Product V quality manual

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COMPANY PROFILE

Our mission

To integrate augmented reality into existing products

Our policies

On customers: We will pay attention to our customer's needs and balance their expectations with those of our suppliers, investors, and employees.

On our team: We will work cohesively and efficiently.

On processes and systems: We will be transparent within the company between management and other employees. We strive to maximize safety.

On continual improvement: We will invest in our employee's learning, success, and independence.

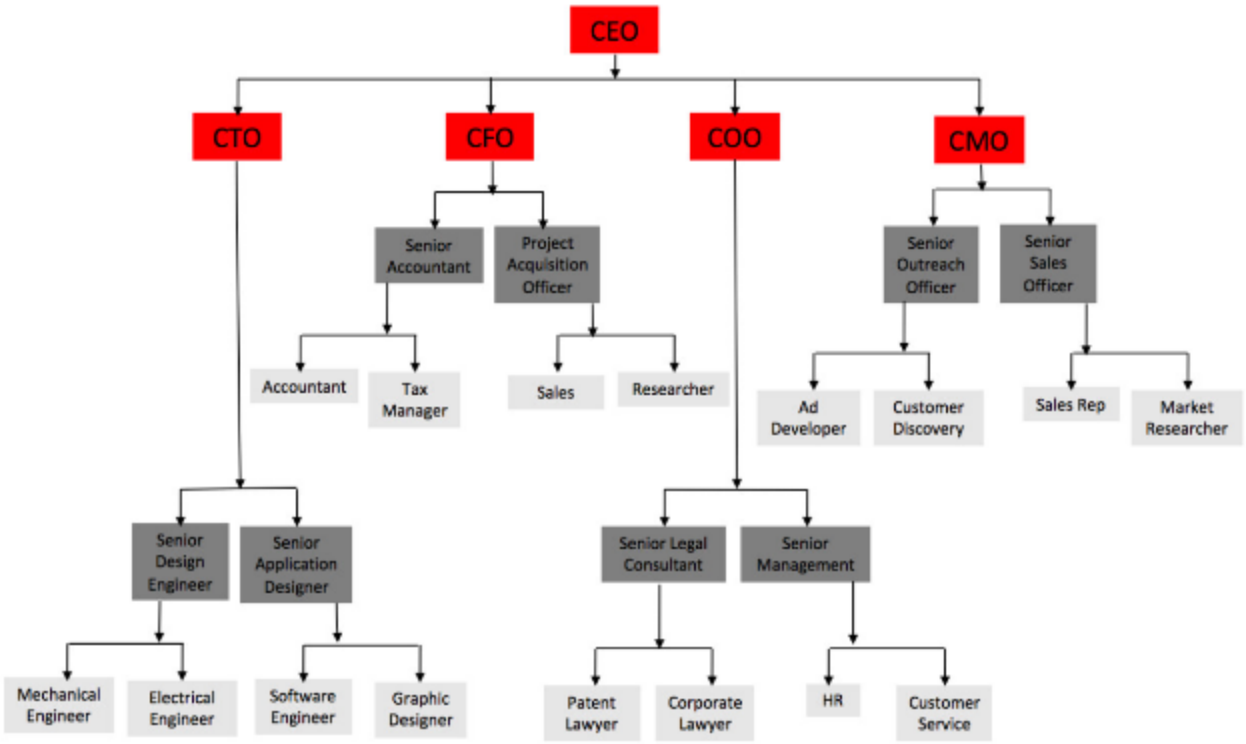
On decisions: We will weigh the pros and cons of each important decision and come to educated conclusions that benefit our company, customers, and employees.

On supplier relationships: We will maintain transparency within relationships we create with suppliers.

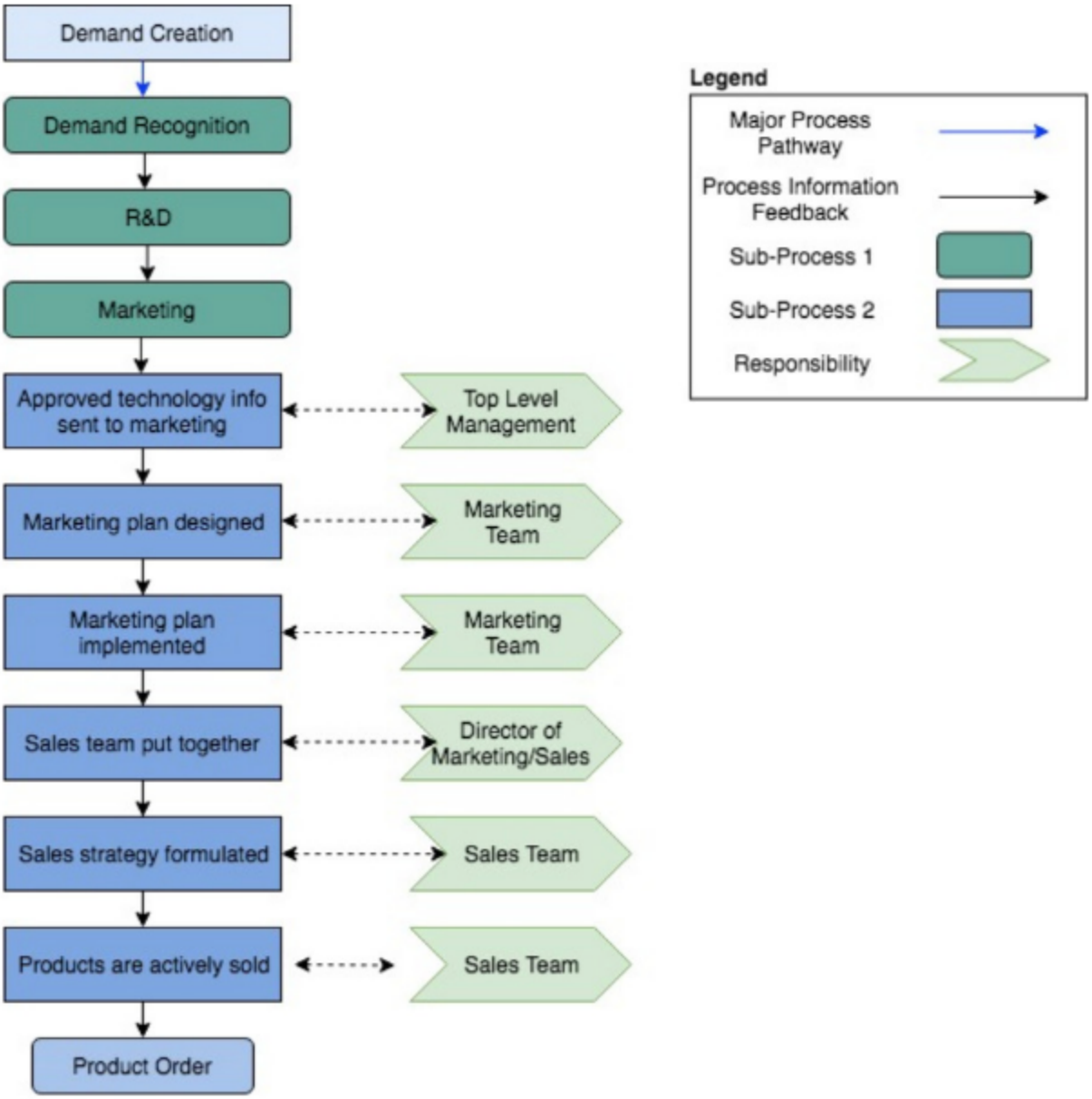
On profits: We will reinvest a portion of profits back into the company to further achieve our mission statement. We will satisfy our investors and strive to improve relationships with stakeholders.

On society, the environment, health, and safety: We will conduct our company in a way that exemplifies safety, improve quality of life, and abide by federal regulations.

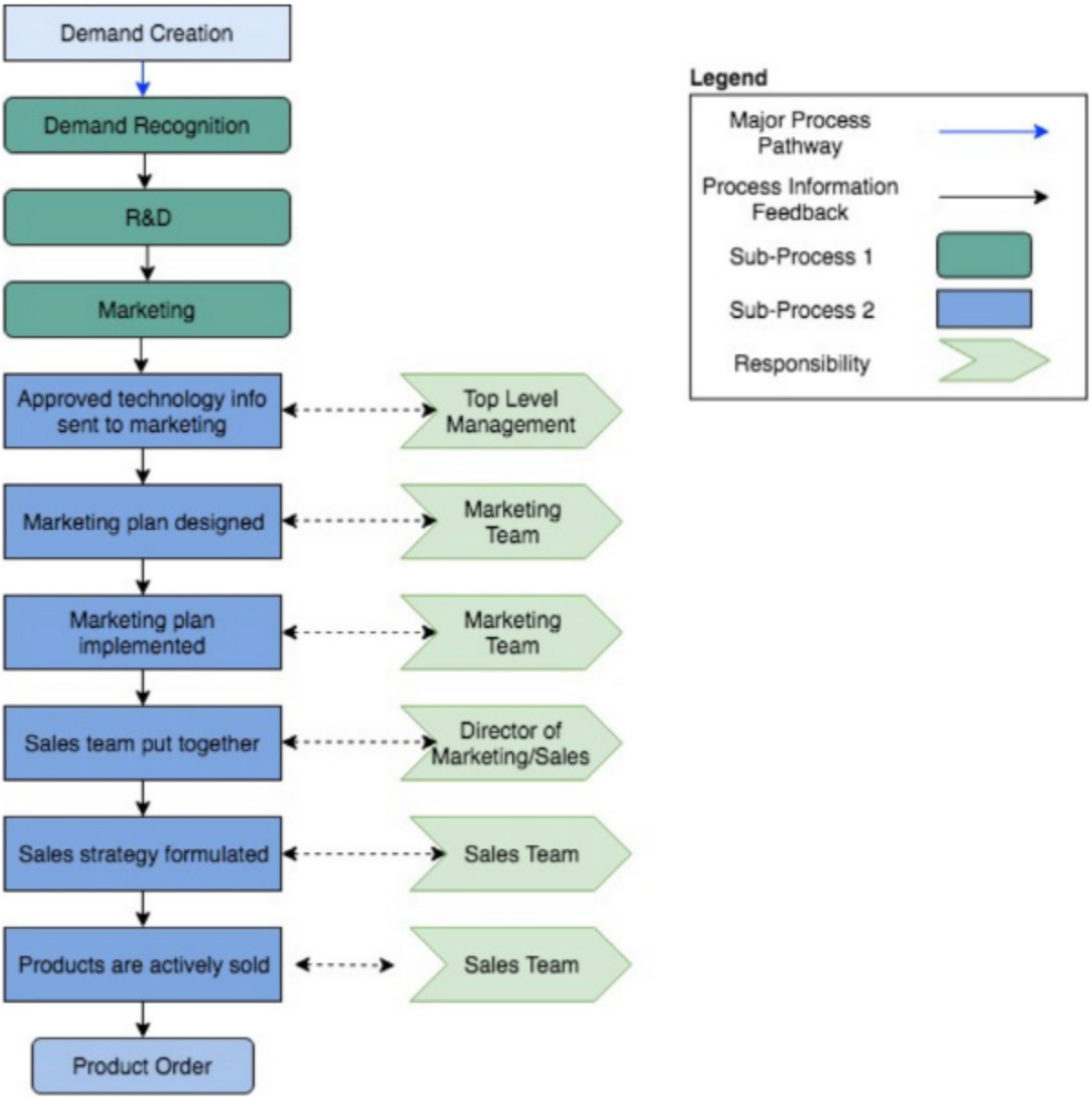
Company Hierarchy



Demand Control



Project and Product Acquisition



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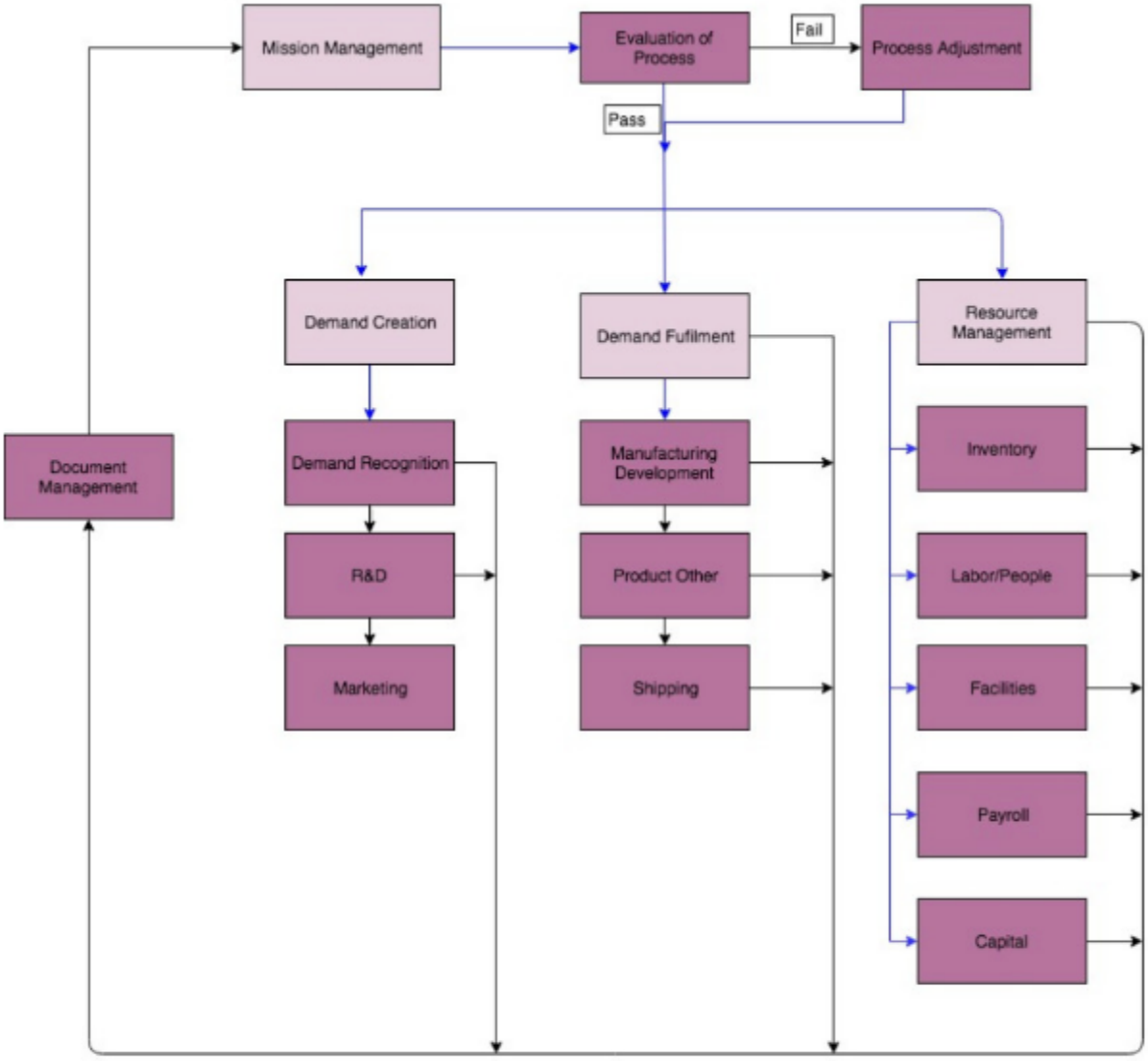
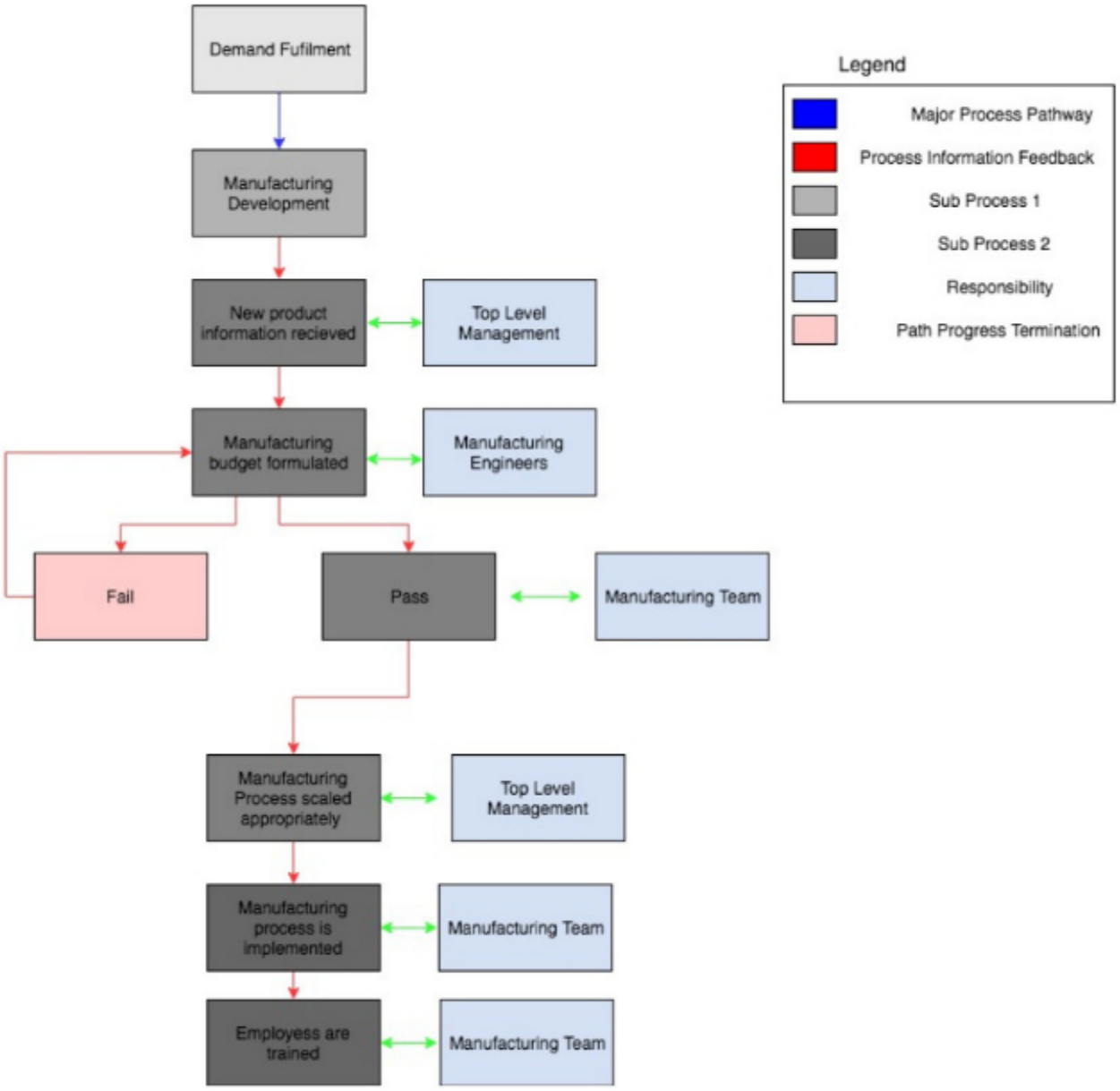
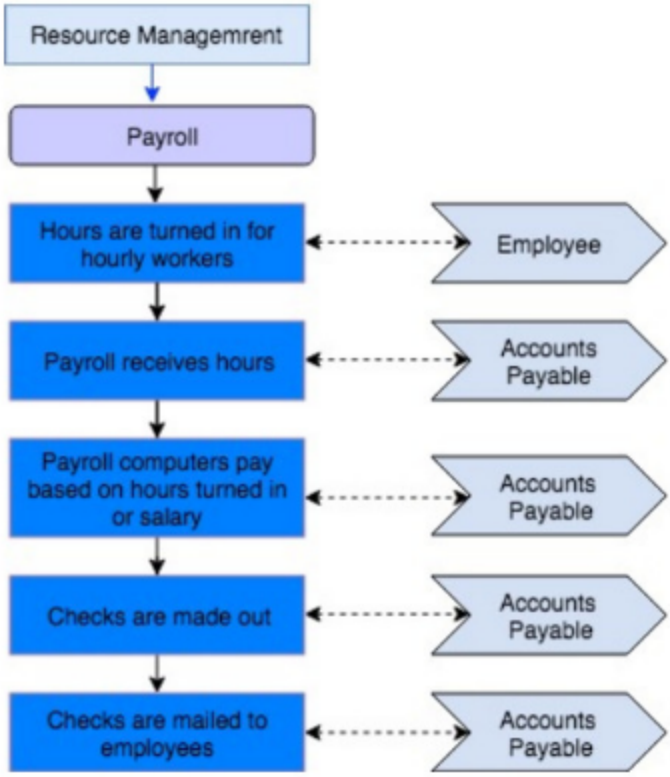
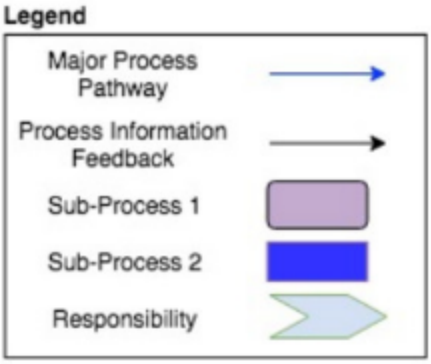


Production Control



Payment Control





Process Objectives

- Paychecks should be sent out on time
- Paychecks should not contain accounting errors

DOT
Department of Transportation National Highway Traffic Safety Administration 49 CFR Part 571 Federal Motor Vehicle Safety Standards; Motorcycle Helmets; Proposed Rule –
This document encompasses many different standards that all govern motorcycle helmet regulations in the USA.
https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/2015-11756.pdf

BSI 6658-85 Type A
BS 6658:1985 specifies the requirements for helmets for riders, drivers and passengers of motor vehicles including participants in competitive events, for whom a high-performance option is included.

EN 22/05
UNIFORM PROVISIONS CONCERNING THE APPROVAL OF PROTECTIVE HELMETS AND OF THEIR VISORS FOR DRIVERS AND PASSENGERS OF MOTOR CYCLES AND MOPEDS
http://www.unece.org/fileadmin/DAM/trans/main/wp29/wp29regs/r022r4e.pdf

SNELL M2020
2020 STANDARD FOR PROTECTIVE HEADGEAR
For Use with Motorcycles and Other Motorized Vehicles
https://www.smf.org/standards/m/2020/M2020-final-Cover.pdf

Consumer Product Safety Act
Title 15, United States Code, Chapter 47, Sections 2051-2089

Consumer Product Safety Improvement Act of 2008 (CPSIA)
Public Law 110–314, August 14, 2008

State of Vermont Stewardship Program for Batteries
Sec. 1. 10 V.S.A. Chapter 168
Product Stewardship for Primary Batteries and Rechargeable Batteries requires manufacturers that sell primary batteries in Vermont to implement an approved collection plan or be a member of an approved stewardship organization.

Wireless Devices Regulations
Mobile and Portable Devices Portable and mobile devices that operate in the Cellular Radiotelephone Service **(47 CFR 22 Subpart H),** the Personal Communications Service (PCS) **(47 CFR 24)**, the Satellite Communications Service **(47 CFR 25)**, the Wireless Communications Service **(47 CFR 27),** the Maritime Service (ship earth stations only) **(47 CFR 80),** and Specialized Mobile Radio Service **(47 CFR 24, 25, 27, 80 (ship earth stations devices only) and 90)** at frequencies of 1.5 GHz or below and their effective radiated power (ERP) is 1.5 watts or more, or if they operate at frequencies above 1.5 GHz and their ERP is 3 watts or more, are subject to RF emissions requirements as specified in the rule part that they operate under. All of these portable and mobile devices are also subject to the routine environmental evaluation for RF exposure requirement of **47 CFR 2.1091** (bottom of page 706) (mobile devices) and/or **47 CFR 2.1093** (page 708) (portable devices) prior to equipment authorization or use.

15 United States Code, Chapter 2, Subchapter I, Sections 41-58
The FTC Act broadly prohibits unfair or deceptive acts or practices in or affecting commerce.

ANSI C18.4M-2017 National Electrical Manufacturers Association 1
Scope 1.1 This standard applies to all chemistries of portable primary cells and batteries standardized in the ANSI C18 series.

RCW 70.240.020
Prohibition on the manufacturing and sale of children's products containing lead, cadmium, or phthalates.

ANSI C18.2M, Part 2-2014
American National Standard for Portable Rechargeable Cells and Batteries—Safety Standard.

American National Standard for Portable Rechargeable Cells and Batteries—General and Specifications
ANSI C18.2M, Part 1-2013
Applies to portable rechargeable or secondary cells and batteries based on the following electrotechnical systems: nickel-cadmium, nickel metal hydride and lithium ion.

American National Standard for Light-Emitting Diode Drivers—Methods of Measurement

NEMA

ANSI C82.16-2015 Describes the procedures to be followed and the precautions to be taken in measuring performance of LED drivers. The scope includes, but is not limited to, LED drivers with these characteristics:

- General lighting, exterior lighting, and roadway lighting applications
- Input supply voltage up to 600 VDC or 600 VAC (50 or 60 Hz)
- Output open-circuit voltage of 600 V or less
- Constant-current or constant-voltage DC output
- Fixed, variable (dimmable), pulse width modulation, or programmable (tunable) output power
- External (standalone) or internal (enclosed in luminaire)

ANSI C18.4M-2017

American National Standard for Portable Cells and Batteries—Environmental

Sets forth some general considerations that should be taken into account when developing battery Standards that balance the need to achieve the intended product performance while reducing adverse environmental effects, and outlines ways in which provisions in battery standards might affect the environment during the stages of its life cycle.

Certificates and Mandatory Third-Party Testing

Section 102 on page 8 of the CPSIA requires every manufacturer or importer of all consumer products that are subject to a consumer product safety rule enforced by the CPSC to issue a general certificate of conformity based on testing of the product and stating that the product complies with the applicable standard, regulation, or ban. The certificate must accompany the product and be furnished to the retailer or distributor.

47 CFR 15, Radio Frequency Devices
Sets forth the requirements for testing and equipment authorization for intentional, unintentional, and incidental radiators. The regulation classifies devices as unintentional (equipment that is not intended to transmit information over the air, e.g., clocks, radios, TVs), **47 CFR 15 Subpart B;** intentional (equipment that transmits information over the air, e.g., remote controls, cordless telephones), **47 CFR 15 Subparts C through H;** and incidental (generates RF energy during course of its operation, though not designed to intentionally emit it, e.g., dc motors, mechanical light switches), **47 CFR 15.13.** The regulation classifies unintentional radiator radio frequency devices as Class A – used exclusively in industrial, business, and commercial applications, and Class B – used in residential environment (e.g., personal computers, calculators, and similar devices). **47 CFR 15** also establishes specific labeling requirements for intentional, unintentional, or incidental radiators depending on the approval process required (i.e. Certification, Verification, or Declaration of Conformity). All products must meet the applicable labeling requirements.

RoHS For Europe and California
RoHS specifies maximum levels for the following 10 restricted substances. The first six applied to the original RoHS while the last four were added under RoHS 3, which takes effect July 22, 2019.

§15.109 - Radiated emission limits.
Sections (a)-(h)

Potential Failure Mode and Effects Analysis in Design (Robust Design FMEA)

PRODUCT V

JAMAR, AARON, KATIE

No.	Item/Function	Potential Failure Mode	Potential Effects of Failure	SEV (1-10)	Potential Causes of Failure	OCC	CLASS	Current Mitigations	Verification	DETECTION	Recommended Actions
1	Battery	Expansion	Fire and/or explosion, burns	10	low product quality, continued exposure to extreme conditions	<1	I	Sourcing quality materials	Voltage testing, discharge testing, exposure testing	80%	Replace battery
2	Battery	Capacity Degredation	Decreased time of usability	6	low product quality, over-charging, imporper use (incorrect input conditions)	<1	I	Sourcing quality materials	Voltage testing, discharge testing, exposure testing	80%	Replace battery
3	Battery	Dead modules or cells	Decreased or non-existent usability	8	low product quality	<1	I	Sourcing quality materials	Voltage testing, discharge testing, exposure testing	80%	Replace battery
4	Battery	Physical dammage	Possible explosion, burns	10	High impact, vehicle accident	N/A	I	Sourcing quality materials	Shock exposure testing	90%	Replace battery
5	Visor	Rotating mechanism failure	Can't open or close visor	10	Dropping, improper use	N/A	II	FEA, material testing	Preproduction samples, production quality sampling during manufacture	90%	Avoid shearing forces on helment when visor is in open position
6	Visor	Wiring from screen to computer fails overtime from bending	screen fails to output data	10	Normal useage	<1	II	FEA,bending fatigue lifetime	Preproduction samples, production quality sampling during manufacture	95%	Avoid shearing forces or tensile forces on wiring
7	Visor	Visor screen dammaged by water, light, dirt, or dust	screen fails to output data	10	Improper care and/or use	<1	II	experimental testing	Analytical testing	95%	Avoid dirt, water, snow, and harmful light sources
8	Visor	Screen peels off from visor inside	Possible blurred vison leading to crash	10	Failed adhesive	<1	II	experimental testing, adhesive testing	Analytical testing	95%	Avoid high heat situation or touching screen
9	Visor	Visor cracking, chipping	Dammaged screen, compromised visor	10	rocks, debris, weather, improper use	<2	II	FEA, experimental testing	Analytical testing, pre production samples	85%	Avoid riding to closely, avoid putting helmet near water and dirty/dusty areas
10	Visor	Dead pixels	Non-working product	10	Failed screen, high impact	N/A	II	FEA, experimental testing	Analytical testing, pre production samples	90%	Avoid high impact, light, modifying helemet
11	Computing Hardware	I/O component failure	Inability to communicate with internally and/or externally	10	Faulty components	<1	III	Sourcing quality materials	Sample tests during manufacture	95%	Replace/repair components
12	Computing Hardware	Defective Board	Non-working product	10	Faulty components	<1	III	Sourcing quality materials	Sample tests during manufacture	90%	Replace/repair components
13	Computing Hardware	Faulty memory module/s	Non-working product	10	Faulty components	N/A	III	Sourcing quality materials	Sample tests during manufacture	90%	Replace/repair components
14	Computing Hardware	Failed OS write to board	Non-working product	10	Faulty components, broken installation method	N/A	III	Sourcing quality materials	Sample tests during manufacture	100%	Reinstall OS

FMEA

No.	Item/Function	Potential Failure Mode	Potential Effects of Failure	SEV (1-10)	Potental Causes of Failure	OCC	CLASS	Current Mitigations	Verification	DETECTION	Recommended Actions
15	Computing Hardware	Failed OS install	Non-working product	10	Faulty components, broken installation method	N/A	III	Sourcing quality materials	Sample tests during manufacture	100%	Reinstall OS
16	Operating System	Various OS bugs	Non-ideal customer interaction experience	6	Less-than-ideal software development, inexperience	6	IV	Applying best practices for software development , hiring quallity developers	Writing test harnesses for features	60%	Update regularly
17	Helmet	Chips in outer layer	Leads to more sever problems, impacts aesthetic	5	Overuse, impact with road debris	<1	V	FEA, material testing	Visual analysis	90%	Avoid areas with large amounts of road debris, visual check of helmet after use
18	Helmet	Damage to internal cusioning (rip, tear, falls apart)	Reduced safety, impacts comfort and fit	7	Crash, overuse, improper use	<2	V	Qulaity testing, comfort testing	Visual and functional analysis	90%	Visual assesment before use
19	Helmet	Deformation of outer structure	Reduced safety, impacts comfort and fit	8	Drop, normal use, crash	N/A	V	FEA, impact testing	FEA, material analysis, tests on preproduction components	100%	Visual assesment/inspection, replace after damaged
20	Helmet	Deformation of internal padding	Impacts comfort and fit of helmet to user	5	Improper use	<2	V	FEA, impact testing, comfort analysis	FEA, material analysis, tests on preproduction components	90%	Visual assesment, regular upkeep
21	Helmet	Cracks due to impact	Reduced safety and potential injury for user	10	Drop, crash	N/A	V	FEA, impact testing, structural analysis	FEA, material analysis	100%	Visual assesment/inspection, replace after damaged
22	Helmet	Cracks due to changes in temperature, pressure, humidity etc.	Reduced safety for user, does not meet regs	9	Inadequate material, extreme exposure	<1	V	FEA, environment analysis/regulation	Material testing, material compatibility testing	100%	Avoid extreme exposure to the elements for extended periods of time

Voice of the Customer

Characteristic 1 - Innovation
Similar products currently on the market require the use of a helmet in conjunction with a small screen. Our ideal product provides seamless connection between field of vision and additional features (current speed, messages, maps, audio controls, etc.)

- As a Product V (PV) user I want a seamless connection between field of vision (real world) and the digital platform features (augmented)
- As a PV user I want the augmented presentation to be viewable in all light conditions
- As a PV user I want the augmented presentation to be contextual to my riding conditions
- As a PV user I want the helmet to be visually appealingAs a PV user I want a completely transparent visor that is void of gridding effects

Characteristic 2 - Safety
By seamlessly integrating vehicle controls into field of vision:

- As a PV user I want the augmented presentation to not distract my activity experience
- As a PV user I want the platform to allow for limited interaction with it while in motion
- As a PV user I want the helmet to achieve safety compliance ratings of domestic and international standards
- As a PV user I want the ergonomics of the helmet to not be a detriment
- As a PV user I want the quality of the visor and helmet to be of a high standard

Characteristic 3 - Cost

- As a PV user I want to spend a reasonable amount for the helmet (subjective)
- As a PV user I want maintenance or replacement of components to be of reasonable cost

Characteristic 4 - Interactions

- As a PV user I want to be able to easily interact with the Visor interface (intuitive)
- As a PV user I want the product to have a reasonable battery life (subjective)
- As a PV user I want the battery to be chargeable through an industry-standard charging interface
- As a PV user I want the augmented platform features to be easily read
- As a PV user I want to be able to integrate my mobile device with the platform
- As a PV user I want my interaction experience free of bugs (software defects)

System Requirement Specifications

Functional Requirements

Requirement 1.1.0 - Visor Usage - General
The visor must be able to seamlessly integrate vehicle controls into the field of vision - visuals are not affected by light intensity or riding conditions. Visor visuals should not distract the user.

Requirement 1.2.0 - Helmet - General
PV must meet all government standards for legal motorcycle helmets.

Requirement 1.3.0 - User Interface - General
User interface should be (touch/audio) controlled. Battery life should be reasonable.

Physical Requirements

Speed, strength, weight, size – TBD

Response times – TBD

Limits of Operation

Requirement 2.4.0 - Operation Limitations - General
PV should not be able to accept user interaction below a TBD speed

Safety

Requirement 2.5.0 - Safety - General
PV must meet FMVSS 218 (DOT) Requirements

Requirement 2.5.1 - Safety - General
PV must meet BSI 6658-85 Type A Requirements

Requirement 2.5.2 - Safety - General
PV must meet EN 22/05 Requirements

Requirement 2.5.3 - Safety - General
PV must meet SNELL M2020 Requirements

Reliability

Requirement 2.6.0 - Reliability - General
PV must be reliable under normal usage and proper care.

Requirement 2.6.1 - Reliability - Connections
PV must quickly and reliably connect to a mobile device.

Requirement 2.6.2 - Reliability - Visor
PV visor hinge must move smoothly and visor must be scratch resistant

Computing Hardware

Requirement 2.7.0 - Hardware - General
PV hardware must be able to make use of minimal memory

Requirement 2.7.1 - Hardware - General
PV hardware must be able to maintain low power requirements to allow for extended battery life

Interface Requirements

Requirement 2.7.0 - Interface - Usability
PV user interaction must be smooth, easy, and intuitive.

Requirement 2.7.1 - Interface - Display
PV interface display must clearly show text

Requirement 2.7.2 - Interface - Charging
PV charging must be easy and with and industry standard cable.

Requirement 2.7.3 - Interface - Connections
PV must be able to communicate and sync with mobile devices

Software

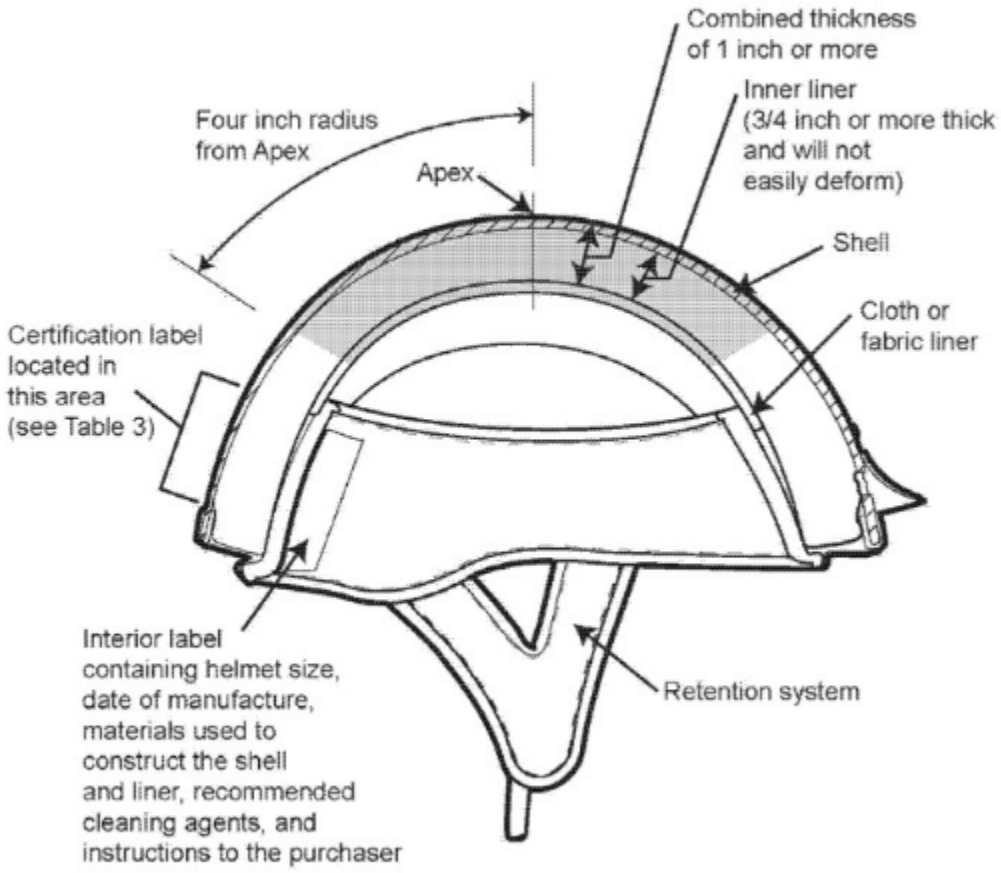
Requirement 2.8.0 - Software - General
PV software development efforts must apply best practices as to mitigate software defects

Requirement 2.8.1 - Software - General
PV software development must be done in a low-level language to accommodate for memory management in an embedded environment

Requirement 2.8.2 - Software - Platform
PV software platform development must be built with extensibility as the top priority

System Architecture

The visor is layered with a thin OLED screen. Visor and helmet design are being developed. Touch sensors are integrated into the helmet to allow the user to control features.



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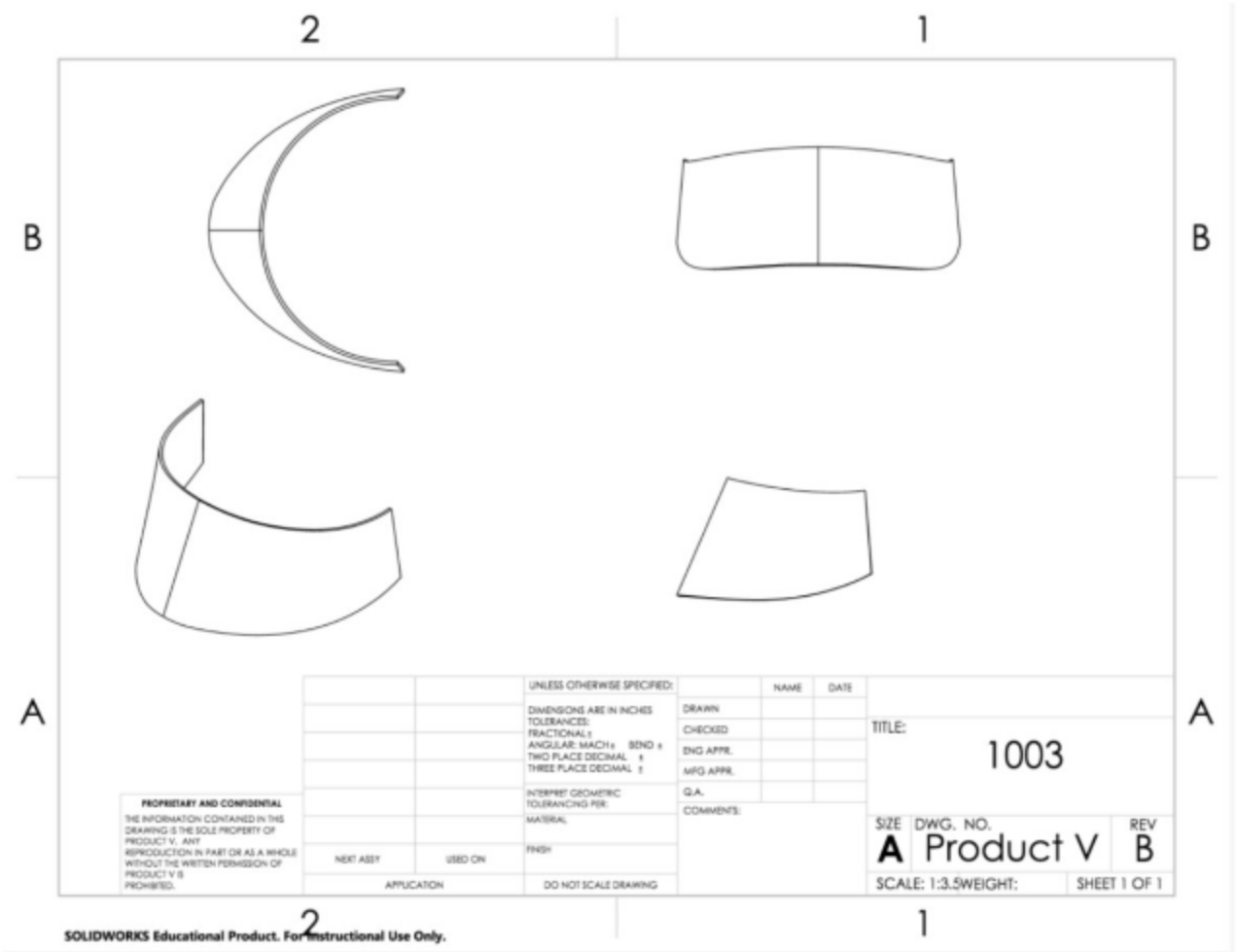


Design Plan

Inputs

- Research into the target customer segment will drive development of overall product and features.
- Funding will be sourced from the Harold Frank Engineering Entrepreneurship Institute.

Business Constraints and Timelines

- Budget will be determined for the initial stage by the involved parties. Funding will drive project to the next stage.
- Business model will be developed. Marketing team will start advertising product for additional funding.
- Begin obtaining IP.
- Contact with distributors.
- R&D will recommend steps moving forward:
  - Potential technologies for seamless visor integration
  - Summary of touch screen sensors
  - Safety assessment of visor and helmet design through stress and strain analysis and impact testing.

Overall Product Goal

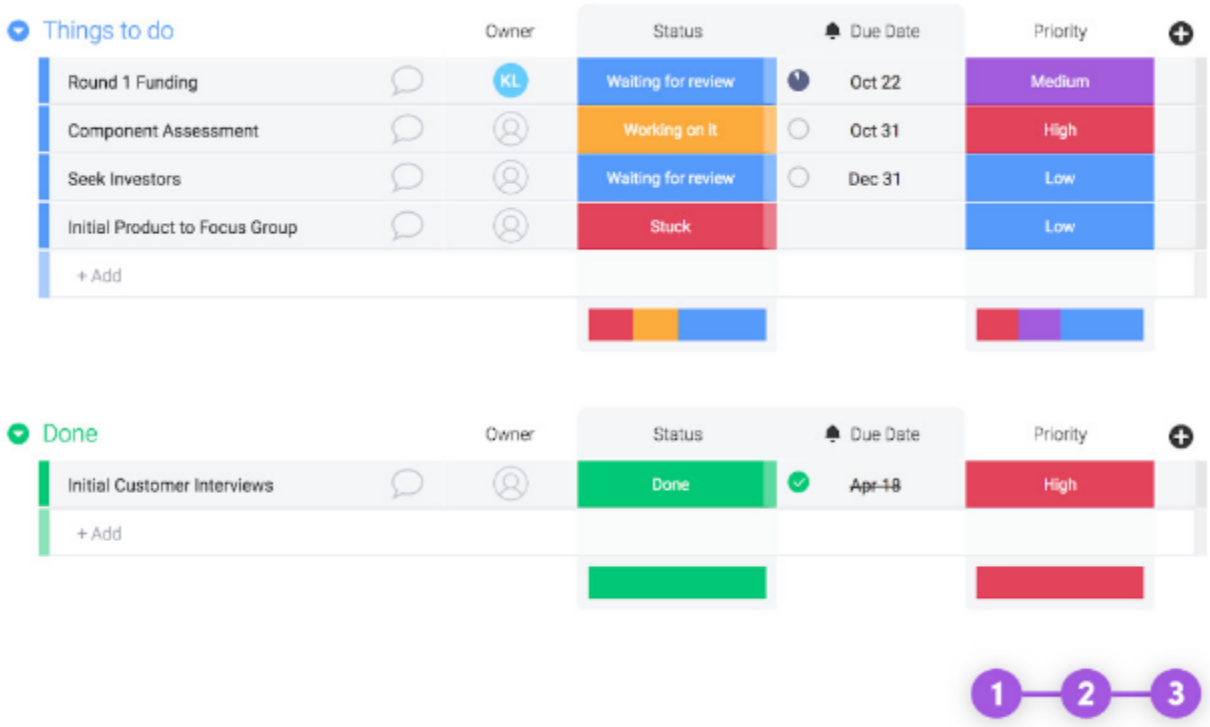
Provide a product that enhances user experience and safety in extreme sports.

Stage 1

Input: $500 - Output: assessment of desired features and necessary components

- Marketing team will provide initial survey of target customer segment
  - Prepare a presentation detailing needs and gains for potential investors
  - Bring assessment of components back to a focus group for analysis
- R&D team will assess components
  - Provide a detailed summary of all necessary features and options for components needed to successfully integrate necessary features
- Financial team will advertise to investors
  - Find funding to move to Stage 2
- Management will oversee all processes and advise steps moving forward
  - Will require formal review board of founders and investors

Gantt Chart - Pre Stage 1



Testing Specifications

Requirement 3.1.0 - Minimum thickness of impact attenuating liner
Impact attenuating liner must have an average thickness of at least 32.3mm, where the average is calculated from the lowest thickness measured to the highest.
Req 3.1.0 - $t > 32.3$ mm

Requirement 3.2.0 - Minimum overall thickness from inside of the inner liner to outer shell
The thickness from the inside of the inner liner to outer shell must be at least 37.8mm thick.
Req 3.2.0 - $t > 37.8$mm

Requirement 3.3.0 - Minimum overall thickness of shell, inner liner, and comfort liner uncompressed
The thickness from the inside of the inner liner to outer shell must be at least 46.2mm thick.
Req 3.3.0 - $t > 46.2$mm

Requirement 3.4.0 - Maximum compression of shell, inner liner, and comfort liner under load
Shell, inner liner, and comfort liner under 22N compressive load must not exceed 3.1 mm change in thickness.
Req 3.4.0 - $\delta < 3.1$ mm - $P = 22$ N

Requirement 3.5.0 - Maintain Internal Temperature when Exposed to Heat
Helmet internal temperature must not exceed 70 degrees C when exposed to 790 degrees C propane torch being moved < 8 inches away over the visor, shell, and chinstrap, for 90 seconds.
Req 3.5.0 - $T_{torch} = 790$ C, $T_{max} = 70$ C, time = 90 s, distance < 8 in,

Testing Validation

Maximum Compression of Shell, Inner Liner, and Comfort Liner Under Load
Testing Protocol: Instron 3340 Series Universal Testing Systems up to 5 kN (1,125 lbf) Force Capacity

The helmet should be able to withstand compressive testing. Complete thickness allows for 3.1 mm deformation, inner lining allows for 1.0 mm of deformation.

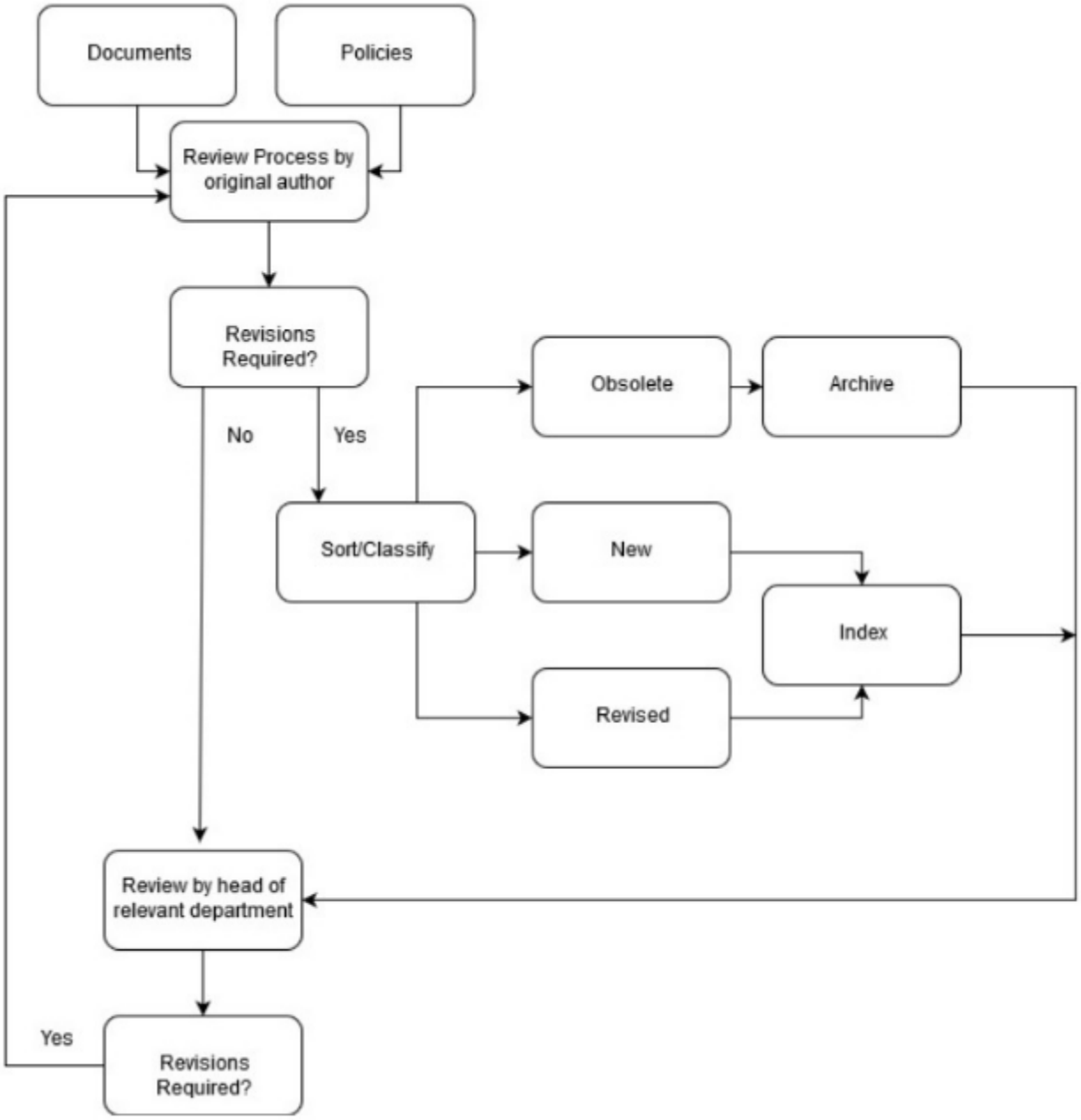
Compressive testing with Instron machine allows for measurements of deformation. These measurements can be used in conjunction with guidelines in Product V's FMEA matrix to determine pass or fail for each specification.

Heat Verification and Validity of Proposed Materials
Testing protocol: Propane torch up to 790 degrees Celsius

The helmet should be able to withstand heat at extreme variability. Material validity allows for ensured safety of the user.

Heat testing with propane torch allows for validation of heat blocking. These measurements can be used in conjunction with guidelines in Product V's FMEA matrix to determine pass or fail for each specification.

Document Control Process



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#5	Product Release Procedure	KL	10/29/19	DHF
#6	Product Mockup v1	JF	9/4/19	DHF
#7	Product Mockup v2	JF	9/18/19	DHF
#8	FMEA Draft #1	JF	10/14/19	DMR

Design History File

This is a compilation of the records that describe the history of the design of a finished product.

The official DHR includes the following sections of files and documents:

Design Planning
- Design Plans
- Sketches, drawings, photos

Design Inputs
- Product Specifications
- Component Specifications

Design Outputs
- Labeling and packaging specifications
  - Packaging methods
  - Instructions for use
- Production Specifications
  - Equipment specifications
  - Production methods & procedures
- Risk analysis results

Design Review
- FMEA
- Acceptance Criteria
- Materials Testing
- Documentation of verification activities

Design Validation
- Validation repo

Design Changes
- History of documented revisions
- Change control procedures

Memo - Example Document

To RO Ramadan, Aaron Oliver FJ Fraction, Jamar Bcc

Cc

Customer Segment Expansion

All,

Currently, our target customer segment is motorcyclists looking to improve safety while riding. Product V may be used recreationally in other forms of extreme sports. Our marketing team is actively focusing on assessing viability in snow sports. In the future it may be possible to expand even farther into use by the military and other types of first responders.

Thanks,
Katie M. Lober
509-942-9681 | Kathryn.Lober@wsu.edu | LinkedIn: https://www.linkedin.com/in/katie-lober/
Washington State University Bioengineering | Honors | Pre-med | 2020
Undergraduate Researcher Gene and Linda Voiland School of Chemical and Biological Engineering | Kinesiology
Vice President Biomedical Engineering Society
Director of Internal Affairs Frank Scholars Society

Send Discard Draft saved at 8:35 PM

Meeting Minutes - Example Document

190904 - Example Document Meeting Minutes_____

In Attendance:

Jamar Fraction, Aaron Ramdan, Katie Lober

Agenda

- Introduction - Jamar
- Updates - Aaron, Katie, Jamar
- Discussion with Questions
- Assignments

Notes

- Katie: Ergonomic involvement - shape, weight, where to place things on the display
- Aaron: Hinge design, choosing materials, creating real mockup, communicable to providers
- Jamar wants to purchase generic visors for inspiration - shipped to aaron to be put into 3-D model.
    - Would need a 3-D scanner, better off trying to find a CAD file online and modifying it.
    - Possibly 3-D printing samples
    - Only requirement is that it be curved for aerodynamic optimization
    - Make visor and fit helmet to that shape.
    - Take a look at the necessary field of view
    - Finish the model by next week; maybe do it from scratch - Aaron
- Google patent search and official patent search - only old patents for projection
- Touching base with patent lawyers - Katie
- Names - everybody brainstorm some ideas for next week
    - VisionARy
- Came up with a solution before a problem
    - Agree that it is limiting
    - Easiest entrance point is through action sports
    - Don't see the helmet as the extent of application
    - Finding places to launch product is very important - CA, AZ, FL, etc.
        - Places where it's warm
        - Age range: 28-50 because additional value comes through safety. Not just cool technology.
        - Safety aspect will be a big safety aspect - F150 ford commercial that uses projection on the windshield for the gages
- Team contract and discuss titles and ownership between founders

Document Filing

Document Creation

Documents are created within the company by employees, suppliers, or customers. All documents fall under NDA. Company documents include all bodies of writing that includes the title Product V or any IP belonging to Product V regardless of when or where the document is produced.

Document Review and Approval

Documents must be approved up the chain of command; the head of a department must approve documents for official review. The author and the head of the department of interest must agree on initial revisions before sending the document to the Document Review Board.

The document in question will then be read through by the Document Review Board. The Document Review Board is composed of at least one founder, one stakeholder, and one project manager outside of the department where the document originated. The Document Review Board may suggest revisions.

Document Revisions

Document revisions suggested by the Document Review Board must be tended to by the author within one week of initiation. From there the document must be approved by one member of the Document Review Board for publishing.

Document Publishing

Documents may be published to the database by the author after official approval after following document filing procedure.

For Obsolete Documents

Obsolete documents will be archived and held for at least ten years. A document may be ruled obsolete only after approval by all three founders.

Supplier Qualifications

Suppliers are defined as an entity that provides either a suitable good or a qualified service to Product V.

All suppliers are subject to NDA.

Product V may agree to partnerships after extensive work with specific suppliers. Partners of Product V may benefit from substantial sales and purchases.

Verification Protocol
Buyers must request company details and create a company profile for approval. Company profile must include the company in question's latest financial statement, an organizational chart, a product process flow chart, and machinery list with capacity. Buyers must also assess reliability of shipping, packaging, and product.

After approval of company profile, buyers may request a quote and product samples with specifications.

Validation Protocol
Samples and initial product will be handed over to R&D QA for initial testing and evaluation.

Product V's quality assurance team is responsible for validating all goods and services from external suppliers. These may include but are not limited to: compression testing, drop testing, impact testing, durability testing, finite element analysis, reliability, etc.

It is the job of Product V's quality assurance team to ensure that all product from suppliers conforms to regulations outlined in Product V's FMEA.

Each product sample will be subject to an individualized series of tests before Product V will move forward with official purchases for production.

Product Release Procedure

Storage Requirements and Specifications

Product V is strictly confidential. All assembly and product information is property of the company. Only employees with key card access will be allowed onto the factory floor.

No unsold stock is to leave the factory floor unless there is unanimous approval by founders. This may be the case for meetings with investors, special marketing campaigns, and promotional events.

Missing stock will result in an in depth investigation.

Defective Equipment Procedure

Product V will be assessed by QA before leaving manufacturing facility for shipment.

Product V will be deemed defective if it fails testing and validation specifications outlined in Product V FMEA.

When a sample of Product V is defective, it will be sent back to R&D for analysis. Once a failed component is isolated, R&D will contact receiving. Receiving will ultimately decide whether or not the failed component was fault of the supplier. Based off of this decision, two paths may be taken.

Supplier Fault: Supplier will be contacted for replacement. If the supplier is unable to produce replacement, it is possible that the supplier in question will lose contract with Product V.

Component Failure: Receiving will contact R&D. R&D will perform production analysis to define point of failure during assembly. Actions will be taken to streamline production.

Packaging Specifications
Amount of product ordered and distance being travelled will determine what packaging and shipping method should be used.

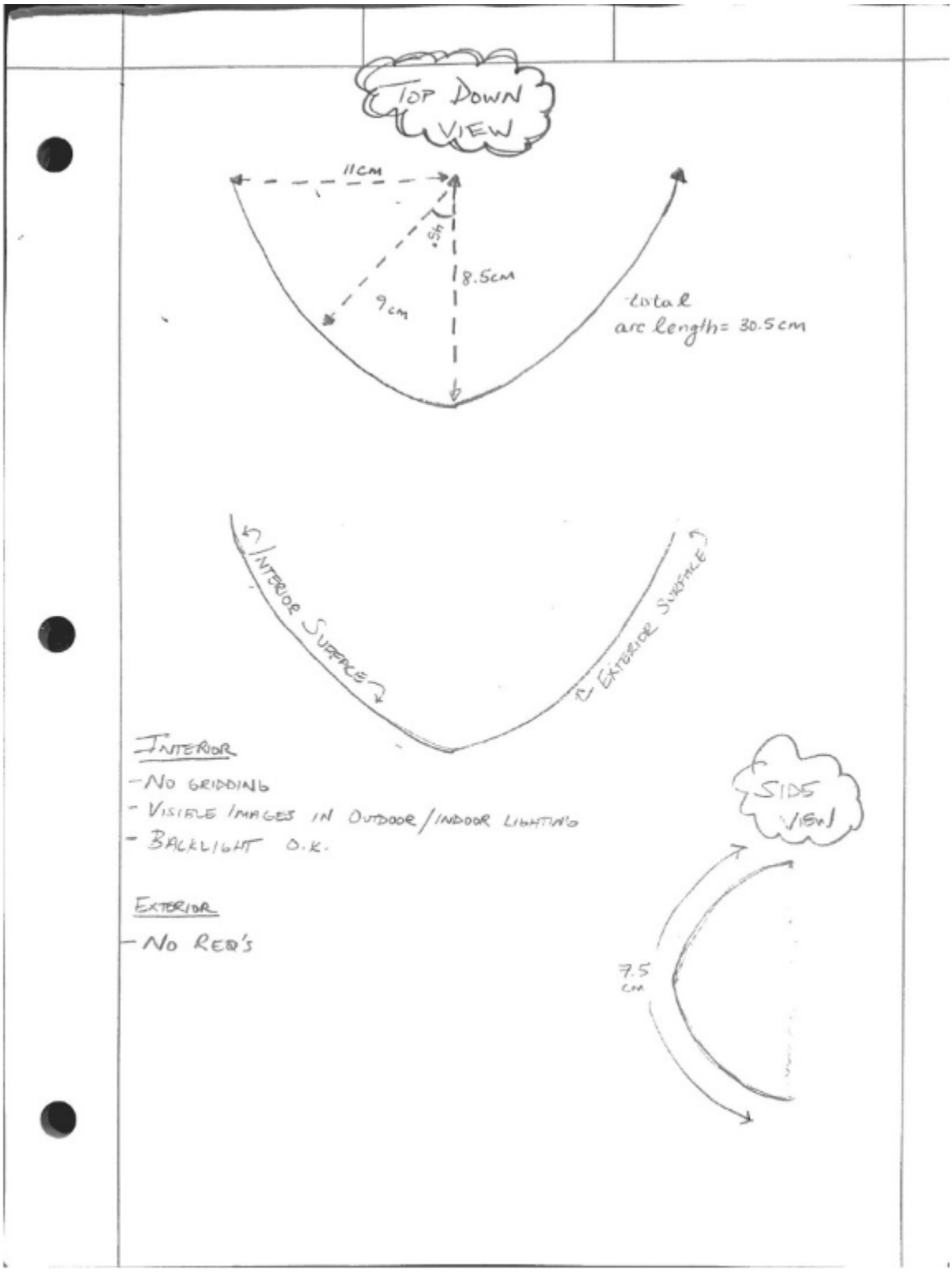
Appropriate material must be used in shipping to ensure Product V integrity: bubble wrap, air pillow, etc.

Once appropriately packaged, shipping containers will be branded with designs designated by marketing team.

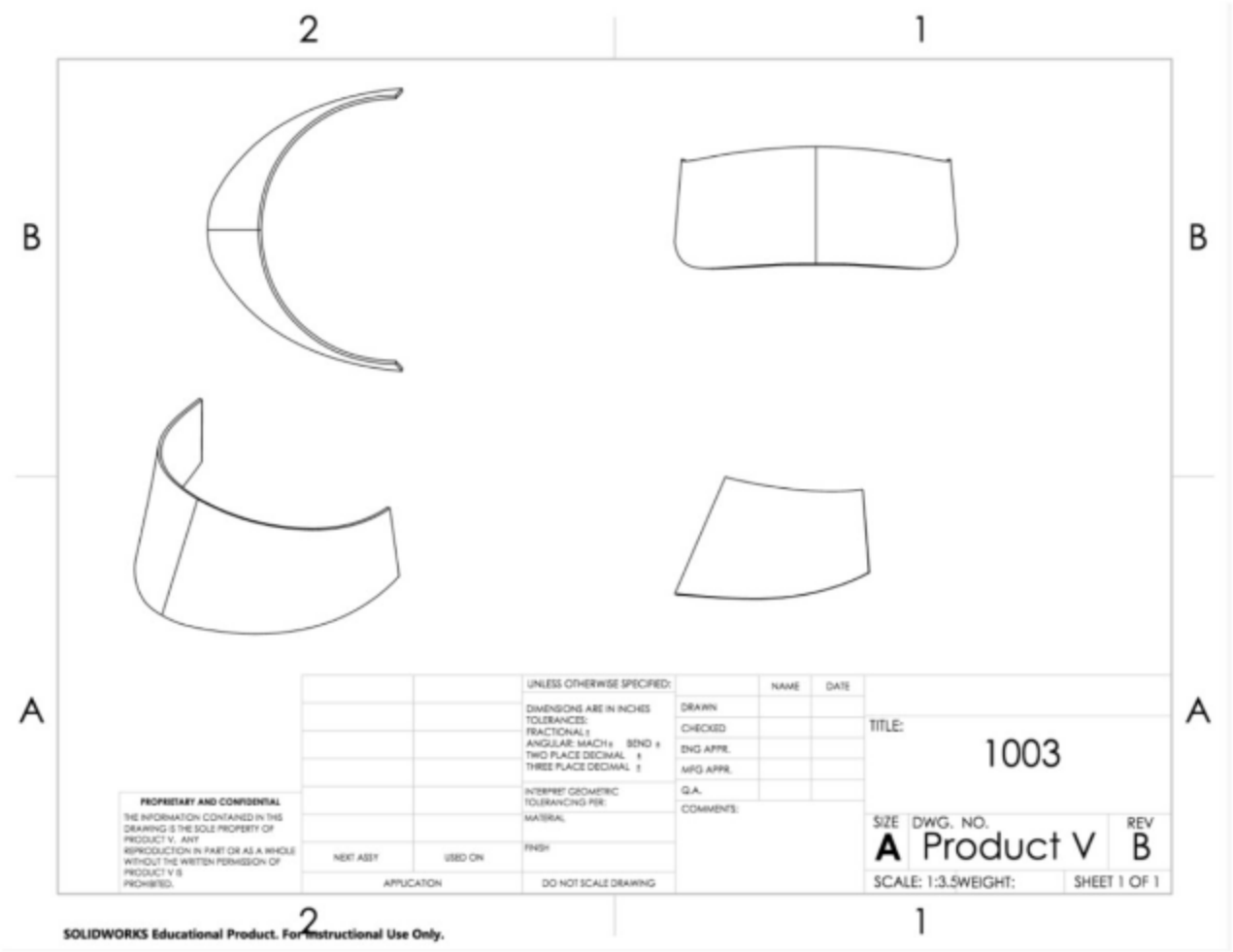
Labels should clearly list the product name, customer information, customer support contact information, identification number, etc.

All shipments will be documented fully.

Document 1 - Product Mockup V1



Document 2 - Product Mockup V2



Device History Record

The Device History Record contains all of the production information related to Product V. The DHR traces each unit through the production and packaging process to demonstrate that our products are manufactured in accordance with our Device Master Record.

The Device History Record contains the following:

- Date of manufacture
- Quantity manufactured
- Quantity released for distribution
- Acceptance records that prove the device is manufactured in accordance with the DMR
- Primary identification and labeling for each production unit
- Any device identification and control number used

Device Master Record

This record contains all procedures and specifications for a finished Product V.

Compilation of Records containing the procedures and specifications for a finished device. Contains reference to locations of documents for manufacturing and processing activities. Also contains information on the design turn, specifications, complete manufacturing procedures, quality assurance requirements, acceptance criteria, packaging, and labeling.

The Device Master Record contains the following:

- Device specifications
- Drawing / physical characteristic diagrams
- Material specifications
- User safety characteristic
- Component drawings
- Manufacturing procedures
- Test specifications
- Test procedures
- Employee training procedures
- System audit procedures
- Standard Operating Procedures (SOPs)

Technical Documentation File

The Technical documentation file (TDF) is a subset of the Device Master Record that includes the following documents:

- Product description
- Intended use
- Labeling
- Product specifications
- Parts list
- Component drawings
- Material specifications
- List of applicable standards
- Instructions for use
- Product verifications
- Testing Data and reports
- Verifications testing data and reports
- Functionality testing
- Risk analysis
- Process and production calibration specifications
- Warnings
- FMEA analysis

Financials

10 year projection assuming a one million dollar investment in year 0.

Additional assumptions include: at year 6, cost of production decreases 12.5%

sales model by year	0	1	2	3	4	5	6	7	8	9	10
N sales	0	250	500	1000	2000	2000	2000	2000	2000	2000	2000
Price	2,500	2,500	2,500	2,500	2,500	2,500	2,500	2,500	2,500	2,500	2,500
Gross Revenue	0	625000	1250000	2500000	5000000	5000000	5000000	5000000	5000000	5000000	5000000
total COGS by year	0	212500	425000	825000	1600000	1600000	1400000	1400000	1400000	1400000	1400000
fixed costs	0	256250	256250	300000	300000	300000	500000	550000	600000	650000	700000
net revenue	0	156250	568750	1375000	3100000	3100000	3100000	3050000	3000000	2950000	2900000
cash flows	-1,000,000	-843,750	-275,000	1,100,000	4,200,000	7,300,000	10,400,000	13,450,000	16,450,000	19,400,000	22,300,000
R&D Investment	1,000,000										
Total ROI	22.3										
AROI	0.3700473976										
Discount Cost of Money	8%										
NPV	$46,513,664.67										
IRR	85%										

Assumptions
$1mil investment at year 0
discount per unit of 3% at 1000 units
discount per unit of 3% at 2000 units
at year 6, the cost of production will decrease 12.5%