Guidelines for defining user requirement specifications (URS) of manufacturing execution system (MES) based on ISA-95 standard

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Abstract. To standardize the authoring of user requirement specifications (URS) for manufacturing execution system (MES) proposed by manufacturing enterprises from users’ perspectives, and facilitate a quick and effective communication between them and MES vendor or integrator, an approach for URS definition was introduced based on the ISA-95 standard, in which a method for requirement elicitation based on goal and scenario was combined. In this approach, a framework for MES problem space was constructed first from three dimensions: generic activity model for manufacturing operations management (MOM), manufacturing operations categories and supporting activities, and then a series of guidelines for standard application, scenario authoring and requirement arrangement were established to guide the users in seeking the needs and writing them in a normalized sentence form step by step. Additionally, a structure of the table of content for URS documentation was recommended to help the users organizing the textual requirement description. Finally, a case study for applying this approach was performed in a pharmaceutical company’s example, which illustrates the application prospect in MES product selection.

1. Introduction

The so-called “stakeholder needs and requirements definition process” defined in the ISO/IEC/IEEE 15288 standard[1] is an important technical process in software and IT projects, and it differs from the "system requirements definition process" that we are usually familiar with. The former puts forward the expectations for the target software system from user’s perspectives in terms of function, behaviour, performance, constraints, etc., and translates them into clear requirements definition in form of documented user requirement specifications (URS) as the outcome. While, the URS, as the input of the latter, is then responded by the system integrators and software vendors. Consequently, the functions and features of the target software system can be obtained on basis of the To-Be analysis of user requirements, as a result, the documented functional specifications (FS) are formed.

Along with the implementation of the “Made in China 2025” strategy and industrial upgrading brought about by smart manufacturing, more and more Chinese manufacturing enterprises have been importing the manufacturing execution system (MES) as an instrument supporting the manufacturing operations management (MOM). However, many MES implementation projects have stalled or failed during the “stakeholder needs and requirements definition process” and “system requirements definition process”, because the users cannot express their needs accurately or provide an
unambiguous URS document, and the system integrator and software vendors cannot understand the users’ demands well. It was shown in the research of Standish Group[2] that one of the reasons why a number of software and IT projects were cancelled or did not achieve the originally goals was inadequate requirements engineering. Most of the cancelled projects were due to lack of clear requirements and well-controlled changes.

In manufacturing enterprise, the activities performed in shop floor encompasses many management functionalities, addressing several types of manufacturing operations from the receipt of raw material to the shipping of finished goods, from production operations to equipment maintenance, and from inventory movements to quality tests[3]. These activities must operate collaboratively under the business management procedures in spite of their different responsibilities. Therefore, it will be an arduous task for the manufacturer to specify the URS for such a MES with global collaborative functions.

There are twofold factors which may lead to risks if are not taken seriously. Firstly, the potential system users from different departments have different understandings of MES, and it is difficult to reach a consensus. Some users focus on the standard operation procedure (SOP) enforcement and data collection from the manufacturing perspective, and consider these as the main functions of MES to be implemented. Some other users, on the other hand, pay more attention to the actual performance of the operations management and control in shop floor from the business management perspective. The division of these two opinions mainly due to the following two aspects:

- Manufacturing processes involve the utilization of resources, execution of processes and transfer of the products, as well as business management and operations. They are actually two facets of the same thing.
- The user group formed on behalf of information technology (IT) and business management are difficult to understand the production control constraints, so they may hardly understand the requirements proposed by the user group formed on behalf of work execution. Likewise, the latter are also difficult to understand the former’s thoughts and visions standing on the position of them.

Consequently, the issue of partitioning functionalities and responsibilities arose. This make it very difficult to build a clearly defined URS, and the evaluation process of MES solutions has become extremely challenging. Furthermore, high requirements have been put forward for the comprehensive skills and practical experience of personnel.

Secondly, the first step of advancing a MES project is to specify the requirements that the system needs to meet. Obviously, the well-defined requirements have been the cornerstone for everything that followed. For example, in a pharmaceutical company, the URS will be undoubtedly put in the initial position of the GAMP cycle, in which there are two verification activities linking system acceptance test (SAT) to URS and SAT to functional specification (FS). Additionally, there is a mapping between URS and FS. The quality management of a MES project must ensure that each function in FS can be mapped to the relevant item in URS and serves as the evidence for SAT.

In summary, the characteristics of MES and special status of URS in project quality management jointly determine that it is not easy to define a qualified URS for MES. However, defining requirements precisely is the key factor for the successful implementation of an efficient and practical MES. The aim of this paper is therefore to propose a practical, normative and operable approach to eliciting and authoring requirements for MES hoping to guide the manufacturer towards their standard URS documents. In a first step, the approach to requirements elicitation for MES will be introduced through reviewing the previous relevant studies (section 2). The results from section 3 provide a set of guidelines for applying ISA-95 standard to eliciting and authoring requirements for MES, as well as some interpretations for these guidelines will be given. In section 4, a case study for a pharmaceutical company’s example will be illustrated and the topic of MES product selection will be discussed briefly. Finally, a conclusion on this study will complete this article (section 5).
2. Basis of requirements definition for manufacturing execution system

One of the purposes of URS is to provide integrators and software vendors with as much detailed information on the enterprise as possible, as well as expectations and requirements for MES, but what exactly the integrators and software vendor need to know before offering the proposal is often vague to many enterprise users who are about to import MES. The best practices of MES implementation showed that the ISA-95 standard entitled Enterprise-Control system integration can be used as a guiding principle for developing URS[4]. This standard clarified the boundaries between the systems in office floor and shop floor, and the upper limit range of functions that a MES may cover.

2.1 Constructing problem space based on ISA-95 standard

A number of literatures that referenced to, elaborated, utilized and enriched the ISA-95 standard have been published. Some software vendors examined in a vendor’s perspective how the ISA-95 standard can be used to develop a MES product that can address both the MOM domain and its integration with the business domain, meanwhile, some of the benefits recognized when applying ISA-95 standard to a product were listed[5]. Some other software vendors proposed extensions for ISA-95 standard to support fully both longer term and dynamic scheduling[6]. There are also some vendors focused on a partial domain of MOM and considered the activities as well as information flow between them in detail for developing some dedicated software tools[7], such as plant performance analysis (PPA), statistical process control (SPC), and so on. Additionally, a neutral institution has conducted a survey[8] in various MES products provided by global vendors on the market using questionnaires, in which the ISA-95 standard was considered as one of important criterion for product evaluation.

The relationship between the MES application components and the ISA-95 standard as well as relationship between MES and MOM was discussed by reference [9]. It is revealed that “the standard-defined terms, models and methods contribute to large extent to the effectiveness of work shop level analysis for production management, as well as to the development of decision support functions implemented in the MES applications”.

2.1.1 Generic activity model of manufacturing operations management.

The third part of ISA-95 standard has defined a generic activity model[10] and summarized all operative activities to be carried out at manufacturing operations management (MOM) level. It is able to assist users in understanding how their workshops operate in daily production management within twofold aspects: business management and work execution. The aforementioned two divided user groups can be therefore harmonized.

Figure 1 illustrates the generic activity model for MOM, in which, the activities can be considered according to the time they occur relatively to the moment of the work execution[11]. Figure 2 shows how this time view applies to the generic activity model.

The types of activities that differ in time include time-independent reference data, as well as pre-work, actual work, and post-work, which are time-dependent and executed in sequence. Reference data refers to data that is used to categorize other data within enterprise applications and databases, and it is distinct from master data that represent business entities, transactional data produced by transactions within applications, as well as meta data which describes the structure of business entities[12]. Reference data is provided by the professional standards organization. The object models of resources (such as material, personnel, equipment, physical asset, process segment) and operations from ISA-95 standard determine the reference data for MES.
The interactions between these activities are roughly described as follows: (1) the pre-work contains detailed scheduling activity and dispatching activity. Detailed scheduling activity takes the operation schedules as input information, solves work arrangements under the constraints of reference data and produces work schedules as output; (2) the arranged work schedules are then assigned to specific resources through dispatching activity, forming a work dispatch list comprising various job orders with semi-finished goods, finished goods, and services as outputs in a certain time span; (3) after receiving the job orders, the equipment and personnel on the workstation start performing specific tasks following SOPs or instructions. During the execution process, personnel send commands to equipment or some control system, and receive responses from them. In this way, personnel and equipment cooperate with each other to complete jobs. The information flow between pre-work and actual work is shown in Figure 3.
2.1.2 Determining system boundaries

According to the characteristics of value added to products and services by these activities, ISA-95 standard classified them into five distinct but similar categories: production, maintenance, quality test, inventory movement and support activities. Four operations management categories can be therefore derived from the MOM generic activity model, which are production operations management, maintenance operations management, quality operations management and inventory operations management.

Generally speaking, most of MES instances support these four categories of operations management, but the functional scope is different. So an example of the boundary between MES and enterprise resource planning (ERP) system was given in the annex of ISA-95 standard Part 3 to explain how activity models can be used to determine the functional scope of MES.

One thing to note is that responsibilities boundary may not match with technical boundary in system integration, that is, the system boundary is to a certain extent independent to the responsibilities of departments, but is dependent on what activities within MOM may be supported by MES. So the boundaries among different information system may vary depending on industry or plant.

2.1.3 Establishing domain framework for manufacturing execution system

In addition to above four types of operations management categories (called core activities), there is also a collection of supporting activities according to ISA-95 standard Part 3, including management of information, management of security, management of documentation, management of configuration, management of compliance and management of incidents and deviations. The supporting activities ensures each of the core activities shall be performed in the right way, and may therefore have influences on MES to be implemented.

The generic activity model, four types of core activities and supporting activities constitute three dimensions of a problem space of MES, in other words, they represent different aspects of the problem.
space, and each functional requirement proposed to MES can be expressed from these three dimensions. So a problem space framework for requirement engineering of MES is obtained, as shown in Figure 4.

![Problem space framework for MES](image)

**Figure 4. Problem space framework for MES.**

### 2.2 Defining requirements using scenarios

Requirement definition language is a language used to write software requirements definition, which can be divided into three classes: non-formal language (also known as natural language), semi-formal language and formal language[13-16] according to their degree of formalization[17]. The formal language establish rules for grammar mathematically, and have clear semantics used to support automatic elicitation and analysis of requirements. At present, however, this method is hardly directly used to define requirements of information system in practice, because it not only needs software tools to provide support for requirements analysis, but also poses high challenges to mathematical literacy of users and system analysts.

In contrast, non-formal language employing natural language is much easier to be accepted by the general users, because of its characteristics of comprehensibility and usability, which however oppositely result in a disadvantage of ambiguity.

#### 2.2.1 Semi-formal methods for requirements definition

In view of feasibility and operability, it is necessary to preserve the advantages of natural language. In this context, the improvement of non-formal requirement definition language is to make the natural language as accurate as possible in terms of presentation. On the basis, the ambiguity can be eliminated with the help of effective communication. It is the semi-formal requirement definition language that was adopted in this study.

In the early years of requirement engineering, a linguistics-based method of requirement elicitation has been proposed, in which the disadvantages of non-formal requirement definition language have been avoided by means of normalized and formatted sentences. Colette Rolland[18-20] initiatively proposed modelling a goal using scenarios which in fact comprises use cases, then authoring the scenarios with formatted sentences. A two-tuple of goals and scenarios <G, Sc> uniquely defines a so-called requirement chunk.

The main advantage of using formatted sentences to author scenarios is that ambiguity of natural language can be eliminated to some extent, as well as the characteristics of comprehensibility and usability can be reserved.

#### 2.2.2 Methodology system of defining URS for MES

The requirement elicitation work often start with As-Is/To-Be analysis. On the basis of analysis on the current situation of business management and execution management, users or system analysts need to
plan how the MES functions should support business management and execution management in future. This analysis process will produce a set of goals for future MES functions to achieve.

The framework methodology we have used to develop our methodology framework is based on Colette Rolland’s guidelines system and the practice of reference [21]. Figure 5 illustrates the methodology framework established in this article, in which the grey rectangles represent what are discussed in detail. It provides an overall procedure for defining URS for MES. The MES problem space can help users to consider the scope of MES functions thoroughly. Guidelines system can direct iterative reasoning with \(<G, Sc>\) through discovering goals and refining scenarios. The URS document structure helps to consolidate the requirements into a unified URS documents.

Figure 5. Methodology framework of defining URS for MES.

3. Guidelines for defining URS of manufacturing execution system

3.1 Guidelines system

The guidelines were divided into three collections depending on the role they play in defining URS, which are ISA-95 standard application guidelines, scenario authoring guidelines and requirements sorting guidelines. In this section, we first present a work flow of defining URS in Figure 6 in general, then each guideline will be presented in subsections in form of \(<caption, definition, notes>\) followed by examples if needed.

Figure 6. General work flow of defining URS.

3.1.1 Guidelines for applying ISA-95 standard

Guideline 1: Operation classification

Definition: Operations are divided into production, maintenance, quality test and inventory movement, depending on the characteristics of value added to products and services by the activities involved in operations.
The different added value are as follows:

- Production leads directly to a series of physical and chemical changes on the raw materials and transfer them into desired final tangible products.
- Maintenance delivers intangible services to keep the equipment and physical assets in normal state all the time, or restore them to normal state when they malfunction.
- Quality test delivers intangible services to judge whether the raw materials, work-in-process (WIP) and products are qualified or not with inspection tools through comparing the results with specification requirement, sometimes including verifying qualification of equipment.
- Inventory movement delivers intangible services to load, unload, handle, store and move the raw materials, WIPs and products, excluding the movement related to production.

Guideline 2: Reference data collecting

**Definition:** On the basis of operation classification, collect reference data of plant resources corresponding to four types of operations within the framework of “object model” defined in ISA-95 standard Part 2.

**Notes:**
Plant resources can include various personnel, materials, equipment, physical assets and process segments used in four types of operations. Reference data about these resources as well as the “operation definition” should be organized in accordance with the structure of “object model”. Operation definition is a generic term of product production rules, maintenance rules, quality test rules and inventory movement rules. In practice, information on operation definition can be found in various kinds of technical data and work instructions, such as process specification, inspection procedure, etc.

Guideline 3: Business process depiction

**Definition:** On the basis of operation classification, depict the as-is activities and information flow between them in detail with distinguishing operation category.

**Notes:**
A business process consist of various activities orchestrated in a certain sequence, and can be depicted in a combined manner of flowchart presented by for example BPMN (Business Process Modeling Notation)[22] and textual form.

Guideline 4: Requirement discovery

**Definition:** From the as-is situations of business process, perform to-be study on the as-is situations using business drivers, and the improved business process shall be obtained. Determine if the activity involved in improved business process needs the MES function support, if needed, define a functional requirement for this activity.

**Notes:**
(1) Determining the relevance of an activity to the MES function can be done by answering the following questions:
- Whether performing the activity requires a MES function support?
- Will data processing be required to be done by a MES function, during the acting of the activity?
- Will data exchanging with external systems be involved, during the acting of activity?
(2) Some examples of business drivers include reduced cycle time, asset efficiency, agile manufacturing, supply chain optimization, traceability, compliance and so on.

Guideline 5: Goals and scenarios introduction

**Definition:** For each functional requirement, elicit the elements including goals, actors, trigger conditions, operation steps from every activity involved in it.

**Notes:**
(1) An activity always intends to meet some default goals which can be elicited by answering the following questions:
- What changes happened to data after the activity was performed?
• What results were produced after the activity was performed?
• How the activity will be improved and optimized after importing a MES function?

(2) The actors of an activity may be personnel of certain roles, departments, units within organizations, or a information system, and can be elicited by answering the following questions:
• Who participate in the performance of the activity, personnel or information system?
(3) The trigger conditions, which determine when an activity is performed, are typically divided into three classes: by messages, by time and following the predecessors. This elements can be elicited by answering the following questions:
• How are the actors informed of performing an activity?
• If the actors are informed by messages, then what kind of messages are sent to them and how they receive the messages?
• If the activity is performed depending on a time schedule, then how the actors are informed?
• If the activity is performed following the predecessor, then whether the end of preceding activities will be responded or not, if not, how the actors are informed of this activity?
(4) An activity is usually composed of several procedural operation steps. This element can be elicited by answering the following questions:
• What operation steps are involved in an activity?
• Who perform these operation steps?
• What equipment and physical assets will be used in the operation steps?
• How will these equipment and physical assets be used in performing the activity?
• Are validations needed in operation steps?

3.1.2 Guidelines for authoring scenarios

Guideline 6: Well-formed formula
Definition: All the textual statements on scenarios should be authored with the following sentence pattern:
Subject: Agent + Verb + Target: Object + Direction: (Source, Destination) + Way: (Means, Manner).
Notes:
(1) In principle, one textual scenario statement should contain only one action that represents one operation step.
(2) Target, direction and way are summarized in a generic term called parameter element.
(3) The elements that constitute a scenario are similar with the elements of a sentence. A scenario will be associated with one subject, one verb and three types of parameters which qualify the verb in different ways.
(4) These elements of a sentence ensure that information needed to describe a scenario are sufficient to support subsequent work of goals refinement and facilitate an accurate common understanding.
(5) User should endeavor to keep scenario descriptions complete when authoring scenarios.
(6) It is noticed that the elements of a sentence are not equal to grammatical items.
(7) More details may reference to literature [18].
Example: Table 1 shows some samples and explains each element in this well-formed formula, in which the element samples are indicated in bold.
The “Goals and scenarios introduction guideline” and “Alternative refinement guideline” will be together applied to an iterative reasoning process. □

**Table 1. Meanings and samples of some elements of sentence pattern.**

| Element | Label in subscript | Meaning in this study | Sample |
|---------|---------------------|-----------------------|--------|
| Agent   | Agent               | An active entity that initiates an action for a purpose, a system or a participant can be treated as an agent | (Operator)\textsubscript{Agent} scans the barcode of material with the scanner, and inputs the lot number of raw material into the system. |
| Verb    | Verb                | predicate that denotes an action | Operator (scans)\textsubscript{Verb} the barcode of material with the scanner, and (inputs)\textsubscript{Verb} the lot number of raw materials into the system. |
| Object  | Obj                 | data or information that are directly affected or imposed by the action, | Operator scans the barcode of material with the scanner, and inputs the \(\text{lot number of raw materials}\)\textsubscript{Obj} into the system. |
| Source  | So                  | the origin of information flow | Operator obtains detail information about raw materials from (the system)\textsubscript{So}. |
| Destinati on | Dest | the end of information flow | Operator scans the barcode of material with the scanner, and inputs the lot number of raw materials into (the system)\textsubscript{Dest}. |
| Means   | Mea                 | equipment, tools used to achieve the goal | Operator scans the barcode of material (with the scanner)\textsubscript{Mea} and inputs the lot number of raw materials into the system. |
| Manner  | Man                 | methods, approach used to achieve the goal | Operator inputs the lot number of raw materials into the system (by means of scanning the barcode (with the scanner)\textsubscript{Man}). |

**Guideline 8: Composition refinement**

**Definition:** If there are multiple options for the parameter element of the sentence, and these options are mutually complementary, then introduce sub-goals and corresponding scenario descriptions for each branch according to “Goals and scenarios introduction guideline”, forming AND relationships between these sub-goals.

**Notes:**
The “Goals and scenarios introduction guideline” and “Composition refinement guideline” will be together applied to an iterative reasoning process. □

3.1.3 Guidelines for sorting requirements

**Guideline 9: Requirement filtration**

**Definition:** Identify the repetitive and conflicting requirements involved in textual scenario descriptions and eliminate them.

**Notes:**
(1) The requirements elicited from people of multiple roles and departments may be repetitive or mutually conflicting especially for a large-scale MES project. It is therefore needed to eliminate them for ensuring a correct subsequent work of functional design.

(2) The following tips can help identifying the potential conflicts:
- Conflicts are more likely to be found in the requirements for the same functionality.
- There may be conflicts between the functionality and input/output of it if they are elicited from different people.
- Due to differences in work experiences and positions, there may be conflicts between the requirements presented respectively by the person and his/her superior. □

**Guideline 10: Priority determination**

**Definition:** The priority level should be determined for each filtered requirement to be implemented.

**Notes:**
It can be evaluated from the following aspects:
• Dominant requirements first implemented — some functionalities must be implemented first, while others can be implemented.
• Most associated requirements first implemented — the functionalities that are most associated to others should be implemented first.
• Most benefited requirements first implemented — the functionalities that may bring about most benefits to enterprises should be implemented first.

3.2 Recommended document structure for URS

Each statement on requirement for MES is elicited through comprehensive application of ISA-95 standard application guidelines, scenario authoring guidelines and requirements sorting guidelines, and is presented as a scenario in the context of a certain MOM category. The problem space framework of MES can be therefore used to document URS naturally. In this section, the main elements of table of contents for MES User Requirement Specifications are listed in Table 2 on the basis of previous best practices[23].

Table 2. Main elements of table of contents for MES User Requirement Specifications (partly).

| Chapter | Chapter Heading | Chapter | Chapter Heading |
|---------|-----------------|---------|-----------------|
| 0       | Introduction    | 4.8     | Maintenance performance analysis |
| 0.1     | Scope of this URS document | 5       | Quality operations management |
| 0.2     | Normative references | 5.1     | Quality definition management |
| 0.3     | Document structure | 5.2     | Quality resource management |
| 1       | Basic description of the enterprise | 5.3     | Detailed quality scheduling |
| 1.1     | General         | 5.4     | Quality dispatching |
| 1.2     | Organizational structure | 5.5     | Quality execution management |
| 1.3     | Physical hierarchy | 5.6     | Quality data collection |
| 1.4     | Process segments | 5.7     | Quality tracking |
| 1.5     | Current application architecture and infrastructure | 5.8     | Quality performance analysis |
| 2       | Business drivers | 6       | Inventory operations management |
| 3       | Production Operations Management | 6.1     | Inventory definition management |
| 3.1     | Product definition management | 6.2     | Inventory resource management |
| 3.2     | Production resource management | 6.3     | Detailed inventory scheduling |
| 3.3     | Detailed production scheduling | 6.4     | Inventory dispatching |
| 3.4     | Production dispatching | 6.5     | Inventory execution management |
| 3.5     | Production execution management | 6.6     | Inventory data collection |
| 3.6     | Production data collection | 6.7     | Inventory tracking |
| 3.7     | Production tracking | 6.8     | Inventory performance analysis |
| 3.8     | Production performance analysis | 7       | Supporting functionalities |
| 4       | Maintenance operations management | 7.1     | Management of information (storage, backup, recovery, redundancy, archiving, etc.) |
| 4.1     | Maintenance definition management | 7.2     | Management of documentation (technical data, records) |
| 4.2     | Maintenance resource management | 7.3     | Management of security (authorization, access right, password) |
| 4.3     | Detailed maintenance scheduling | 7.4     | Management of compliance (GMP, 21 CFR Part 11) |
| 4.4     | Maintenance dispatching | 7.5     | Management of configuration (change management, versioning, audit trails) |
| 4.5     | Maintenance execution scheduling | 7.6     | Management of incidents and deviations (recording of alarms and deviations) |
| 4.6     | Maintenance data collection | 8       | Interfaces with external systems interfaces with ERP, PDM, LIMS, WMS, Computerized Maintenance Management Systems (CMMS) and control system |
| 4.7     | Maintenance tracking | 8.1     | |

Limited to space, only headings of level 1 and level 2 are listed in Table 2, chapters 3, 4, 5, 6 and 7 should be detailed into headings of level 3 to describe the as-is situations and to-be scenarios.
Additionally, the requirements on other aspects of MES should also be described in the URS, such as database, response speed, graphical user interface (GUI), scalability, deployment mode (C/S, B/S), etc. Finally, an audit page should be inserted into the appropriate place of the URS document for signing and approval.

As necessary, the terms and abbreviations used in the URS document should be listed in the appendix, together with samples of the bill of materials (BOM), process flow charts, work records (or batch production records), work schedules, etc.

It is necessary to state that the recommended table of contents for URS document is based on the maximum scope of a project. The requirements outside the scope of project need to be removed from the actual URS document after the scope of project is determined.

4. Case study and discussion

The methodology proposed in this paper has been applied to a pharmaceutical company denoted by “A”. It is turned out that the URS document defined by this methodology can make the communications between users and system integrators easier and more efficient. The effects are particularly obvious especially for the internationally known MES product vendors, because most of these vendors are able to provide MES platforms that are compliance with the ISA-95 standard, so that , the functions provided by the MES product can be corresponded well with the requirements listed in the URS document. Thus, URS defined in this way is more suitable for MES products survey and selection before importing MES applications.

Company “A” has selected a MES product on the market on the basis of URS. When selecting a MES product, company “A” investigated the implementation approaches involved in solutions provided by vendors for each requirement within URS, from various perspectives, such as which requirements can be supported by the standard modules of MES products, which need to be implemented in a customized way or by functional configuration, and so on. Figure 7 illustrates the practices of selecting the MES products, which have been done by company “A”.

![Figure 7. Practices of MES products selection based on URS.](image-url)

It is not easy to be “qualified” users for enterprises, because they need to obtain a clear understanding of the production control activities and business planning activities that occur in their own plants, before importing a manufacturing execution system. It is a great challenge for enterprises to build a flexible and constantly evolving manufacturing execution system successfully. This goal can...
be achieved only when the enterprises reach a high level of maturity and recognize the necessity of continuous improvement.

The ISA-95 standard reconciles business management with execution management and harmonize their visions. The whole standard, especially Part 3, can be regarded as a tutorial on understanding the functionalities and information flow within manufacturing execution system, and has great reference value for defining URS. It is hoped that more and more users can participate in requirement elicitation process and make a good use of these guidelines when implementing a manufacturing execution system, for facilitating an effective communication with system integrator and software vendors.

5. Conclusions
In this paper, the issues arose in the implementation of manufacturing execution system were discussed first, then the significance of URS in a manufacturing execution system implementation project was highlighted. The problem space framework of manufacturing execution system was constructed from three dimensions based on ISA-95 standard and contributions by members of ISA95 standard committee. All of the requirements for MES applications will emerge in the problem space. So the problem space framework has laid a foundation for requirements elicitation. On the other hand, a semi-formal requirement definition language was introduced mainly based on contributions by Colette Rolland. The guidelines for defining URS of MES were also enumerated and justified one by one.

It can be stated that — as result of applying this methodology to a pharmaceutical company’s MES project — the guidelines proposed by this paper have been proved to be effective on defining a normative and clear URS, as well as selecting a suitable MES product on the market.

In the situation of smart manufacturing, the emerging information and communication technology (ICT) should be paid more attentions to when implementing the manufacturing execution system on one hand, and the ISA-95 standard will be updated and supplemented with models of operations management events which can enable users to better identify their requirements for MES.

Acknowledgments
The authors wish to thank all the members of ISA95 for sharing information across the standard committee. The support of the third author Yan Wang who is a consultant engaged in pharmaceutical process validation is acknowledged.

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