<System Name>

This document defines the <system> that is proposed to serve the <organization/department/unit> for the purpose(s) of < >. Implementation of the system is scheduled for <date>. The estimated initial cost of system development is < >.

|  |  |
| --- | --- |
| Written by: |  |
| Version: |  |
| Date: |  |

Version Control:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Version | Date | Scope of Change | Name | Signature | Chapter/Page |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Approval Path:

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Company | Date | Signature |
|  |  |  |  |
|  |  |  |  |

Table of Contents

[1. Goals 2](#_Toc124065735)

[2. Application 3](#_Toc124065736)

[3. Technology and Infrastructure 6](#_Toc124065737)

[4. Implementation 7](#_Toc124065738)

[5. Cost – Resources 9](#_Toc124065739)

# 1. Goals

## 1.0 Overview – Highlights

### 1.0.1 Introduction

### 1.0.2 Document Overview

### 1.0.3 Glossary

## 1.1 Client / Main User

## 1.2 Goals and Objectives

## 1.3 Problems

## 1.4 Organizational Context

## 1.5 Time Frame

## 1.6 Feasibility and Risks Analysis

### 1.6.1 Risks – project feasibility

### 1.6.2 Cost/benefit – business feasibility

### 1.6.3 Product Risk management

# 2. Application

## 2.0 Overall Architecture – Highlights

### 2.0.1 Architecture Design Chart (PM 3.5)

## 2.1 Main Characteristics

### 2.1.1 Software Description (PM 3.2)

### 2.1.2 Operational Environment (PM 3.2.2)

### 2.1.3 Device Features Controlled by Software (PM 3.2.1)

### 2.1.4 Constraints

#### 2.1.4.1 Regulation objectives

## 2.2 Users and Interfacing Systems

## 2.3 Subsystems

## 2.4 Operational Interface

## 2.5 Processes

## 2.6 Transactions

## 2.7 Modules (Programs)

## 2.8 Control Procedures

## 2.9 Subroutines (Common Objects)

## 2.10 Coding Tables

## 2.11 Data Modeling (Logical Files)

## 2.12 Database (Physical Files)

## 2.13 Data Dictionary (Fields)

## 2.15 Reports (and Queries)

## 2.16 Input (Forms)

## 2.18 Safety Requirements

### 2.18.1 Startup Requirements

### 2.18.2 Shutdown Requirements

### 2.18.3 Failure and Recovery Requirements

### 2.18.4 Sensors and Alarms Requirements

### 2.18.5 Maximum and minimum ranges of allowed values

### 2.18.6 Error Handling Requirements

### 2.18.7 Safety Certification Standards Requirements

## 2.19 Security and Privacy

## 2.20 Traceability Matrix

## 2.21 Workload, Performance, and Capacity

## 2.22 External Interfaces and Links

## 2.23 Special Requirements

## 2.24 Design Control Requirements

### 2.24.1 § 820.30(a) Design Control General

### 2.24.2 § 820.30(b) Design and development planning

### 2.24.3 § 820.30(c) Design input

### 2.24.4 § 820.30(d) Design output

### 2.24.5 § 820.30(e) Design review

### 2.24.6 § 820.30(f) Design verification

### 2.24.7 § 820.30(g) Design validation

### 2.24.8 § 820.30(h) Design transfer

### 2.24.9 § 820.30(i) Design changes

### 2.24.10 § 820.30(j) Design history file

# 3. Technology and Infrastructure

## 3.0 Architecture – Overview and Highlights

## 3.1 Hardware Components

## 3.2 Software Components

## 3.3 Peripherals

## 3.4 Special Equipment

## 3.5 Off-the-shelf Software

## 3.6 Consumables

## 3.9 Communications

## 3.10 Operating System

## 3.11 Database Management System (DBMS)

## 3.13 Development and Maintenance Tools

### 3.13.1 Development standards and programming standards (PM 3.6 B2)

## 3.15 Operation and Production Tools

# 4. Implementation

## 4.0 Overview – Highlights

## 4.1 Parties Involved

## 4.2 Work Plan

### 4.2.0 Development Methodology

### 4.2.1 Overall Development Plan

### 4.2.2 Detailed Plan

## 4.3 Next/Immediate Phase

## 4.4 Ongoing Operation

## 4.5 Documentation Index

### 4.5.1 Operational documentation

### 4.5.2 Development process documentation

## 4.6 Service and Maintenance

### 4.6.1 Help desk – Call center

### 4.6.2 Application maintenance

### 4.6.3 Infrastructure and technology maintenance

### 4.6.4 Ongoing Implementation

### 4.6.5 Everyday costs

## 4.7 Integration into the Organization – Deployment

## 4.8 Robustness and Reliability

### 4.8.1 Testing plan

### 4.8.2 Availability and survivability

### 4.8.3 Scope of Validation

#### 4.8.3.1 In-Scope

#### 4.8.3.2 Out-of-Scope

### 4.8.4 Related Validation

## 4.9 Configurations

### 4.9.0 List of configurations (installations)

### 4.9.1 Development and Testing configuration

### 4.9.2 Main (central) configuration — primary server

### 4.9.*X* Additional site configuration / distributed configuration *X*

## 4.98 Open Issues (and Alternatives)

## 4.99 Future Plans

# 5. Cost – Resources

## 5.0 Executive Summary of Costs — Highlights

## 5.1 Set-Up Cost (Development and Installation)

### 5.1.1 First/upcoming version or delivery unit

### 5.1.2 Additional versions and delivery units

#### 5.1.2.1 <first delivery unit>

#### 5.1.2.*x* <subsequent delivery unit>

## 5.2 Ongoing Costs

### 5.2.1 First (upcoming) version or delivery unit

### 5.2.2 Additional versions and delivery units

## 5.3 Cost by Configuration

## 5.4 Price List

## 5.5 Cost Summary

### 5.5.1 Cost of ownership

### 5.5.2 Cost scheduling

## 5.98 Open Issues (and Alternatives)

## 5.99 Anticipated Future Costs