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Commissioning Fundamentals and a Practical Approach

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Introduction

Have you ever had something not to work but only discovered long after start-up? Do you have an uneasy feeling that something might not be installed correctly, but don't know how to verify? Then try commissioning. Actually, Commissioning is nothing new. What good engineer would not confirm an installation works? But if commissioning is documented poorly, it is inadequate. If it is done improperly, it is inadequate. Projects routinely have problems. One part of the solution to minimizing project problems is to have a robust and documented Commissioning process (assuming the design is robust in the first place). However, we can go to far and judge success by the weight of the paper generated. How can Commissioning be implemented meaningfully in the real world? This course will attempt to answer this question.

The Author has been a leader in the Pharmaceutical industry in the application of documented Commissioning to minimize the regulated paperwork required for Validation/Qualification. He shares his learned experience in this course in the practical application of commissioning, whether in a regulated industry or not. This course is to a general audience – see separate material for specific applications to the Pharmaceutical industry.

Course Content

Why Commission?

Commissioning is necessary to ensure facilities, equipment, and systems are installed and function properly, and are successfully turned over. A documented Commissioning approach offers traceable verification, and ensures a systematic approach that minimizes commissioning oversights. Effective Commissioning minimizes punchlist items, and improves startup by eliminating problems up-front. Further, certain Commissioning activities may be used to support documentation requirements for regulated industries.

Commissioning Defined

Commissioning is a well planned, documented, and managed engineering approach to the start-up and turnover of facilities, systems, and equipment to the End-User that results in a safe and functional environment that meets established design requirements and stakeholder expectations.[i] That is, Commissioning verifies what was specified *was* installed, that it functions properly, and it was successfully turned over to the user *and* reasonably ensures the next step verification for regulated industries will be successful.

Given this definition, engineers have always commissioned projects to a degree. For example, when a new pump is installed, the proper rotation and flow rate is verified. Before it is installed, the model number and materials of construction are confirmed. Another example is an HVAC system. The airhandler is confirmed to be leveled and adjusted. The controls are tested. At the end, a test and balance contractor adjusts circuit setters for proper water flowrates, and to

adjust dampers for proper airflow. At the end of a project, the operators and maintenance staff are trained. To have a record of what was installed, as-built drawings and Operations and Maintenance manuals are developed. This is commissioning. All these activities can be summarized in distinct Commissioning categories: Pre-Commissioning activities, Setting-to-Work, Inspections, Testing, and Turnover. (Note: Setting to Work is a potential fourth category, but may be included under Inspection or Testing as needed.)

Pre-Commissioning

Pre-commissioning activities are Site Acceptance Tests (SAT) and Factory Acceptance Tests (FAT) as well as other similar activities. FAT's are useful in protecting the business aspect of an investment, by testing the equipment or system at the factory. This allows the system to be tested and deficiencies corrected in a manufacturing environment before it arrives on-site with surprises. The SAT verifies proper equipment and operation on-site. For many projects, especially those with single equipment systems, the SAT may constitute the majority if not all the Commissioning inspection and testing requirements. Further, SAT's (and FAT's with caution) may include elements sufficient for aspects of a regulated activity verification. If a FAT is provided, the SAT could be a reduced regimen. However, be careful in that changes made after the FAT in the factory (outside a controlled setting) could affect acceptable outcomes.

The following are typical elements of FAT's/SAT's, as applicable:

- Confirm fundamental scope definitions (or Acceptance Criteria) and Specifications
- Functionality –operate equipment/systems during test
- Alarms and safeties
- PLC/Controls thorough checkout/challenge
- Utilities
- Maintenance needs
- Calibration
- Labeling
- Training and turnover

Setting-to-Work

Setting-to-work and other regulation and adjustments are needed prior to energizing the system or full startup. This could include factory representative start-up, calibration, and other considerations needed before fully operating the equipment and beginning other aspects of Commissioning.

Inspection

Inspection is the process by which the construction and installation is verified as in accordance with the detailed design, specified construction standards and materials and any relevant legal or regulatory demands related to these areas.[ii] From the examples above, *confirm the pump model number* and *verifying the airhandler was properly leveled* are Inspection activities. Inspection activities generally do not include testing, and often are better handled on forms separate from testing. (There are exceptions when for succinctness or clarity Inspection items are included with Tests.) Inspections are usually visual confirmations. The questions to ask when developing an Inspection checklist are,

- What needs observing to ensure the equipment is properly installed?

- What needs inspecting to ensure project definition requirements, Acceptance Criteria and other regulatory issues are met?
- What inspections are needed to reasonably ensure any subsequent regulated verification will pass?
- How will Inspection activities be structured/documented so repetition during any regulated verification is not required?

When these basic questions are answered, commonsense will prevail. There is no need to create volumes of documents of marginal value. Yet, documentation must be adequately thorough. The key is to be specific with Inspection line items to ensure documentation is traceable.

Testing

Testing is the process by which adjustments to, and regulation of, individual systems are demonstrated as within the required tolerances, system components are demonstrated as delivering the required capacity or duty, the functions of the systems are demonstrated as delivering the required capacity of duty, the functions of the system are demonstrated to be as specified and appropriate.[iii] Referring again to the commissioning examples earlier in the article, checking the pump's *flow rate* and *performing test & balance* on the HVAC system are all testing activities. Essentially, testing is needed on what was installed to ensure the equipment or system operates as specified and required. The questions to ask when determining test requirements are,

- What level of testing is needed to ensure the equipment is properly functioning as specified?
- What tests are needed to ensure fundamental design requirements, Acceptance Criteria, and other regulatory issues are met?
- What testing is needed to ensure (within reason) any required regulatory verification will pass?
- How can the testing be documented/structured so it will not need to be repeated during any regulated verification?

As with Inspection, when the basic questions are answered, commonsense will prevail. There is no need to create volumes of useless test documents when the documentation is adequately thorough. As with Inspection, a documented paper trail is recommended to demonstrate (and document) that equipment and systems are adequately tested.

The project is not fully commissioned until Turnover is also completed. Training, Project Closeout (documentation), and Commissioning Documentation are parts of a successful project turnover as follows:

Training

Unless staff are properly trained, they will be unable to safely and efficiently operate and maintain the facility, equipment, or system. The commonsense questions to ask before determining training requirements are:

1. On which equipment/systems is training required?
2. Who needs to be trained?
3. What training do they need? (Not everyone needs the same training).
4. How must training be recorded?
5. What are the required qualifications of the trainer?

Project Closeout, Documentation

A project is not complete until all associated documentation is completed and turned over to appropriate individuals. This includes as-built drawings and specifications, Operations and Maintenance Manuals, etc.

Commissioning Documentation

Good commissioning is well documented commissioning. Commissioning documentation could be included in a Commissioning Report for more complex projects. For more complex projects, a formal Commissioning Plan is helpful to define the commissioning process. But before we discuss the elements for a higher documented Commissioning process, let's ensure we InVEST wisely in Commissioning.

InVEST Wisely in Commissioning

When establishing Commissioning requirements, it is important to remain focused on commonsense objectives to make the effort meaningful and cost effective. The acrostic InVEST is helpful in establishing the focus:

- Integrate: Integrate Commissioning with any other documentation required for a regulated industry if permitted. Don't automatically do things twice. *Integrate* also means to include commissioning activities in various vendors'/subcontractors' scope of work, as well as design documents.
- Verify: Ask: does the Commissioning activity adequately verify the equipment or system is what was specified and works as it should?
- Ensure Regulated Documentation Success: Ask: does the commissioning effort sufficiently ensure any regulated testing or inspection activities will be successful – first time?
- Sensible: Do enough but don't over do it
- Traceable: Document it. Remember the saying, "If you don't document it, you didn't do it."

Establishing Commissioning and Documentation Requirements

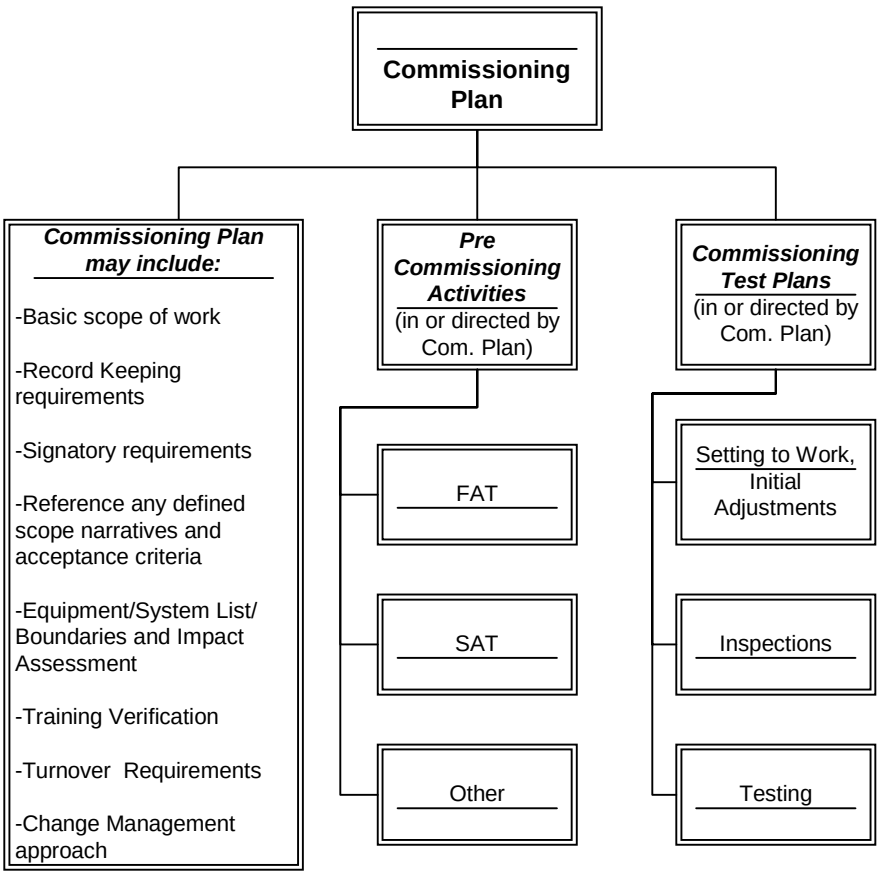
Before developing Commissioning Documentation, establish the extent of Commissioning needed, and design efficient and effective Commissioning around the needs of the project (hopefully as expressed in well-written and thorough project definition documentation. Typical Commissioning Documents may include the following, depending on project complexity.

- Overall Commissioning Plan – for large and more complex projects, especially those in regulated environments – this is a masterplan for Commissioning when the approach needs preplanning and structure. On smaller projects/single equipment, consider relying on Standard Operating Procedure (SOP) requirements rather than a separate overall Plan.
- Pre Commissioning: Includes Factory Acceptance Test (FAT), Site Acceptance Test (SAT), and possibly other early inspection/test activities. These are usually structured for individual systems, and can be included in or required by Commissioning Plan or Test Plans. These could be stand alone for individual equipment/systems, and/or include essential elements of the Commissioning Test/Inspection Plans

- Commissioning Test and Inspection Plans: These could be stand alone for individual equipment/systems. These may also supplement areas not covered by FAT's/SAT's. Further, self-contained Commissioning Checklists can be used for simple/small work. Don't create unnecessary volumes of documentation.
- Commissioning Checklists: For smaller/simpler projects, consider a single Commissioning Checklist in lieu of more extensive documentation above. These overall checklists may include the following:
    - Verify item specified was installed
    - Utility connection
    - Functionality checkout
    - Verify calibration completed
    - Verify closeout documentation completed
    - Verify training or orientation completed
    - CMMS (Computerized Maintenance Management System) entry
    - Other internal requirements

Note: When sufficient Commissioning direction is provided in specifications or in drawings and for non-regulated applications, at a minimum consider developing a detailed checklist to ensure commissioning is completed, and documentation is turned over. This is especially useful in non-regulated applications where a high-level of documentation is not required.

The following is a hierarchy diagram of typical commissioning documentation:



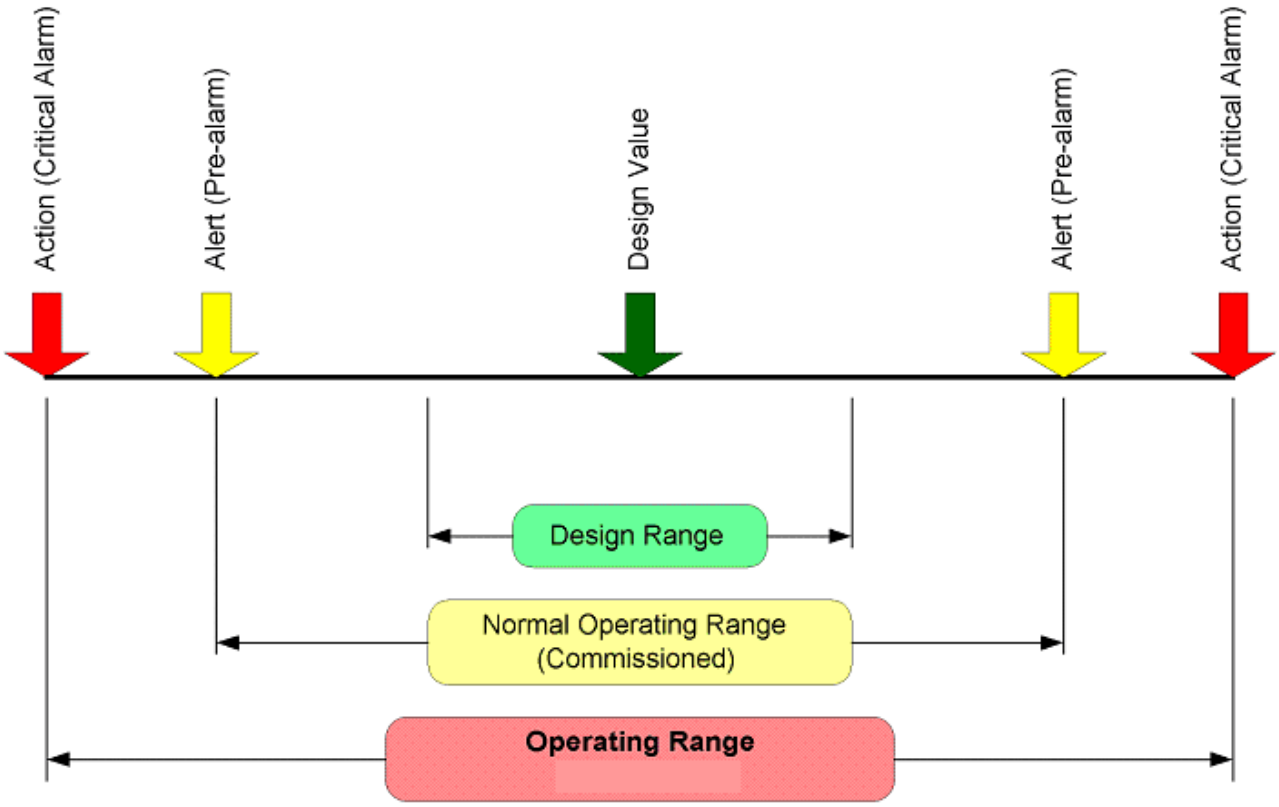
Now that we've reviewed the typical Commissioning documentation, we need to consider values to which we will Commission. When we perform Commissioning, we need to evaluate equipment and systems to specific quantifiable criteria.

SMART Commissioning Acceptance Criteria/Ranges

Another helpful acrostic is SMART, which should be considered when assigning values for Commissioning verification. Often, limits can be set that are not attainable by the installed equipment, nor are needed for the operation. The acrostic *SMART* as follows can assist us in making meaningful acceptance criteria:

- Sensible: Be practical when assigning commissioning acceptance ranges. Is the range really needed? What does the project really require? Can the equipment deliver this range consistently? Do the ranges also meet business/payback objectives? Energy efficiency?
- Maintainable: Will the range be maintained over time?
- Accurate: Is the range measurable? Are realistic tolerances considered? Can equipment consistently meet this target?
- Range: Is a reasonable range assigned? Rarely can point values be maintained. Design values must be well within commissioned ranges to minimize nuisance alarms.
- Traceable: Has/can the attainment of the range be verified and documented? Can it be verified later?

The International Society of Pharmaceutical Engineers (ISPE) Baseline Guides present Design, Normal Operating, and Operating Ranges. *Design* is the value to which the equipment or system is designed (see references). Normal Operating is the range, wider than Design, at which a pre-alert could occur for maintenance notification – this could be the Commissioned range (or the Commissioning range could be tighter if needed.) Even wider is the Operating range useful for in regulated industries (the range in which safety is maintained or product tolerances are controlled.) It is crucial to have a less stringent Operating range than the Normal Operating range, both of which should be less stringent than the design range or value. For example, the desired Operating range of a filler may be 300 vials or bottles per minute, the Commissioned (Normal Operating) might be 320, and the Design 340. If the Operating range was set at the design value or range, occasional failures would likely occur. (For this example, don't forget to also check at the lower speed during Commissioning – some equipment may not operate properly at slow speeds.) Buffers should be provided in these ranges. Remember, once Operating ranges are assigned, there could be a Quality intervention required when there are excursions – obviously, this should be avoided. Ideally, acceptance criteria should be determined early, and be a part of the primary scope definition document against which final Commissioning documents are drafted. (Note: For some examples, the chart could be inverted.)



So far, we have reviewed practical approaches to Commissioning, as well as its definition. The following section offers a few practical examples of how Commissioning might be applied. (Obviously, you will need to craft approaches specific to your applications.)

Specific Examples

How do we Commissioning those typical systems? Obviously, any application could differ, requiring more or less of the listed considerations. But the following reflect practical experience of the Instructor. Given the complexity of the various systems or with some combinations of systems, overall Commissioning Plans should also be considered where needed.

Computer/Controls

- Items to consider
  - Hardware/Software verification and testing
  - Security
  - Part 11 issues (for certain FDA regulated applications which includes such considerations as traceability, electronic signatures, security, etc.)
  - Functionality/challenge
  - Alarms
  - Trends
  - Data verification and integrity
  - Human interface/graphics
  - Backup
  - Input/output verification
- Include verification of items being controlled - somewhere!
- Commissioning vehicle: Most commissioning activities (inspections/tests) can be captured in FAT/SAT

Packaging/Fill Equipment

- Items to consider
  - Verify specified equipment installed
  - Utility connections
  - Instrumentation/calibration
  - Controls interface
  - Proper installation/alignment
  - Materials of fabrication
  - Safeties/ergonomics
  - Additional for sterile
  - Run product!
    - Line Speeds
    - Labeling
    - Tolerances
    - Proper Product Encapsulation
    - Finish Form Acceptance Criteria
    - Cartoning
- Commissioning vehicle:
  - Most commissioning activities (inspections/tests) may be captured in FAT/SAT
  - Supplement with Commissioning Test Plans

Process/Manufacturing

- Items to consider

- Verify specified equipment installed
- Utility connections
- Proper installation/alignment
- Materials of fabrication, passivation
- Operating parameters (flow rates, mixing, heating, cooling, vacuum, reactions)
- Adjustments, balancing, tests (pressure, etc.)
- Instrumentation/calibration
- Safeties/ergonomics
- Acceptable product

- Commissioning vehicle: Commissioning Plan, Commissioning Test Plans, and FAT/SAT on individual major equipment when needed. If the project essentially consists of a single equipment, FAT/SAT could satisfy most of (if not all) the Commissioning Test/Inspection activities.

HVAC

- Items to consider
  - Temperature
  - Relative Humidity
  - Particle Counts
  - Differential Pressure
  - Air Change Rate
  - Laminar flow issues
  - Room Classifications
- Commissioning vehicles
  - Pre-Commissioning Activities (FAT/SAT): Airhandler (AHU) and Building Management System (BMS)
  - Major equipment factory start-up (Setting-to-work, etc.)
  - Commissioning Test Plan
    - Sequence of Operation Challenge
    - Standard Tests and Inspections (such as IO verification, Calibrations, etc.)
    - Test and balance
    - HEPA Filter certifications
    - Trends
    - Viable/Non-viable counts
    - Inspection activities

Purified Water

- Items to consider
  - TOC's
  - Conductivity
  - Production rates
  - Micro
  - Other
- Commissioning vehicles
  - FAT/SAT of equipment
  - Commissioning Test Plan:
    - Challenge installed system to meet acceptance criteria, alarms, safeties, automatic operation, etc.

- SCADA/PLC checkout
- Trends
- Inspection activities

Compressed Air

- Items to consider
  - Viable and non-viable particle counts
  - Moisture (dew point)
  - Flow rate/Pressure
  - Oil free?
- Commissioning vehicles
  - Pre-commissioning: SAT's of major equipment
  - Commissioning Test Plan
    - Challenge installed system to meet acceptance criteria, alarms, safeties, automatic operation, etc.
    - Trends
    - Inspection activities

Implementing Commissioning

The first step in implementation is to draft a robust Commissioning Plan or have a predefined approach. For Commissioning to be successful, and more importantly, meaningful, the process must be properly defined. Start by assigning a single responsible individual, a Commissioning Team Leader. Establish a multidiscipline team to be a part of the commissioning documentation approval and development. But the Commissioning Team Leader (CTL) cannot do it by himself or herself. Even if time were not an issue, no one can have the technical expertise in all areas to develop meaningful tests and procedures. Much of the administrative aspects can be typical or require only minor modifications, and other templates/formats are useful. Including the development of Inspection Checklists and testing requirements in Architectural/Engineering consultant's or equipment integrator's scope of work can be effective financially and technically. The design engineers of record are most qualified to know what needs to be Inspected and Tested. However, the engineers of record must be familiarized on basic procedures as to how to develop proper formats for the specific Client, which can be accomplished by examples and written procedures. Much of the test requirements are routinely identified as part of the project specifications, which must be referenced or included in the Commissioning Plan or confirmed as part of a verification checklist.

Writing the entire Commissioning documentation can be accomplished completely by outside consultants, but they must be adequately trained on the Owner's procedures. Complete outsource plan writing can be less effective than having an internal CTL at the Owner to at least develop the backbone of the document and coordinate/insert outsourced Inspections and Tests forms and requirements.

Once the Commissioning documentation is written, who will do the Inspections and Tests? Again, the CTL cannot do all inspecting and testing (nor will be qualified to do so) by himself/herself. Assistance is needed. For Inspections, Construction Managers or integrators can provide cost effective support in this area. They often appreciate the opportunity to have Inspection checklists upfront, since it minimizes punch list items later. This approach usually adds minimal additional cost to the project. Most testing is typically performed by traditional testing agencies, such as geotechnical consultants, test and balancers, particulate monitoring companies, etc. as

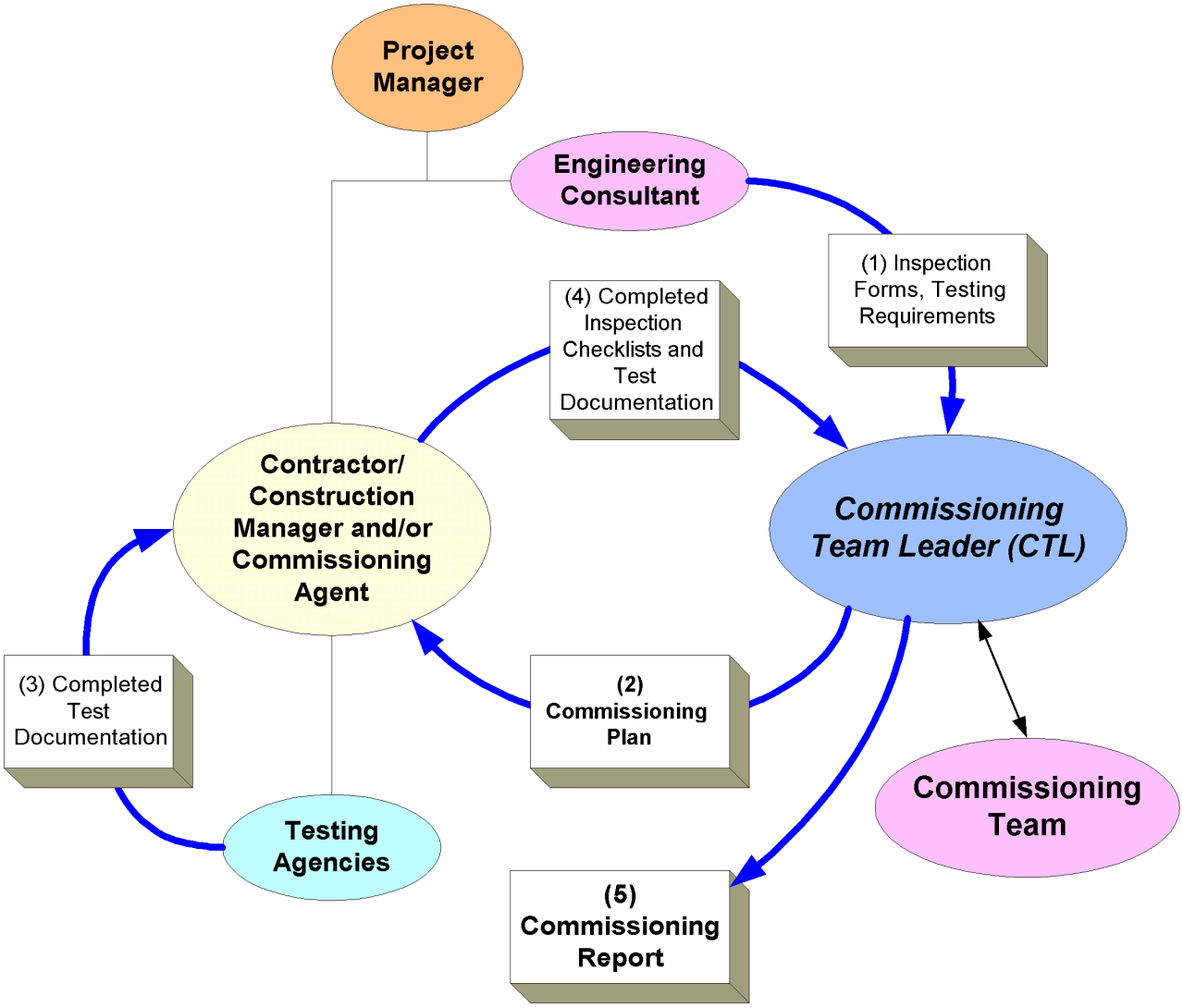
routinely defined in a project's specifications. However, specialized tests often require extra assistance/guidance. A good example is a computerized system; it is often best to require the design engineer of record to write and witness the sequence challenge test. He or she best understands the acceptable outputs of the system and the logic needed.

Commissioning for each project must be tailored to its needs, considering internal resource constraints. Another alternative (and usually more costly) is to outsource the complete commissioning implementation to a commissioning consultant. However, as with all outsourcing, careful scrutiny by qualified internal resources is needed to ensure Owner-specific requirements are met.

Below is a graphic of an example of an efficient Commissioning Process that has worked well for building projects (there are others) which relies on the Engineering Consultant and Construction Manager (CM) to perform much of the Commissioning activities, while maintaining a CTL to coordinate the process (this example has a dedicated Commissioning Team Leader (CTL) who develops the Commissioning Plan and directs the Commissioning process, relies on the Engineering Consultant to produce Inspection and Testing requirements, and acquires Commissioning execution through the Contractor/Construction Manager.

The approach is essentially a 5-stage process.

1. The consultant develops essential inspection and testing requirements for the CTL.
2. The CTL assembles the above and supplements as needed, completing other commissioning documents such as a Commissioning Plan if required.
3. Testing vendors provide standard test results to the CM.
4. The CM completes other Commissioning requirements, assembles 3 and 4, and forwards to the CTL. Outsourced Commissioning activities are under the direction of the CTL.
5. The CTL reviews, approves, and assembles the materials into a Commissioning Report.



Timing of Commissioning

Sufficient scope detail should be included in Requests for Proposals/Quotes (RFP/Q's) to enable consultants and contractors to include scope and pricing in their quotations. At a minimum, a draft of the Commissioning Plan should be issued with bid documents. The cost of specialized tests or inspections will be less if captured under a competitively bid environment. A Commissioning Plan or other suitable documented commissioning directives should be approved by the Commissioning Team Members and issued prior to construction beginning.

The implementation of Commissioning should begin concurrently with construction. There will be items on the Inspection Checklists and Test requirements that will be concealed by construction and cannot be viewed later.

Course Summary

Commissioning is a worthwhile exercise. It minimizes punch lists and provides higher assurance of project success. Commissioning is an important exercise to ensure what we installed is what we specified, and it works as specified. However, commonsense should prevail. Do no more or no less than is needed, and your project will benefit. Remember to *InVEST* wisely (Integrate Commissioning with Qualification, Verify, Ensure Qualification Success, Sensible, Traceable/Document it) and set *SMART* Acceptance Criteria in the beginning (Sensible, Maintainable, Accurate, Range, Traceable). To get more information, see various trade organizations (ASHRAE, ISPE, etc.). Tried and tested Commissioning approaches and documents are available. But mostly, learn by doing it!

References

[i]"Pharmaceutical Engineering Guides for New and Renovated Facilities – Volume 5 – Commissioning and Qualification"
[ii] Ibid
[iii] Ibid