Build4 Scale
U.S. Department of Energy

Regulation, Certification, and Industry Standards

Module 6A Impact on Product Design and Quality

Motivation

Why is this module important?

Why do regulations, certifications, and industry standards matter?

- To sell to certain markets, many products need to meet government regulations (environment, consumer safety, etc.) and industry test standards, or require specific certifications
- These topics are important for startups to understand the barriers imposed by specific industries, whether it is regulations, certifications, or standard requirements

"There is no such thing as free regulation."
– John Hutton

Motivation

Common mistakes and misconceptions

- Overlooking important industry requirements that will require changes in your product's design, capabilities, and/or manufacturing process
- Assuming that regulations, certifications, and industry standards are the same
- Losing sight of industry standards for development that can derail your commercialization efforts

Module Outline

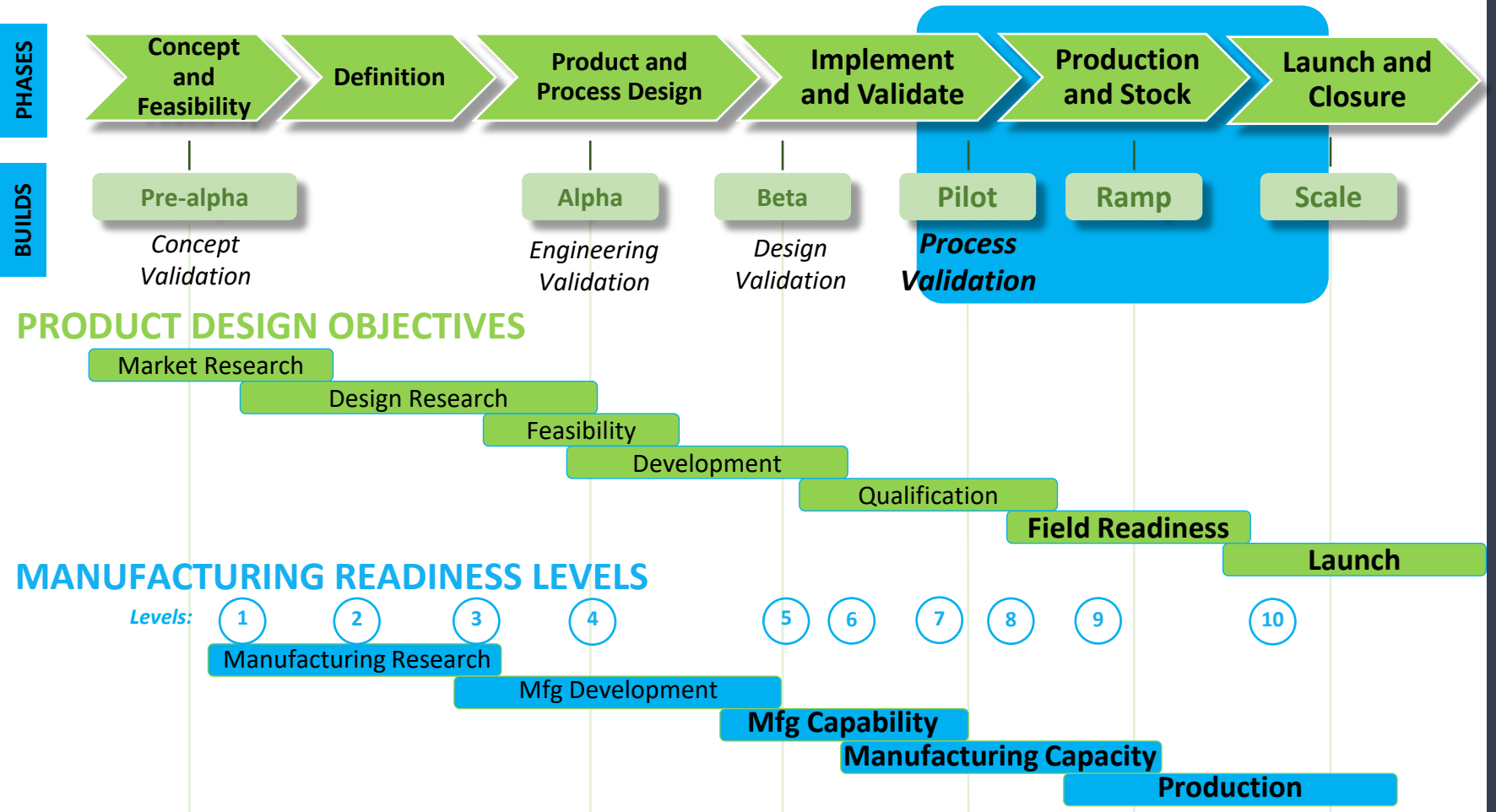
- Learning objectives
- Determining level of regulation based on industry
- Differences between regulation, certification, and industry standards
- Industry regulations and test standards
- Resources for regulations, certification, and industry standards
- Industry case studies

Learning Objectives

- LO1. Differences between regulations, certification, and industry standards
- LO2. The impact of regulations, certification, and industry standards on your business plan and ability to scale-up
- LO3. How to define the regulations, certifications, and industry standards for your business and products
- LO4. Best practices for meeting regulations, certification, and industry standards

Regulations And Certifications

Where does this fit into the development cycle?



Impact on Product Design and Quality

Manufacturing Readiness Levels

(MRL)

Material Solutions Analysis				Technology Development		Engineering and Manufacturing Development		Production and Deployment	Operations and Support
Basic manufacturing Implications identified	Manufacturing Concepts identified	Manufacturing Proof of Concept developed	Capability to produce the technology in a laboratory environment	Capability to produce a prototype components in a production-relevant environment	Capability to produce a prototype system or subsystem in a production-relevant environment	Capability to produce systems, subsystems or components in a production-relevant environment	**Pilot line capability demonstrated. Ready to begin Low-Rate production**	**Low Rate Production demonstrated. Capability in place to begin Full-Rate Production**	**Full-Rate Production demonstrated and lean production practices in place**
1	2	3	4	5	6	7	**8**	**9**	**10**

This module's content is relevant at these MRLs

Pre-alpha → **Alpha prototypes** → **Beta prototypes** → **Pilot prototypes**

Heavily Regulated Industries

How to begin your search

- Research your well-established competition to identify relevant standards, regulations, and certifications (leverage their knowledge, research and investment in legal work)
- Ask your customers to identify relevant regulations and certifications
- Become familiar with and join committees and other organizations that lead the development and publication of industry standards, regulations, and certification

Heavily Regulated Industries

Examples

- Energy
- Transportation
- Medical/Healthcare
- Food
- Defense

A market is more likely to be heavily regulated if:

- Consumer safety/protection is key
- Litigation potential of product failures is high
- Corporate abuse of rules and regulations is prevalent
- Government policies favor protection of consumers and private citizens over that of manufacturers

Key Questions

Regulation, certification, and industry standards

- How are they different?
- How do they impact my ability to sell into markets?
- Do they create a risk or an opportunity for my product?
- How do they impact my ability to scale-up production?

Regulations And Certification

Basics

- **Regulation**: In government, a regulation is a piece of the delegated legislation drafted by subject-matter experts to enforce a statutory instrument. In some cases, the legislation is specifically designed to regulate industries. In private industry, regulation is driven by self-regulatory organizations and trade associations that allow industries to set rules with less government involvement.
- **Certification**: For product certification, this refers to processes intended to determine if a product meets minimum standards, similar to quality assurance. Each country has its own certification systems and organizations.

Industry Standards

Basics

- **Industry standard**: An industry standard model is a set of universal operational process methods or tools that apply to most companies within a specific industry. It identifies the core dimensions, materials, and methodologies those companies may use and supports business best practices. The language or style of the model is widely accepted. Standards are often self-imposed by industry in an attempt to reduce variability and lower overall cost.

Regulations And Certification

Examples – Automotive industry

- **Regulation**: U.S. regulation requires automakers to increase fuel economy to 54.5 miles per gallon for cars and light-duty trucks by model year 2025
- **Certification**: The EPA is responsible for calculating the average fuel economy for each manufacturer
  - —**Corporate Average Fuel Economy** (CAFE) certification is done one of two ways:
    - Either the manufacturer provides its own fuel economy test data and audited by EPA, or
    - The EPA obtains a specific make-and-model vehicle and tests it in its own test facility

Industry Standards

Examples – Automotive industry

- **Standards**: **Code of Federal Regulations** (CFR) Title 40, Part 1066—Vehicle-Testing Procedures industry standard required testing procedures for measuring exhaust, evaporative, and refueling emissions
- **Society of Automotive Engineers** (SAE) international standard incorporates driving cycles that produce fuel consumption data relating to urban, suburban, and interstate driving patterns

Design And Manufacturing Drivers

Regulations and standards

To determine which regulations and test standards will drive your product design and manufacturing processes:

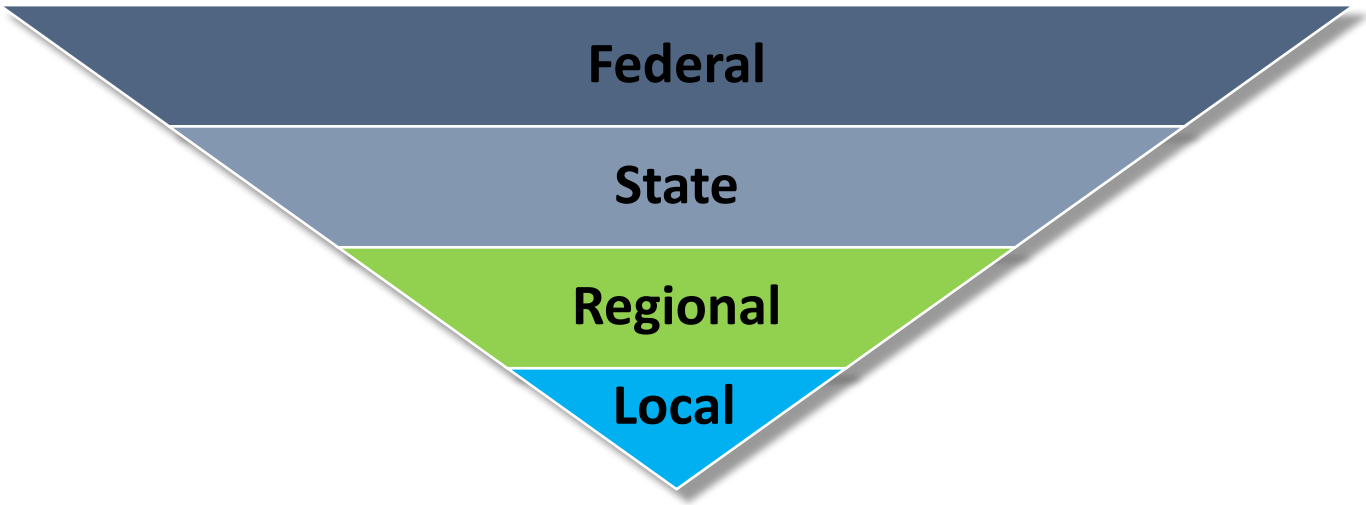
- Research the “drivers” behind the regulations and test standards
- Understand government and industry influence on regulations and certification standards
- Identify key product-failure points with competing products
- Research consumer reports and warranty claims
- Research the testing requirements of organizations that develop and publish industry standards

Design And Manufacturing Drivers

Regulations and standards (cont.)

- Determine what testing can be done in-house versus externally (i.e., through independent test labs). When tests are required by an independent third party internally, confirm your product past test prior to sending for third party testing. This will save you time and money.
- Determine how testing and certification impact costs. Are they required for several generations of prototypes and/or several product variations?
- Understand lead times needed for testing and certification and how this impacts time-to-market for the launch of your product

Regulation Drivers



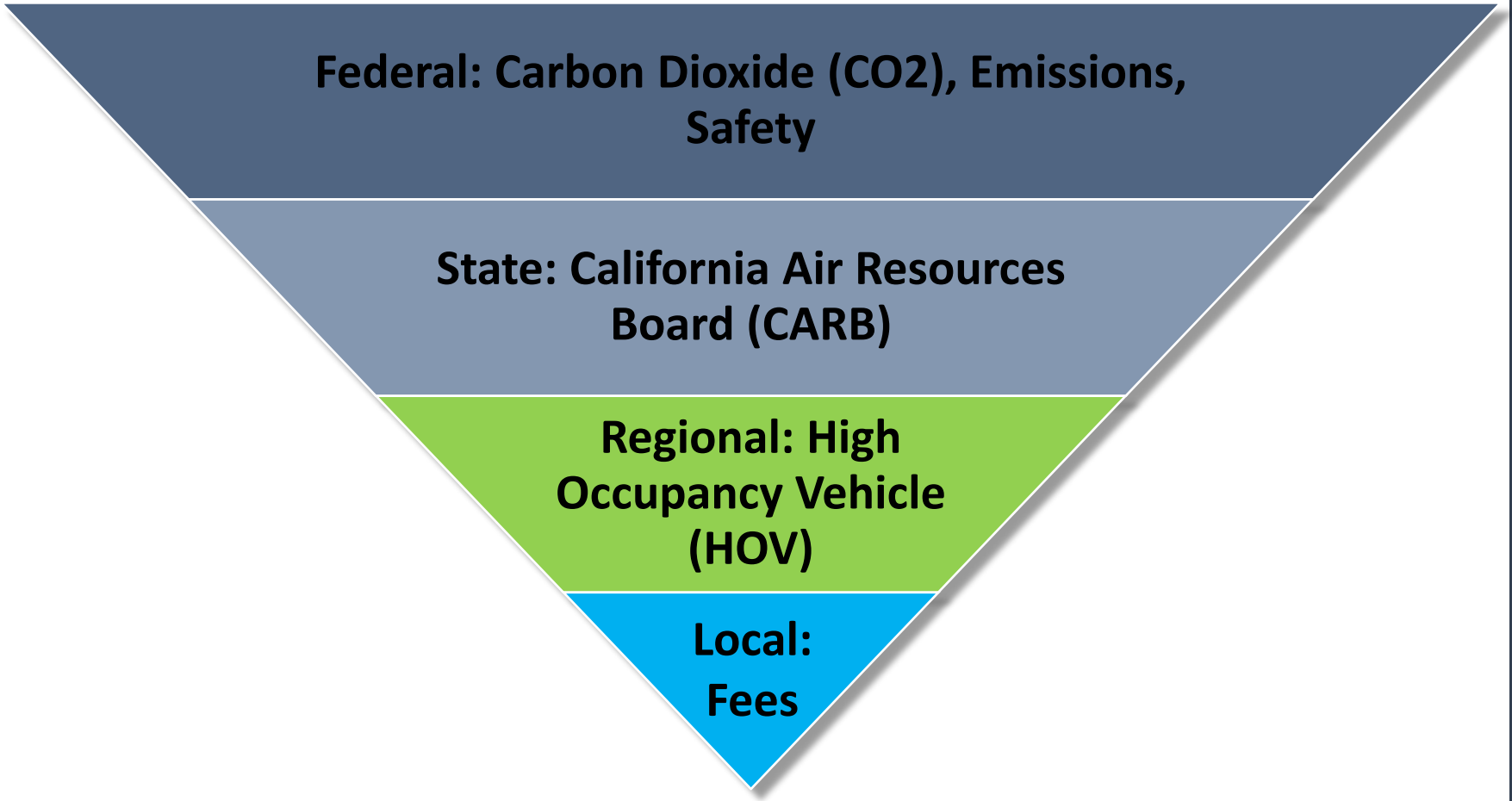
U.S. Government: multi-layered infrastructure

Issues/risks:

- Uncertainty about timing
- Duration (admin change)
- Negotiation of incumbents
- Interactions/responses of “layers”

Regulation Drivers

Example 1 – Automotive industry



Regulations

Example 1 – Automotive industry (cont.)

Federal:

- CAFE requirements driving vehicles design for better fuel economy
- Renewable Fuel Standard (RFS) pushing development of biofuel vehicles
- Electric vehicle purchase incentives to consumers

States:

- EV incentives drive regional demand (e.g., $6,000 in Colorado)
- California and New York state clean-truck vouchers
- More subtle: Gas prices and taxes; road, bridge, and highway infrastructure spending; parking fees, toll and HOV waived for clean vehicles; special lane designation for clean vehicles

Regulations

Example 1 – Automotive industry (cont.)

Regional:

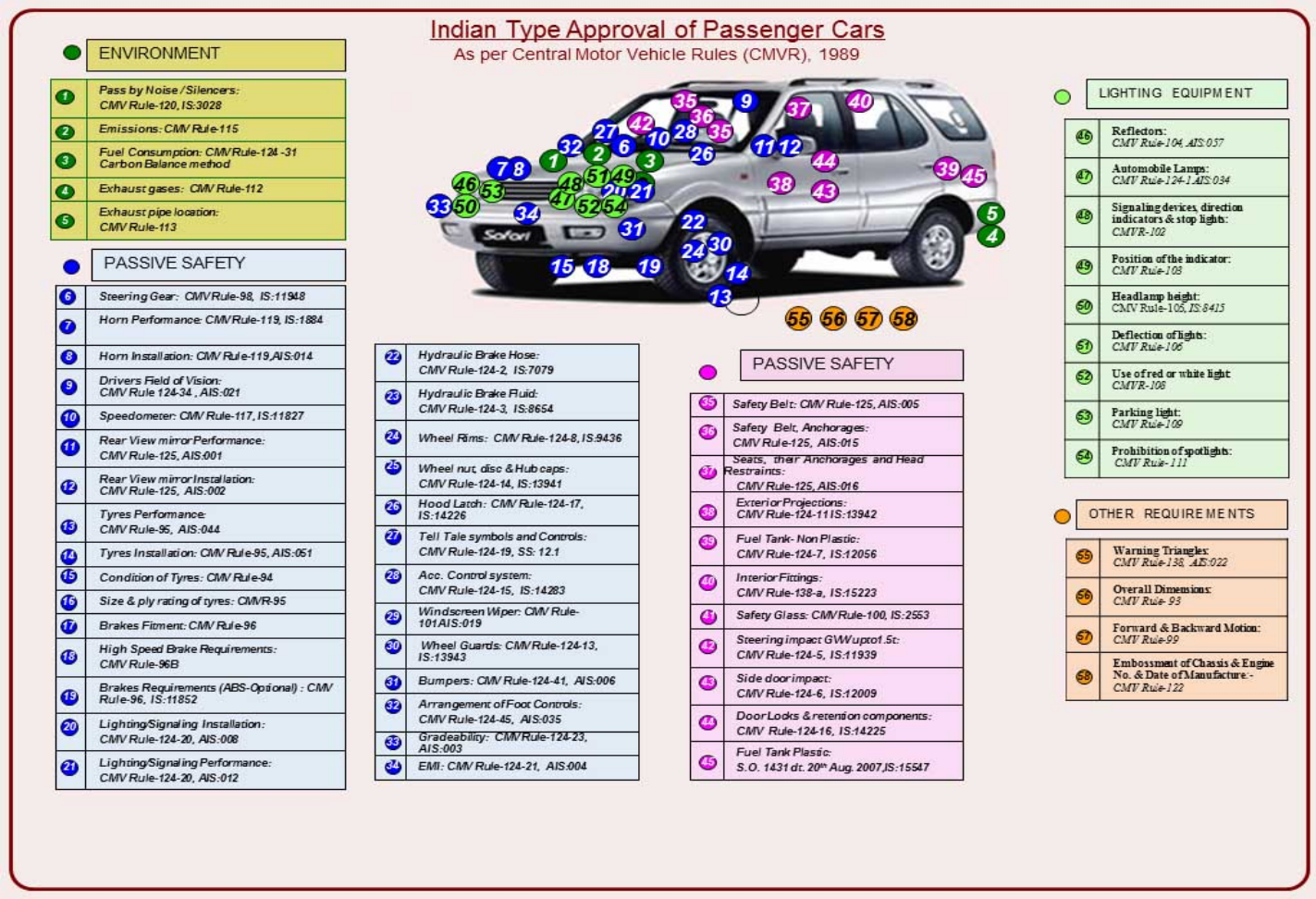
- South Coast Air Quality Management District off-road diesel NOx clean-up funds in regional area

Local:

- Drive Clean Chicago electric-truck voucher program
- European city "congestion" charges to reduce traffic congestion and emission (e.g., London not allowing vehicles other than mass transit in the city)

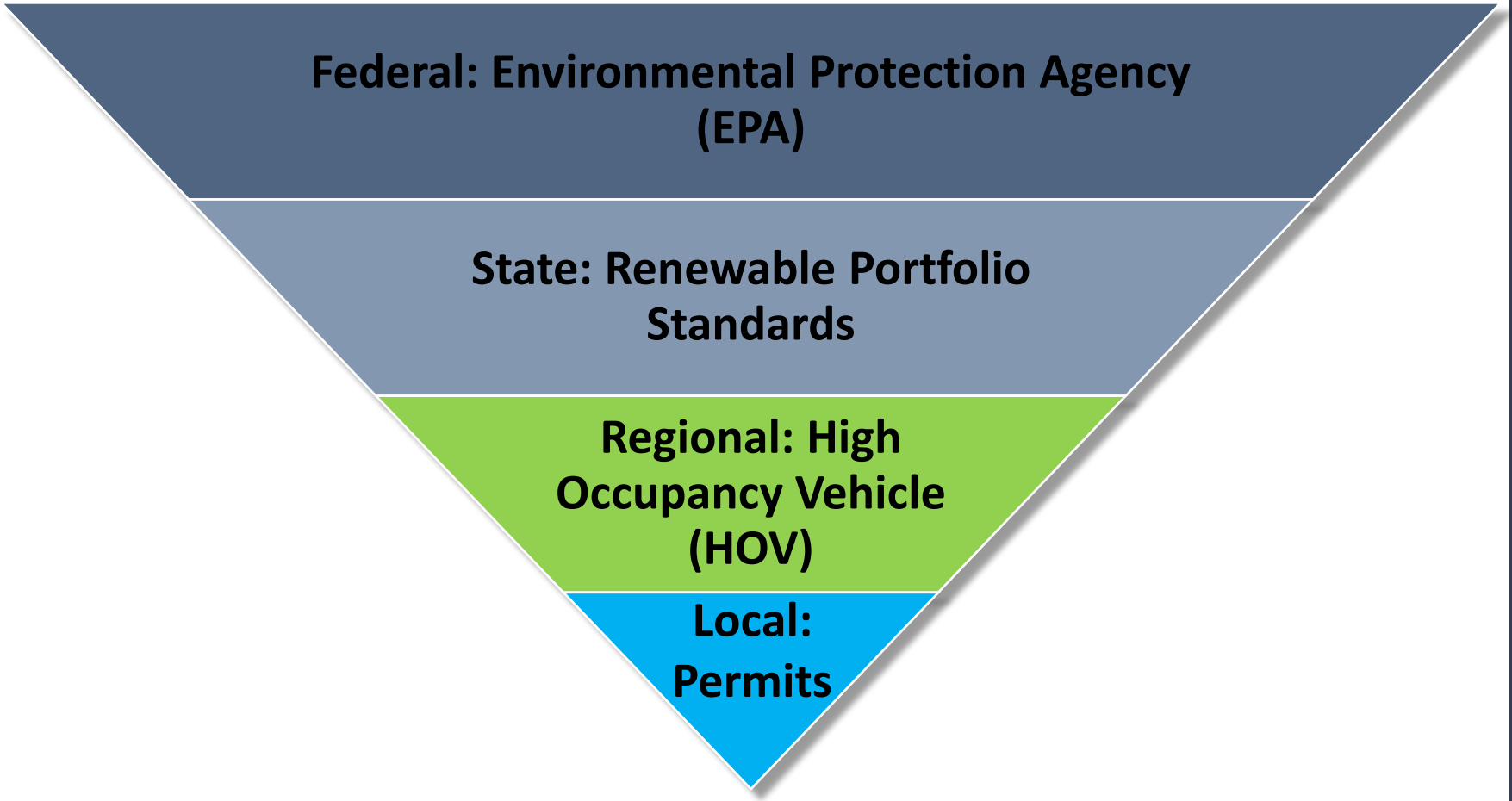
Regulations

Example 1 – Automotive industry (cont.)



Regulation Drivers

Example 2 – Energy industry



Regulations

Example 2 – Energy industry (cont.)

Federal:

- Clean Power Plan establishing carbon pollution emission guidelines for existing stationary sources
- Investment/Production Tax Credits (ITC/PTC) for renewable-energy generation projects

States:

- Renewable portfolio standards (RPS) – Requires state utilities to include specific percentages of renewable power generation
- Energy efficiency standards for utilities
- Net metering laws establishing limits on users of renewables to sell back power to the grid
- Rebates and incentives for consumers to adopt renewable energy or energy efficient products and efficiency measures

Regulations

Example 2 – Energy industry (cont.)

Regional:

- Grid-interconnectivity rules, fees, and permits
- County-level energy-generation zoning and siting laws

Local:

- Power-generation siting laws, fees, and permits
- Transportation routing and road-building requirements

Resources

Government regulations

- Environmental Protection Agency (EPA):
  https://www.epa.gov/laws-regulations
- Environmental Protection Agency (EPA):
  https://www.epa.gov/laws-regulations
- Federal Energy Regulatory Commission (FERC):
  https://www.ferc.gov/
- Department of Transportation (DOT):
  https://www.transportation.gov/regulations
- Federal Motor Carrier Safety Administration (FMCSA):
  https://www.fmcsa.dot.gov/regulations
- Consumer Product Safety Commission (CPSC):
  https://www.cpsc.gov/
- Occupational Safety and Health Administration (OSHA):https://www.osha.gov

Resources

Certification

Hazardous materials:

- Employee handling: OSHA https://www.osha.gov
- Disposal: EPA https://www.epa.gov/hw, Restriction of Hazardous Substances (RoHS) http://rohs-certificate.com/RoHS.aspx
- Transportation: DOT https://www.phmsa.dot.gov/hazmat/outreach-training/training-modules

Consumer products:

- Conformité Européenne (CE) https://en.wikipedia.org/wiki/CE_marking, NSF http://www.nsf.org/services/by-industry/consumer-products/, CPSC https://www.cpsc.gov/Business--Manufacturing/Testing-Certification/

Resources

Certification (cont.)

Product and process quality: (cont.)

- QS http://certifications.thomasnet.com/certifications/glossary/quality-certifications/automotive-industry/qs-9000/
  ISO 9000 https://www.iso.org/iso-9001-quality-management.html

Environmental:

- ISO 14000 https://www.iso.org/iso-14001-environmental-management.html

Energy Efficiency:

- Energy Star https://www.energystar.gov/

Resources

Certification (cont.)

Radio Frequency:

- Federal Communications Commission (FCC) https://www.fcc.gov/general/radio-frequency-safety-0

Electrical Products:

- UL http://www.ul.com/code-authorities/electrical-code/

Resources

Industry standards

Automotive:

- SAE http://standards.sae.org/automotive/
- AIAG http://www.aiag.org/
- USCAR http://www.uscar.org/guest/index.php

Energy:

- NAESB https://www.naesb.org/
- Oil and gas http://oilandgasstandards.org/
- Wind power http://www.awea.org/standards-development
- Solar power http://www.seia.org/policy/health-safety/codes-standards

Regulation-Driven Opportunity

Case study 1 – Start-up electric vehicle company

A company that took advantage of regulations as an opportunity to introduce their new product

Federal:

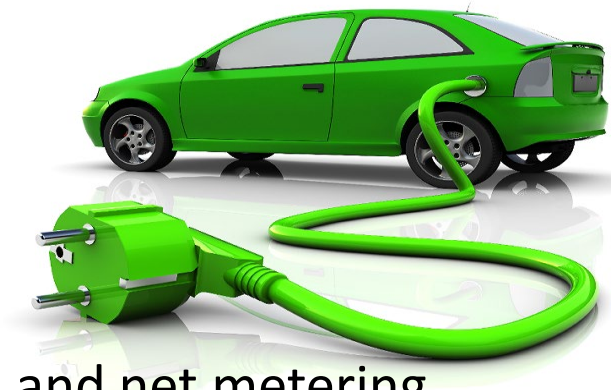
- CAFE requirements allowing entry for new vehicles OEM's
- Federal EV rebates for consumers make EV's more affordable
- Federal subsidies for EV charging infrastructure reduce consumer EV range anxiety

Regulation-Driven Opportunity

Case study 1 – Start-up electric vehicle company (cont.)

State:

- California Zero Emission Vehicle (ZEV) regulation requiring large volume and intermediate volume car manufacturers to bring to and operate in the State a certain percent of vehicles with near-zero tail pipe emissions and EV companies are able to monetize and sell their extra ZEV credits to other auto OEM's who don't meet requirements.



- Subsidies for residential solar installations and net metering allow California home owners to charge their EV for free and sell back excess power from EV to grid
- Some state's put up blocks not allowing EV companies to sell to consumers direct (i.e., state of Michigan vs. Tesla)

Regulation-Driven Opportunity

Case study 1 – Start-up electric vehicle company (cont.)

Regional:

- South Coast Air Quality Management District (SCAQMD), the air pollution control agency for all of Orange County and the urban portions of Los Angeles, Riverside and San Bernardino counties, institutes carrot and stick policies that provide businesses and fleets with incentives for investing in EV's

- Counties make investments in regional EV Charging infrastructure to reduce EV range anxiety for consumers

Regulation-Driven Opportunity

Case study 1 – Start-up electric vehicle company (cont.)

Local:

- Los Angeles sustainable city plan promise that 50% of new city fleet vehicles purchased each year would be EV by 2017
- Cities provide free parking and free EV charging for EV owners
- City "congestion" charges are adopted to reduce traffic congestion and emission providing incentive for urban fleet owners to switch to EV's (i.e., taxi's)

Regulation-Driven Opportunity

Case study 2 – Natural gas fracking company

Natural gas fracking equals huge market potential:

- 2014: Tens of thousands of new wells to be drilled in North America
- Hundreds of thousands of existing wells are hydro-fracking candidates

Fracking Well Site

Jonah Gas Field of Wyoming
EnCana Gas Wells with Fracking

Regulation-Driven Opportunity

Case study 2 – Natural gas fracking company (cont.)

- Opportunities that could benefit from a compact LPG-fueled fuel cell paired with a solar array can provide 24/7/365 power

Supervisory Control And Data Acquisition (SCADA)

Containment Pond Monitoring

Corrosion Protection

Regulation-Driven Opportunity

Case study 2 – Natural gas fracking company (cont.)

Site Regulations at a natural gas well head:

- Class 1. Zone 1/Division 1. Hazardous Location
  - —Gas, vapor, or mist will be present or expected to be present for long periods of time under normal operating conditions. As a guide for Zone 1, this can be defined as 10 - 1,000 hours/year or 0.1 – 10 percent of the time

Install location

Regulation-Driven Opportunity

Case study 2 – Natural gas fracking company (cont.)

Requirements:

- Well Head Sites
  - —Hazardous Location, Class 1, Zone 1
- Product Certification
  - —CSA America FC3-2004 Portable Fuel Cell Power Sys
  - —CSA America FC1-2014 Fuel Cell Power Sys
- Product Integration
  - —IEEE, NFPA, ASME, ANSI
- Quality System
  - —ISO 9001

Regulation Driven Markets:

- SCADA
- Corrosion
- Pond monitoring

References

- SAE International: Fuel Economy – Automotive Standards http://topics.sae.org/fuel-economy/standards/automotive/
- EPA: Vehicle Certification and Compliance Testing https://www.epa.gov/vehicle-and-fuel-emissions-testing/vehicle-certification-and-compliance-testing
- SAE International: Fuel Economy Measurement Road Test Procedure http://standards.sae.org/j1082_200802/
- NextEnergy and University of Michigan Center for Entrepreneurship I-Corps Energy and Transportation https://nextenergy.org/icorps/

List Of Terms

In glossary

- **Field Readiness** is critical process during product development when a company determines their product's readiness for release. This process takes place after learning market's problems, building a solution and preliminary testing is successfully completed and release is anticipated. (Repeat from 2B)
- **Launch** is the stage of development when all testing is so the company can vet the reception of the product before a full go-to-market investment is made. Market entry/commercialization is the stage in which the product is introduced to the target market. (Repeat from 5A)
- **Manufacturing Capability** process is a unique combination of tools, materials, methods, and people engaged in producing a measurable output; for example a manufacturing line for machine parts. All processes have inherent statistical variability which can be evaluated by statistical methods. (Repeat from 2B)
- **Production** is the processes and methods used to transform tangible inputs (raw materials, semi-finished goods, subassemblies) and intangible inputs (ideas, information, knowledge) into goods or services.
- **Regulation** is an abstract concept of management of complex systems according to a set of rules and trends.
- **Certification** refers to the confirmation of certain characteristics of an object, person, or organization. This confirmation is often, but not always, provided by some form of external review, education, assessment, or audit.
- **Industry Standard** is the generally accepted requirements followed by the members of an industry.
- **Corporate Average Fuel Economy (CAFE)** are regulations in the United States, first enacted by the United States Congress in 1975, after the 1973-74 Arab Oil Embargo, to improve the average fuel economy of cars and light trucks (trucks, vans and sport utility vehicles) produced for sale in the United States.
- **Code of Federal Regulations (CFR)** is the codification of the general and permanent rules and regulations (sometimes called administrative law) published in the *Federal Register* by the executive departments and agencies of the federal government of the United States.

List Of Terms

In glossary (cont.)

- **Society of Automotive Engineers (SAE)** is a US-based, globally active professional association and standards developing organization for engineering professionals in various industries.
- **Renewable Fuel Standard (RFS)** is an American federal program that requires transportation fuel sold in the United States to contain a minimum volume of renewable fuels**.**
- **SAE International** initially established as the Society of Automotive Engineers, is a US-based, globally active professional association and standards developing organization for engineering professionals in various industries.
- **EPA** is an agency of the federal government of the United States which was created for the purpose of protecting human health and the environment by writing and enforcing regulations based on laws passed by Congress.