A technical discussion of Good Electronic Records Management using Rational software from IBM
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Good Electronic Records Management (GERM) Using IBM Rational ClearCase® and IBM Rational ClearQuest®

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Document Summary

This paper describes a solution for addressing "Good Electronic Records Management" (GERM) compliance issues, using the context of the Food and Drug Administration's 21 CFR Part 11 as an example.

Transforming a company's software development practices within the highly regulated food and drug industry can be a challenging undertaking. The complexities of GERM are enormous -- from understanding the FDA requirements, to creating a Good Manufacturing Process, from training employees to implementing the tooling.

Proven software development processes and configuration management processes can simplify the deployment of GERM in a software development group. Industry-leading products from IBM Rational -- ClearCase® and ClearQuest® -- provide robust Configuration Management and Change Request Management solutions for the administration of artifacts produced throughout the lifecycle of automated systems. Although these solutions provide out-of-the-box capabilities that satisfy current practices for GERM, software development teams should take steps to extend these capabilities in order to provide additional record safeguards.

This document is intended to provide insight into the current capabilities and possible strategies for the operation, use, and extension of the ClearCase and ClearQuest products to address Electronic Signatures; Electronic Records compliance, using 21 CFR Part 11 as an example.

Assumptions

Making a transition to GERM practices requires established policies, procedures, and processes, as well as product customization to support these processes. The Rational Unified Process (RUP)®[1] provides a solid process framework, and makes it possible for customers to draft policies, procedures, and practices for the non-automatable enforcement of policies and procedures required by regulations.

[1] RUP is in wide use in the software development industry and is generally recognized as a standard framework for software engineering work. The RUP process framework can be tailored for traditional methodologies, e.g., iterative and waterfall methodologies, as well as for emerging methods using COTS products and component-based techniques that rely on reusable software components. Additional information on RUP, as well as a product demonstration can be found at www.rational.com.

Intended Audience

The following document is intended for those readers who understand the regulatory or industry practices pertinent to records management for their industry.

Product Descriptions

Rational ClearCase -- Rational ClearCase is a Configuration Management (CM) and Version Control (VC) system designed for the storage of electronic artifacts. ClearCase is implemented as a file system that emulates and extends the behavior of most native file system. Within ClearCase, it is possible to store not only software, but also nearly any file type that can be stored on the native file system. Examples of these file types include, documents, requirements, models, code, directories, etc.

Rational ClearQuest -- Rational ClearQuest is a Change Request Management (CRM) system used for the tracking of modification requests or issues (software bugs) regarding automated systems. ClearQuest is highly configurable, capable of accommodating nearly any automatable process design. ClearQuest allows for user defined, work flow support (customizable state machines), fields, forms, and email notification.

Document Format

Each major paragraph of 21 CFR Part 11 is discussed, supplying interpretation from IBM Rational of that section as it relates to Configuration Management and Change Request Management with Rational products.

An Introduction to 21 CFR Part 11

The Code of US Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The CFR is divided into 50 titles that represent broad areas subject to Federal regulation. Each title is divided into chapters that usually bear the name of the issuing agency.

Title 21 is owned and controlled by the Food and Drug Administration. Although the contents of these titles are developed and maintained by the respective agencies, cross referencing of title content is not unusual. In an effort to eliminate redundant and contradictory regulations, most agencies cross reference title content to assemble regulations with a consistent message.
For example, agencies cross reference titles, paragraphs, and subparagraphs to construct a regulation that defines electronic signature requirements in Title 21.

IBM Rational Interpretations

IBM Rational has developed this document to describe how 21 CFR Part 11 can be satisfied through the use of Rational ClearCase and ClearQuest. Paragraphs containing actual text from the Code of Federal Regulations, Title 21 Part 11, are provided below in italics. . Interspersed throughout the regulation descriptions are interpretive statements to explain how ClearCase and/or ClearQuest provides or can provide capabilities to satisfy each section of the regulation. Approximately one third of the regulation serves as a context for defining an automated solution for compliance. The remaining two thirds of the regulation apply to how the technology is used and managed by the regulated establishment. Sections of the regulation that are not followed by a IBM Rational Interpretation section are such usage and management sections of the regulation.

[Note: italics below indicates text reproduced verbatim from the Code of Federal Regulations Title 21 Part 11]

Code of Federal Regulations Title 21 Part 11; Electronic Records; Electronic Signatures

Subpart A--General Provisions

Sec. 11.1 Scope.

(a) The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable,

and generally equivalent to paper records and handwritten signatures executed on paper.

(b) This part applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations. This part also applies to electronic records submitted to the agency under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in agency regulations. However, this part does not apply to paper records that are, or have been, transmitted by electronic means.

(c) Where electronic signatures and their associated electronic records meet the requirements of this part, the agency will consider the electronic signatures to be equivalent to full handwritten signatures, initials, and other general signings as required by agency regulations, unless specifically excepted by regulation(s) effective on or after August 20, 1997.

(d) Electronic records that meet the requirements of this part may be used in lieu of paper records, in accordance with Sec. 11.2, unless paper records are specifically required.

(e) Computer systems (including hardware and software), controls, and attendant documentation maintained under this part shall be readily available for, and subject to, FDA inspection.

IBM Rational Interpretation – This section describes those record artifacts of interest to the FDA (who shall be referred to later in this document as "the Agency") that are codified in predicate regulations and which will be considered equivalent to paper records provided that Part 11 conditions are fulfilled.

Sec. 11.2 Implementation.

(a) For records required to be maintained but not submitted to the agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that the requirements of this part are met.

IBM Rational Interpretation – If customers choose to store regulated artifacts within ClearCase and ClearQuest, then this document (21 CFR Part 11) is applicable[2].

[2] It is possible to use both paper documents as well as electronic records together, otherwise referred to as "Hybrid Systems". In order to construct a compliant ClearCase and ClearQuest environment, manual procedures may require written logs and signatures to associate those electronic records stored in ClearCase and ClearQuest.

(b) For records submitted to the agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that:

(1) The requirements of this part are met; and

(2) The document or parts of a document to be submitted have been identified in public docket No. 92S-0251 as being the type of submission the agency accepts in electronic form. This docket will identify specifically what types of documents or parts of documents are acceptable for submission in electronic form without paper records and the agency receiving unit(s) (e.g., specific center, office, division, branch) to which such submissions may be made. Documents to agency receiving unit(s) not specified in the public docket will not be considered as official if they are submitted in electronic form; paper forms of such documents will be considered as official and must accompany any electronic records.

Persons are expected to consult with the intended agency receiving unit for details on how (e.g., method of transmission, media, file formats, and technical protocols) and whether to proceed with the electronic submission.

IBM Rational Interpretation – In most situations it is unlikely that Customers will be using IBM Rational tools in the delivery and transmission of electronic submissions. However, there may be situations where Customers are sourcing software products used in assembly and delivery of electronic submissions. In such situations IBM Rational products may underlie the construction and service of these computing environments or even the submission artifacts themselves and therefore may be subject to regulatory inspection. In such cases it is important to ensure that procedures reflect the management of the lifecycle of any artifacts controlled through the use of ClearCase and ClearQuest.

Sec. 11.3 Definitions.

(a) The definitions and interpretations of terms contained in section 201 of the act apply to those terms when used in this part.

(b) The following definitions of terms also apply to this part:

(1) Act means the Federal Food, Drug, and Cosmetic Act (secs. 201-903 (21 U.S.C. 321-393)).

(2) Agency means the Food and Drug Administration.

(3) Biometrics means a method of verifying an individual's identity based on measurement of the individual's physical feature(s) or repeatable action(s) where those features and/or actions are both unique to that individual and measurable.

(4) Closed system means an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

(5) Digital signature means an electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified.

(6) Electronic record means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

(7) Electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

(8) Handwritten signature means the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark.

(9) Open system means an environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.

IBM Rational Interpretation – The Agency has provided these definitions for clarification of certain terms used in the Rule. It should be noted, relative to the terms 'biometric' and the techniques to capture handwritten signature images, that ClearCase and ClearQuest APIs make it possible to utilize these forms of identification that go beyond UserID and password combinations. Provided APIs make it possible to communicate to, devices that capture and verify biometric data and devices that capture handwritten signatures.

Subpart B--Electronic Records

Sec. 11.10 Controls for closed systems.

Persons who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine.

IBM Rational Interpretation – Both ClearQuest and ClearCase function as closed systems. ClearQuest utilizes its own native application authentication mechanism. ClearCase leverages Operating System authentication on the client where ClearCase is installed. In either case, appropriate procedural controls should be drafted or modified to ensure proper treatment is given to UserIDs in either environment. Separate UserID and Password for the signing of ClearQuest records should be used. Naturally, procedures should be established for the creation of these UserID/Passwords as well.

Such procedures and controls shall include the following:

(a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.

IBM Rational Interpretation – Validation of Configuration Management systems should align with typical Good Systems Practices just like any other computing environment or computing tool used for and in the support of a regulated activity. What

this means is that customers should prepare computer validation practices that encompass a Systems Life Cycle (SLC) approach. In situations where SLC activities involve buying technologies from the marketplace, evaluation of suppliers (supplier audits) is important. An example of such a good systems practices for audit activity is described in the Parenteral Drug Association's document "Technical Report 32, Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations."

> *(b) The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.*

IBM Rational Interpretation – ClearCase provides the ability to recreate any version of an element checked-in to the ClearCase system, allowing users the ability to view, in human readable form, the content of the repository. If specific tools are used for the creation of ClearCase artifacts, it may be necessary to use these same tools to provide human readable versions of the artifact in question. Microsoft Word, for example, stores documents in a proprietary form. If Word documents are stored in the ClearCase repository, Word will be required to read those documents once retrieved from ClearCase. It is for this reason, that it is suggested that not only should artifacts be versioned, but the tools used to produce these artifacts be versioned as well.

ClearQuest can also support recreation of a record for any specified date, through the use of hooks and/or reports.

> *(c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.*

IBM Rational Interpretation – ClearCase and ClearQuest are designed to store records indefinitely for the platforms they support; this means the archival of digital information is possible. However, long term retention of records, as part of the record life cycle, is a complex issue involving considerations for record format, record content, and record context, not to mention the need for selective record discard (purging) at the end of the record's useful life. Support for purging records is also available. Customers should establish a record retention policy for both ClearCase and ClearQuest, and they should determine who will purge records. Customers are also advised to consult with their Records Managers to determine how best to utilize ClearCase and ClearQuest tools for archival purposes.

> *(d) Limiting system access to authorized individuals.*

IBM Rational Interpretation – As previously indicated, access to ClearQuest is constrained through unique UserID and password combinations. ClearCase access is constrained by workstation authentication. However, access control mechanisms can also be added through the usage of ClearCase triggers or ClearQuest hooks. You can also setup access privileges for specific elements to ensure different levels of access to different elements.

(e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.

IBM Rational Interpretation – ClearCase automatically records all operations against all objects stored in its repository. ClearQuest requires the creation of a hook to support field level logging of transactions against its data. However, in both cases, ClearCase and ClearQuest store Date-Timestamp information relative to Greenwich Mean Time. Examination of ClearCase metadata and or the ClearQuest History and Field Log data, can be used to delineate any changes that have occurred and when.

Through the use of this logging capability, records that have been modified since they were placed in the repository can readily be identified and discernable from unmodified records.

(f) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.

IBM Rational Interpretation – ClearQuest operation is based upon a user customizable state machine. In other words, ClearQuest supports the automation of user-defined workflows. Records are manipulated by moving them through the various states in a user-defined process. Data is gathered by the ClearQuest product based upon what conditions or actions need to be fulfilled (is the field required) to move from one process state to another process state, e.g., states or steps in an approval process. ClearCase can also be extended to fully support state machine capabilities. Support for ClearCase state machines can be facilitated through the use of external applications using the ClearCase API and attribute based triggers.

Customers implementing a customized state machine will need to ensure that ClearQuest automated workflow is based on manual policies, and procedures during their design.

ClearCase may also be extended to support its own or shared user administration capability. One strategy to consider for this type of support is to depend upon the authentication infrastructure supplied in ClearQuest. This strategy would allow consolidation of Userid(s) for signature purposes to single storage and administration point.

(g) Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand

.

IBM Rational Interpretation – As previously outlined in item 11.10(f) above, ClearQuest data can be programmatically required. Required data can include the need for appropriate digital or electronic signatures prior to permitting the promotion of the record to any subsequent state. This capability can also be supported in the ClearCase environment, as suggested, through ClearCase/ClearQuest integration. It is important however, to underscore the use of appropriate physical access measures in conjunction with the functionality described in this document.

> *(h) Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.*
>
> *i)(Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.*

IBM Rational Interpretation – IBM Rational offers its customers a vast array of technical training in the use of its tools. Configuration of Rational tools to accommodate 21 CFR Part 11 would require customers to create appropriate training that conforms to the operational procedures of their particular configuration. The IBM Rational services organization and many IBM Rational partners can help to customize and deliver training as needed.

> *(j) The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under* their electronic signatures, in order to deter record and signature falsification:
> *(k) Use of appropriate controls over systems documentation including:*
> *(1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.*
> *(2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.*
>
> *Sec. 11.30 Controls for open systems.*
>
> *Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in Sec. 11.10, as appropriate, and additional measures such as document encryption and use of appropriate digital*
> *signature standards to ensure, as necessary under the circumstances, record authenticity, integrity, and confidentiality.*

IBM Rational Interpretation – All of IBM Rational products, including ClearCase and ClearQuest, are designed to support open development and support environments; thus, these products can be used in an open system context as described. ClearCase and

ClearQuest offer the ability to automate the capabilities outlined in section 11.10 to facilitate the use of additional measures.

Sec. 11.50 Signature manifestations:

(a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:
(1) The printed name of the signer;
(2) The date and time when the signature was executed; and
(3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.
(b) The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).

IBM Rational Interpretation – All of the data required in items 11.50(a) through (b) can be stored within ClearQuest records or as ClearCase versions and metadata in a secure unmodifiable environment.

Details for the reporting of this data from ClearCase are explained in Appendix A.

Sec. 11.70 Signature/record linking.

Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.

IBM Rational Interpretation – ClearQuest signatures can be stored directly on each signed record, thereby establishing a direct linkage to the data being signed. ClearCase elements have appropriate signatures stored as metadata on the actual version of any given document, thereby linking the specific instance of a document to its applicable signature. It is often suggested that signatures should be inserted into source documents as finished informational entity. This approach may make sense for artifacts that receive some type of final approval, and are then never modified again. ClearCase can support this capability.

However, software components -- or more accurately, software code -- can and will be corrupted through the insertion of foreign data streams. Furthermore, the extremely evolutionary (continuously modified) nature of source code makes it impractical to insert a large number of signature data streams over the lifetime of a source object. For this reason, ClearCase employs the metadata structures, which permits direct attachment of data streams to the exterior of source documents. (A more lengthy explanation of this is covered in Appendix A.)

Subpart C--Electronic Signatures

Sec. 11.100 General requirements.

(a) Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.

IBM Rational Interpretation – Although this particular section of the regulation is really oriented toward procedural control, it is often misinterpreted as an automation requirement. Rational ClearCase and ClearQuest can support unique UserID/password combinations. Use of this functionality, however, requires notification to the Agency when electronic signature methods will be used in the signing of electronic records.

(b) Before an organization establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.

(c) Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be the legally binding equivalent of traditional handwritten signatures.

(1) The certification shall be submitted in paper form and signed with a traditional handwritten signature, to the Office of Regional Operations (HFC-100), 5600 Fishers Lane, Rockville, MD 20857.

(2) Persons using electronic signatures shall, upon agency request, provide additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature.

Sec. 11.200 Electronic signature components and controls.

(a) Electronic signatures that are not based upon biometrics shall:

(1) Employ at least two distinct identification components such as an identification code and password.

IBM Rational Interpretation: Support for UserID and password is accommodated though the use of hooks in ClearQuest or triggers in ClearCase. Appropriate encryption methods can be applied in either case. As stated previously, appropriate procedures will need to be drafted to ensure that established signature passwords were created by the intended identity. If support for capturing of said handwritten signature is configured, consolidated reporting of signatures to the signature authority could be supported using ClearQuest reporting.

i) (When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be

executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual.

(ii) When an individual executes one or more signings not performed during a single, continuous period of controlled system access, each signing shall be executed using all of the electronic signature components.

IBM Rational Interpretation – Without modifications to the Rational products, it is not expected that "*a series of signings"* will be supported. It is anticipated that each state change in either ClearCase or ClearQuest will require separate signatures, thus requiring both UserID and password components.

(2) Be used only by their genuine owners; and

(3) Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals.

IBM Rational Interpretation – ClearCase and ClearQuest are designed to ensure they are operationally secure. Bypassing these security mechanisms requires two or more individuals in collaboration.
This section of the regulation is often misinterpreted as a requirement for the implementation of primary and alternate signature support.

Sec. 11.300 Controls for identification codes/passwords:

Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include:

(a) Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.

IBM Rational Interpretation – ClearCase and ClearQuest provide for unique UserID/password combinations. .

(b) Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging)

IBM Rational Interpretation – ClearCase and ClearQuest can be configured to periodically evaluate, recall, and/or expire passwords as required. ClearCase password expiration is accomplished through native operating functionality in Windows or Unix. ClearQuest password expiration can be accomplished through the construction of an external ClearQuest API based application. This application should run as a service, and periodically terminate user passwords as well as signature material.

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(c) Following loss management procedures to electronically de-authorize lost, stolen, missing, or otherwise potentially compromised tokens, cards,

and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.

IBM Rational Interpretation – ClearCase and ClearQuest can be configured to electronically de-authorize both ClearQuest or ClearCase Application UserID/password combinations or signature UserID/password combinations. Please see 11.300(b) above for a complete description of the suggested approach.

(d) Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management

IBM Rational Interpretation – ClearCase and ClearQuest can be configured to electronically notify signature or logon administrators of misuse/abuse during the signature process. Regardless of solution, the intended strategy is to employ measures to preclude the misuse of UserID and password combinations. Extension of this capability as monitoring solutions can be implemented as ClearQuest hooks and/or ClearCase triggers.

(e) Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner.

IBM Rational Interpretation – ClearCase and or ClearQuest can be configured to utilize external security tokens, pass cards, and other external devices.

Compliance Safeguards:

Customers and IBM Rational specialists who implement the recommendations contained herein must be vigilant in the construction of procedural documentation and operational logs. These documents should be designed to comply with current good practices as well as applicable regulations for their industry.

Solution Implementation: A Practical Guideline

Overview

The subsequent sections of this document describe implemenatation of a compliant solution to address the needs of regulated markets. This section of the document is particularly focused on addressing the needs of those customers impacted by Electronic Signatures and Electronic Records. Although this document is oriented toward the development of a proposed solution involving only ClearCase and ClearQuest, the capabilities outlined here resolve many issues for storage of requirements, application models, designs and code, etc.

The solution presented is designed to address compliance issues for configuration management of software applications used for the creation, modification, and storage of regulated systems. Examples of this type of application include medical device software, pharmaceutical clinical trials software, trading floor systems software, and federal systems software systems that will be developed in secret/top secret environments.

Solution Orientation

The overall solution implemented is similar to the classic ClearCase/ClearQuest integration model.

In conformance with standard development practices, consideration has been given to the idea that each product (ClearCase and ClearQuest) should function independently from the other. However, companies operating in regulated environments require the implementation of current good practices for robust configuration management systems. These current good practices assume the use of change request management, version control, automated workspace management, and build management. In order to fulfill these requirements the solution requires the use of both ClearCase and ClearQuest. Therefore, the emphasis of this solution is predicated on a design that emphasizes their integration.

The ultimate solution will allow users to promote ClearCase element versions and ClearQuest defects through a user defined state model.

Installation, Operation, and Process Quality Testing

In any regulated environment, the question of IQ, OQ, and PQ testing is bound to arise. Although these terms may seem foreign to those not acquainted with them, they are nothing more than qualification tests that substantiate that the product is installed correctly, operates correctly, and conforms to its intended design.

The easiest of these tests to create is the Installation Quality Qualification (IQ) Test, because it has been a part of ClearCase and ClearQuest products since their inception. The IQ tests for ClearCase and ClearQuest reside in their respective installation logs. During each phase of installation, the Rational script, by design, checks for proper installation of each component and logs the result accordingly.

The Operational Quality Qualification (OQ) Test can be created easily as well, but it will require slightly more work. An Operation QualityOQ Test validates that the product as configured operates as designed by the manufacturer.

In this particular case, the test should be conducted after the prescribed solution for ClearTeam Secure is implemented. In order to create an OQ test, write a script that executes the following ClearCase operations.

1. create an element
2. checkout on main
3. checkin on main
4. allow your configuration to capture your UserID, via authentication, as metadata
5. label the element on main
6. checkout/checkin, once again trapping UserID via authentication
7. checkout and autobranch from the labeled version
8. checkin, once again authenticating the user
9. checkout /main/LATEST
10. perform a trivial merge to /main/LATEST from your branched version
11. checkin, authenticating the last time

You have now exercised all of the basic functions of ClearCase and its integration to ClearQuest for user authentication. This activity substantiates proper ClearQuest operation and builds on what the supplier (IBM Rational) has done in testing the product for the marketplace.

Creation of the PQ ora Performance Quality Qualification (PQ) Test is a little harder. The layman's definition of a PQ test is the testing of the application as it is intended to be used over time. PQ testing is an evaluation of the applications ability to demonstrate reliability, or throughput capabilities.

Customer expectations vary regarding the overall performance of any product. IBM Rational suggests that customers utilize an appropriate tool for performance evaluation. IBM Rational does offer such a tool, in its Test Studio Suite allowing customers to create load or performance, functional and regression tests.

IBM Rational regularly assists customers in the use of these tools for creating such tests.

Appendix A.

Integrating ClearTeam Secure to Data Acquisition Devices:

In order to properly integrate an external device with ClearCase and/or ClearQuest for the purposes of biometric capture, one should replace the MD5 encryption solution described in the paper above with calls to your data acquisition device.

Furthermore, it will also be necessary to modify the external authentication tool to interrogate the project record type to identify the biometric mechanism in use for the project the checkout is against.

Finally, appropriate adjustments must also be made to your ClearQuest Signature record type in order to ensure that data acquired through your external device can be stored appropriately. If you intend to use you externally acquired data for authentication, as opposed to simply authorizing on-going activity, there will be other considerations. For example, if your device utilizes a proprietary method for authenticating the signature of an individual (i.e., hand writing pressure variations, in conjunction with pen stroke dimensions and linearity), you made need to plan your implementation carefully.

In order to determine this you must first decide what vendor will provide your biometric data acquisition tool. Several types of products exist in the market place to facilitate data acquisition. Finger printing, retinal scanning, handwritten signature capturing, and capturing hand dimensions are just a few examples.

Be certain that your can either store all necessary data to authenticate the individual within the ClearQuest signature record type, or that sufficient access is available from all ClearCase clients to the authentication data and external authentication source. Although this is not a absolute requirement, it does make the task of automating and programmatically controlling tool behavior using ClearQuest Hooks or ClearCase Triggers easier.

Most manufacturers of these biometric solutions offer ActiveX and COM based API solutions for integrating their products with existing applications.

Consolidated Element Version Data and MetaData Reporting:

In an effort to ensure consistent reporting of ClearCase Metadata with its respective Element version data, it may be necessary to create a script. This script must dump the content of a given element version, along with the associated metadata for the requested version. This can be accomplished easily as a two-line script on Windows platforms or Unix.

An example of such a script for windows would be the following:

```
type %1 > dummy.txt
```

cleartool describe -l %1 >> dummy.txt

Where %1 is a script argument containing the name of a plain text file to be reported.

The script can be executed directly from the command line. A more elegant implementation would be to use the ClearCase Context Menu Editor to add a call to the script to the Windows Explorer or ClearCase Explorer. The script could then be invoked via a right click context menu event.

The resulting output would be all of the text of the selected element version, including all of the MetaData appended to the selected element version as well.

An example of the Unix variant of this script might be something like this:
Cat $1 > dummy.txt
Cleartool describe –l $1 >>dummy.txt

Naturally, argument variables will vary based upon the shell implemented. A more effective solution in the Unix context might be the creation of an executable that accepts as an argument the version extended pathname of an element to process.

It is important to note that artifacts stored in a proprietary format may require more scripting to accommodate appending of ClearCase MetaData to them. This is because the artifacts using proprietary storage methods may not operate properly when raw text data is appended or inserted at the end of a given element.

However, one can easily imagine the creation of a scripts that utilize the ClearCase type manager capabilities that might allow a Word document, for example, to be opened and subsequently appended with ClearCase MetaData.

The ability to support such reporting will be on a case-by-case basis.

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