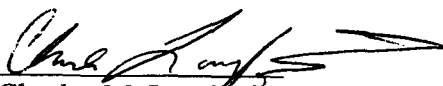



Countermeasure Evaluation and Validation Project (CEVP) Database
Requirement Documentation

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Final Report

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Abstract

The initial focus of the project by the JSC laboratories will be to develop, test and implement a standardized complement of integrated physiological test (Integrated Testing Regimen, ITR) that will examine both system and intersystem function, and will be used to validate and certify candidate countermeasures. The ITR will consist of medical requirements (MRs) and non-MR core ITR tests, and countermeasure-specific testing. Non-MR and countermeasure-specific test data will be archived in a database specific to the CEVP. Development of a CEVP Database will be critical to documenting the progress of candidate countermeasures.

The goal of this work is a fully functional software system that will integrate computer-based data collection and storage with secure, efficient, and practical distribution of that data over the Internet. This system will provide the foundation of a new level of interagency and international cooperation for scientific experimentation and research, providing intramural, international, and extramural collaboration through management and distribution of the CEVP data.

The research performed this summer includes the first phase of the project. The first phase of the project is a requirements analysis. This analysis will identify the expected behavior of the system under normal conditions and abnormal conditions; that could affect the system's ability to produce this behavior; and the internal features in the system needed to reduce the risk of unexpected or unwanted behaviors. The second phase of this project have also performed in this summer. The second phase of project is the design of data entry screen and data retrieval screen for a working model of the Ground Data Database. The final report provided the requirements for the CEVP system in a variety of ways, so that both the development team and JSC technical management have a thorough understanding of how the system is expected to behave.

1. Introduction

This document specifies the requirements that the University of Wyoming development team and the JSC Space Life Science Division deem necessary for development of the Countermeasure Evaluation and Verification Project (CEVP) database and Internet-based data transfer system. The goal of this work is a fully functional software system that will integrate computer-based data collection and storage with secure, efficient, and practical distribution of that data over the Internet. This system will provide the foundation for a new level of interagency and international cooperation for scientific experimentation and research, providing intramural, international, and extramural collaboration through management and distribution of the CEVP data.

This document describes the requirements for the CEVP system in a variety of ways, so that both the development team and JSC technical management have a thorough understanding of how the system is expected to behave. The requirements are divided into three sections.

The first section, Functional Requirements, provides a textual description of each major function that briefly states the purpose of the function and the activities performed by that function. These functions are then described in more detail through the use of Work Breakdown Structures (WBSs), data flow diagrams, input/output design diagrams, and data dictionaries. Where a functional requirement is directly related to a function on the WBS, the WBS number will follow the requirement number in parentheses. The document then describes the general outputs of the system and the user inputs required for each major function.

The second section describes the non-functional requirements for the system. These requirements include physical environment, interface, users and human factors, performance, documentation, and security. The information about each requirement will vary according to the requirement type. The final section of the document outlines the administrative requirements, including team organization, tentative project schedule, and review procedures.

The requirements in this document address the major issues as currently defined for the CEVP system. At this point, all the data items to be contained in the CEVP database have not been identified, nor has the mechanism for approving distribution and access been completed, reviewed, and approved. It is expected that these constraints on the system will be evolving for some time. As those constraints change, the system requirements will also need to be changed. This nature of the project must be kept in mind by the development team and technical liaisons.

In addition, the system is expected to eventually provide an interface with other independent databases managed by other groups, as shown in Figure 1. The protocol of connecting those systems to the CVEP database is a major concern. However, those

systems are also under construction, and solid information about them is not yet available. The current International Space Station (ISS) Data and Communications requirement stipulates that an "Interface Engine" be used to connect the databases, but that Interface Engine is not yet in place. Therefore, this document should be viewed as a first attempt to define the requirements for the CEVP database and data transfer system, and that changes to these requirements are to be both expected and accommodated in the design, implementation, and testing of the system.

2. Functional Requirements

System overview

The overall goal of the CEVP system will be to efficiently disseminate Integrated Testing Regimen (ITR) data, in accordance with Data Sharing Agreement (DSAs) signed by participating investigators and crewmembers, to JSC Discipline Experts, ISS International Partner facilities, and extramural investigators collaborating with NASA experts. The Internet-based data transfer system will support addition to and extraction of ITR data for the CEVP database. Ultimately, the CEVP database should interface with other Medical Operations databases (including LSAH/CMIS and LSDA), which house Medical Requirements information, as well as support the inclusion of data from in-flight research.

Security will be an issue of major concern since the CEVP database will contain confidential human medical and non-medical information that will be distributed over the Internet. All functions described below will be available only to those persons who have been authorized to do so, either through a DSA or for administrative purposes, as explained under "Users" in the nonfunctional requirements section.

CEVP Components and Interface Overview

SEE FIGURE 1.1 (attached)

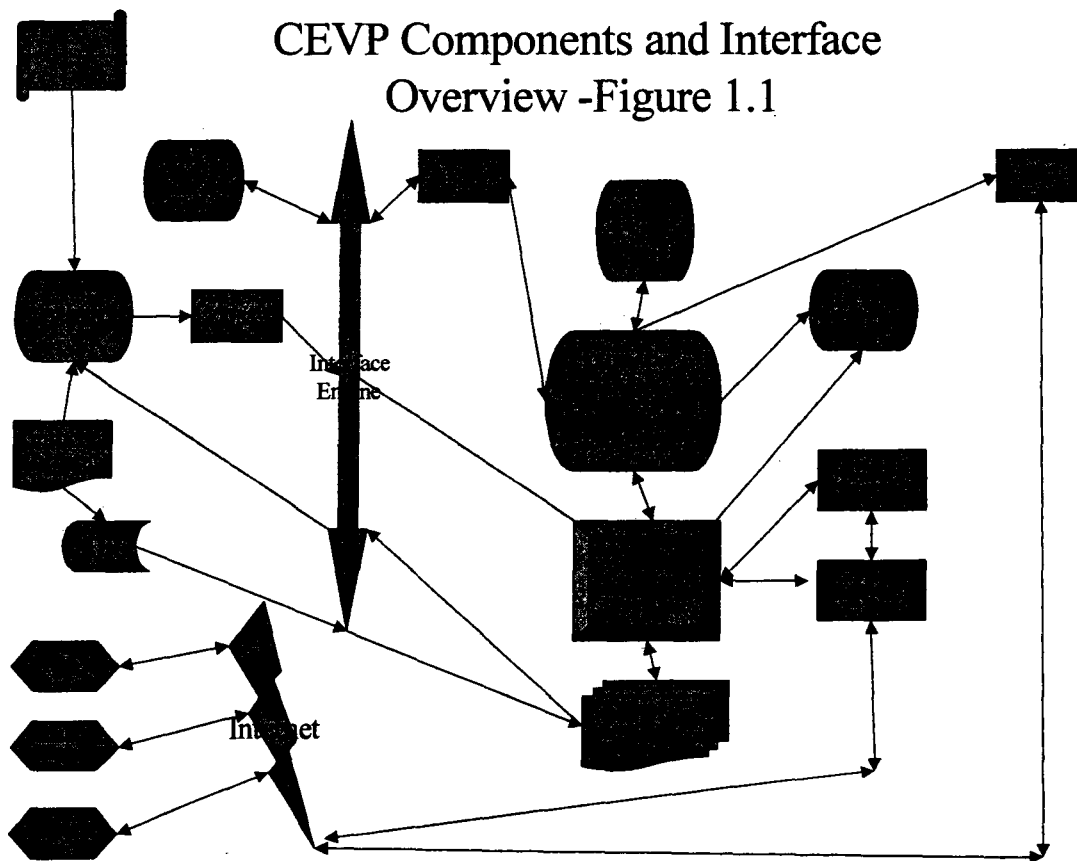
CEVP Ground Data Dbase Overview

SEE FIGURE 1.2 (attached)

Major Functions Overview

Access and Update – The Access function will provide access to the data in the CEVP Ground Data Database. Access is provided in three modes: Intramural, Extramural, and International; research-oriented users at JSC, other users in the US, and at International Partner sites will be able to access the CEVP Ground Data Database through the Internet. Direct (non-Internet) access to the database will be limited to administrative users.

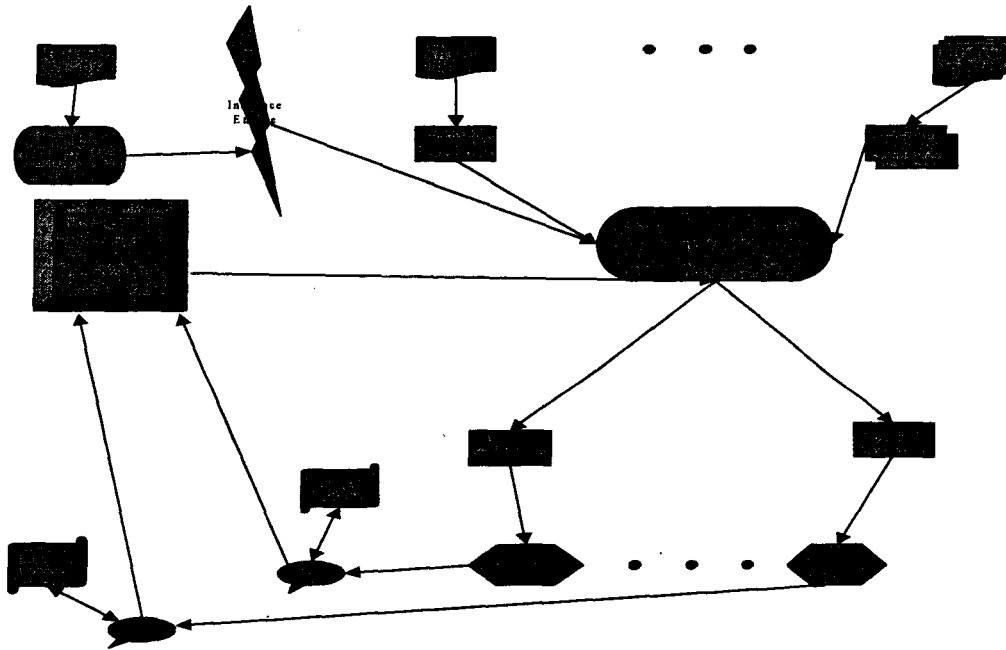
Authorized users will be able to extract and view a listing of selected data from the CEVP Ground Data Database in a variety of ways. This function also supports the download of collected data by all approved users for subsequent analysis. This module will be secure in that only authorized users will have access to the data, and that the data to which these users have access are only those items or records described in the applicable Request forms(s). In addition, data distributed to authorized users outside of JSC will be protected from unauthorized viewing through encryption, tunneling protocols, or similar mechanisms.



The Update function will allow users to download data into the CEVP Ground Data Database for subsequent analysis. Only authorized users will be permitted to download data to the database. Updates will be checked for consistency with the CEVP Ground Data Database structure so that they do not corrupt the existing database or any records that it contains.

Backup, Archive, and Restore - The Backup and Archive functions will support copying records from the CEVP Ground Data Database to other storage devices. This will ensure availability and integrity of the "active" database in case of equipment failure

CEVP Ground Data Database Overview Figure 1.2



or external damage. The Backup function will allow the system administrator to create a mirror copy of the entire database on a separate hard drive or external medium (tape or Zip drive). The device to which backups are performed should be configurable by the administrator.

The Archive function will allow the administrator to selectively remove records from the active database and move them into an archive or other database, such as LSDA. The Restore function will allow records in an archive to be reinserted into the active database.

Modify and Download – These functions are restricted to the system administrator. Modify allows the administrator to add/delete/modify data fields in the database. This function will also allow the administrator to add, delete, or modify data items for each field in the database in a manual mode. The download function allows the administrator to modify and move data downloaded from other systems (such as LSAH/CMIS or LSDA) into the CEVP database.

Report Generator – This function will be used by the system administrator to view or print data from the CEVP Ground Data Database. It will be able to generate, view, and print reports for the various laboratories at JSC or other remote sites. If a specific user wants a standard report or customized report, the request will be made to the system administrator.

Analysis – This function will support analysis of the data in the CEVP Ground Data Database for the users. This function will have three sub-forms: Statistics, Computation, and Modeling.

3. Non-functional Requirements

Physical Environment

The database should be maintained on a dedicated machine connected to the Internet through the JSC network. The operating environment should be the most recent version of Microsoft Windows NT. The database should be implemented in the most recent version of Microsoft Access 2000 or Microsoft SQL. (Note: it is unlikely that Access will support the number of records expected in the CEVP Ground Data Database. However, the working model may be implemented in Access and later converted to SQL. The user interface of the system may also be programmed in Access 2000.) This server should have the following minimum configuration:

- Pentium III 750 Mz
- 256 Mb RAM
- Dual hard drive, 10 Gb capacity
- 19" Monitor
- HP Laser Printer (direct attachment)
- External High-Capacity Tape/Zip Drive for backups
- Uninterruptible power supply

Interface with other Systems

An Interface Engine will be used to support sharing of data between the CEVP Ground Data Database and other systems in JSC and other related networks. The CMIS project is going to use HIE Cloverleaf Interface Engines for connecting existing systems to ISS data systems at JSC.

According to its designers, the HIE Cloverleaf Interface Engine is a core technology suitable for any industry that replaces costly point-to-point interface development with a configurable hub and spoke architecture. The engine creates a high-performance messaging platform that supports asynchronous and synchronous connections to a range of programs, databases, objects, and protocols. Graphical configurations clients allow

quick development of flow logic to direct, modify, and support business integration rules. Proactive management, alerting, and testing functions are all included. The system is available for both UNIX and native Windows NT platforms. HIE Cloverleaf supports multi-user interface development environment and popular communications protocols, including TCP/IP, SNA, and MQSeries.

Users and Human Factors

User Type: System Administrator (or Super User)

User Role: Responsible for activities relating to managing the CEVP Ground Data Database, including but not limited to network management, database update, database management, security management, answering user's questions, and technical support for the CEVP Ground Data Database.

Experience and Technical background: Computer Science and/or Science

User Type: Life Science Laboratories Staff

User Role: Access the CEVP Database without special authorization. High priority user.

Experience and Technical background: Science

User Type: PIs (General User)

User Role: Access the CEVP Database with special authorization as defined in applicable request from lower priority user.

Experience and Technical background: Science

User Type: LSAH/CMIS and LSDA Staff

User Role: Define interfaces to CEVP database, help in downloads between databases. Low priority user.

Experience and Technical background: Science

Performance

Any query of the CEVP Ground Data Database should be as efficient as possible. Most queries should take less than 10 seconds, and any query that takes more than 30 seconds for fewer than 2000 records is unacceptable. A progress indicator will be displayed for a query that takes more than 10 seconds. Note: these requirements do not consider delays caused by network congestion or routing failures.

Documentation

The following lists the deliverable documentation for the CEVP Ground Data Database and data transfer system:

- Users Manual (On-line help will be provided as well)
- System Administration Manual

- Requirements Documentation
- Design Documentation
- Source Code
- Test Plan and Results of Testing

Security and reliability

All human clinical or research data obtained will be subject to the Privacy Act of 1974 and secured using the "level two" security status set out by the Johnson Space Center Automated Information Systems Security Manual for the LSAH. To this end, the following requirements apply.

The CEVP Ground Data Database server should be located in a physically secured area at JSC so manual/non-networked access to the machine can be limited to administrators or designated JSC personnel. The CEVP Ground Data Database server and any peripheral machines used for data distribution should be within the JSC security firewall and thus protected from unauthorized logins and attacks to the extent possible with the existing mechanisms or future upgrades.

The CEVP Ground Data Database system will be logically isolated from other systems and accessible only as described in the interface section above. Access to the CEVP Ground Data Database will be limited to administrators or other specifically authorized JSC personnel, as described in the users and human factors section. No PI or other end user will be allowed to update or query the database directly.

Data marts in the CEVP Ground Data Database system will be constructed only by administrators, and only in response to a legitimate request from an authorized PI or other end user. The requests will be verified as to the user's identity and conformance to an approved request form that explicitly specifies the information to be made available to the user through a data mart.

Data transmitted between the CEVP Ground Data Database system and an authorized PI or other end user will be secure according to the policy stated above. All data will be transmitted using virtual private networking (or a similar technology) to encrypt and encapsulate the data and prevent its interception or viewing by unauthorized persons. This technology will support encryption to the fullest extent allowed by United States policy for the end user location.

A formal security policy for all data distributed between the CEVP Ground Data Database system and end users will be developed, including guidelines for protecting the confidentiality of both data and authorization at the end user site. However, it will be the end user's responsibility to follow these guidelines, as well as any set out in the request form, and maintain security in accordance with all applicable NASA policies. The security policy to be developed will not supersede any existing or future NASA policy.

To prevent attempts to penetrate or attack the CEVP Ground Data Database system, no publication or presentation about the system will explicitly describe or identify any machine, location, or security mechanisms used. Any such publication describing the techniques or mechanisms used in this system will avoid discussion of the specifics of CEVP security.

The CEVP Ground Data Database system is not intended to be a highly available system. The Backup and Archive function described above is intended to assure that no data is lost in the event of a system or server failure, although it is possible that some transactions may need to be restarted should the system fail during query or update of the database or a data mart. If a security breach is detected, the system will shut down until the problem is resolved; however, the security of the data will not be compromised due to a shutdown or failure of the system

4. Administrative Requirements

Team Organization

The development effort will be coordinated by Dr. Rex Gantenbein of the University of Wyoming. His primary responsibilities will be the supervision of the participants and preparation of deliverables as outlined here and in the original Offer to Perform Services.

Requirements gathering of the working model will be the responsibility of Dr. Sung Shin of South Dakota State University. In addition, Dr. Shin will assist with demonstrating the fulfillment of the system requirements through scenario analysis, determining the appropriate interfaces with other systems established at JSC, and obtaining cooperation with other JSC entities regarding data gathering, distribution, and archiving.

Mr. John Kim, a M.S. student at the South Dakota State University, will support the database implementation of the working model, with funding from NASA JSC grant NAG91176 (as revised). Security implementation of the working model will be performed by Mr. Tom James, a Ph.D. student at the University of Wyoming, with funding from a NASA JSC Graduate Student Research Program Fellowship. Mr. James will be assisted in the development of the secure Web interface by another University of Wyoming student to be hired for the Fall 2000 semester with funding from NASA JSC grant NAG91176 (as revised).

The technical monitor for this project is the CEVP manager, Mr. Charles M. Lundquist of the Life Sciences Research Laboratories at JSC.

Project Schedule

In Phase I of the project, the development team will deliver a revised version of the requirements documentation for the CEVP Ground Data Database and an implementation of the working model for the ground data. The Phase II system will incorporate these interfaces, as well as refine the number, types, and structure of the actual database items as they change in response to the interfaces and experiments developed during this period.

The Phase I prototype and documentation will be delivered no later than April 30, 2001. The Phase II system will be completed no later than August 31, 2001.

Review Process and Procedures for Change

Dr. Gantenbein will provide monthly progress reports to Mr. Lundquist. These reports will detail progress to date, issues and/or problems, costs in relation to the agreed-upon budget, and near-term goals. Mr. Lundquist and other parties at JSC will review these reports and discuss them with Dr. Gantenbein and other members of the development team. Through these reviews, desired changes to the development plan or project structure can be voiced and decided upon.

Once the definition of the CEVP system as specified by the Requirements Documentation is agreed to, all changes must be approved by the development team and the technical monitor.

5. A Working model Implementation for CEVP Ground Database

The goals of developing the CEVP Working model for the CEVP Ground Data Database are as follows:

1. Review mechanisms available for security in the CEVP project.
2. Review the current design of the CEVP project.
3. Investigate the advantages and disadvantages of the current approach to the CEVP project.
4. Investigate possible data input and output modes for the CEVP project.
5. Investigate the interface requirements with respect to other systems or archive databases at JSC.
6. Write and validate a complete requirements document for the CEVP project.
7. Store Ground Data into the CEVP Ground Data Database by the summer of 2001.

Architectural Design for CEVP Ground Data Database

The proposed operating system for the implementation will be WINDOWS NT. The project team will use Microsoft ACCESS 2000 and Microsoft Active Server Pages (ASP) technology for the implementation.

Data Entry for each lab

Authorized labs will be able to enter the ground data into the CEVP Ground Data Database only through Data Marts (DMs), which will be accessible over the Internet (and through the JSC intranet) using a Web browser such as INTERNET EXPLORER or NETSCAPE. It may be necessary to specify a particular browser in order to assure that all features of the data entry system integrate properly.

A Menu Driven System will be used for the data entry by each lab. Each lab will be authorized to access only its own DM(s) for data entry.

The DMs and the CEVP Ground Data Database itself will be located on a secure database server within the JSC firewall. Security from Data entry to DM will include both user authentication (password) and Windows NT-provided virtual private networking. Security between the DM and the database will be provided by the secure database server.

CEVP Administration & Committee

The CEVP Administrator & Committee will review a request for access to data in the CEVP Ground Data Database through a request form submitted by each PI. On approval of the request, the Administrator will create a DM for the PI. The data items listed on the request form will be extracted from the CEVP Ground Data Database to the DM for the appropriate PI.

The CEVP Administrator will maintain the CEVP Ground Data Database and DM for each PI.

The CEVP Administrator will update the DM for PI if PI requests an update for a structure of an appropriate DM.

Data Retrieval for each PI

All authorized PIs will be able to view a listing of selected data from the CEVP Ground Data Database as specified by the appropriate DSA. This function also supports the download of collected data from the DM by all approved PIs for subsequent analysis. This function will be secure in that only authorized users will have access to the data, and that the data to which users have access is only those items or records previously approved.

The DM for each PI has a limited lifetime, which will be specified individually for each DM. The DM will be deleted once its lifetime has terminated.

The Update function will allow only the CEVP Administrator to update the CEVP Ground Data Database. This function will be protected by authentication on the database itself.

The CEVP Ground Data database server will provide security from the CEVP Ground Data Database to each DM. Security from the DM to the PI will include authentication (password) and Windows NT-provided virtual private networking.

Data Entry Screen Design for Each Lab.

- Architectural Design for the Data Entry
- Data Entry for Patient Information
- Screen Design for Cardio Lab
- Screen Design for Bone Lab
- Screen Design for Exercise Lab
- Screen Design for Nutritional Status Assessment

Data Retrieval flowchart and Screen Design

- Ground Data Retrieval Flowchart
- Architectural Design for Retrieval

Appendix

Acronyms

CEVP – Countermeasure Evaluation and Verification project

DFD – Data Flow Diagram

I/O – Input and Output

RD – Requirement Documentation

DSA – Data Sharing Agreement

ITR – Integrated Testing Regimen

WBS – Work Breakdown Structure