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A Computer-Aided Environment for ISO-9000 Standards Certification

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Abstract

ISO-9000 series standards have been accepted as standards of international quality systems worldwide in industries. Currently, there is no software used to design, construct and maintain quality system complied with ISO-9000 completely. Existing softwares only automate some aspects of quality management, such as document management, process control, and gradation tracing. This paper presents an ISO-9000 Certification Aided enviRonmEnt, ISOCARE, that is a Process-Centered Software Engineering Environment. ISOCARE integrates sets of aided tools to support Process Supporting ISO 9000 certification, which can helps further organizations to obtain ISO-9000 certification.

Keywords: ISO-9000, software process technology, process-centered software engineering environment, quality management system, network-centric computing.

1. Introduction

ISO 9000 is a generic standard of Quality Management Systems (QMS). Obtaining ISO-9000 certification, organizations can promote in competitive ability and increase business opportunity. Difficulties occur when applying ISO 9000 into a QMS, e.g., what have to do and what have to be documented [9]. Problems also come out in executing QMS after obtaining ISO 9000 certification, e.g., waste in documentation or products without higher quality [6]. It is helpful to provide a system to help organizations construct and fulfill QMS complied with ISO 9000. There are many systems proposed, however, these systems usually focus on parts of ISO 9000. For example, some systems [3][4] help companies in building documented quality system without aids in execution of procedures. To help companies meet the ISO 9000 certification, it might be better to provide an environment with more properties, such as enacting the documented procedures, flexibility to modify process, management of documents, and integration of necessary assistant tools.

The essence of high quality software may lie in the development process [16]. *Process-centered Software Engineering Environments* (PSEEs) can guide the progress of software development and supply the necessary integrated tools [1]. The success of software process technology indicates that supporting ISO 9000 certification in PSEE is feasible. There also exist other step-by-step approaches proposed to support ISO 9000 registration in [21][22][24]. In these approaches, the implementation and certification of ISO 9000 can be mapped into processes and earn benefit from PSEEs.

Based on process model, we have presented a methodology [6] to build and execute QMS complied with ISO9000 for software development processes. To support the methodology, this paper presents a PSEE-based system, called ISO-9000 Certification Aided enviRonmEnt, ISO-CARE. To construct ISO-CARE, we first re-considered our PSEE environment with the characteristics of ISO-9000, such as quality objectives, commitment, etc. Our methodology divides QMS life cycle into four steps: pre-processing, designing, execution, and modification. Thus, the kernels of ISO-CARE, including PLAN language, PDE, and PASE, were derived (by modifying) from our PSEE correspondingly and a set of process model templates for internal quality auditing have been created. Besides, a set of tools such as those for documentation management are also introduced to simplify the building and construction of QMS.

2. ISO 9000 and Current Supporting Environments

2.1 ISO 9000 Series of Standards

The ISO 9000 standards are series of international quality standards; they can be applied to the QMS to help produce qualified products [12][18]. ISO 9001, 9002 and 9003 are three individuals but related standards, as shown in Figure 1, and a company can select a suitable standard based on its characteristics. The generic nature of the ISO 9000 series makes it difficult to apply the series to an application directly. To overcome the difficulty, a guidance document, ISO 9000-3, has been developed to provide detailed information on implementing ISO 9001 in a software environment [12][18].

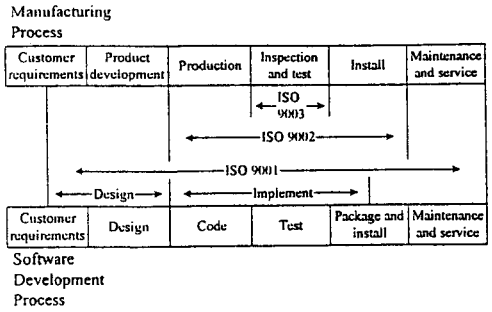

Figure 1. Relationship of ISO 9000 standards to the development process

A QMS that is complied with ISO standards requirement can be discussed from the following viewpoint [18]:

(1) Personnel part: different roles, including worker, quality manager, purchaser and subcontractors need to be aware of and make sure of their own responsibility.

(2) Product part: all product parts, including internally developed parts, product documentation, and subcontracted parts, must be controlled, identifiable, traceable, and verified.

(3) Project items: phases of project development, such as requirement, project plan, design output, test plan, service plan and quality record, must be controlled; and the QMS should demonstrate its effectiveness and auditability correspondingly.

(4) Support items: the support items include quality policy and objectives, procedures, internal quality system audit, etc. These support items must be documented, effective, controlled and continually improved.

2.2 Comparison of Current Supporting Environments

With the acceptance of ISO 9000 standard series globally, more and more applications or environments which claim ISO 9000-supported appear on the software market [2][3][4][5]. Table 1 is a comparison of current ISO 9000-supported environments. Most of these ISO 9000-supported environments are developed over Lotus Notes; they take advantage of the groupware software, such as workflow applications with integrated electronic mail, built-in development tools, database management, etc. However, most environments focus on documentation required by ISO 9000. Existing environments only automate parts of ISO 9000 requirements via workflow in Lotus Notes. These cause that processes and procedures lie in documents only and can hardly not be executed in real world. Too much paperwork and too many rules only make organizations more bureaucracy [20].

	Distribution technology	Documentation system	Process/ Procedure enactment	Tool integration	Steps to ISO 9000 conformance
QMX4.5	Lotus Notes	User create	Lotus Notes Workflow	Lotus Notes groupware	On-line help manual
Q-Plus	Lotus Notes	Automatic generating from templates	N/A	Lotus Notes groupware	On-line help manual
Design Procedure	Client-Server	Automatic generating from templates	N/A	Flowchart drawing tools	On-line help manual
ISO Achiever plus	Lotus Notes	Automatic generating from templates	Lotus Notes Workflow	Lotus Notes groupware	On-line help manual
THExPERT	Lotus Notes	Automatic generating from templates	Lotus Notes Workflow	N/A	On-line help manual

Table 1. Comparisons of ISO 9000-supported environments

ISO 9000-3 characterizes the quality system as an integrated process throughout the entire software life cycle. Using an additional integrated system, such as the PSEE, to achieve process enactment can be a feasible way.

3. A PSEE for ISO

3.1 PSEE architecture

PSEE is an environment supporting software development activities. The high-level architecture of a PSEE is shown in Figure 2.

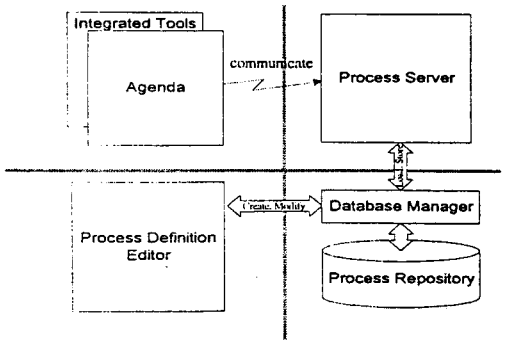

Figure 2. The high-level architecture of a PSEE

A process model may contain activities to be done, artifacts to be manipulated, roles to execute the activities and resources to be consumed. Process models and other information are stored in a process repository. A process model is enacted as a process in a process server. Participants can monitor the progresses of processes, acquire a task, and report the result through agendas. Integrated tools are designed to help accomplish tasks for users who involved in the PSEE. Besides, users can define a process model with process definition editor (PDE) in a process modeling language (PML).

3.2 Support ISO 9000 in a PSEE

There are several characteristics of ISO 9000 conforming quality system [18]. These requirements and how to satisfy them in perspectives of PSEE are:

(1) Quality objectives. In PSEE, quality policy can be treated as an artifact dispatched to all the roles and maintained by certain roles consisting of highest-levels of management. Moreover, the process designer has to model the strategies achieving the quality policy into processes clearly.

(2) Commitment, involvement, and attitude. All employees and managers must be committed and devoted to achieving the quality objectives. The documented procedures must be modeled into process models involved all people to achieve the objective addressed in quality policy.

(3) Control. For items related to the product or development of the product, there need owners with authority to approve changes and procedures for requesting, reviewing, and approving changes. Authority can be modeled as certain roles responsible to some activities or artifacts in PSEE. And the procedures can be modeled into enactable processes.

(4) Effectiveness. It is needed to demonstrate and improve its effectiveness, and determine the cost of quality. Assistant tools are necessary to analyze the results of enactment of processes to show the effectiveness and the cost. The analysis can also be used to improve the processes.

(5) Auditing. During the development process, ISO 9000 requires the ability to show where the process proceeds, what has been done, and what has yet to be done. In PSEE, the progress can be monitored at a process server.

(6) Documented quality system. The quality system, including processes and procedures, should be documented. It needs tools to accomplish the tasks of documentation.

(7) Continual improvement. The quality system should be continually monitored and reviewed for weaknesses and that improvement be identified and implemented.

Our methodology [6], to build and execute QMS complied with ISO 9000, divides QMS life cycle into four steps: pre-processing, designing, execution, and modification, as shown in Figure 3.

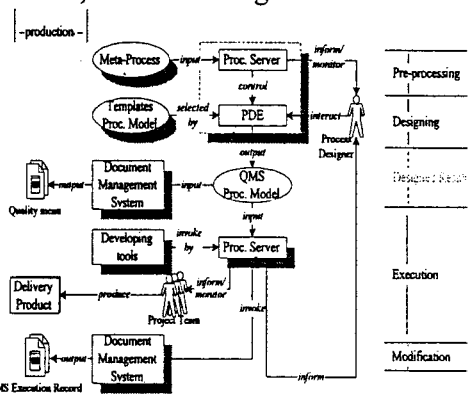

Figure 3. A process-centered view of ISO 9000 in ISOCARE

A meta-process is designed to help process designers to follow steps to build ISO-complied QMS. In pre-processing step, it enacts a meta-process to guide the process designer to understand the ISO 9000. A meta-process also guides process designers to design process models as QMS complied with ISO 9000 via the PDE in designing step. After finishing QMS design, it enacts these process models designed in a process-enacting environment. With the execution of process models, the manager can audit QMS periodically, or to modify the QMS in real time. After executing the process models, it may need the performance and the result to do further process improvement required in ISO 9000.

Conclusively, to support ISO 9000 standards, the following assistant components need to be modified from PSEE:

(1) Process definition editor: It helps process designers build up their process model, and

deals with importing of process model templates for process designers to modify.

(2) Process enacting environment: Process models are enacted in the process enacting environments. This environment also provides the functions such as process monitoring and execution records.

(3) Integrated assistant tools: *Process analyzer* serves as a syntax checker of process models. *ISO standard compliance checker* examines the process models of QMS whether they comply with the ISO standards. *Documentation management system* handles all the documents required by ISO 9000, like automatic generation, version control, etc.

4. Components of ISOCARE System

4.1 System Overview

ISOCARE is a PSEE-based system. There are process models such as meta-process model or project-performing process model in PROP-ISO. These process models are defined in PLAN language. PDE provides interfaces to define process models in PLAN. PASE acts like a process server and provides an interface between users and enacted process models. The integrated tools built in ISOCARE work as assistants to facilitate ISO 9000 certification. As class for objects, to simplify or increase reusability for process modeling, process model templates are needed. Similarly, document templates are required to create specific documents. Based on these inputs, the architecture of ISOCARE can be shown in Figure 4. When a meta-process model is enacted at PASE process server, it will provide management representation in PDE to guide process designers use PDE to edit process models of QMS conformable to ISO 9000. These process models will be enacted to realize QMS of companies. Assistant tools can be invoked to generate related products while executing QMS.

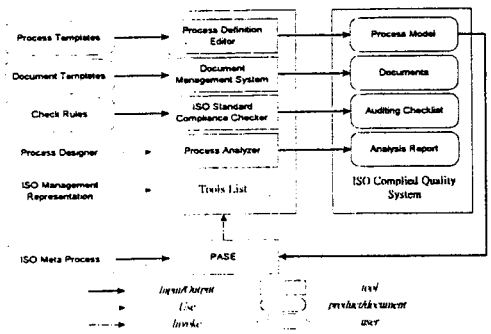

Figure 4. An architecture of ISOCARE

4.2 PLAN, PDE and PASE

4.2.1 PLAN

PLAN is an OO and state-based PML [15]. There are four kinds of entities in a process model shown in Figure 5. *Role* describes the hierarchy and organization of a company. *Activity* is used to model the procedures for the work. *Artifact* can model the artifacts, documents and products. *Resource* contains the producers' goods consumed or assigned to accomplish tasks. From the discussions in section 2.1, process designers can model a QMS into process models in PLAN. Personnel can be modeled in *Role*. Product is subset of *Artifact*. Project and support items are part of *Activity*. And *Resource* indicates what is consumed to support the QMS.

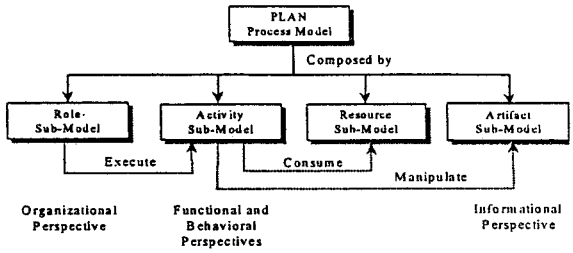

Figure 5. An architecture of process model in PLAN

4.2.2 PDE

PDE is an environment for process designers to edit a process model. PDE gives process designers a distinct viewpoint of a process model to edit. These viewpoints include graphic, form and tree [14]. The extension of PDE to support PROP-ISO is the ability to import process model templates. Figure 6 is the process model template of Internal Quality Auditing from the viewpoint of tree. It contains three sub-models representing artifacts, activities and roles required in IOA. While a meta-process is enacted to ask designers construct a process model including IQA required in ISO 9000, they can import IQA process model templates. Figure 7 shows a scenario of importing process model templates. When editing the IOA process of the process model of QMS, a process designer decides to import templates and PDE will import *IQA.artifact* to *Internal Quality Audits Doc.* and *IQA.activity* to *Internal Quality Audits*. The process analyzer then will be invoked to find whether inconsistencies exist.

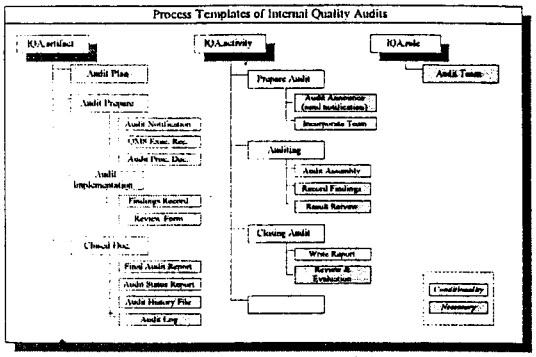

Figure 6. Process model templates of Internal Quality Auditing

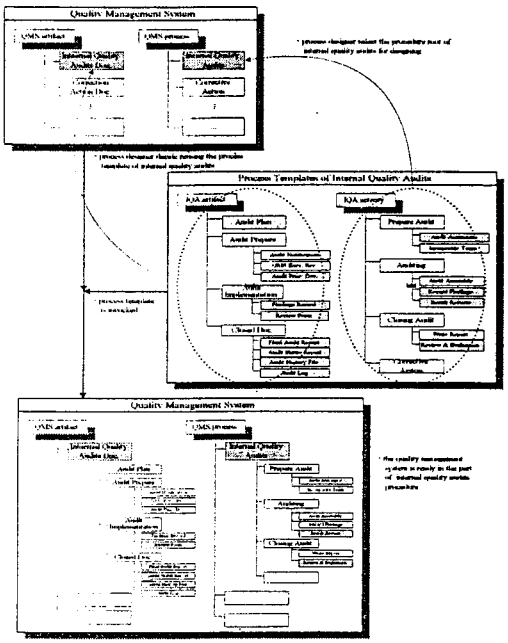

Figure 7. Importing process model templates

4.2.3 PASE

PASE consists of process server, agenda, on-line expert and other tools on the clients. Detailed design issues are discussed in [13]. The architecture is in Figure 8.

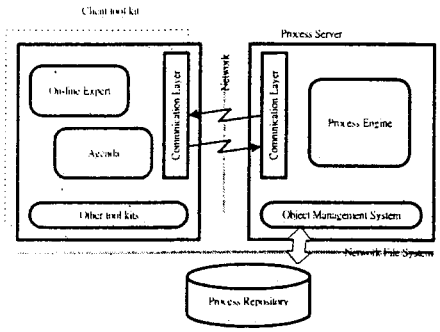

Figure 8. The architecture of PASE

PASE was designed for a general purpose PSEE. For ISOCARE, PASE needs some additional extensions as follows:

(1) Logs and records: In ISOCARE, the process server monitors, records and time-stamps communications between clients and accesses to the process repository.

(2) Traceability: It is able to move data from an artifact or an activity to other related artifacts and activities [25]. For an artifact or activity, the process server can retrieve activities that affect the artifact or the artifact list in the activity from process repository.

(3) Periodic enactment: A process server should keep those activities with "date" in waiting state and monitor if it is time to enact these activities.

Figure 9 is a snapshot of PASE agenda. The left frame is current task list and related artifacts. The procedures that were documented before can be listed to certain user on the agenda for enaction. Related artifacts can be accessed through hyperlinks. PASE agenda makes "*the right one does the right thing at right time.*" The right frame contains the detail information of designated task.

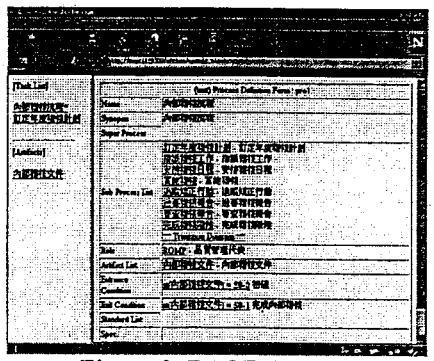

Figure 9. PASE Agenda

5. Integrated Tools in ISOCARE

5.1 Documentation Management System

Documentation management system maintains the document required by ISO 9001. The document required by ISO 9000 can be structurized into a four-level model [7]. Quality manual, quality procedure documents and work instructions can be generated by extracting information from process models and filled extracted information into corresponding document templates. The relative extracted information is shown in Table 2. For quality manual, it demonstrates why the company sets up QMS. It can be written by the company manager, or be automatically generated from the synopsis statement defined in each activity in process models. Quality procedures document the quality plan and define the implementation strategy. They can be generated from information about role, activity, entrance condition, and department of agent defined in process models. Work instructions show the

detail implementation steps and can be generated from state transition of process models. Quality records are the result of execute QMS and can be generated from collecting the logs of PASE process server.

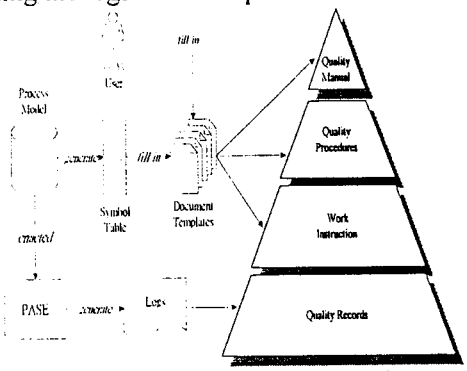

Figure 10. Document generation

As Figure 10 shows, documentation management system extracts entities from process models, constructs symbols and its relative values into symbol table, replaces symbols in document templates with relative values in symbol tables, and then generate documents automatically. Users can also fill the document templates by themselves. An example of symbol table is shown in Table 3. All the values of symbols are defined in process models. Figure 11 shows an example of document templates. All words in anchors are symbols. Users can edit their generated document template with text editors in the same style [7][8].

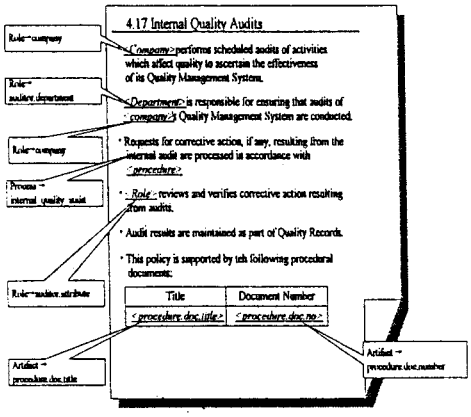

Figure 11. Example of document template

Document Pyramid		Document Management System Generation
Quality Manual	– Why	Synopsis in Process Model
Quality Procedure	– Who	Role in Process Model
	– What	Activity in Process Model
	– When	Entrance Condition in Process Model
	– Where	Department of agent in Process Model
Work Documents	– How	Process State Transition Diagram
Quality Records	– Evidence	Employee Write down, Logs of PASE

Table 2. Document Generation Rule

Symbols	Values	Defined in
<Company>	ABC Company	Role Tree->Company
<Department>	QM Division	Role Tree->Auditor.department
<procedure.doc.title>	Auditing Initial Plan	Artifact->procedure.doc.title
<.....>	.....	.....

Table 3. Example of symbol table

Document management system also provides the function of version controls required in document control in ISO 9000, including:

(1) Re-issue documents after a practical number of changes have been made;
(2) Remove out-dated documents from circulation;
(3) Provide appropriate documents at all locations where quality systems are performed.

Figure 12 is the result of the generated document of Internal Quality Auditing from process models. .

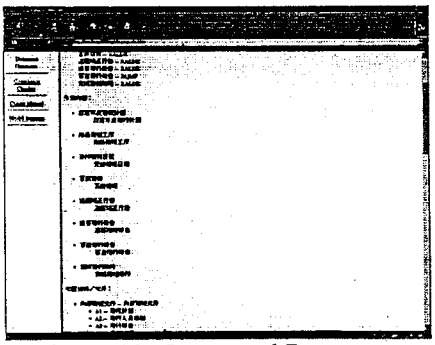

Figure 12. Generated Document

5.2 Process Analyzer

After modification of process models, process model inconsistency may occur. These inconsistencies

include unfilled fields of an entity, entities not referenced, mismatched entrance conditions and exit conditions, etc. Process analyzer then handles these inconsistent conditions as a syntax checker of PLAN. To find out unfilled fields of an entity, process analyzer has to check every object in a process model whether there is any undefined attributes. To find out these artifacts or activities that are not referenced, process analyzer constructs linked graphs of state transitions of activities and artifacts. Process analyzer also helps scheduling QMS by translating process model for graphic analysis. Many algorithms can be applied to the process models. Examples are Petri-Net, CPM/PERT algorithms, etc [23].

5.3 ISO Standard Compliance Checker

ISO standard compliance checker inputs the QMS, and outputs the crosscheck list by the form of ISO 9000 clause versus process model.

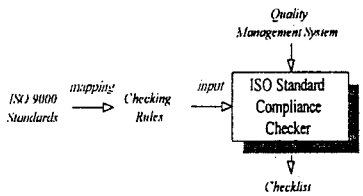

Figure 13. ISO Standard Compliance Checker

ISO 9000 compliance checker serves as a semantic checker rather than a syntax checker. The major design task is mapping the requirements of ISO 9000 into the checking items of semantemes in PLAN. For example, one requirement in ISO 9000 is:
"Internal quality audits shall be carried out by personnel independent of those having direct responsibility for the activity being audited."
The compliance checker has to find out the role tree of the process model defined in PLAN. In QMS, a role is in charge of the internal quality audits and the role of the activity is audited. Because a role tree shows the organization and hierarchy of a company, compliance checker can check the role tree to see whether two roles in the same department to determine independence of responsibility. Table 4 is part of check rules. Each check rule is a small function of ISO standard compliance checker.

Requirement of 4.17 Internal Quality Audit		Check Rule
The Audit Team	• Auditors aren't directly involved in the audit.	Entity: role of auditor doesn't in the audited dep.
	• Auditors have sufficient seniority in the company to reflect the importance of audit	Guide: guidance exists
	• Auditors are trained in auditing technique.	Relation: reference procedure of training exists
	• Records of the training are maintained.	Relation: reference artifact of training records exists
Audit Procedure	• Auditors are provided with written procedure	Entity: artifact of procedure documents exists
Audit Plan	• Audit interval	Entity: process element of time control defined
	• Role who creates this schedule	Entity: agent exists

Table 4 ISO 9001 requirements and check rules

6. Implementation of ISOCARE over WWW

Figure 14 shows the system diagram of ISOCARE on NCC model. The whole ISOCARE system can be divided into three servers. Web server plays a role as a gateway of ISOCARE. Users use Web browser to browse and execute their project activities. Web browser interacts with Web server by HTTP. The requests from users are parsed at Web server and sent to process server or object server. The results from servers are collected at Web server, transformed into HTML, and then sent to Web browsers of users. Web server cooperates with Web date repository which stores documents and assistant tools. Web server is also in charge of user authentication and dispatching messages to process server. Over Internet, Web server can be run on a firewall machine to increase the security of ISOCARE.
Process server, according to the messages from Web server, manipulates process models, maintains the consistency of process models, performs state

transition of process models, and records all the results of enacting. Object server runs as a database management system, and is in charge of process repository management, storage of process models, and data access control.

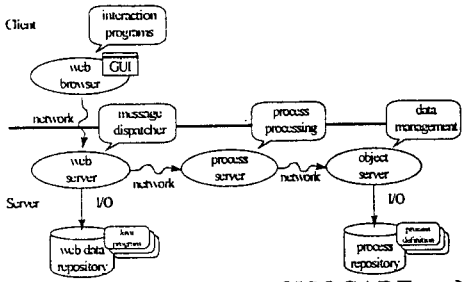

Figure 14. An architecture of ISOCARE on NCC model

When the users use ISOCARE, they use their Web browser such as Navigator or Internet Explorer to connect to Web server. Then agenda and hyperlinks to the assistant tools also appear on the browsers. These integrated tools are written in Java language so that user can access these tools without problems in compatibility.

7. Conclusion

In this paper, an ISO 9000-supported environment, ISOCARE, with software process technology constructed over WWW is presented. With ISOCARE, companies can build their QMS over Intranet within their organizations and extend it to Internet easily. Unlike other ISO-supported environments, ISOCARE provides not only an application to facilitate generation of documented procedures but also an environment to enact these procedures.

The characteristics of ISOCARE over Internet/Intranet including:

(1) Fully supporting ISO 9000 in documentation and procedure execution;
(2) A specific PSEE with QMS;
(3) Built in Java to increase portability and compatibility.

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