Build4 Scale

U.S. Department of Energy

Sustaining Quality and Warranty

Module 7B Preparing for the Production Ramp

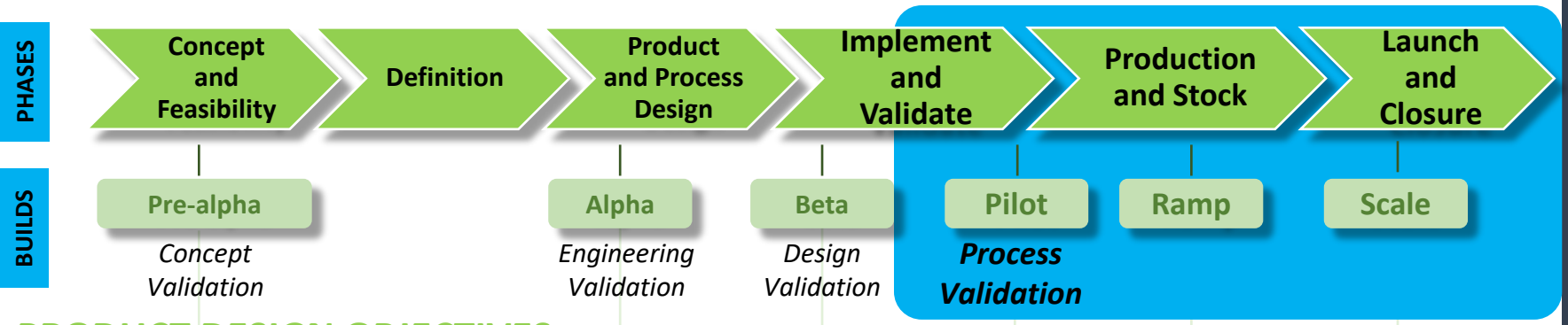
Motivation

Why is this module important?

- Scaling activities can affect product quality and reliability, but quick identification of problems keeps corrective action costs low
- Scaling the process from beta prototype builds into actual delivered pilot and production builds with the following goals:
  - —Catch product reliability problems quickly and early on in the production process
  - —Ensure that warranty and service strategies are appropriate and cost effective
  - —Prioritize risk-mitigation efforts based on impacts to total cost on the bill of materials, customer satisfaction, and time to market

Pilot And Scaling

Where does this fit into the development cycle?



PRODUCT DESIGN OBJECTIVES

Market Research
Design Research
Feasibility
Development
Qualification
Field Readiness
Launch

MANUFACTURING READINESS LEVELS

Levels: 1 2 3 4 5 6 7 8 9 10

Manufacturing Research
Manufacturing Development
Mfg. Capability
Manufacturing Capacity
Production

Preparing for the Production Ramp

Module Outline

- Learning objectives
- Reliability overview
  - —Key drivers and lifecycle review
  - —Scale-up objectives
- Production scale-up and risk mitigation
- Transition to “screening” test methods
- Initiation of data monitoring and feedback loop procedures

Learning Objectives

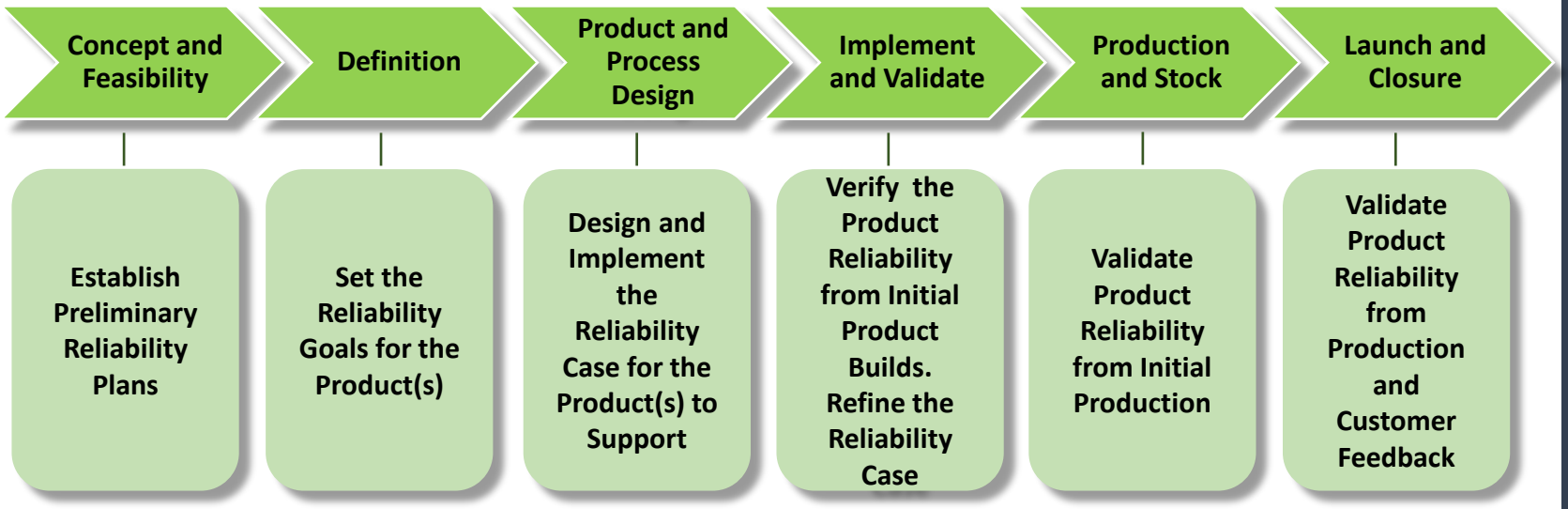
- LO1. Understand activities and options involved with scale-up for sustaining quality, warranty, service, and repair
- LO2. Understand how to use **failure mode and effects analysis** (FMEA) outputs to prioritize activities and decisions

Reliability Overview

Key drivers and lifecycle review

PHASES

RELIABILITY



- Reliability and quality activities should occur at all stages of the product lifecycle
- Reliability predictions and FMEA outputs drive prioritization of activities:
  - —E.g., impacts on time to market, total cost, and customer satisfaction

Reliability Overview

Scale-up build objectives

Reliability testing objectives by build version:

- **Pre-alpha testing**: establish reliability goals
- **Alpha testing**: test and refinement of product design
- **Beta testing**: test and refinement of manufacturing process
- **Pilot testing**: validate design and manufacturing prior to production
- **Production ramp**: validate warranty and service impacts

Production Scale-Up

Cross-functional team engagement

Ensure that overall program implementation meets goals for time to market, cost, and customer satisfaction with unification across the following teams:

- Marketing/sales
- Quality/reliability
- Product design
- New product introduction (NPI)
- Manufacturing
- Service and repair
- Technical publications
- Supply chain

Production Scale-Up

Beta to pilot to ramp transitions

- Use reliability goals and confidence metrics as gates

Decision tradeoffs when goals are not met:

- Cost to achieve higher reliability or confidence
- Cost of delayed launch
- Cost of warranty and service implications

Tip: NPI and other teams may need to stay involved in the pilot and production ramp to maintain accountability to these goals

Production Scale-Up

Production ramp activities

- Transition from beta "use simulation" to final product "screening" test methods:
  - —All pilot builds and beyond are intended as deliverable products
- Initiate appropriate test, data collection, and feedback loop procedures
- Identify pilot customers and develop a feedback plan
- Set use agreements, warranty, and service plans in motion
- Release support documentation

Production Scale-Up

Activity prioritization and risk mitigation

Key Steps to Risk Management:

- Identify
- Analyze
- Control
- Transfer
- Reduce
- Assess

Production Scale-Up

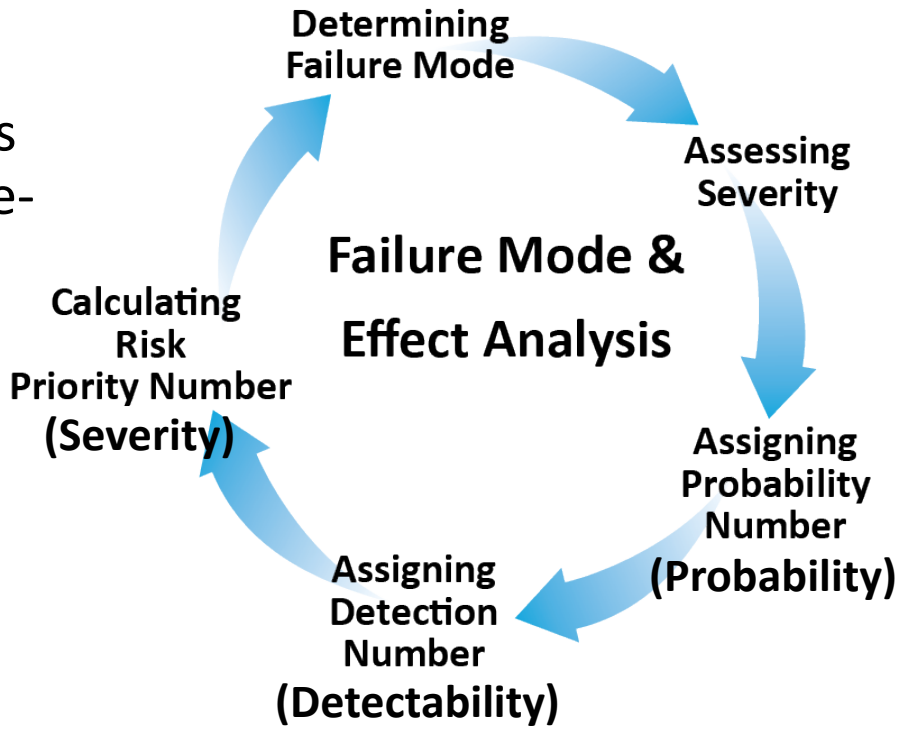
Activity prioritization and risk mitigation (cont.)

Steps for Effect Analysis:

- FMEA outputs become inputs for quality and warranty scale-up decisions

3-Dimensional View of Risks:

- **Detectability**, D
- **Probability**, P
- **Severity**, S
- Set a score of 1–3 for each dimension



Tip: assigning appropriate FMEA risk scores of 1–3 for D, P, and S and multiplying them together identifies the highest-risk, highest-value items for prioritization

Failure Mode And Effects Analysis

Example

Detectability (D) x Probability (P) x Severity (S) = Risk

Risk	D	P	S	Risk	Mitigation Activity
Use life for component X is less than the required product use life	2	3	2	12	Plan for service strategy to replace part if more cost effective than increasing component performance
Product downtime has significant impact on customer operations	3	2	1	6	Plan for fast-responding repair service or achieve sufficient reliability confidence through additional test and data collection
High infant mortality rate will damage reputation and sales	3	1	3	9	Test reliability predictions during scale-up with feedback loop to correct important root causes

Mitigation activities should not affect subsequent risk assessment scores unless significant risks get lost in reprioritization

Transition to Production

"Screening" test methods

- In previous beta testing stages, use simulation (i.e., **accelerated life testing** [ALT]) is conducted with appropriate severity to fail the product and identify potential problems (a design quality exercise)
- The knowledge gained from ALT can be used to reduce the severity of failure conditions for developing appropriate production "screening" tests (a manufacturing quality exercise)

Reminder: ALT is a testing strategy whereby the engineer extrapolates a product's failure behavior at normal conditions from life data obtained at accelerated stress levels. Since products fail more quickly at higher stress levels, this strategy allows the engineer to obtain reliability information about a product in a shorter time frame (i.e., mean life expectancy and probability of failure at a specific time)

Stress Screening

Highly accelerated stress screening

- **Highly accelerated stress screening** (HASS) uses accelerated stresses beyond a product's specifications to detect product defects during manufacturing and production
- **Non-destructive inspections include out of box audit** (OBA), functional testing, x-ray, and visual methods
- **Destructive test examples include ongoing reliability tests** (ORT), tear down, and break open

Any screening test implementation should add value to the product based on prior risk-mitigation or cost-mitigation decisions. Other design factors or servicing plans might be alternatives to screen testing.

Data Collection and Feedback Loops

Initiation and procedures

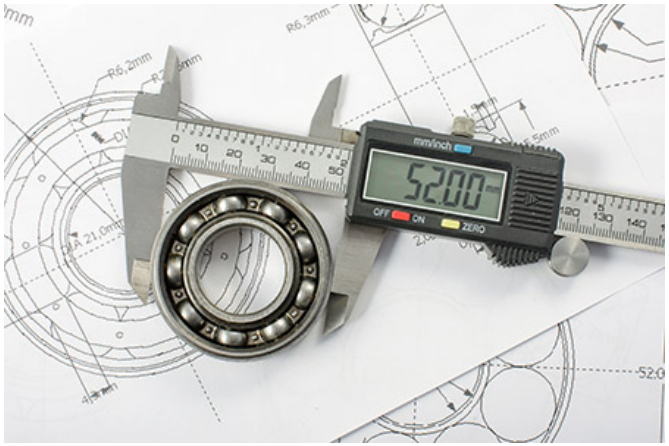
The primary objective is ensure early failure rates match reliability predictions and goals; available tools include the following:

- HASS testing, OBAs, and production line inspections:
  - —Last process in production flow before shipping a product to ensure that all manufacturing and test processes have been completed
  - —Data about the manufactured product acquired prior to delivery
  - —Could be conducted as a high-percentage check early in production and a low-percentage check later in production ramp

Data Collection and Feedback Loops

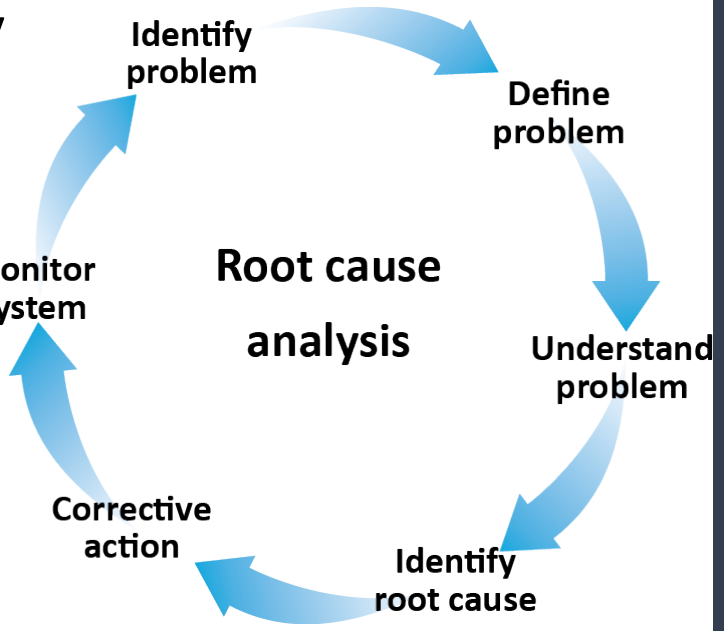
Initiation and procedures (cont.)

- **ORTs**
  - —Periodic checkpoints and direction resets
  - —Predefined number of products in the manufacturing line are randomly picked each day of production and subjected to environmental stresses to induce damage
- **Cumulative distribution function analysis**
  - —Actual field data for predicting unexpected failure trends
- **Root cause analysis** (detailed on next page)
  - —Analysis for understanding and determining corrective action



Root Cause Analysis

- Root cause analysis is used to identify the root causes of faults or problems:
  —e.g., asking ‘why’ five times
- A factor is considered a **root cause** if its removal from the problem-fault sequence prevents the fault from recurring
- A **causal factor** is one that affects an event's outcome, but it is not a root cause. Removing a causal factor can benefit an outcome, but it does not prevent its recurrence with certainty



Allows for proper determination of failure source, impact to reliability, and corrective action options

Pilot Customers

Best practices

- Consider non-disclosure agreements if product-launch schedule will be prolonged to avoid premature release of sensitive information to the public
- Encourage the customer to provide feedback
- Define a range of customer use cases (e.g., industry or global location) to generate the most useful feedback
- Seek customers who are willing to host onsite installation and usage activities
- Consider discounted pricing for early adoption and access to data

List Of Terms

In glossary

- Ongoing Reliability test (ORT) is a hardware test process usually used in manufacturing to ensure that quality of the products is still of the same specifications as the day it first went to production or general availability.
- Process Validation is the analysis of data gathered throughout the design and manufacturing of a product in order to confirm that the process can reliably output products of a determined standard.
- Bill of Materials (BOM) is a list of the raw materials, sub-assemblies, intermediate assemblies, sub-components, parts and the quantities of each needed to manufacture an end product.
- Failure Mode and Effects Analysis (FMEA) was one of the first *highly structured, systematic* techniques for failure analysis. It was developed by reliability engineers in the late 1950s to study problems that might arise from malfunctions of military systems. An FMEA is often the first step of a system reliability study.
- Pre-alpha Testing refers to testing associated with concept validation. This validation could be customer discovery based of could require documented evidence that establishes a high degree of certainty that a particular product or process will consistently meet established criteria for concept success and reliability goals.
- Alpha Testing is in-house testing of a pre-production model or version, to locate or estimate design flaws or deficiencies.
- Beta Testing is second level, external pilot-test of a product (usually a software) before commercial quantity production. At the beta test stage, the product has already passed through the first-level, internal pilot-test (alpha test) and glaring defects have been removed.
- Pilot Testing is a small-scale campaign, survey, or test-plant commissioned or initiated to check the conditions and operational details before full scale launch.
- Production Ramp-Up is the start or increase in *production* ahead of anticipated increases in product demand and also in an effort to confirm all production assumptions.
- Detectability is the ability to detect a failure before it causes harm. The purpose of considering detection in any scenario is to ensure that potential or actual failures can be identified with enough time to take action before the user is adversely affected.

List Of Terms

In glossary (cont.)

- **Probability** is the likelihood of the hazard occurring and is ranked on a point scale.
- **Severity** is the amount of damage or harm a hazard could create and is usually ranked on point scale.
- **Accelerated Life Testing (ALT)** is the process of testing a product by subjecting it to conditions (stress, strain, temperatures, voltage, vibration rate, pressure etc.) in excess of its normal service parameters in an effort to uncover faults and potential modes of failure in a short amount of time
- **Highly Accelerated Stress Screening (*HASS*)** uses accelerated stresses beyond a product's specifications to detect product defects during manufacturing and production
- **Non-Destructive Inspections** or non-destructive testing (NDT) is a wide group of analysis techniques used to evaluate the properties of a material, component or system without causing damage.
- **Destructive Tests** on-going reliability tests (*ORT*), tear down, break-open, etc. the product to test for its compliance to specification.
- **Root Cause Analysis** is a method of problem solving used for identifying the root causes of faults or problems
- **Cumulative Distribution Function (CDF)** is the cumulative distribution function (CDF) of a real-valued random variable *X*, or just distribution function of *X*, evaluated at *x*, is the probability that *X* will take a value less than or equal to *x*.
- **Root Cause** is an initiating cause of either a condition or a causal chain that leads to an outcome or effect of interest.
- **Causal Factor** is those elements that lead to variation in the *quality* of the finished product. The Events and *Causal Factors* (ECF) chart depicts the necessary and sufficient events and *causal factors for* accident occurrence.
- **Non-Disclosure Agreements** - is a legal contract between at least two parties that outlines confidential material, knowledge, or information that the parties wish to share with one another for certain purposes, but wish to restrict access to or by third parties.