

Development of a production management system for automated and manual process mixed manufacturing

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Abstract: In batch plants of process industries such as medicines, fine chemicals, and foods, it is necessary to have functions executed by computers and operators, such as cooperative management of the plant computers, management of manual operations, and management of dynamic changes for equipment control. To provide such functionality, this report presents twenty-five recipe elements, such as a start element for a control computer program, and a binder for the work procedure, which can be used in a library. Then the report shows the checking function of the master table and its lexicons. Validities of the recipe element are shown through an application in two plant types.

1. INTRODUCTION

Automated and manual operations are intermingled in the manufacturing of medicines, fine chemicals, and foods. In such industries, DCSs (Distributed Control Systems) and PLCs (Programmable Logic Controllers) are widely utilized for automation of processes, and MESs (Manufacturing Execution Systems) or some dedicated operation guidance software are used to support the procedures executed by manual operations, like cleaning, measurements, receiving of materials and so on.

In the PAT (Process Analytical Technology) initiative of the US FDA (Food and Drug Administration), to maintain and improve product quality, the process understanding is emphasized (FDA, 2004). Recently in Japan, the recognition that manufacturing process management is important to the safety of foods is increasing. In both cases, the management of all the manufacturing processes is very important.

There have been systems that propose a supervisory control function that automates and guides the manual operations of a DCS based on a skilled operator's expertise (Kobayashi and Takatsu, 1999). In some batch manufacturing processes, manually operated processes are included, so the need is increasing for a computer system which can treat both automated and manually operated procedures and can manage all the manufacturing processes.

In this report, based on the models of S88 (ISA, 1995), we propose the functions such a computer system should have.

2. FEATURES OF BATCH PROCESS PLANTS

2.1 Computer systems in batch process plants

Utilization of computers in process plants was developed from loop control and sequence control of a continuous

system, and today's computer systems have extended functionality and are covering wider areas, according to the features of the applied process. Table 1 shows the functional hierarchy of the control system proposed by S88 and S95 and the areas covered by computer systems (Tanaka, 2004).

Table 1. Functions of computer systems for manufacturing

Level of Functionality		Computer System		
Level 4	Scheduling	MES	Scheduler	Process computer
Level 3	Management			
Level 2	Supervision	DCS	SCADA	
Level 1	Control		PLC	
Level 0	Process			

2.2 Problems of control systems

In batch plants, automated and manually operated process are intermingled and DCS, MES and PLC are used together (Fig. 1). MES has level-3 functionality, which manages the whole manufacturing process of a product. The DCS and PLC (and SCADA (Supervisory Control And Data Acquisition System)) carry out execution and surveillance of the control that have level-1 and 2 functionalities (Table 1). Some dedicated systems, for example, measurement guidance systems, also have functions of level-1 or 2.

Communication between such computer systems can be easily realized now through standardization of OPC (OLE (Object Linking and Embedding) for Process Control) and so on. And standard models to represent data have been established by S88 and BatchML (ISA, 2001).

On the other hand, in actual computer systems and production processes, such items like equipment, procedures, and conceptual models, such as collaboration or data, are not necessarily based on the standards of S88 or BatchML.

In BatchML, since its schema assumes adoption in both assembly and process-oriented industries, some

customizations are needed for items such as recipe elements, according to its use, and for extension mechanisms such as "Any" or "Other" according to the functions and interface of the computer being cooperated with.

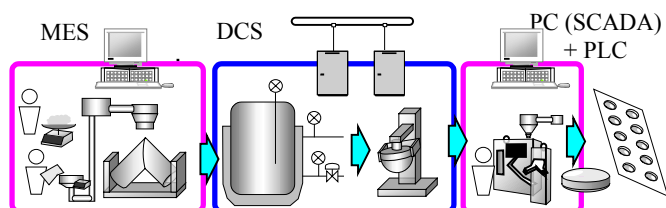


Fig. 1. Image of the targeted batch process plant

2.3 Subjects in production control

In an actual production process, the production procedures are composed from automatic and manual operations that are intermingled with each other and in various combinations. For example, in some cases, continuing, rerunning or finishing of an automated make-up process is decided by the results of a manual sampling and inspection step. In other cases, one product manufactured within one lot is charged into a reactor tank as a substitutive material by manual operation, and the remainder are supplied from a material tank by automatic control. In some cases, using a substitutive material changes the make-up procedure and the amount of material, in the other case, the available scale changes the production procedure.

To manage the manufacturing process for a product, detailed information and consistent recording of procedures and materials used are required.

3. ARCHITECTURE OF A PRODUCTION CONTROL SYSTEM

3.1 Requirements of the production control system

Based on the above subjects, we decided that the following functions are required. In addition, since managing the manufacturing of a product is considered as a function which MES should take charge of, the functionality demands shown here are mainly included in the MES.

(1) Liaison of control equipment In S88, a manufacturing process is expressed and managed by a master recipe procedure supposing certain production equipment, and a control recipe procedure is generated based on a master recipe procedure and used for a real production. Details of control are managed as a equipment control procedure depending on a control unit. Using such models is expected to reduce the dependability of master recipe procedure on the control unit. By giving the function to express the starting and stopping of the control programs and setting and reading the data on arbitrary DCSs or PLCs as a master recipe procedure, and by modularizing the connection from a master recipe procedure to the program mounted in the actual DCS, PLC, etc., it becomes possible to realize cooperation with various computers of levels 1 and 2 just by customizing this connection module.

(2) Liaison of equipment control and manual operation In order to respond to the production procedure in which automatic control can be changed to manual operation and vice versa, we considered that the manual labour applicable to levels 1 and 2 is an equipment control procedure executed by a worker. The work guidance function manageable by a detailed work procedure equivalent to automatic control, and the work guidance function in which a work instruction can be replaced by an equipment control procedure performed by the DCS and/or PLC and vice versa, are required.

(3) Change of control recipe and equipment control during manufacturing Being able to change the operation procedure, work instruction and control program of levels 1 and 2 dynamically is necessary not only when generating the control recipe procedure, but also during production.

(4) Management of operation procedures not related to lot The management function corresponding to the work process, which is carried out once per a selected numbers of lots, such as exchange of a used-up piece of equipment like a filter, is also needed.

(5) Facilitation of defining recipe procedure In a plant which manufactures more than 100 kinds of products with two or more process cells and/or pieces of equipment, the master recipe procedure supposing two or more process cells and/or pieces of equipment which fulfils specific conditions is also required. A function to change equipment control procedures or to change the data passed to the procedures by parameterizing the equipment and materials that are assigned by the scheduler is also required for the control recipe procedure generation function. In addition, the functions that check master recipe procedures and equipment control procedures are also needed.

3.2 Architecture

Based on the above demands, the architecture of the developed MES is shown in Fig.2. This system is composed of functional modules to generate a control recipe from master recipe and to carry out manufacture process control, stock control, materials ordering and receiving, in cooperation with a DB (Database). Although not shown in the figure, screen and sheet managing modules are also used and they cooperate with other modules through the DB.

The main tables and the relation with the concepts of S88 and the schema of BatchML are shown in Table 2. Though based on the concept of S88, the translatability from our existing system was also taken into consideration, so the original DB schema was adopted. In S88 the recipe procedure is represented by five hierarchies of procedure, unit procedure, operation, phase, and lower phase; our system adopted five layers as the maximum, and in addition, under the lowest layer, it prepared a layer which defines Steps with which work guidance and equipment control procedure are connected. For the physical model, we adopted the architecture in which we can define arbitrary hierarchies; the Terminal, the Measuring Equipment, and the Container are used as separate items in the table.

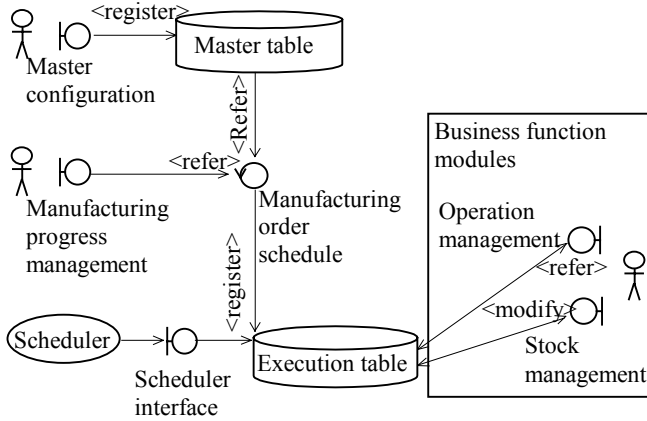


Fig. 2. System architecture of developed Manufacturing Execution System (MES)

Table 2. Correspondence between the tables of the developed MES and BatchML

No	Table Names in Developed System	BatchML Elements	Concept in S88
1	Recipe_Procedure	Recipe element	Unit procedure
2	Detail_Recipe_Procedure		Operation Phase
3	SOP_Procedure		Phase
4	Attribute of Nos. 1-3	Link	
		Transition	
		Step	
5	SOP_Parameter	Parameter	
6	Attribute of Recipe	Equipment requirement	
7	Material_Recipe	Formula	
8	Charge_Item	Parameter	
9	Process_Cell	Equipment element	Process cell
10	Asset (Unit)		Unit, Equipment
11	Terminal		Control
12	DCS		Others
13	Measuring Equipment		
14	Container		
15	Physical_Element		
16	SOP_Parameter		Equipment procedural element
17	Virtual_Tag		
18	Program		
19	OP (DCS Sequence)		
20	Attributes of Nos. 10, 13 and 14	Equipment property	
21	Physical_Element_Spec		

3.3 Cooperation between work guidance function and levels 1 and 2 of the computer system

To correspond with the demands shown in Sec. 3.1 (1) and (2), preparing pre-defined recipe elements are important for a system. So we prepared 25 lexicons used for expressing the levels 1 and 2 control program and work guidance. These were made as recipe elements of the lowest layer (Table 3). Nos. 1-13 are lexicons used for directions of work, and

control of flow. Nos. 14-21 are lexicons used for cooperation in the computer system, and work guidance and dynamic change of equipment control procedure. Nos. 22-25 are lexicons corresponding to work steps, such as checking the state and specifications of production equipment, and confirming of a track record. Although these can be expressed by combining lexicons of Nos. 1-21, and a lexicon that performs SQL (Standard Query Language), to avoid the risks that arise from enabling the execution of an arbitrary SQL and to simplify the definition of SQL, we installed these functions as independent lexicons.

Table 3. Lexicons of recipe elements showing operations

No	Lexicons to Represent Production Procedure
1	Transition (OK)
2	Input text
3	Judgement (OK/NG)
4	Selection from list
5	Judge and change next operation (OK/NG)
6	Select from list and change next operation
7	Read bar-code
8	Logical calculation
9	Numerical calculation
10	Lowest level procedural loop
11	Abort remaining steps and restart current operation (or phase)
12	Abort remaining steps and jump to another operation (or phase)
13	End of procedure (or phase)
14	Start DCS or PLC operation
15	Stop DCS or PLC operation
16	Set data into DCS or PLC
17	Get data (measured value, settings, etc) from DCS or PLC
19	Dynamic operation binder
18	Selection of bondable pattern
20	Rebind last bound pattern
21	Temporal data registration to operation binder
22	SQL select statement execution
23	Physical element status data modification
24	Checking the usage condition of equipment
25	Taking account of the measured result

Since judgments like Nos. 3 or 5 may have a big influence on the order of execution of the recipe element and timing, we thought that these judgment steps should be clearly kept as manufacturing records, so we did not consider them as mere transition conditions, but we treated them as a recipe element of a judgment act of a plant operator.

We think the question "What kind of functional elements are most suitable?" has more than one solution. But by using these 25 lexicons, master recipes of the manufacturing process with the following differences can be described, so we think these lexicons are sufficiently comprehensible for application to the manufacturing management of the batch process in the targeted field.

- (1) From the viewpoint of equipment: The lexicons are applicable for situations ranging from a production process

which makes a product using a few tanks and manual operation being a large portion of the procedures, to a production process using a multi-pass type plant in which many tanks are connected by pipelines and automatic control has responsibility for a large portion of the operation and control procedures.

(2) From the viewpoint of a product: The lexicons are applicable for situations ranging from a manufacturing process which has the production items with one package form, to a process which has the production items with two or more package forms like the case of some intermediate products. Also the lexicons are applicable for situations ranging from a manufacturing plant with only a few production items to a plant with 100 or more production items.

3.4 Functions for flexibility of the master recipe

The switching of the equipment control procedure carried out by the computer system and a plant operator shown in 3.1 (3) is described below. The developed system corresponds to this demand using lexicons Nos. 19-21 of Table 3. The work procedure and the control sequence are managed as a library parameterized by the equipment, product and so on, and these can be bound with No. 19 according to the on-site judgment.

An example case is one in which manual injection is switched to automated injection, with a predetermined quantity being supplied as a whole. The recipe procedure is shown by Fig. 3 using the notation of S88.

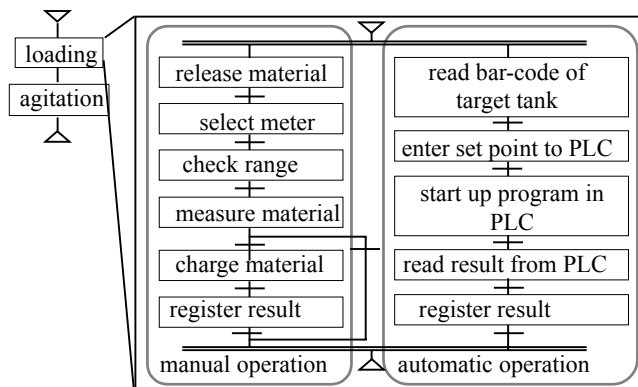


Fig. 3. Diagram of a sample case within S88 notation

Although in the measurement processes, the manual operations and the automated operations are switched, they are performed in-series. But when generating the control recipe, the occurrence of switching cannot be expected, so equipment control is set up as an automatic control or work guidance according to the default setting. In the bound equipment control procedure, when button (1) is pushed on a screen like that in Fig.4, another already defined equipment control procedure can be chosen and switched to. In some cases, according to the scale to be used, the applicable equipment control procedure can be changed. The system has a table that relates the identification code to the equipment. By referring to this table, the identification code corresponding to the equipment is made into a selection condition and the system can narrow down the candidates for

selection to a part of the equipment control procedure. In this case, the arbitrary equipment control procedure can be chosen from suitable ones for the equipment to be used by means of the combo box and the O.K. button of Fig. 4 (2).

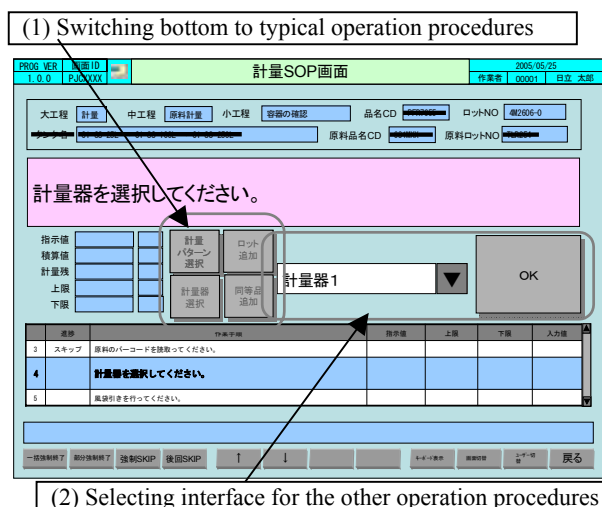


Fig. 4. User interface for dynamic switching of operation procedure

For example, when switching from a manual injection to an automated injection, it is necessary to set the injection amount into the controller, this is got by deducting the amount injected by manual operation from the scheduled amount. To hand over the information acquired or determined in one bound equipment control procedure to another equipment control procedure, we installed a function to memorize data with an arbitrary key string as data of a higher order recipe element (No. 19), and the data are taken out using the same key. Using this function, data can be delivered among arbitrary equipment control procedures that share the same key. When control programs are made to use an identification code of the injected material and the tank as their parameters, such data can be delivered between some equipment control procedures by using this function.

In some cases, programs that execute injection or some other level 1 and 2 operations are made depending on the material or tank to be used. For such cases, we installed the function that related the identification code of a program to the injected material code or tank code. Using these functions we could not only set up parameters, but also change the program itself to be used by the equipment control procedure.

A step from the phase or operation procedure may have some information to be displayed or passed to a control program, and some of this information cannot be determined when generating the control recipe procedure. For example, when defining a procedure to check the expiration date of materials using the read result of a bar code read-out step to prevent the injection of expired material, a function to refer to the results of some other step is required. So we gave the function that can refer to the execution result of another step to the system.

In the case of using alternative materials, a correction of the amount is sometimes required, and for reworking, the lost amount of solvent such as through heating, must be

calculated. Thus, the system is sometimes required to carry out some complicated processing of data according to the production equipment or process in use. To dynamically bind such functionality, we installed a function to bind the DLL (Dynamic Link Library) to the lexicons of the calculations (recipe element of No. 9) and the logic judgments (recipe element of No. 8). In the case of a numerical value being required as a result of a recipe element, the recipe element of No. 9 is suitable to bind a specialized DLL to execute the required calculation, and in the case of requiring a logical result, the recipe element of No. 8 is suitable.

3.5 Other functions

Corresponding to Sec. 3.1 (4), we installed the function to generate internal production order. Using this, we could carry out execution management and recording of work based on a standard operation procedure for work which is hard to incorporate in a production plan like filter exchanges, cleaning and etc.

In order to describe the equipment control procedure parameterized by the equipment, the Virtual Tag function was installed in the developed MES. This function replaces the Virtual Tag Code embedded into the arbitrary character strings of the attributes of the record corresponding to the lexicons shown in Table 3 and parameters, to the appropriate code corresponding to the equipment code at the time of production. For example, the program and/or its parameter described using the Virtual Tag are automatically modified according to the utilized equipment without changing the control recipe procedure. By just replacing a character string representing the actually used equipment by the Virtual Tag, this function can be applied to the master recipe procedure which is already in operation, so the coverage of the master recipe procedure can be expanded safely and it can respond also to the requirement shown in the first half of Sec. 3.1 (5).

3.6 Master records checker

To define the master recipe procedure in which some step to be carried out from now on refers to the result of the step already done, we have to input the appropriate code which identifies the referred-to step. Thus, the record of two or more tables needs to be mutually defined consistently. To satisfy this demand, we developed an XML extended DSL (Domain Specific Language) for checking the table and also developed a tool which checks the defined records of all tables using the checking contents indicated in the DSL.

Usages of some tables and/or their attributes are sometimes modified in an application, this occasionally happens at an interface to other systems like the DCS, PLC and scheduler etc. Using the tool that checks the defined records based on checking contents described by the developed DSL, the developed MES can easily respond to such needs by modifying only the contents of checks.

In order to make it possible to use this DSL, even if the user is not a programmer or an engineer well versed in the

functional programming language, some lexicons in the procedural language, like loop processing and substitution to a variable, was also prepared.

The functionalities of prepared lexicons are shown in Table 4. The checking contents are described as a proposition, which consists of a paired declaration part like "not null", "unique", "reference to", etc., and a conditional part showing the conditions on which the declaration is applied.

Table 4. Lexicons of language developed for master checking

No	Functionality of Lexicons to Represent Checking Points
1	Attribute, variable or record of table is null (or not null)
2	Attribute is number (or string or date)
3	Attribute or combination of attribute is unique in table
4	Attribute or variable is included in designated attribute of designated table or enumerated string list
5	Attribute or variable is equal (or not equal) to some other attribute (or variable)
6	Attribute or variable is greater (or smaller or greater equal, and so on) than some other attribute (or variable)
7	Set is equal to another set
8	Attribute or variable is matched to designated string format
9	Some attributes of a record are simultaneously null (or not null)
10	Get some records from table and substitute into variable
11	Get the number of attributes (or records) that meet designated conditions
12	Call boolean function to check programmed condition - Operation parameter can be solved as numerical value - Operation parameter can be solved as string value - Operation parameter has unit code - Two operation parameters have units convertible with each other

At the time of execution, for example, it is only necessary for the step calculating the amount of adjustment based on the result of the inspection step to confirm whether the result of the referred step can be evaluated as a numerical value. But at the time of defining and checking the master recipe procedure, since a result does not exist, it is necessary to replace the declaration "the result of the step is a numerical value" by another declaration which can be evaluated at the time of master checking. If such replacement is required by the user of this DSL, it would become difficult to maintain the checking contents according to the employment of each site and we thought that only the users who are well versed in internal processing of this check tool can maintain the checking contents. For this reason, some macroscopic declarations like "the result of the step is a numerical value" were prepared, and the definition was made possible without replacement. No. 12 of Table 4 is a macroscopic declaration. The function to define a new macroscopic declaration using the functions of Nos. 1-12 of Table 4 was also installed.

4. APPLICATION EXAMPLE

We have applied the developed system to three sites and are promoting application to more two sites. From this application example here, we show that the equipment

control procedures, in which detailed work management and control computer cooperation are required, can be expressed by 25 kinds of lexicons (Table 3) for handling batch processes in medicines, fine chemicals, and foods. We also show the validity of one function shown in Sec. 3.4 (dynamic binding of operation procedure) and the tool of Sec. 3.6 by outlining the application of this system to two sites (Site A and Site B). A beverage field maker owns Site A, and fine chemical field maker owns Site B, so their manufacturing processes differ considerably.

4.1 Outline of plants

For Site A, the plant consists of 4 top layer processes. These processes have two or more tanks and apparatuses and each top layer process has network type process flow. The plant also has a single path type process flow between these top layer processes. For a process with two or more tanks having the same purpose, management of competition with shared resources, such as pipelines is executed by shifting the timing of the operation, and the combined operation of two or more lots is managed by starting production of the following lot serially from the tank of the upstream process while completing the operation for the previous lot. The plant product has one package form and the kinds of products manufactured are a few. Finally, this site is considered to be a typical plant as assumed by S88.

For Site B, the plant has about 100 independent main reactors and there are a maximum of three tanks arranged in a single path process flow and about 100 manufacturing lots may be handled simultaneously. Many manual operations are involved especially in measurement processes. The packaging forms of the product are dependent on the lot and they are treated as one of the indicated values of a manufacturing lot like the lot size. The kinds of manufactured products number in the hundreds.

4.2 Effects

For Site A, the operations related to one tank with other tanks of the same purpose under some top layer process were defined as the second layer master recipe procedure, and the equipment control procedure was made to correspond to it, 1:1. The scheduler assigned the tanks and the reactors of each top layer process to be used in a manufacturing lot, so the developed system was customized to generate the control recipe procedure based on the master recipe procedure of the second layer corresponding to the assigned tanks and reactors. Using such a cooperative mechanism, complicated control of the piping path that changes for every lot in the combined operation of two or more lots was realized without installing complicated logic on the DCS. Addition of a production item without modifying the DCS is also confirmed. The validity of the cooperative function with a control computer (like the DCS) was thus checked through this application to Site A.

For Site B, there were many manual operations that have big effects on product qualities, so one or two lots typically are wasted per year due to human error. Introduction of our

developed system prevented incorrect operation and stabilizes the product quality and eliminated wasted lots. Also introduction of this system provided progress management from lot level surveillance to process level and procedure level surveillance. Through the application to site B in which there were some complicated procedures, including the processes breaking off and rerunning, the validity of the flow control functions were assured. To make the master recipe procedure adaptable to a different tank, the validity of a Virtual Tag function was assured, too.

Through the application to both sites, we found that connecting the equipment control procedure with a master recipe procedure using the recipe element of Nos. 14-21 of Table 3 was effective for changing the computer system by changing only the module which worked on the back side of the these recipe elements.

Although after registration of a master, checks with a few test runs are required, by using the master check tools, times of the test runs can be halved and the man days are cut sharply.

5. CONCLUSIONS

Based on the concept shown by S88, the MES was developed that aimed at the batch production management used in process industries like medicines, fine chemicals, and foods. Twenty-five recipe elements were shown as lexicons expressing a manufacturing process. Using such elements, we found that the system could express and manage the production process including changing of the recipe procedure according to the materials or apparatuses used, and the switching of manual and automated operations.

We developed a checker system of the master records; this consisted of a definition of the checking contents and a checker tool. Using this architecture, checks corresponding to employment of tables peculiar to a site were possible.

REFERENCES

- FDA (2004). *Guidance for Industry PAT - A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance*, Report dated September 2004.
- ISA (1995). *ANSI/ISA-S88.00.01-1995 Batch Control, Part II: Models and terminology*, ISA.
- ISA (2001). *ANSI/ISA-S88.00.02-2001 Batch Control, Part II: Data Structures and Guideline for Language*, ISA.
- Kobayashi, Y. Takatsu, H. (1999). *Exapilot, operational efficiency increase support package*, in: *Control Applications, 1999 Proc. of the 1999 IEEE International Conf., on, 22-27 August 1999, Hawaii. IEEE, Vol. 2*, pp1740-1743.
- Tanaka, K. (2004). *Keieikanri Tono Interface No Hyoujunka S95*, in: *Batch Process Kougaku*, Tokyo, Maki Syoten, pp-195. [in Japanese].