

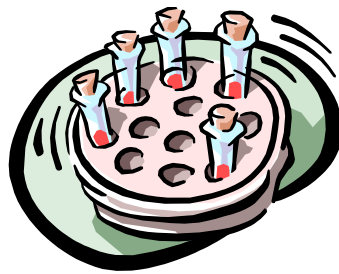
**Widget Laboratories
Systems Analysis
Complaint Handling System**

Lead Analyst: John Doe


Complaint Handling System

System Analysis
and Design
Widget Laboratories

Widget Laboratories



...is a division of Widget Diagnostics, Inc. The division is engaged in the development, manufacture, sale and service of a variety of clinical laboratory instruments such as serum and blood chemistry analyzers.



Project Implementation Team

- Software/Database Specialist/Business Analyst (Team Leader)
- Product Quality Specialists
- Field Quality Specialist
- Customer Support Specialists
- Field Service Representative
- Investigators

The project implementation team consists of members from the different organizations and departments that handle the complaint data in some way:

Software/Database Specialist/Business Analyst (Team Leader): representative of the software team responsible for developing software solutions for the customer complaint handling system. This person will act as the **team leader** and take requirements for the software portion of the system to the software design team. This person will also interface with management when the analysis is complete and to present solutions.

Product Quality Specialists: representing the personnel responsible for coordinating larger investigations in compliance with quality assurance procedures. Product Quality needs the ability to track investigations and record required elements for level three complaints.

Instrument Quality: representing personnel involved in complaints regarding hardware and software for the various instrument product lines

Reagent Quality: representing personnel involved in complaints regarding reagent manufacture and performance

Field Quality Specialist: representing personnel involved in tracking and evaluating investigation resolutions for compliance to quality procedures and producing customer responses. This group needs the ability to record customer responses and route investigations to the appropriate investigator and route completed solutions to customer support

Customer Support Specialists: representatives from each major product line for personnel involved in receiving, documenting, troubleshooting and elevating customer complaints. This group needs the ability to record and elevate customer complaints efficiently and accurately as well as to find troubleshooting information quickly while interfacing with the customer.

Field Service Representative: representing service personnel who repair and maintain instruments at customer sites. This group has similar needs to customer support with the added need to record parts used and billing for service.

Investigators: representatives from each area of investigation and resolution. This group needs the ability to receive and track investigations assigned to them, record solutions and send responses to the product or field quality groups.

What is the Complaint Handling System?

- Records, investigates, resolves and tracks customer complaints
- Identifies and helps correct deficiencies in and improve the performance of the instruments manufactured by Abbott Diagnostics Division
- Consists of a customer support group, a field service group, a field quality assurance group, a product quality assurance group, and investigators from the manufacturing and engineering areas.

Complaints are received via telephone by the customer support group and recorded into a computer database utilizing textual description and codes generated by a computer application that delineate the problem, the instrument, the part and the resolution. Codes are used for tracking complaint metrics.

Level one complaints are resolved and closed by the customer support group. Level two complaints are elevated to the appropriate field quality assurance group, which then forwards each level two complaint to the appropriate investigative unit. The investigative unit determines and records the cause of the problem and, if needed, a resolution. The complaint and, if required, the resolution, is evaluated and recorded in a hard copy document by the field quality assurance group and a customer response letter is produced. Level three complaints are large-scale, high-priority investigations that impact patient results or operator safety and require management by the appropriate product quality assurance group and investigative unit. Level three complaint investigations are recorded as hardcopy documents in one or more three ring binders.

The customer complaint database is also used to track complaint metrics associated with each instrument and part to discover trends in types of problems for a particular part or instrument.

Why do we need this system?

- The Federal Food and Drug Administration requires the efficient retrieval of all information pertaining to a medical device
- Easy determination of complaint level
- Uniform troubleshooting of customer complaints
- Reduce keystrokes needed to record information by expanded use of codes and macros.

Why do we need this system?

More reasons

- To record all information regarding an instrument or part electronically in a uniform manner.
- Compliance with operating procedure timelines:
 - Level one investigations resolved within 5 calendar days
 - Level two investigations resolved within 14 calendar days
 - Level three investigations resolved within 60 calendar days

Why do we need this system?

Rest of Reasons

- Enable retrieval of all information pertaining to complaints by a variety of parameters
- Enable complaint tracking and trending by a variety of parameters

The Widget Diagnostics Division requires a complaint handling system that allows all levels of complaints and their resolutions to be recorded accurately and retrieved quickly. All information regarding a specific complaint, instrument or part should be easily retrievable. The system should also be capable of expediting complaint investigations in order to meet investigation, resolution, and customer notification timelines set forth in the complaint handling operating procedures. The system should create uniformity and standardization in the performance and recording of complaint investigations and resolutions across product lines.

Data Gathering Methods

- Reports available from current systems
- Observation
- Questionnaires
- Formal Interviews

Some required information was available as reports from various information-recording systems. The number of complaints per month, turn around time and range of turn around times as well as examples of complaints were obtained from the current call management system (WWCMS) by dumping the data to spreadsheets in either Excel or Lotus 1-2-3 spreadsheets.

The operating procedures were available in the manual. Widget is required by the FDA to strictly follow its own operating procedures. The FDA performs periodic audits to ensure compliance.

The methods and time required for recording customer data, processing the data, performing the investigation and processing closure of the complaint were observed actions with notes taken by the observer. Action logs were also used for customer support personnel to record the time it took to troubleshoot a call and record it in WWCMS. Clearance for the customer support personnel to do so was sought from management as this activity could be seen as delaying taking customer calls. Field and product quality personnel engaged in back-end paperwork also used action logs for closure of complaints.

To find the strengths and weaknesses of the current data gathering software (WWCMS) and the current investigation tracking methods, questionnaires were given to representative customer support personnel, investigators, field quality personnel and product quality personnel from each product line. Formal interviews followed to clarify any points raised by the questionnaires. Formal interviews were sought from management of customer support, investigational areas and quality areas to determine what management saw as problems.

Observation example:

An observer sat unobtrusively in the laboratory while the investigator performed testing on returned product and representative products from the warehouse. Notes were taken regarding use of procedure manuals, use of time during testing, interruptions and prioritization, reports written and any observed standardization of any of the above activities.

Questionnaire example:

Legend: SA = strongly agree, A = agree, D = disagree, SD = strongly disagree

1. It is easy to create and fill in a table in WWCMS
SA A D SD
2. It is easy to correct errors in spelling or data entry in WWCMS
SA A D SD
3. Typing data into WWCMS can be done quickly
SA A D SD
7. Please comment on the strengths of the WWCMS system.
8. Please comment on the weaknesses of the WWCMS system.
9. What additional features would you like to see in WWCMS?
10. What features in WWCMS do you never use?

Formal Interview of Management:

Explain the type of data you require to perform your function and whether this data is easy or difficult to obtain from the present system.

Do presentations by the various quality departments contain the same information for each product line?

Is there a mechanism for elevating issues to the appropriate personnel?

Data Gathered

- Operating procedures
- Number of complaints handled per month
- Average turn around time
- Range of turn around times
- At least 5 examples of each level of complaint
- Methods and time required for recording data
- Methods and time required for processing data
- Methods and time required for investigating complaint
- Methods and time required for closure processing
- Strengths and weaknesses of the current software
- Strengths and weaknesses of current investigation tracking

The following data was gathered for analysis:

- All operating procedures pertaining to complaint handling
- Number of complaints handled per month separated into levels (one, two and three) as well as into the different instrument product lines
- Average turn around time for each level of complaint and each instrument product line
- Range of turn around times for each level of complaint and each instrument product line (shortest and longest)
- At least 5 examples of each level of complaint per product line
- Methods and time required for recording customer data at point of customer contact
- Methods and time required for processing customer complaint data for each level of complaint per product line
- Methods and time required for investigating each level of complaint per product line
- Methods and time required for closure processing for each level of complaint per product line
- Strengths and weaknesses of the current customer data gathering software (WWCMS) such as ease of use, error correction, creating tables, charts if needed, overall look of screen, ease of extracting data for investigation
- Strengths and weaknesses of current investigation tracking such as the use of a manual method, standardization of spreadsheets, relevancy of data on spreadsheets, notification of investigator and quality personnel of work to be done

During the data-gathering phase we encountered certain problems including:

- The perception that time was being wasted during the initial data-gathering phase such as the time taken to fill out action logs.
- Since previous measures to improve the system have not taken the users into account, non-management personnel felt that they filled out the questionnaires only to have their opinions disregarded.
- Observers may have been welcome but the urge to tell the observer all of the problems with the current system rather than perform the work the observer was to watch was overwhelming.
- Knowledge that an observer was watching may have led some personnel to follow the book when they usually take short cuts.
- Investigators, who currently feel their investigation role is at best a back-burner priority, may fear being “stuck” in the investigation role with no further chance for work in development.

- Management was sometimes unaware of the different ways data is currently recorded and processed and the formal interview session failed due to lack of knowledge by management of the inner workings of the data presentation process.

Although these problems occurred there was little impact on data gathering. All personnel were very cooperative.

Analysis Results

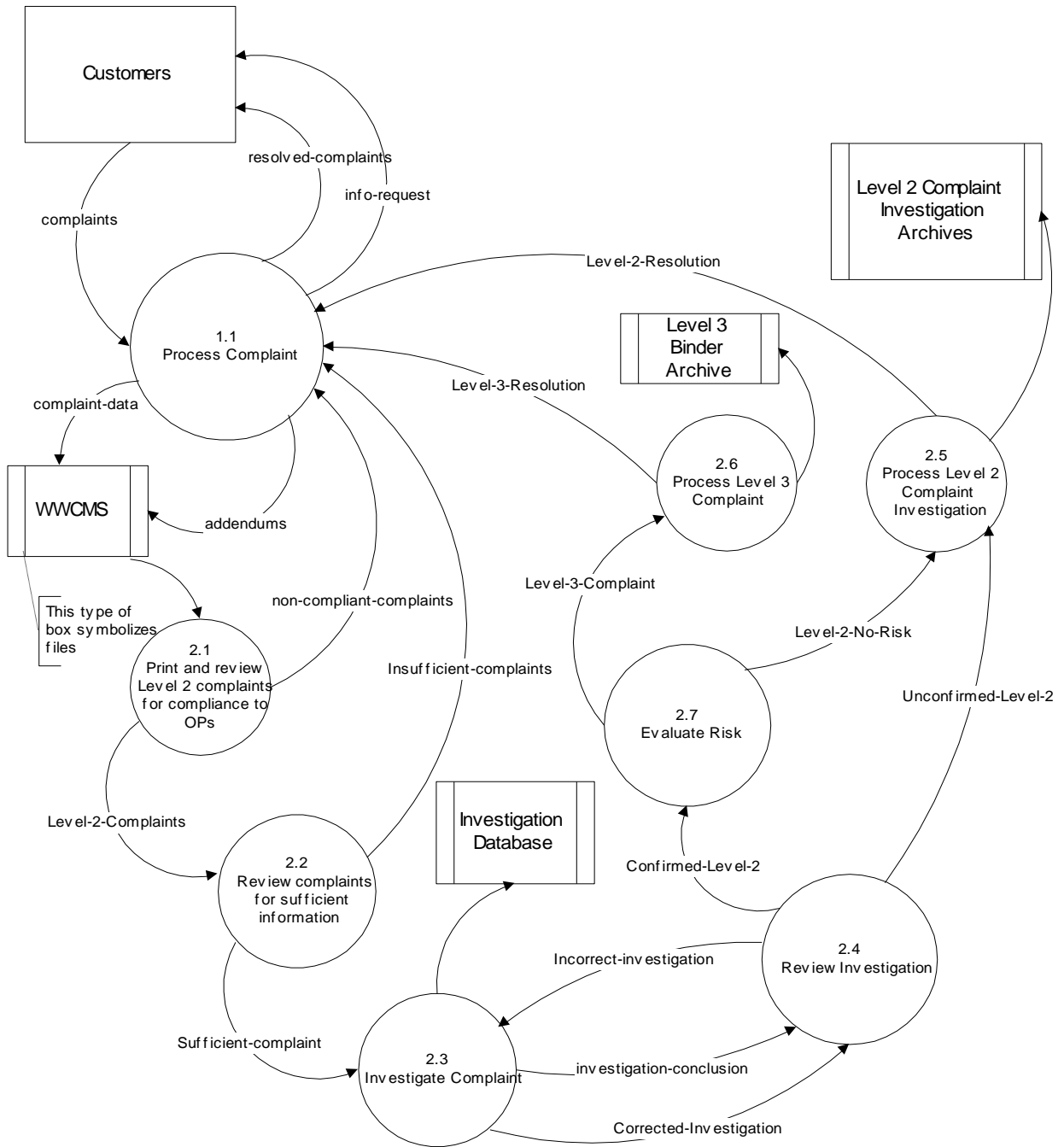
- Complaint information resides in many files
- Investigations are low priority to investigation staff
- Most investigations miss deadlines for completion
- Troubleshooting and investigations are not standardized.
- Operating procedures are vague and cumbersome.
- Unclear who is responsible for investigation prioritization or completion.
- Unclear what defines a level one, level two or level three complaint.

An analysis of the complaint handling system has been completed and the following problems have been identified:

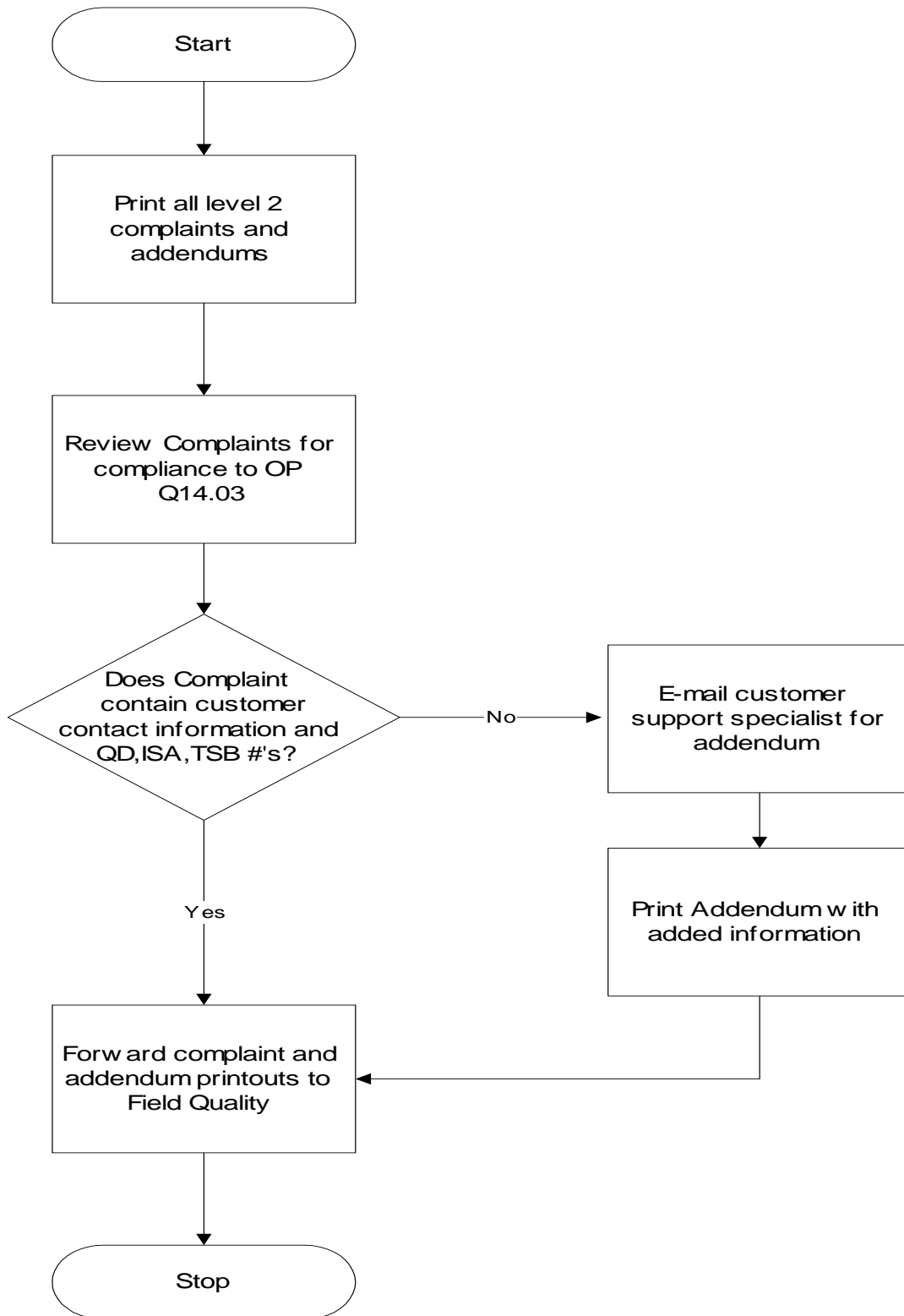
- Complaint investigation information is currently residing in different electronic databases as well as paper files with information that is not present in the electronic files.
- Investigations are low priority with the investigation staff with higher priority given to development of new products or of features for current products.
- Most investigations and complaint resolutions are not completed in the timeframe required by the operating procedures. Many are more than 120 days old with no feedback to the customer of the status of the investigation. Investigations are not formally tracked.
- Investigations are not standardized for common issues.
- Troubleshooting is not standardized in the customer support area.
- Operating procedures are vague and cumbersome. Numerous forms are required and some are redundant or have little relevancy to the investigation.
- It is unclear who is responsible for investigation prioritization or completion. There is no responsible party with authority driving investigations per the timeline in the procedures.
- It is unclear from the procedure what defines a level one, level two or level three complaint.

The depth and breadth of these problems requires a redesign of the entire complaint handling system. The formal analysis and design may be made difficult due to lack of cooperation of the mid-management level and some of the staff. This issue must be addressed before a successful analysis and design can be performed. If the management and staff do not cooperate with the investigators, a successful design will not be possible. Additionally, some records are missing and documentation has been poor regarding investigation procedures.

Data Flow Diagram of Current System:

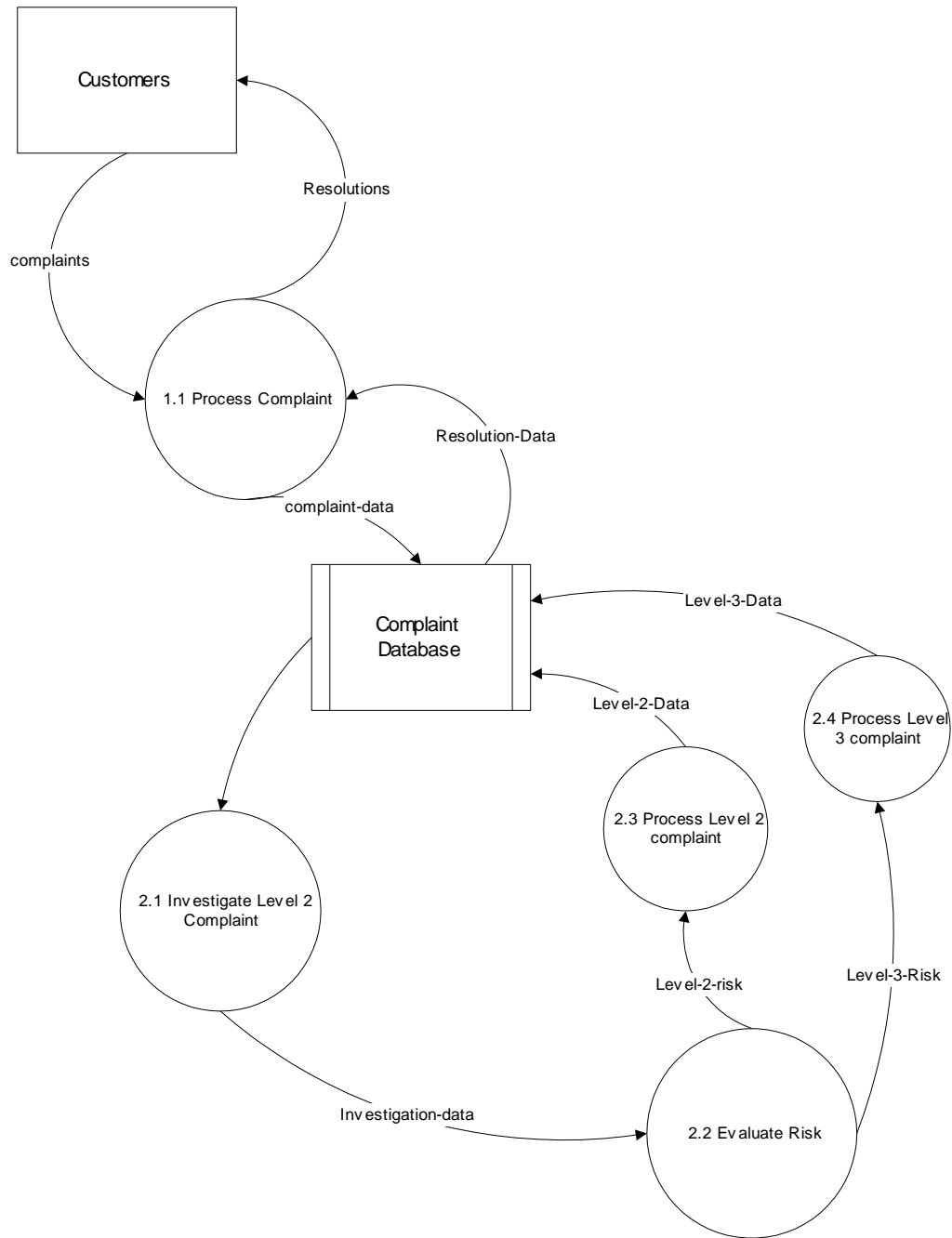


This diagram shows the flow of the data only, not the physical carrier of the data. The circles represent processes and the boxes with bars are the various files where data is stored. As you can see, the data is processed in numerous places. Each process is performed by a particular group and passed on to the next group. The carrier can be electronic file for one process, printed hardcopy for the next process, a fax for another and then back to electronic files typed from the printed hardcopy. The next flowchart is but one example of a process in the current system.



The process above is a simple process of a few steps that is performed for each complaint by the FQA group. The complaint is then passed on to Field Quality for another process. This process and others can be combined.

Data Flow Diagram of Proposed System



As with the data flow diagram of the existing system, this diagram shows the flow of data rather than the flow of documents. Several processes have been combined and the new system will take advantage of current database technology. All documents will be electronic in nature and all information will reside in a single system instead of several different systems. Data recording will be enhanced with tables, diagrams, drop down menus, coding tools and a more readable format.

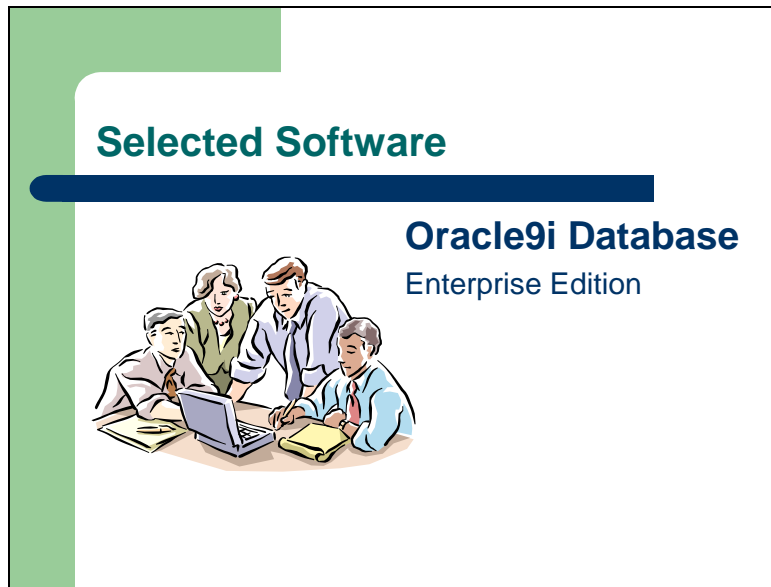
Software Requirements

- Electronic signature
- Multiple levels of security permissions
- Custom templates for data entry
- Import from other applications
- Routing of complaints and notifications to next responsible party
- Flexible and scalable

These are some of the main requirements. The full requirements were used for software selection. The full requirements are as follows:

- The system shall use SQL (Structured Query Language) for data management with future capabilities for XML Query.
- The system shall have the capability to securely support electronic signatures.
- The system shall handle data flow at a rate that allows access to all data within 10 seconds of engagement of search parameters.
- The system shall be capable of assigning multiple levels of security permissions so that users cannot access and/or change and/or add and/or delete data unless authorized.
- The system shall allow creation of custom templates for data entry in text, numerical, table, presentation and spreadsheet formats.
- The system shall import documents and data from Microsoft applications, Lotus applications, Acrobat applications, Oracle applications, and the World Wide Customer Management System.
- The system shall be flexible enough to accept documents from other applications as needed.
- The system shall route complaints to the correct party to which they are assigned per complaint codes.
- The system shall notify the correct party of complaint assignments and await confirmation of notification. If confirmation is not received in the designated time period, the system shall notify the party's management in addition to re-notifying the party.
- The system shall route documents for review and signature according to pre-formatted lists.
- Search and retrieval of complaint data for any product shall be performed using product name, product code, serial number, lot number, part number, range of dates, complaint level or any combination thereof.
- Data shall be capable of being printed to paper or saved to CD-ROM for review within 2 hours of request.
- All reports shall format data for easy location of information on screen or paper.
- The system shall store all complaint levels and be capable of mining the data for trends in complaints for all products.

- The system shall be capable of automatically mining data and printing reports for trend analysis on a time-designated basis, e.g. monthly.
- The system shall be capable of 99.9% up time.
- The system shall be capable of remaining in service during maintenance.
- The system shall be capable of packaging all documents as one record for a particular complaint, including original complaint documents, investigation documents, quality documents and customer responses as well as documentation and tracking of quality assurance audits, corrections and changes to the record.
- The system shall be scalable to handle increasing amounts of data.
- All data shall be secure both during changes to the data as well as from outside hazards such as hackers.



Oracle9i Database Enterprise edition was considered along with Filemaker Pro 6 and IBM DB2 7.2 Enterprise Edition.

Filemaker Pro 6 was not selected because it could not scale high enough to handle the volume of complaint data and documents generated at Widget Laboratories. This database was more suitable for smaller enterprises.

IBM DB2 7.2 was an excellent alternate selection. It was not recommended because Oracle is already present at Widget Laboratories making installation simpler. Administrators and managers are already familiar with it. IBM DB2 concentrated on ease of use and streamlining but performance was not as powerful in throughput or searching nor as flexible as Oracle9i. IBM DB2 does not guarantee the reliability that Oracle9i does.

Strengths of Oracle9i

- “superior feature set, reliability and performance...[with] the most advanced management and performance tools.” PC Magazine
- Delivery of 620 pages in throughput tests
- Heavy emphasis on reliability and problem tracking
- Complex queries in SQL allowed
- Maintenance of single server and security model

Oracle9i Database is highly recommended by PC Magazine (pcmag.com), which evaluated Oracle9i alongside other comparable database packages and found Oracle9i to have a “superior feature set, reliability and performance...[with] the most advanced management and performance tools.” Oracle9i outperformed other database applications, such as IBM DB2 7.2 and Microsoft SQL Server, in throughput tests where it delivered 620 pages per second. Oracle placed heavy emphasis on reliability and problem tracking.

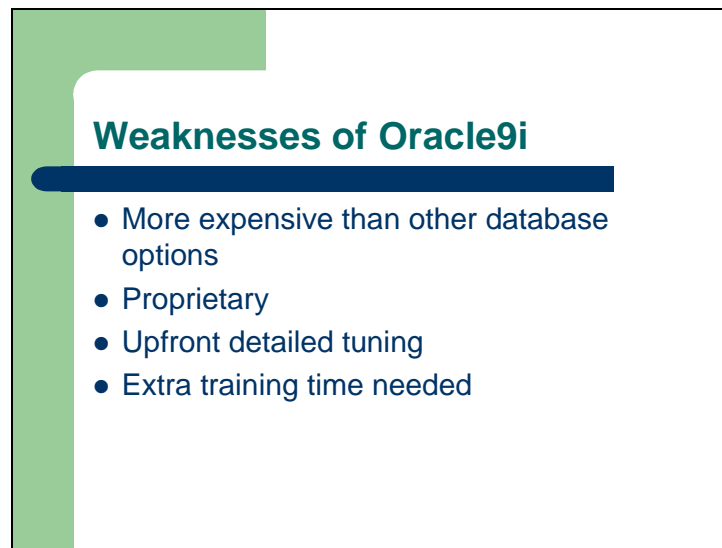
DM Review Magazine (dmreview.com) used the Oracle9i Database as a solution for their customers requiring high-end analytic functionality as well as manageability and scalability. They found that Oracle allowed complex queries from their customers due to the multidimensional calculation engine and multidimensional data types therefore no specialized analytical server was needed. The queries can be entered as SQL queries. In addition, database administrators only need to maintain a single server and security model.

More Strengths of Oracle9i

- Highly scalable
- Built-in data mining functions
- Single repository for relational and analytical data
- Collaborative

Computerworld (computerworld.com) also applauded Oracle’s scalability and reliability, stating that IT departments handling large amounts of data can rely on Oracle9i for data clustering. All reviewers cited Oracle’s ability to support OLAP (Online Analytical Processing) as a determining factor in choice of database options.

Stylusinc.net agreed with other reviewers that Oracle9i was an excellent choice because “Oracle9i includes built-in OLAP, Data Mining and ETL functions so that the database can act as a single repository for relational data as well as analytical data. Oracle9i also includes infrastructure for developers to create hosted applications with common, collaborative software services.”



Weaknesses of Oracle9i

- More expensive than other database options
- Proprietary
- Upfront detailed tuning
- Extra training time needed

PC Magazine notes that Oracle9i is more expensive and proprietary but the advanced performance and features were worth the price. Other concerns were that the database requires detailed up-front tuning, however, the management tools made this activity go more smoothly. Modules for upgrades also cost more than other database vendor products.

The reviewers for all magazines noted that Oracle9i would require extra training time for administrators and managers in order to leverage the new features of Oracle9i and for new users to learn the Oracle system.

Reasons for Recommendation

- Abbott Laboratories already uses the Oracle database application
- Abbott need only expand on the licensing agreement
- Oracle9i meets more of the requirements than other database applications on the market
- Oracle offers a high level of support for its product.

I am recommending the Oracle9i Database application for a number of reasons:

- Widget Laboratories already uses the Oracle database application in the manufacturing area; therefore the IT department is already familiar with the application.
- Widget need only expand on the licensing agreement with Oracle to scale up the usage of this application.
- Oracle9i meets most of the requirements stated above:
 - It uses SQL query language
 - It is highly scalable
 - It handles data flow at high levels of speed
 - It allows multiple levels of permissions to be defined as user roles
 - It supports sophisticated search and retrieval activity
 - Clustering enhances high level reliability
 - Data mining is handled easily
 - It offers selective data encryption and enhanced PKI-based sign-on for security of data
 - It offers legacy database data gateways to handle data from non-Oracle sources
 - It offers XML support
 - It can store and manage large amounts of data
- Search and retrieval can be achieved within the time limits set by the requirements.

More Reasons for Recommendation

- Finding individuals experienced in its use will not be difficult.
- Oracle has a reputation for living up to its claims.
- Oracle is capable of importing data from all applications currently in use at Abbott Laboratories, including Microsoft Office Applications and Lotus Applications.

- Oracle offers a high level of support for its product. In addition, the ubiquity of the product means finding individuals experienced in its use will not be difficult.
- Oracle has a reputation for living up to its claims.
- Oracle is capable of importing data from all applications currently in use at Widget Laboratories, including Microsoft Office Applications and Lotus Applications.

The Oracle9i Database Application, Enterprise Edition, meets more of our requirements than other packages on the market and is already in use on the site.

Why were other applications not selected?

- Filemaker Pro 6.0 was not scalable enough
- IBM DB2 7.2 was not as powerful or flexible as Oracle9i

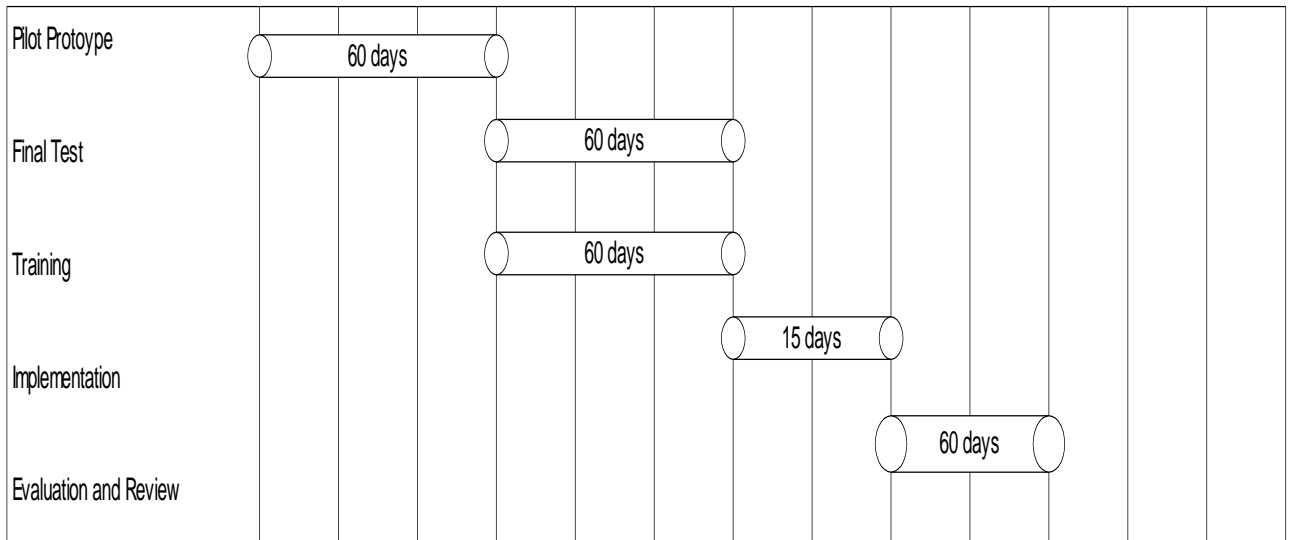
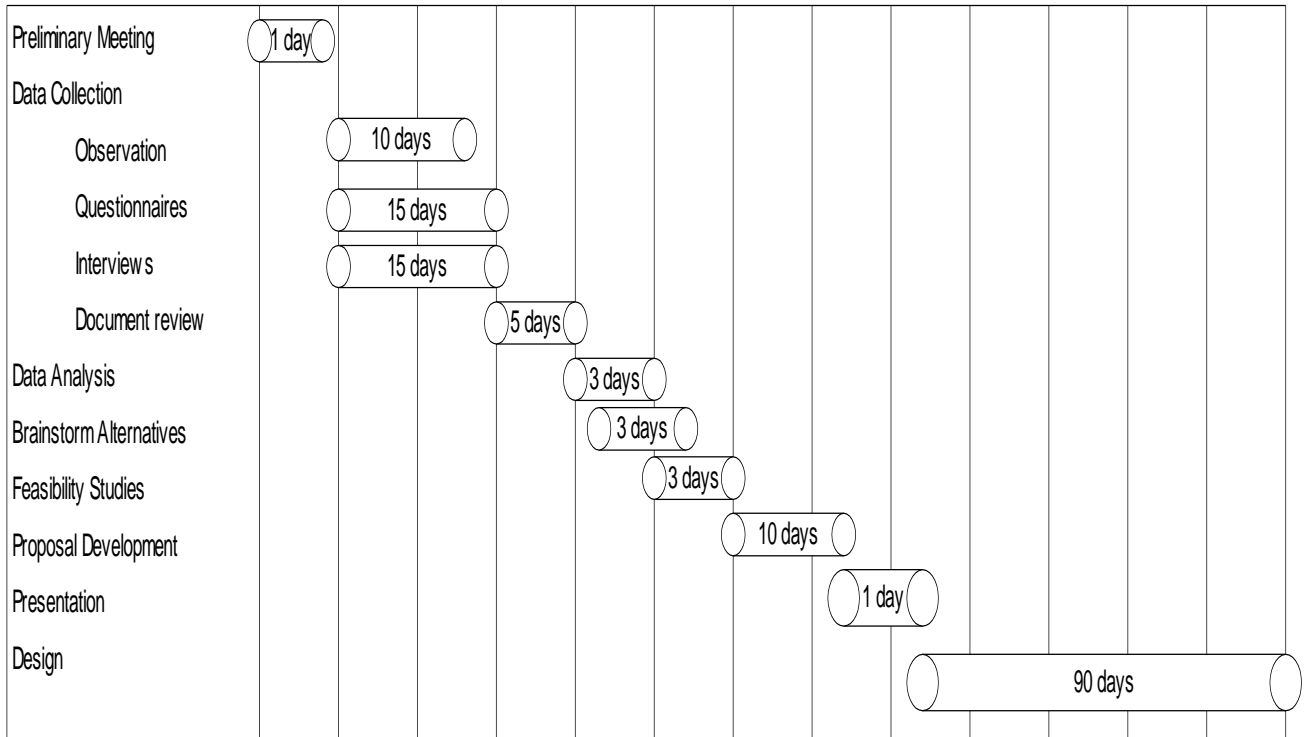
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IBM DB2 7.2 is an excellent alternate selection. It was not recommended because Oracle is already present at Widget Laboratories making installation simpler because it would be an upgrade. Administrators and managers are already familiar with it. IBM DB2 concentrated on ease of use and streamlining but performance was not as powerful in throughput or searching nor as flexible as Oracle9i. IBM DB2 does not guarantee the reliability that Oracle9i does.

Timeline

September 10, 2002	Preliminary Meeting – Introduction of Team Members (6) and Statement of Project Precise Problem Definition Data Collection Needs Action Item Assignments for Data Collection
October 24	Meeting to analyze collected data Brainstorm alternatives
October 26	Discuss alternatives and reduce to three Action Item: Feasibility Study of final alternatives
November 2	Discuss feasibility of alternatives in detail Determine final alternative for proposal Action Item: Develop Proposal for presentation
November 10	Presentation of proposed solution Acceptance required in 2 weeks
November 24	Signing party for accepted proposal
November 28	Begin Design
March 1, 2003	Pilot prototype system
May 1	Final test period/training prior to implementation
July 1	Implement new system
September 1	Review and evaluation of system

Timeline runs from Preliminary Meeting to Design then Pilot Prototype to Evaluation and Review:



Test Plan

- 90-day reliability testing
- Functional testing: test cases for each combination of items
- Capacity: throughput and response when 10,000 test cases are run in 1 minute

Reliability

A 90-day reliability test will be conducted to ensure the database downtime requirement is met. In addition, information regarding staff usage of the system shall be reviewed for problems.

Functionality

A package of test cases representing each level of complaint for each instrument type and all parts thereof shall be created to test the functionality and capacity of the system. Test cases with missing required elements shall also be created and added to the package to test the reminder prompt feature for tickets with missing elements prior to closure or elevation.

Requirement	Test	Expected Result
Drop down menu with all products listed by instrument type.	The drop down menu shall be audited against listing of products.	Drop down menu shall contain an accurate listing of all products and parts.
Problem and solution code tool to create codes for problems and solutions according to action and product.	Test cases containing at least one example of each problem and solution shall be input into the tool and the resulting code audited against the code definition for accuracy.	The problem and solution code tool shall create accurate codes for each problem and solution entered.
Forms containing fields for contact information, instrument model and serial numbers, problem and solution codes, text and tables.	Test cases containing contact information, instrument model and serial numbers, problem and solution codes, text and tables shall be input for each instrument model and information for placement into text and tables. Test cases with missing required elements shall be entered.	Forms shall accept all information and prompt user for required elements that were not input prior to request for elevation or closure.

Printed forms (tickets) shall be easily read and decoded for investigation	Printed forms (tickets) shall be reviewed by a focus group of investigators and quality personnel for readability and accuracy.	Printed forms shall contain information in a format such that the user can easily identify all needed data.
Forms containing fields for investigational reports including text, tables, and drop down menus for common information	Test cases containing investigational reports shall be input for each instrument model and investigation type.	Forms shall accept all information that is input.
Reports containing information for each part and product shall be available for trend analysis	Reports for each part and product shall be created and reviewed for accuracy of calculations for failure rates	Report contains accurate information concerning each product or part and the problem that occurred. Each report shall cover a single part and contain information by month of the type of problem by problem code.
Notification to appropriate parties at each phase of routing for each complaint level and product.	Test cases for each complaint level and product shall be entered and traced through the process for that level to cause notifications to be sent.	The correct party shall be notified at each step of the process for each product and each complaint level.
Data entry to forms intuitive	A focus group of customer support representatives, investigators and quality personnel shall enter data into the forms and provide feedback. Some information shall be imported from spreadsheet and word processing applications.	Information shall be easily entered into the database forms. The forms shall accept imported information with no loss of data or format.
Forms can be routed for quality assurance requirements such as risk evaluation and level three complaint processing and signature	Complaints with risk evaluations and level three complaints shall be entered and routed through the process	Each party required to review the information shall receive the information and provide electronic signature approval.

Capacity

A set of 10,000 test cases comprised of all levels of complaints at all phases of investigation shall be dumped to the system within a period of one minute. Throughput and system response time shall be monitored and compared to throughput and system response time when only 100 test cases are dumped to the system. Any crash of equipment or software shall be investigated to pinpoint causative agent.

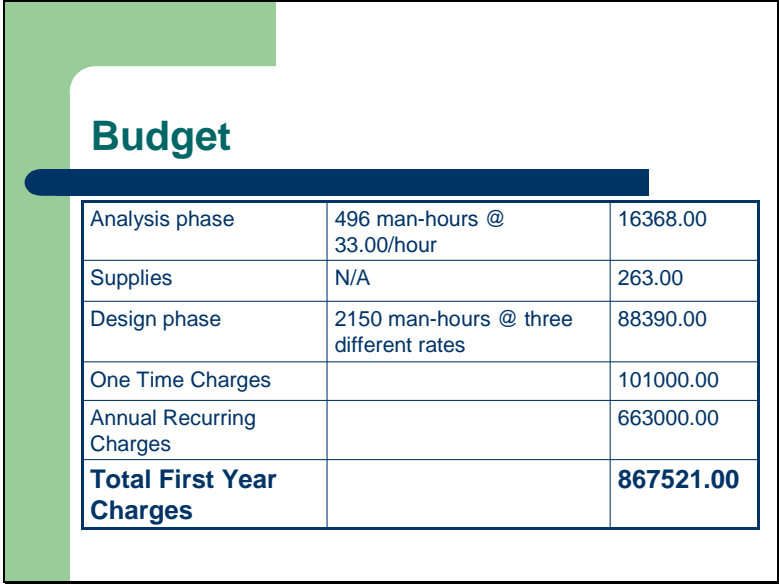
Definitions

Downtime: System is not available for data entry or report generation for at least some of users.

Reliability: System is available for data entry and report production 99.9% of the time for all users.

System Response time: The time the system takes to accept an entry and move to the next field, form or area of database after the enter key is pressed.

Reliability: A 90-day reliability test will be conducted to ensure the database downtime requirement is met. In addition, information regarding staff usage of the system shall be reviewed for problems.



Budget		
Analysis phase	496 man-hours @ 33.00/hour	16368.00
Supplies	N/A	263.00
Design phase	2150 man-hours @ three different rates	88390.00
One Time Charges		101000.00
Annual Recurring Charges		663000.00
Total First Year Charges		867521.00

Analysis Phase:

Problem Definition	24 man-hours x 33.00/hr	792.00
Development of Questionnaires and Interview Questions	96 man-hours x 33.00/hr	3168.00
Observation	40 man-hours x 33.00/hr	1320.00
Examine Existing Documentation	48 man-hours x 33.00/hr	1584.00
Examine all requested data	48 man-hours x 33.00/hr	1584.00
Develop Data Flow Diagrams, Flowcharts, Narratives	240 man-hours x 33.00/hr	7920.00
Total	496 man-hours @ 33.00./hr	16368.00

Supplies Required:

Packets of Questionnaires and Interview Questions: Copies from master documents, stapled:	5 cents/pg copying \$1.50 per packet collation and stapling
CSC Questionnaire 3 pages 50 pkts	Copying: 448 pgs x .05 = 22.40 Collation and stapling: 123 pkts x 1.50 = 184.50 Total: 206.90
CSC Interview 5 pages 10 pkts	
FQ Questionnaire 4 pages 15 pkts	
FQ Interview 6 pages 5 pkts	
PQA Questionnaire 5 pages 10 pkts	
PQA Interview 6 pages 3 pkts	
Investigator Questionnaire 3 pages 25 pkts	
Investigator Interview 3 pages 5 pkts	
Pencils	Available from Widget Laboratories
Software: Visio Microsoft Word, Excel, Power Point	Available from Widget Laboratories
Notepads: 8 1/2 X 11	3 packs @ 3.00 ea = 9.00
Large Presentation size tablets	2 @ 16.46 = 32.92
Color markers	2 pks @ 3.00 ea = 6.00
3.5-inch diskettes – 2 boxes/10 HD diskettes	2 boxes @ 3.00 ea = 6.00
Tape – clear	4 pk @ 2.79 = 2.79
Total	263.61

Design Phase (includes Implementation):

Creation of Functional Specifications	24 man-hours x 33.00/hr	7920.00
Determination of Alternative Solutions	96 man-hours x 33.00/hr	3168.00
Feasibility Studies for 3 Alternative Solutions	72 man-hours x 33.00/hr	2376.00
Develop Proposal	72 man-hours x 33.00/hr	3168.00
System Selection	80 man-hours x 33.00/hr	2640.00
Presentation	6 man-hours x 33.00/hr	198.00
Creation of Prototype Database	480 man-hours x 48.00/hr	23040.00
Pilot Prototype	320 man-hours x 48.00/hr	15360.00
Final Test	320 man-hours x 48.00/hr	15360.00
Training	320 man-hours x 20.00/hr	6400.00
Full Implementation	320 man-hours x 48.00/hr	15360.00
Review and Evaluation	40 man-hours x 33.00/hr	1320.00
Subtotal: Analyst(s)	390 man-hours x 33.00/hr	12870.00
Subtotal: Database Programmer(s)	1440 man-hours x 48.00/hr	69120.00
Subtotal: Trainer(s)	320 man-hours x 20.00/hr	6400.00
Total		88390.00

Implementation: see Design Phase budget

Estimated Operating Costs

One Time Charges:

Oracle9i Enterprise Edition – Processor Perpetual		40000.00
Oracle9i Data Mining Module – Processor Perpetual		20000.00
Oracle9i Tuning Pack		3000.00
Oracle9i Diagnostics Pack		3000.00
Oracle9i Enterprise Integration Gateways		35000.00
Total One Time Charges		101000.00

Annual Recurring Charges:

Personnel (database administrators x 2 annually), including benefits		450000.00
Oracle9i Service and Support (annually)		200000.00
Oracle9i Licensing – DBA(s) - each	5000.00	10000.00
Office Space and Equipment – DBA(s) each	1500.00	3000.00
Total Recurring Charges		663000.00

Total Charges for first year:

Analysis		16368.00
Design		88390.00
Supplies		263.61
One Time Charges		101000.00
Recurring Charges for 1 year		661500.00
Total		867521.61

Why Change the System?

In the past five years Widget Laboratories Diagnostics Division has received several warning letters from the Food and Drug Administration regarding Widget's failure to respond to customer complaints appropriately and in a timely manner. Additionally, each FDA audit requires large numbers of complaint records to be compiled. With the current system, this activity utilizes many man-hours for printing, sorting and collating complaint reports that are in different formats depending upon the complaint level.

Internally, the manual nature of the system creates obstacles to investigation and file storage as well as information sharing. If a single system stored complaint files as well as other files within the manufacturing and research and design areas, issues could be highlighted to engineering and manufacturing staff in order to correct or prevent the same issues in current instruments and those under development. The current system does not share information with these areas. Manufacturing and research and design have no awareness of issues in the field.

The World Wide Call Management System is now in its sixth year of use. Technology has advanced to the point that WWCMS is obsolete and is at the end of its life cycle. Now is the appropriate time to replace the system with the best that new technology has to offer.

The Oracle9i Database System contains all the features required to update the complaint handling system. Widget already has a relationship with Oracle, utilizing the Oracle database system for manufacturing and shipping. Discounts are offered to large corporations with such relationships with Oracle, Inc. In addition, there are already database administrators at Widget familiar with the Oracle system. Because Oracle is a well-known system, additional personnel with experience using Oracle should be easily found if needed. Oracle has made it possible for their large application to be managed by the fewest people possible with management tools integrated into the package. After a set-up and training period Oracle should run smoothly until the next upgrade is needed.

Widget should expend the necessary funds to procure this excellent system in order to more fully comply with FDA regulations and directives as well as to decrease support costs for the many disparate systems now in use.