

# Requirement related Failures

*Requirements Development and Management Service*

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# Failures...





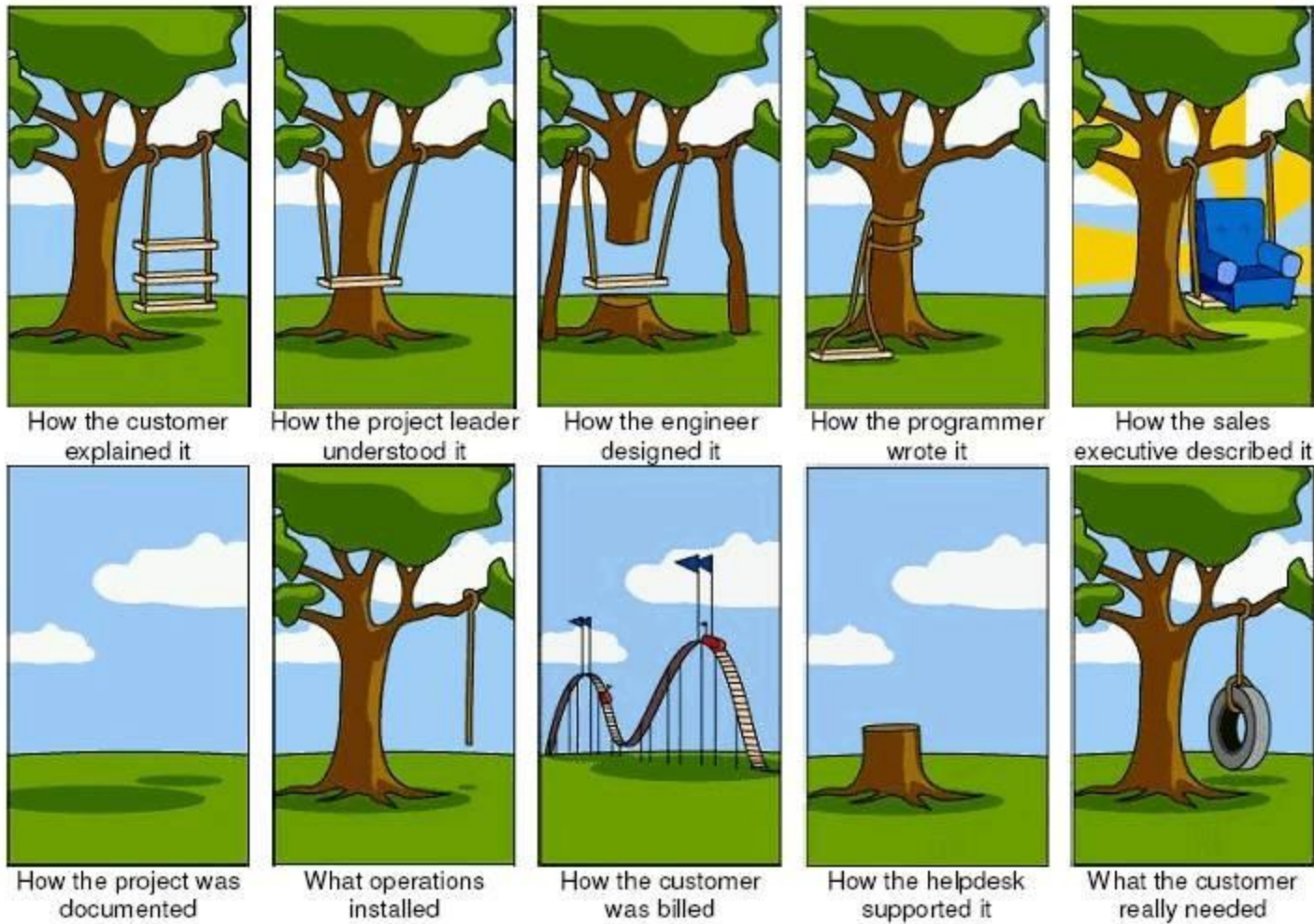
[www.macasev-margins.blogspot.com](http://www.macasev-margins.blogspot.com)

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# Requirements from....



# What communication lead to.....



# Mind Reading?



# MODEL CALCULATIONS

## "Garbage In-garbage Out" Paradigm



# Good Investment



Fig.1 Why getting requirements right is critical



# 10 Requirements to Good Requirement

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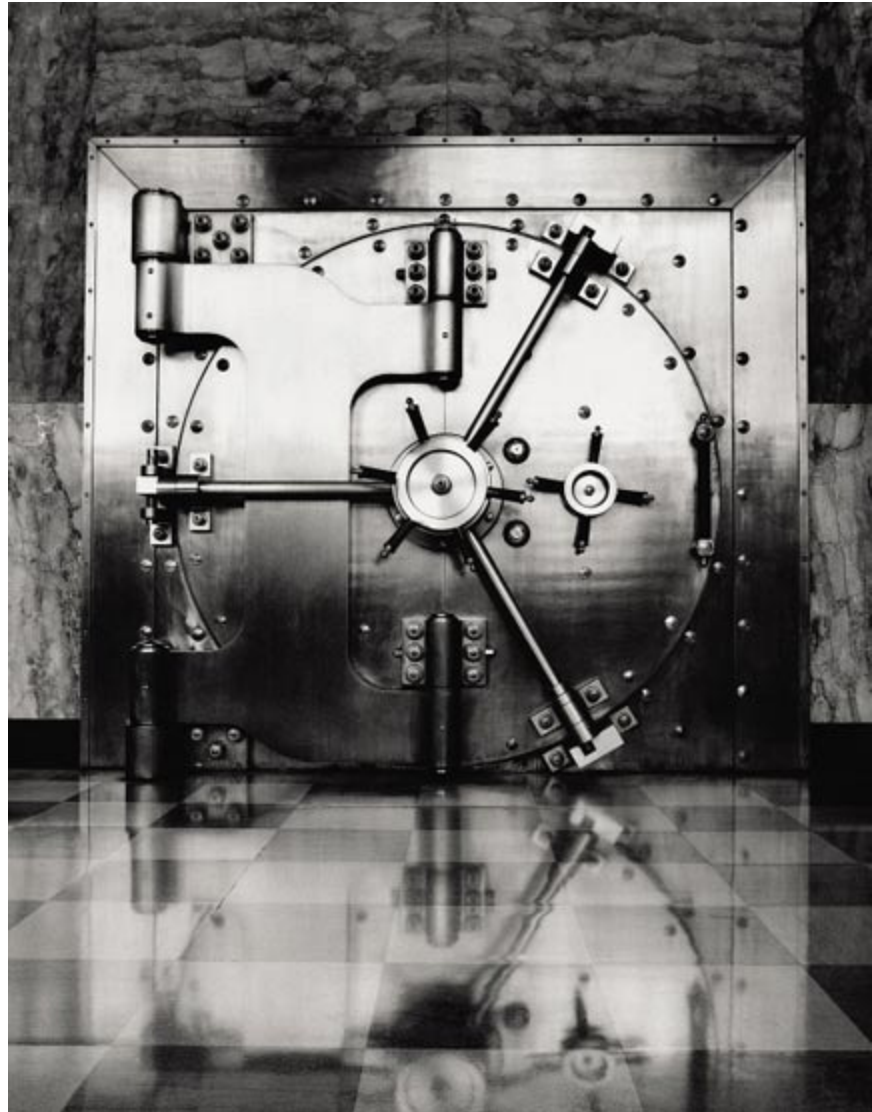
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# 10 Requirements

1. **Source of Trust**
2. **Process, Process, Process**
3. **Trained People**
4. **Right Stakeholders**
5. **Definition of Good Requirement**
6. **Verification & Validation**
7. **Role & Responsibility**
8. **Traceability**
9. **Standard Templates**
10. **Right Way to Document**

## Source of Trust

- Email?
- File?
- Home Grown System?
- Whiteboard?
- Sticky Note?



# Process, Process, Process



# Trained People



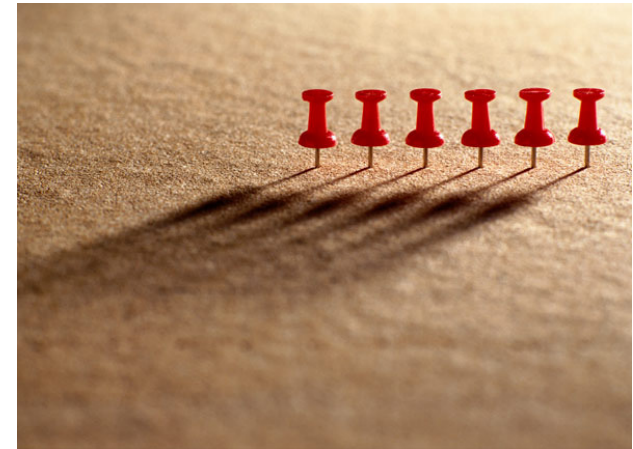
- **Business Know how**
- **Communication Skill**
- **Documentation Skill**
- **Know the process**
- **etc**

# Right Stakeholders



## Definition of Good Requirement

- **Clear, concise, unambiguous**
- **Grammatically correct**
- **Positive statements**
- **Needed**
- **Verifiable**
- **Attainable – technically, cost, schedule**
- **Include rationale**
- **Well organized**



# Verification & Validation

- **Validation – Do the Right Thing**
- **Verification – Do the Thing Right**





# Role & Responsibility

**Roles**

			
<p><b>Foreman</b> This Knight will use their Politics to help build your city more quickly.</p>	<p><b>Marshal</b> This Knight will use their Combat to help quicken the training of your troops.</p>	<p><b>Alchemystic</b> This Knight will use their Intelligence to help run your Alchemist Lab.</p>	<p><b>Steward</b> This Knight will use their Resourcefulness to improve your Resource</p>

# Traceability

## User Reqts

1. 820.300 Design and Development Planning
  - Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation.
  - The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process.
  - The plans shall be reviewed as design and development evolves.
  - The plans shall be updated as design and development evolves.
2. 820.300 Design Input
  - 2.1. Each manufacturer shall establish procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient.
  - 2.2. Each manufacturer shall maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient.
  - 2.3. The procedures shall include a mechanism for addressing incomplete requirements.
  - 2.4. The procedures shall include a mechanism for addressing ambiguous requirements.
  - 2.5. The procedures shall include a mechanism for addressing conflicting requirements.
  - 2.6. The design input requirements shall be documented by a designated individual(s).
  - 2.7. The design input requirements shall be reviewed by a designated individual(s).
  - 2.8. The design input requirements shall be approved by a designated individual(s).
  - 2.9. The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.
- 2.10. Questions
  - 2.10.1. Summarize the manufacturer's written procedure(s) for identification and control of design input.
  - 2.10.2. From what sources are design inputs sought?
  - 2.10.3. Do design input procedures cover the relevant aspects, such as: (Mark all that apply and list additional aspects.)
    - 2.10.3.1. intended use
    - 2.10.3.2. user/patient/clinical
    - 2.10.3.3. performance characteristics
    - 2.10.3.4. safety
    - 2.10.3.5. limits and tolerances
    - 2.10.3.6. risk analysis
    - 2.10.3.7. toxicity and biocompatibility
    - 2.10.3.8. electromagnetic compatibility (EMC)
    - 2.10.3.9. compatibility with accessories/auxiliary devices
    - 2.10.3.10. compatibility with the environment of intended use
    - 2.10.3.11. human factors
    - 2.10.3.12. physical/chemical characteristics
    - 2.10.3.13. labeling/packaging
    - 2.10.3.14. reliability
    - 2.10.3.15. statutory and regulatory requirements
    - 2.10.3.16. voluntary standards
    - 2.10.3.17. manufacturing processes
    - 2.10.3.18. sterility
    - 2.10.3.19. MR/compatibility/failures and other historical data
    - 2.10.3.20. design history files (DHF)
  - 2.10.4. For the specific design covered, how were the design input requirements identified for selection?
  - 2.10.5. For the specific design covered, how were the design input requirements reviewed for adequacy?

## Technical Reqts

- Comply with FDA Design Control Guidance GMP Regulation
1. Capture design and related information
    - 1.1. Input electronically formatted data
    - 1.2. Reference external information sources
    - 1.3. Reference external documentation
  2. Store design and related information
    - 2.1. Organize requirements
      - 2.2.1. Organize by Design Control Guidance Element
      - 2.2.2. Organize by user relationships
    - 2.3. Ensure all design elements are available
    - 2.3.1. Store design elements by Design Control Guidance Element
    - 2.3.2. Store design elements and their historical values
  3. Manage all user needs
    - 3.1. Identify the source of the user need
    - 3.2. Identify all user types (groups)
    - 3.3. Identify the customer (s)
    - 3.4. Profile the expected patterns
    - 3.5. Define the expected use cases
    - 3.6. Define the acceptance criteria for each user need
  4. Manage design input requirements
    - 4.1. Identify the source of the requirement
    - 4.2. Identify the associated user need
    - 4.3. Capture requirement description and attributes
    - 4.4. Capture acceptance criteria
    - 4.5. Assign responsibility for each requirement
    - 4.6. Manage incomplete requirements
    - 4.7. Manage ambiguous requirements
    - 4.8. Manage conflicting requirements
    - 4.9. Approve all requirements
  5. Manage acceptance
    - 5.1. Ensure the acceptance of every user need
    - 5.2. Ensure the acceptance of every design input requirement
    - 5.3. Document the results of every user need acceptance test
    - 5.4. Document the results of every design input requirements test
    - 5.5. Make acceptance results available
  6. Manage change
    - 6.1. Maintain history of design element changes
      - 6.1.1. Make complete change history available
      - 6.1.2. Maintain history within and across any organizational procedure
      - 6.1.3. Maintain history within and across any project milestone
      - 6.1.4. Maintain history within and across any Design Control Guidance Element
    - 6.2. Capture frequency and nature of element changes
      - 6.2.1. Provide rationale for change
      - 6.2.2. Describe decisions made
      - 6.2.3. Identify approval authority for the change
      - 6.2.4. Capture date, time, and signature of approving authority
    - 6.3. Create tracked design elements
      - 6.3.1. Create tracked design elements within and across any organizational procedure
      - 6.3.2. Create backward traces to design elements within and across any project milestone

## Design

- 1.1. Identify impacted elements due to a change in another element
  - Traceability Reports: consistency with driving design elements
  - Impact Reports: other design elements affected
  - Links to impacted design elements
- 1.1.1. Create backward traces to design elements within and across any organizational procedure
  - Traceability Reports: Procedure Attribute
- 1.1.2. Create backward traces to design elements within and across any project milestone
  - Traceability Reports: Milestone Attribute
- 1.1.3. Create backward traces to design elements within and across Design Control Guidance Elements
  - Traceability Reports: Linked design elements
- 1.1.4. Create forward impacts to design elements within and across any organizational procedure
  - Impact Reports: Procedure Attribute
- 1.1.5. Create forward impacts to design elements within and across any project milestone
  - Impact Reports: Milestone Attribute
- 1.1.6. Create forward impacts to design elements within and across Design Control Guidance Elements
  - Impact Reports: Linked design elements
- 1.2. Associate changed design elements with related elements
  - Link Change Design Object with affected design element(s)
  - Traceability Links and Reports from affected design element(s)
  - Impact Links and Reports from affected design element(s)
- 1.2.1. Associate design element changes with decisions, rationale, and approval authority information
  - Change Decision Objects with following Attributes:
    - Disposition Attribute
    - Decision Attribute
    - Rationale Attribute
    - Owner Attribute
    - Management Approval Attribute
- 1.2.2. Provide associations within and across any organizational procedure
  - Change Design Object Traceability Link on Procedure Attribute
  - Change Design Object Impacts Link on Procedure Attribute
- 1.2.3. Provide associations within and across any project milestone
  - Change Design Object Traceability Link on Milestone Attribute
  - Change Design Object Impacts Link on Milestone Attribute
- 1.2.4. Provide associations within and across Design Control Guidance Elements
  - Change Design Object Traceability Link to traced design elements
  - Change Design Object Impacts Link to linked design elements
- 1.3. Manage the change process
  - Design Change Module
  - Design Change Reports
  - Object History
  - Object History Reports
  - Versions
  - Baselines

## Test Cases

- 1.1. Identify impacted elements due to a change in another element
  - Traceability Reports: consistency with driving design elements
  - Impact Reports: other design elements affected
  - Links to impacted design elements
- 1.1.1. Create backward traces to design elements within and across any organizational procedure
  - Traceability Reports: Procedure Attribute
- 1.1.2. Create backward traces to design elements within and across any project milestone
  - Traceability Reports: Milestone Attribute
- 1.1.3. Create backward traces to design elements within and across Design Control Guidance Elements
  - Traceability Reports: Linked design elements
- 1.1.4. Create forward impacts to design elements within and across any organizational procedure
  - Impact Reports: Procedure Attribute
- 1.1.5. Create forward impacts to design elements within and across any project milestone
  - Impact Reports: Milestone Attribute
- 1.1.6. Create forward impacts to design elements within and across Design Control Guidance Elements
  - Impact Reports: Linked design elements
2. Associate changed design elements with related elements
  - Link Change Design Object with affected design element(s)
  - Traceability Links and Reports from affected design element(s)
  - Impact Links and Reports from affected design element(s)
- 2.1. Associate design element changes with decisions, rationale, and approval authority information
  - Change Decision Objects with following Attributes:
    - Disposition Attribute
    - Decision Attribute
    - Rationale Attribute
    - Owner Attribute
    - Management Approval Attribute
- 2.2. Provide associations within and across any organizational procedure
  - Change Design Object Traceability Link on Procedure Attribute
  - Change Design Object Impacts Link on Procedure Attribute
- 2.3. Provide associations within and across any project milestone
  - Change Design Object Traceability Link on Milestone Attribute
  - Change Design Object Impacts Link on Milestone Attribute
- 2.4. Provide associations within and across Design Control Guidance Elements
  - Change Design Object Traceability Link to traced design elements
  - Change Design Object Impacts Link to linked design elements
3. Manage the change process
  - Design Change Module
  - Design Change Reports
  - Object History
  - Object History Reports
  - Versions
  - Baselines

# Standard Templates

Project Passed

User Requirements

Version: 4.0  
Printed by: Paul R  
Printed on: 01 Dec

Generated from DO

### Contents

- 1 Introduction
- 1.1 Schedule
- 2 User types
  - 2.1 Nationalities
  - 2.2 User sizes
- 3 Requirements
  - 3.1 Capability Requirements
    - 3.1.1 Carrying Capacity
    - 3.1.1.1 Number of People
    - 3.1.2 Movement
    - 3.1.2.1 Speed and Acceleration
    - 3.1.2.1.1 Backwards
    - 3.1.2.1.2 Forwards
    - 3.1.2.2 Distance
    - 3.1.2.3 Stopping
    - 3.1.3 Fuel economy
    - 3.1.4 Safety
    - 3.1.5 Noise levels
      - 3.1.5.1 Interior
      - 3.1.5.2 Exterior
    - 3.1.6 Ease of Access
      - 3.1.6.1 Access to controls
      - 3.1.6.1.1 Brakes
      - 3.1.6.1.2 Visibility
      - 3.1.6.1.2.1 Daylight
      - 3.1.6.1.2.2 Night time
      - 3.1.6.1.2.3 Weather
      - 3.1.6.1.3 Speed control
      - 3.1.6.1.4 Clutch
      - 3.1.6.1.5 Gears
      - 3.1.7 Equipment mal
      - 3.1.8 Entertainment
      - 3.1.9 Maintenance
      - 3.1.10 Servicing
      - 3.1.11 Indication requirements
      - 3.1.12 Re-fueling
      - 3.2 Constraint Requirements
        - 3.2.1 Construction
        - 3.2.2 Terrain
        - 3.2.3 Availability

Printed from DOORS

### 1 Introduction

#### 1.1 Schedule

This module contains the user requirements for passenger cars as of August 2006. All requirements are subject to change.

### 2 User types

This section describes the nature of the user types.

#### 2.1 Nationalities

The car will be used in the countries of New Zealand, Japan, and the United States.

#### 2.2 User sizes

The car shall be suitable for users with a weight of up to 100 kilograms.

### 3 Requirements

This section contains the user requirements for passenger cars.

#### 3.1 Capability Requirements

##### 3.1.1 Carrying Capacity

###### 3.1.1.1 Number of People

Four average size adults shall be able to travel in comfort for a period of 3 hours.

Height (m)	Number of People
1.3 to 1.5	4
1.5 to 1.8	4
1.8 to 2.0	4

Users shall have easy entry and exit.

The top level of cars are those in the price range \$15,000 to \$30,000 at 1993 prices.

##### 3.1.2 Movement

###### 3.1.2.1 Speed and Acceleration

###### 3.1.2.1.1 Backwards

The car shall be able to move backwards.

###### 3.1.2.1.2 Forwards

Users shall be able to accelerate from 0 to 100 kilometers per hour in less than 10 seconds.

###### 3.1.2.2 Distance

Users shall be able to travel 1000 kilometers without the need for any form of additional fuel.

###### 3.1.2.3 Stopping

Users shall be able to stop safely.

Users shall be able to stop with the vehicle maintaining a straight track over the stopping distance when the steering is maintained to within + or - 10% of a straight line by the user.

###### 3.1.3 Fuel economy

Users shall be able to obtain fuel consumption better than that provided by the 95% of cars built in 1996.

Obj id	User requirements for passenger car	Risk	Budgeted Cost	Actual Cost	System requirements
SOW 360	Follow this internet link to view the market of this car: file:///C:/doos3.1/training/pict.bmp				
SOW 13	<b>3.1 Capability Requirements</b>		2773	197	
SOW 14	3.1.1 Carrying Capacity		224	82	
SOW 15	3.1.1.1 Number of People		224	82	
SOW 17	Four average size adults shall be able to travel in comfort for a period of 3 hours. This level of comfort is defined as being equivalent to the standard of comfort provided by the top 40% of cars produced in 2000.	High	56	56	SR-104 2.14.1.0-1 From: System Requirements The car shall be able to carry 4 average size adults in average comfort for a period of 3 hours. Last change: 11 February 1997
SOW 20	Two average size adults and 3 average size children shall be able to travel in comfort for a period of 3 hours.		59	12	
SOW 21	Users shall have easy entry and exit.	Low	95	3	SR-121 2.14.7.2.0-1 From: System Requirements The car shall be able to accommodate the internal lighting system Last change: 11 February 1997
SOW 18	The top level of cars are those in the price range \$15,000 to \$30,000 at 1993 prices.	Medium	0	0	
SOW 19	Five average size adults shall be able to travel in comfort for a period of 3 hours.	Low	14	14	
SOW 22	3.1.2 Movement		495	115	
SOW 23	3.1.2.1 Speed and Acceleration		203	100	
SOW 24	3.1.2.1.1 Backwards		43	3	

Printed from DOORS

Page 2 of 12

Printed 01 December 1997

Fiscal Year	Idaho	Montana	Oregon	Washington
FY 1992	10,000	15,000	12,000	11,000
FY 1993	12,000	16,000	14,000	13,000
FY 1994	14,000	18,000	16,000	15,000

Page 2 of 6

Printed by Paul Raymond

# Right Way to Document

The image displays four overlapping screenshots from Rational software tools, illustrating a comprehensive documentation workflow:

- Top-Left:** A screenshot of the DOORS (IBM Requirements Management) interface. It shows a table with columns for ID, User Requirements, Functional Requirements, Design, and Test Plan. The 'User Requirements' column contains the text '3.1.1.2.3 Stopping' and 'Users shall be able to safely.' The user name 'Dave Mason' is visible at the bottom.
- Middle-Left:** A screenshot of the 'Requirements Definition Workbench' showing a process flow diagram. The diagram includes a 'Customer' actor, a 'Teller' actor, and a 'Bank' actor. The process starts with 'Need an a/c', followed by 'Fill out application form for opening an a/c', and 'Receive application form'.
- Middle-Right:** Another screenshot of the 'Requirements Definition Workbench' showing a use case diagram. It features a 'Customer' actor connected to a 'Branch Manager' actor, with the diagram titled 'Sales and Service UseCases'.
- Bottom-Right:** A screenshot of a web browser displaying the 'PLURAL' e-commerce website. The site features a navigation bar with 'LEARN', 'SHOP', 'SUPPORT', and 'MY ACCOUNT'. The main content area is titled 'Phones and Devices' and includes a 'Main Promotion' section with various phone categories and prices: 'CAMERA PHONES' (54), 'MUSIC PHONES' (23), 'PDG / SMARTPHONES' (14), 'Refurbished' (00), and 'Pre-paid phones' (00).



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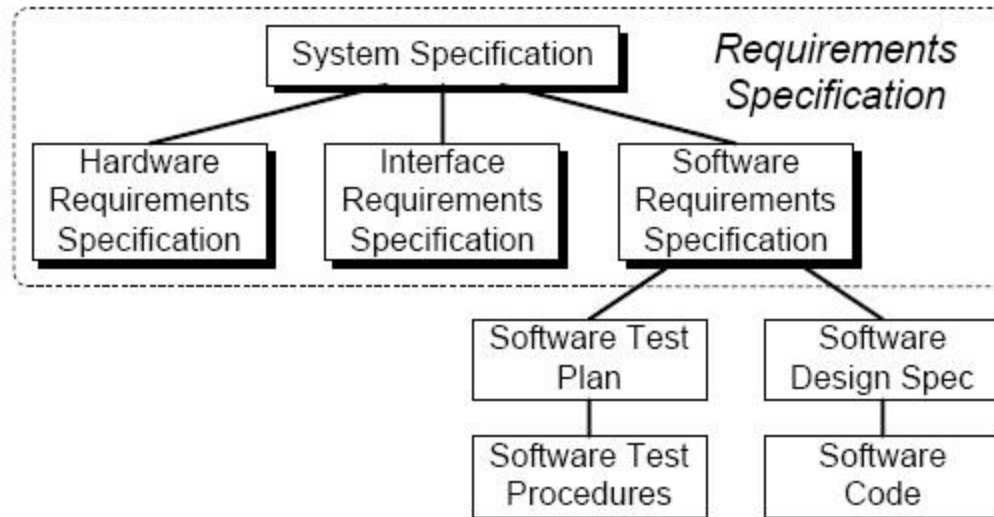


Figure 4-4 Requirements Specification and Follow-on Products



A problem has been detected and windows has been shut down to prevent damage to your computer.

The end-user manually generated the crashdump.

If this is the first time you've seen this Stop error screen, restart your computer. If this screen appears again, follow these steps:

Check to make sure any new hardware or software is properly installed. If this is a new installation, ask your hardware or software manufacturer for any windows updates you might need.

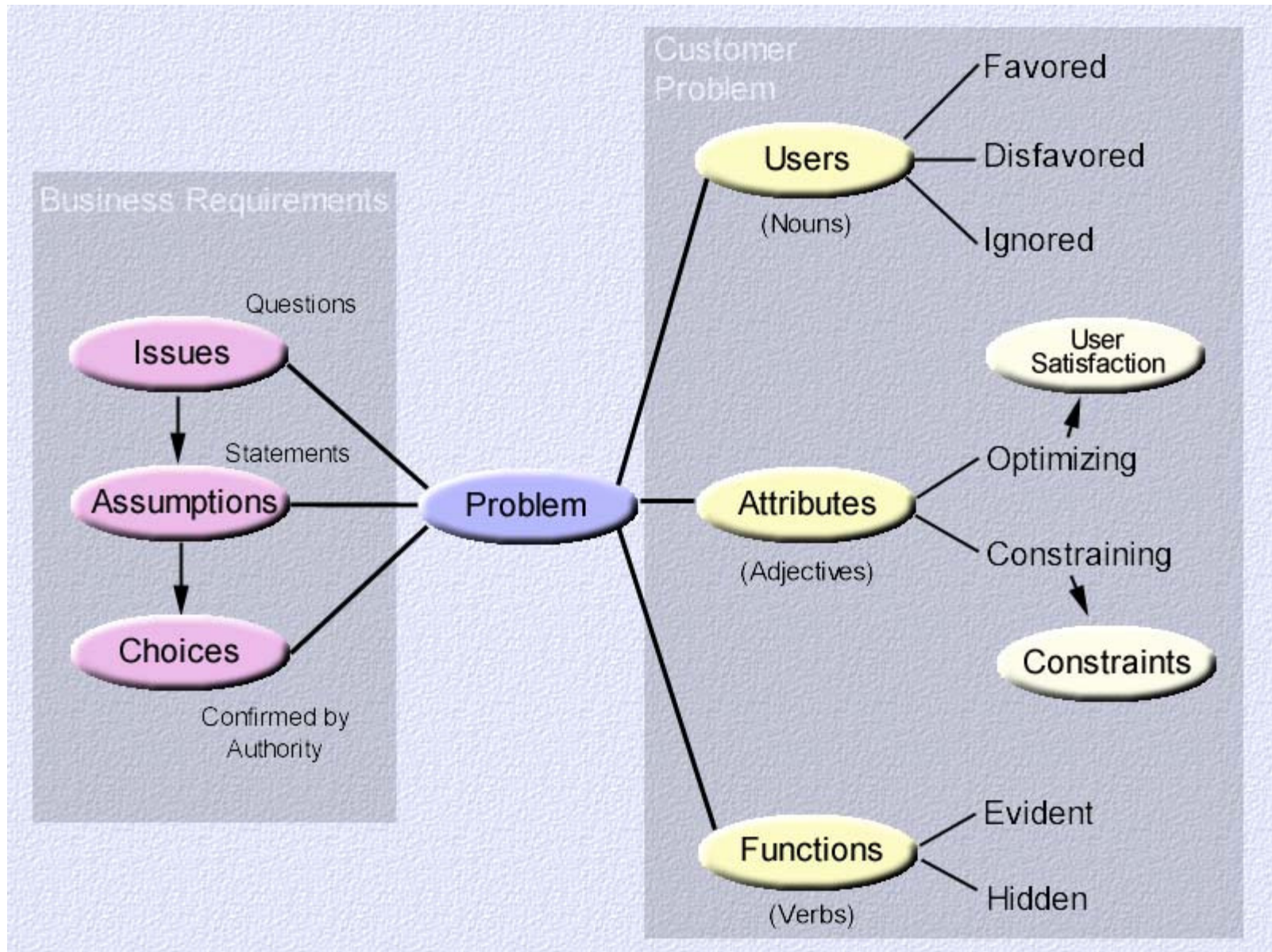
If problems continue, disable or remove any newly installed hardware or software. Disable BIOS memory options such as caching or shadowing. If you need to use Safe Mode to remove or disable components, restart your computer, press F8 to select Advanced Startup options, and then select Safe Mode.

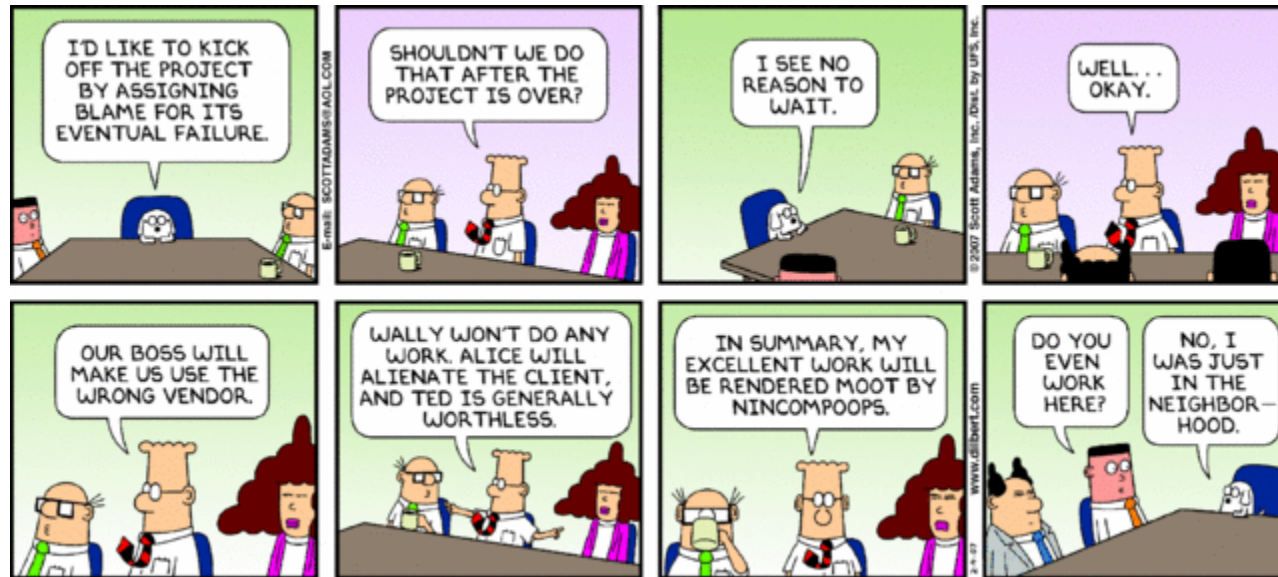
Technical information:

\*\*\* STOP: 0x000000E2 (0x00000000,0x00000000,0x00000000,0x00000000)

Collecting data for crash dump ...  
Initializing disk for crash dump ...  
Beginning dump of physical memory.  
Dumping physical memory to disk: 100  
Physical memory dump complete.  
Contact your system admin or technical support group for further assistance.











# Why do you do Requirements Management?

