AACE INTERNATIONAL RECOMMENDED PRACTICE

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COST ESTIMATE CLASSIFICATION SYSTEM - AS APPLIED IN ENGINEERING, PROCUREMENT, CONSTRUCTION, AND QUALIFICATION FOR THE PHARMACEUTICAL AND RELATED INDUSTRIES

AACE INTERNATIONAL

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COST ESTIMATE CLASSIFICATION SYSTEM – AS APPLIED IN ENGINEERING, PROCUREMENT, CONSTRUCTION, AND QUALIFICATION FOR THE PHARMACEUTICAL AND RELATED INDUSTRIES

TCM Framework: [illegible] – Cost Estimating and Budgeting

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TCM Framework: 7.3 – Cost Estimating and Budgeting

August 7, 2020

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1. PURPOSE

As a recommended practice (RP) of AACE International, the *Cost Estimate Classification System* provides guidelines for applying the general principles of estimate classification to project cost estimates (i.e., cost estimates that are used to evaluate, approve, and/or fund projects). The *Cost Estimate Classification System* maps the phases and stages of project cost estimating together with a generic project scope definition maturity and quality matrix, which can be applied across a wide variety of industries and scope content.

This recommended practice provides guidelines for applying the principles of estimate classification specifically to project estimates for engineering, procurement, and construction (EPC) and qualification work for the pharmaceutical and related industries. This document supplements the generic cost estimate classification RP 17R-97 [1] by providing:

- A section that further defines classification concepts as they apply to the pharmaceutical and related industries.
- A chart that maps the extent and maturity of estimate input information (project definition deliverables) against the class of estimate.

As with the generic RP, the intent of this document is to improve communications among all the stakeholders involved with preparing, evaluating, and using project cost estimates specifically for the pharmaceutical and related industries.

The overall purpose of this recommended practice is to provide the pharmaceutical and related industries with a project definition deliverable maturity matrix that is not provided in 17R-97. It also provides an approximate

representation of the relationship of specific design input data and design deliverable maturity to the estimate accuracy and methodology used to produce the cost estimate. The estimate accuracy range is driven by many other variables and risks, so the maturity and quality of the scope definition available at the time of the estimate is not the sole determinate of accuracy; risk analysis is required for that purpose.

For development of this recommended practice input from representatives from major pharmaceutical and engineering companies serving the pharma industry and supporting organizations as Parenteral Drug Association (PDA), International Society for Pharmaceutical Engineering (ISPE), Project Management Institute (PMI) and AACE International (AACE) has been involved (the companies are not named for confidentiality).

An objective for this RP is to support the pharmaceutical industry with a recommended maturity level of project definition deliverables (Table 3). In general, pharmaceutical projects are like other process industry projects, However, there are a few areas of difference. These include issues such as room cleanliness standards and validation/qualification after commissioning. Improving the early definition of commissioning and validation/qualification plans as part of the estimate process has been shown to help improve project performance.

This document is intended to provide a guideline, not a standard. It is understood that each enterprise may have its own project and estimating processes, terminology, and may classify estimates in other ways. This guideline provides a generic and generally acceptable classification system for the pharmaceutical and related industries that can be used as a basis to compare against. This recommended practice should allow each user to better assess, define, and communicate their own processes and standards in the light of generally accepted cost engineering practice.

2. INTRODUCTION

For the purposes of this document, the terms *pharmaceutical and related industries* are assumed to include all engineering, procurement, construction and qualification work associated with new and revamp facilities in the pharmaceutical and biopharmaceutical industry, but also to an increasing extent nutraceutical which approach pharmaceutical grade quality[1]. These facilities support the manufacturing and packaging of products regulated as drugs or medicines (or of near quality such as nutraceuticals). These facilities typically combine specialized process plant scope, packaging scope facilities and waste handling scope, and specialized building scope. The manufacturing is all done indoors in a highly controlled environment. Their scope is similar to that of other indoor process facilities except for the level of quality and process and environmental control. In terms of stage-gate processes, these projects also include a more extensive, rigorous and regulated start-up and commissioning phase than typical process plants, termed *qualification and validation*. Qualification typically has sub-phases of installation and operational qualification (IQ/OQ) that verify that the facility was installed correctly and operates as intended respectively [2]. Additional defining deliverables are required for this work which can be of extensive duration (and added uncertainty). For non-medicine nutraceuticals, there are food safety qualification practices of a similar nature but less regulated.

In terms of the basic physical scope of the facilities, API facilities are to a great extent simply process plants and buildings. These are covered in RPs 18R-97 and 56R-08 respectively [3] [4]. It includes the site and building (site development and architectural, civil and structural works, mechanical systems [e.g., HVAC], power and lighting, and so on) and the process facilities (equipment, piping, electrical, controls and so on). However, aseptic production facilities are of a more specialized nature, including as they do, such characteristics as hygienic piping, valves and fittings, impervious and aseptic building finishes, and clean room HVAC to name a few. Project execution strategies may vary between the site and building scope and the process scope as the nature of the work and contractors involved will vary. Note that if a pharmaceutical facility related project consists of a site and building or process

[1] Biopharmaceutical medicines have a biological basis, while pharmaceutical medicines have a chemical basis. Nutraceuticals are mostly food supplements not regulated as medicines, but their production quality may approach that of medicines.

element that is of a more standard nature (e.g., an office building or warehouse adjacent to the plant) and lacks the specialized features and qualification requirements, RPs 18R-97 and 56R-08 can be applied.

The common thread within the pharmaceutical industry (for the purpose of estimate classification) is its reliance on project definition documents (project charter; user require specification; validation master plan; schematic layout; major equipment specification and more) as primary scope defining documents. These documents are key deliverables in determining the degree of project definition, and thus the extent and maturity of estimate input information.

The design documents may consist of site master plan, schematic facility layout, equipment general arrangement, personal, equipment, material and waste flow diagrams, process and utility flow diagrams (PFDs), process and utility piping and instrumentation diagrams (P&IDs), equipment datasheets and specifications, electrical single line diagrams, and HVAC flow diagrams. Additional design is required to support the protection, control and automation of the processes and facilities. The cost estimates covered by this addendum are for engineering, procurement, construction (EPC) and qualification work only.

The owner, agency, or contractor may require individual cost estimates at each of these estimate classifications or phases. The owner, agency or contractor may provide specific input on the project data or design deliverable requirements.

This guideline reflects generally-accepted cost engineering practices. The recommended practice was based upon the practices of a wide range of projects from around the world as well as published references and standards [1] [2] [4]. Company and public standards were solicited and reviewed, and the practices were found to have significant commonalities.

This RP applies to a variety of project delivery methods such as traditional design-bid-build (DBB), design-build (DB), construction management for fee (CM-fee), construction management at risk (CM-at risk), and private-public partnerships (PPP) contracting methods.

3. COST ESTIMATE CLASSIFICATION MATRIX FOR THE PHARMACEUTICAL AND RELATED INDUSTRIES

A purpose of cost estimate classification is to align the estimating process with project stage-gate scope development and decision-making processes. For the pharmaceutical and related industries, the stage-gate process is commonly used. [4] As mentioned, the qualification phase differentiates this process from some others. However, institutional stage-gate processes and names of phases and estimates vary considerably; each user must compare the stages of the process governing their work and decide how the classification aligns with them. Examples of variations are given later.

Table 1 provides a summary of the characteristics of the five estimate classes. The maturity level of project definition is the sole determining (i.e., primary) characteristic of class. In Table 1, the maturity is roughly indicated by a percentage of complete definition; however, it is the maturity of the defining deliverables that is the determinant, not the percent. The specific deliverables, and their maturity or status are provided in Table 3. The other characteristics are secondary and are generally correlated with the maturity level of project definition deliverables, as discussed in the generic RP. [1] Again, the characteristics are typical but may vary depending on the circumstances.

	Primary Characteristic	*Secondary Characteristic*		
ESTIMATE CLASS	**MATURITY LEVEL OF PROJECT DEFINITION DELIVERABLES** Expressed as % of complete definition	**END USAGE** Typical purpose of estimate	**METHODOLOGY** Typical estimating method	**EXPECTED ACCURACY RANGE** Typical variation in low and high ranges at an 80% confidence interval
Class 5	0% to 2%	Concept screening	Capacity factored, parametric models, judgment, or analogy	L: -25% to -50% H: +40% to +150%
Class 4	1% to 15%	Study or feasibility	Equipment factored or parametric models	L: -20% to -40% H: +30% to +75%
Class 3	10% to 40%	Budget authorization or control	Semi-detailed unit costs with assembly level line items	L: -10% to -25% H: +20% to +50%
Class 2	30% to 75%	Control or bid/tender	Detailed unit cost with forced detailed take-off	L: -5% to -15% H: +10% to +30%
Class 1	65% to 100%	Check estimate or bid/tender	Detailed unit cost with detailed take-off	L: -3% to -15% H: +5% to +20%

Table 1 – Cost Estimate Classification Matrix for the Pharmaceutical and Related Industries

This matrix and guideline outline an estimate classification system that is specific to the pharmaceutical and related industries where special requirements and qualifications apply. Refer to Recommended Practice 17-97 [1] for a general matrix that is non-industry specific, or to other cost estimate classification RPs for guidelines that will provide more detailed information for application in other specific industries or less specialized facilities. These will provide additional information, particularly the *Estimate Input Checklist and Maturity Matrix* which determines the class in those industries. See Professional Guidance Document 01, *Guide to Cost Estimate Classification.* [5]

Table 1 illustrates typical ranges of accuracy ranges that are associated with the pharmaceutical and related industries. The +/- value represents typical percentage variation at an 80% confidence interval of actual costs from the cost estimate after application of appropriate contingency (typically to achieve a 50% probability of project overrun versus underrun) for a given scope. Depending on the technical and project deliverables (and other variables) and risks associated with each estimate, the accuracy range for any particular estimate is expected to fall within the ranges identified. However, this does not preclude a specific actual project result from falling outside of the indicated range of ranges identified in Table 1. In fact, research indicates that for weak project systems and complex of otherwise risky projects, the high ranges may be two to three times the high range indicated in Table 1. [6]

In addition to the degree of project definition, estimate accuracy is also driven by other systemic risks such as:

- Level of familiarity with technology.
- Unique/remote nature of project locations and conditions and the availability of reference data for those.
- Complexity of the project and its execution.
- Quality of reference cost estimating data.
- Quality of assumptions used in preparing the estimate.
- Experience and skill level of the estimator.
- Estimating techniques employed.
- Time and level of effort budgeted to prepare the estimate.
- Market and pricing conditions.
- Currency exchange.

- Regulatory, community, and landowner risks.
- Political, environmental, and other regulatory circumstances.

Systemic risks such as these are often the primary driver of accuracy, especially during the early stages of project definition. As project definition progresses, project-specific risks (e.g. risk events and conditions) become more prevalent (or better known) and also drive the accuracy range.

Another concern in estimates is potential organizational pressure for a predetermined value that may result in a biased estimate. The goal should be to have an unbiased and objective estimate both for the base cost and for contingency. The stated estimate ranges are dependent on this premise and a realistic view of the project. Failure to appropriately address systemic risks (e.g. technical complexity) during the risk analysis process, impacts the resulting probability distribution of the estimate costs, and therefore the interpretation of estimate accuracy.

Figure 1 illustrates the general relationship trend between estimate accuracy and the estimate classes (corresponding with the maturity level of project definition).

Depending upon the technical complexity of the project, the availability of appropriate cost reference information, the degree of project definition, and the inclusion of appropriate contingency determination, a typical Class 5 estimate for a pharmaceutical and related industries project may have an accuracy range as broad as -50% to +150%, or as narrow as -25% to +40%. However, note that this is dependent upon the contingency included in the estimate appropriately quantifying the uncertainty and risks associated with the cost estimate. Refer to Table 1 for the accuracy ranges conceptually illustrated in Figure 1 [8].

Figure 1 also illustrates that the estimating accuracy ranges overlap the estimate classes. There are cases where a Class 5 estimate for a particular project may be as accurate as a Class 3 estimate for a different project. For example, similar accuracy ranges may occur if the Class 5 estimate of one project that is based on a repeat project with good cost history and data and, whereas the Class 3 estimate for another is for a project involving new technology. It is for this reason that Table 1 provides ranges of accuracy values. This allows consideration of the specific circumstances inherent in a project and the industry sector to provide realistic estimate class accuracy range percentages. While a target range may be expected for a particular estimate, the accuracy range should always be determined through risk analysis of the specific project and should never be pre-determined. AACE has recommended practices that address contingency determination and risk analysis methods. [9]

If contingency has been addressed appropriately, approximately 80% of projects should fall within the ranges shown in Figure 1. However, this does not preclude a specific actual project result from falling inside or outside of the indicated range of ranges identified in Table 1. As previously mentioned, research indicates that for weak project systems, and/or complex or otherwise risky projects, the high ranges may be two to three times the high range indicated in Table 1.