STUDY

### 3.1 RISK-BASED VALIDATION APPROACH

Our approach comprises concepts that have been successfully used in other contexts. At its heart, the method employed in the envisioned approach resembles a classical success tree. Given the behaviors and performance expected of a system,

we enumerate the functions and performance values required for success. However, unlike a conventional success tree, we investigate the means for explaining and quantifying relationships between functions that enable success. Moreover, we determined a means for understanding the sensitivity of each top-level success factor on lower-level dependencies. Knowing functional dependencies and system sensitivities allows defining demonstration test cases that maximize functional coverage and cases in which multiple demonstrations are necessary. **Latent risk can then be evaluated by rolling up how much of the system functions are uncovered weighted by their sensitivities.** We believe this approach will be successful because while it is based on a novel methodology, the underlying construct comes from applying standard probabilistic methods with well-known advantages and applications.

### 3.2 EXAMPLE OF RISK OF FAILURE

Figure 3 illustrates an exemplar risk of failure. Figure 3 is a highly simplified modification of Figure 1 that adds failure risk probabilities to associations. As shown, UC-1 risks complete loss if validation objective-1 is not accomplished. Similarly, validation objective-1 has a 0.3 probability of failure if validation scenario-2 is not accomplished. And validation scenario 2 has a 0.5 probability of failure if demonstration-2 is not accomplished. Without accounting for many important details, nuances, cross-correlations, etc., if demonstration-2 was cut, then the chance that UC-1 fails is  $0.5 \times 0.3 = 0.15$ . Looking at UC-2, the probability that it fails is  $0.5 \times 0.3 \times 0.85 = 0.1275$ .

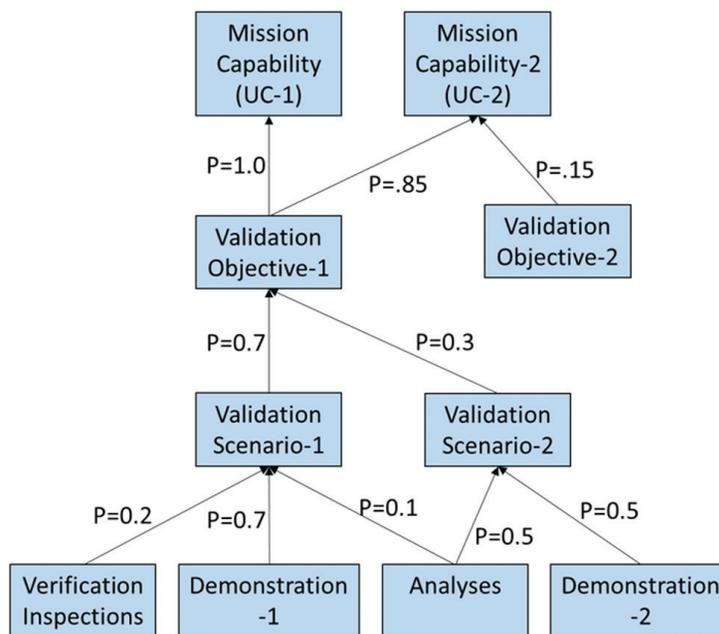


Figure 3. Risk of Failure Example

### 3.3 EXEMPLAR PROBLEM

Our exemplar problem is based on the use of an Unmanned Aerial Vehicle (UAV) to detect forest fires. The particulars of the example are presented below:

- Domain: Forest Fire Detection using UAV
- System comprises a UAV and a central control facility
- Mission Capability
  - Detect forest fires within 5 minutes of appearance
  - Day and night operation

- Geolocation accuracy < 2 meters
- Fire size resolution < 1 meter
- 24/7 coverage
- Data sent to central control facility
- < 2 second data transmission latency (sensors to central control)
- Manual and autonomous operation
- Stakeholders
  - Fire crews (fire crew safety, access to fire, quickest responses possible, location and type of structures)
  - Campers and hikers (safety, exit routes)
  - Home and structure owners (safety, evacuation warning, exit routes)
  - Fire commanders (fire assessment, team deployment strategy, external help needed, communication with news and rangers)
- Validation Objective
  - Detect hot spot > x degrees above ambient temperature
    - High priority
  - Detect smoldering (smoke)
    - Medium priority
- Validation Method
  - Preconditions
    - Available test area (produces fire and smoke)
    - UAV assembled and all subsystems working
    - Central control assembled and all subsystems working
    - UAV hovering over test area
  - Scenario-1: Small fire day and night (2m x 2m)
  - Scenario-2: Large fire day and night (20m x 20m)
  - Scenario-3: Smoke day
  - Success criteria:
    - System does not report fire or smoke when none are present
    - System correctly identifies fire and reports size and location
    - System correctly identifies smoke and reports its location
- Risk Assessment
- The central idea is to build a tree similar to the one presented earlier
- Using that tree, we can do a “what-if” analysis, e.g.
  - What-if we don’t look for smoke then that directly impacts the second validation objective which impact the first capability
  - What-if we discover that the best geolocation that we can achieve is > 30 meters, then we might send incorrect information to teams on the ground which could jeopardize their safety
- Using the metamodel we can build an assessment tool that enables evaluating impact of deleted or reduced testing, look for overlaps and gaps, and help prioritize validation demonstrations (Figure 4).

Primary capability				Detect forest fire within 5 minutes of appearance		Geolocation accuracy < 10 meters		Day and Night Operation								
Validation Objective		Detect hot spot > x degrees above ambient	0.7	0.3	Detect smoldering (smoke)	1	Nadir pointing, CE90	0.4	Low, natural light	0.2	Low artificial light	0.4	Daylight			
Scenarios	Temp = ambient	0.1	Temp < ambient	0.1	Temp > ambient +x	0.8	Smoke > limit	1	Point fires located at N, S, E, W compass points	1	Twilight	1	Midnight, sodium lighting	1	Noon	1

Figure 4. Partial Spreadsheet Risk Implementation for Fire Detection System

Figure 4 illustrates a partial spreadsheet risk implementation for the fire detection system. Appendix B provides a blowup of this figure. Mission capabilities are highlighted in light green on the left, validation objectives are in the middle and validation scenarios are in yellow. Values highlighted in green adjacent to each scenario and objective represent risk values. Spreadsheet formulas roll-up the latent risk of not achieving each mission capability. For example, if the scenario “Temp > ambient +x” is not performed then the risk of not detecting a forest fire within 5 minutes of appearance is  $0.8 * 0.7 = 0.56$ .

### 3.4 VALIDATION DEMONSTRATION

We will demonstrate the use of risk-based validation approach for a UAV-based Fire Detection System. The concept of operations (CONOPS) of the system is presented below.

The UAV has 2 cameras: infrared and visible. The UAV accesses GPS for location information. The UAV can be commanded to hover over a particular area, follow a predetermined pattern, or (with ground support) autonomously or via a “joystick” follow the spread of a fire. The UAV takes images with both cameras and sends the images to a processing facility that creates image products. These products are made available to forest service personnel. The products consist of raw images, heat maps, smoke patterns, fire motion indications, and metadata correlated with ground position and time.

Exemplar implications of this demonstration are presented below.

- Behaviors
  - Pattern searching
  - Joystick searching
  - Hovering
- Products
  - IR and visible image display (raster)
  - Heat maps (vector)
  - Smoke cover (vector)
  - Fire motion (vector)
  - Change detection (vector)
  - IR and visible video (video)
- Constraints/Requirements
  - Night & day operation
  - < 2-meter ground location accuracy
  - < 10 millisecond product time tag accuracy
  - > 2 IR and raster simultaneous images/second
  - < 30 second raster product latency (from image capture)

- < 1 minute vector product latency (from last image captured)
- Validation Demonstrations
- Start with a “validation” success tree, as shown in Figure 5.

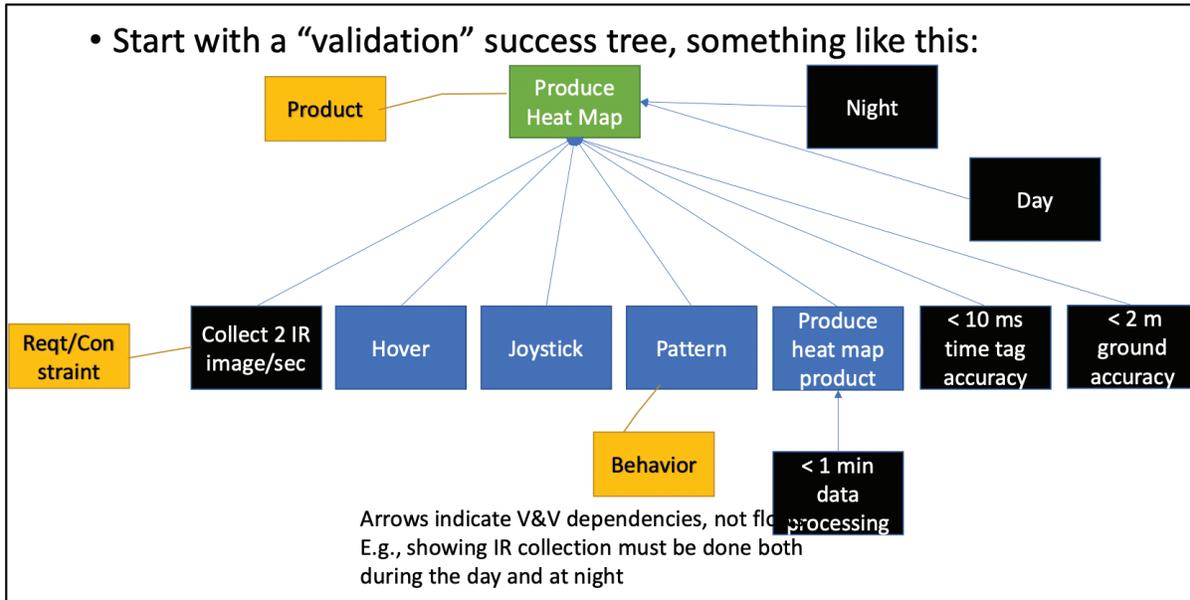


Figure 5. Validation Tree

### 3.5 VALIDATION RISK ANALYSIS

From the behaviors and performance expected of a system, we enumerate the functions and performance values required for success (as noted earlier). Unlike a conventional success tree though, we investigated the means for explaining and quantifying relationships between functions that enable success. Moreover, we help determine the means for understanding the sensitivity of each top-level success on lower-level dependencies. Knowing functional dependencies and system sensitivities enables defining test cases that maximize functional coverage as well as those cases in which multiple tests are necessary. Latent risk can then be evaluated by rolling up how much of the system functions are uncovered weighted by their sensitivities.

### 3.6 VALIDATION PROCESS

- For each validation entity, we determine a validation objective and acceptance criteria.
- From the objectives & acceptance criteria, we next determine the “importance” of each dependency to the validation event above it. For example, showing that we can collect 2 IR images/second is not important to produce a heat map. However, creating day and night heat maps is very important
- Using the priorities above, we can evaluate whether a validation event can be “relaxed,” meaning that lower-level results or analyses might be acceptable vs. validation events that must be performed under realistic conditions
- Aggregating the results of the previous enables determining what must be a part of an overall end-to-end test, the rigor needed, the resources needed for performing the validation event, and how validation events can be minimized and still cover the system validation space
- An instantiated metamodel aids decision-making and could help identify options should cost, schedule or other issues arise that prevent fully implementing all identified validations.

- For example, if we never demonstrate smoke cover product generation using realistic day and night images of fires taken under various ground, wind, lighting, etc., conditions then there is a risk that the system will not correctly identify and track smoke that could endanger ground and air firefighters and civilians because it is not certain that fire artifacts are correctly produced.

### 3.7 KEY RESULTS

In this study, we developed and illustrated the feasibility of a formal approach to risk-based validation. Specifically, we developed a formal ontology of the domain, along with an illustrative model for computing the risk of failure. We developed a validation model and specified the details of the risk-based validation approach within the context of acquisition of an Unmanned Aerial Vehicle-based Fire Detection System. We specified the entire process for Risk-Based Validation. These results have prepared us to undertake a successful Phase II effort. In Phase II, we will work on a real-world acquisition problem within the agile T&E area that is of significant interest to the DoD acquisition community in general and AIRC in particular.

## 4. PHASE II PROPOSAL OVERVIEW

There are at least two aspects to future work in Phase II: building a practical validation model (which will require a few tweaks to the ontology) and tools for creating an ontologically rigorous model consistent with reasoning about inconsistencies and redundancies. We will attack the first goal by looking for validation patterns in realistic scenarios. There are many options and tools available for achieving the second goal that we will evaluate.

In a potential Phase II, we will leverage the scenario dashboard created on our SERC project. (The dashboard is a part of the testbed that we successfully transitioned to University of Virginia, Virginia Tech, University of Arizona, and The Aerospace Corporation). The dashboard is a software tool which enables simulation of systems involving vehicles, including UAVs, under user-defined scenarios. In addition to pure simulation, the dashboard allows control of physical vehicles through radio and wifi communications, which we have used to set up physical scenarios on a laboratory scale. Extension to field-scale scenarios is a long term goal.

Key to the dashboard's usefulness is the ability to run a single scenario with a range of conditions and outcomes determined by setting initial conditions and adverse event probabilities using arbitrary probability distributions. In this way, the likelihood and severity of risks can be evaluated, particularly the conjunction/correlation of multiple adverse events which often are only considered individually.

Clearly, simulations of systems such as the exemplar forest fire detection cannot take the place of actual experimental validation, especially when complex phenomena are involved. For example, a UAV flight above a developed fire is subject to convective air turbulence which will at least lower the accuracy of ground imagery and which may induce worse effects. However, it is not practical to include such phenomena with full fidelity in the dashboard simulation even if they were fully understood. As another example, assessments of communications latency derived from a simulation would carry significantly less weight in comparison with experimental assessments. On the other hand, simulations can be invaluable in determining the tree of causation that is essential to the risk-based validation process. In the Phase II work, initial demonstrations of this process will use the dashboard. We anticipate that later, in actual deployment, a similar program of simulations can be useful in designing validation scenarios and analyzing the latent risks that would result from performing one set of experimental validations in comparison with another.

Risk-based validation will enable acquisition organizations to focus more closely on those system components and functions that pose the greatest threat to system quality and personal safety in the event of a failure. It reduces the cost of validation within the acquisition organization, and as a result throughout DoD. A DoD-wide shift toward a risk-based validation approach from a traditional one will allow introduction of innovations without adversely affecting system quality, operations, personal safety, and well-being.

All members of a potential Phase II research effort will be the same and all are U.S. citizens. We have candidate transition sites identified and will work with AIRC to finalize selections and accomplish transition(s).

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## APPENDIX A: Glossary

**Acquisition:** the conceptualization, initiation, design, development, test, contracting, production, deployment, logistics support, modification, and disposal of systems, supplies, or services to satisfy the acquisition organization needs. These needs are associated with use in or in support of operational missions.

**Experimentation:** the process of conducting a scientific procedure in a physical laboratory or simulation with a view to gaining insights into the behavior of a system, product, or process under nominal and contingency conditions.

**Ontology:** a set of concepts and categories in a particular domain (e.g., systems acquisition) along with their properties and inter-relationships. Used to scope modeling, question-answering, and facilitating interoperability and integration of heterogeneous elements.

**Metrics:** measures of quantitative assessment of a system, product, or service for nominal and contingency operations.

**Prototyping:** the process of building an early model of a system, product, or service to reduce risk in key aspects of the system, product, or service while allowing stakeholders to evaluate to evaluate the design and refine requirements. A prototype can be a “throwaway” or “reusable and extensible.”

**Use Case:** a set of possible sequences of interactions between a system and users in a particular environment and related to a particular goal. It is a means to organize system requirements from the perspective of users.

**Verification:** the process of determining whether the system, product, or process was built right. It precedes validation.

**Validation:** the process of determining whether the right system, product or process was built. It follows verification.

**Risk:** refers to the likelihood of a system breaking down under certain conditions causing undesirable outcomes or unintended consequences.

**Risk-Based Validation:** an approach to validation in which qualification and validation processes are informed and guided by an assessment of risks posed by an equipment/system/product feature, process step or capability, or technology maturity level.



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