Commissioning Under the Influence…

Redefining the Traditional Role of the Commissioning Agent in the Design and Construction of the Building Envelope

Fiona Aldous
Senior Associate
Wiss, Janney, Elstner Associates, Inc.

Daniel J. Lemieux, AIA
Consultant
Wiss, Janney, Elstner Associates, Inc.

Synopsis

Building envelope commissioning has evolved as a process that is both influenced by and a consequence of the changing roles of the architect and contractor. Examine the changing roles and consider the solutions:

- Architect as generalist;
- Contractor (subcontractor) as specialist; and
- Owner as realist - aware of the differences, concerned with quality; however, wed to schedule, market forces, and budget, responds with engagement of consultants (typically building envelope and risk management, etc).

Does the complexity of building envelope design, mandate knowledge of building construction, and science specific to the study of the enclosure beyond that of traditional commissioning to comprehensively serve the process as outlined by the NIBS Commissioning Guideline #3?

- Review the opportunities for the commissioning agent and the building envelope consultant with respect to the phases of commissioning.

In all likelihood, the requirement to perform building envelope commissioning will occur on complex facades and/or sensitive building typology such as hospitals and laboratories and/or unique and specialized building systems and/or as an overall component of the risk management strategy such as condominium buildings. Commissioning of the envelope when performed under professional influence provides greater comprehension and structure to the process, translating to a more efficient development of holistic building design and quality of contract documents. The design development phase has the greatest possibilities for creating coordinated and detailed envelope assemblies to facilitate a quality installation. If left to the field installation phase, the commissioning process will serve only to document rather than complement the overall design development and commissioning processes.

- Review of case studies. Compare and contrast traditional commissioning and commissioning under the influence of building envelope consultant.
- Overview of building envelope consultant's role in peer review, detail assistance/ development, construction observation, and testing phases.
- Discuss the building envelope commissioning agent and the building envelope consultant: the opportunities for the future.

About the Authors

Fiona Aldous is a Senior Associate in the Washington DC office of Wiss Janney Elstner, Inc (WJE). She has extensive experience in the peer review and investigation of modern building envelopes, providing detailing assistance to architects and designing repairs for various walls types, curtain walls, windows, roofing and waterproofing. She has lectured as an assistant professor at the School of Architecture at Ball State University in the area of design and construction, and worked as a field superintendent constructing new pharmaceutical facilities. She is an active member in the local BEC, and committee member of NIBS Guideline 3: Exterior Enclosure Technical Requirements for the Commissioning Process.

Daniel J. Lemieux, AIA, is Consultant and Unit Manager for Wiss, Janney, Elstner Associates, Inc.'s (WJE) Washington, D.C. office. Since joining WJE in 1996, he has successfully completed over 300 projects in the area of building envelope failure investigation, repair design, and architectural rehabilitation - several of which have been honored both locally and nationally for design and restoration excellence. He is an active member of ASTM, AAMA, APT, and CSI; was co-author and editor for the building envelope chapters of the web-based Whole Building Design Guide; and remains a contributing member of the committee currently developing NIBS Guideline 3: Exterior Enclosure Technical Requirements for the Commissioning Process.

Commissioning Under the Influence…

Redefining the Traditional Role of the Commissioning Agent in the Design and Construction of the Building Envelope

Commissioning is a term that is both widely recognized and well-understood in the design and construction profession. This is particularly true in the context of mechanical systems engineering, where commissioning has been defined as the need to "…provide documented confirmation that building systems… are planned, designed, installed, tested, operated and maintained in compliance with the Owner's Project Requirements."[1] In the context of building envelope design and construction, however, commissioning has begun to evolve as an entirely different process. Driven in part by the recent boom in condominium development across the United States and corresponding fear of mold-related claims on those projects within the design and construction communities, building envelope quality assurance programs and commissioning has evolved as a process that is both influenced by, and a consequence of, the changing roles of the architect and contractor in the traditional design and construction process. As architects and contractors continue to shield themselves from potential liability associated with these claims, developers have increasingly turned to highly specialized building envelope design consultants to bridge the chasm between design and construction. This paper will examine the evolving role of the building envelope specialist in that process and how that role has begun to influence, and arguably will redefine, the traditional role of the Commissioning Agent.

More Than Shelter

Architecture in its purest form begins with the need for shelter from the surrounding environment. Over time, this most basic of human needs has evolved in a variety of interesting and often unpredictable ways. Although the influences of religion, politics, and culture are immediately recognizable to most of us, the influences of geography, climate and exposure on the evolution of the building envelope can be far more subtle and complex. The contemporary building envelope in North America is today as much about science as it is art - complex and evolving arrangements of form, function, and material; building envelopes are reflective of our cultural values and, more critically, endeavor to respond to the evolving needs of building users and occupants, while maintaining adequate levels of human comfort through base building systems and activities that place significant demands on energy and natural resources.

Increasingly complex building design, chronically "sick" or otherwise failing buildings, diminishing natural resources, a growing concern regarding indoor air quality, and increasing costs of energy are but a few of the issues that send a clear mandate for an increase in the quality of design and construction of the contemporary building envelope. Not forgetting, the ever-present reality of human error during the design, construction and operating phases, combined with the impact from environmental forces upon the building, there is little doubt why buildings often fail to achieve performance of the highest possible standards. To this end, commissioning of the building envelope and an expanded and more technically-oriented role for the Commissioning Agent may form the basis of a plan that will resolve this crisis and move us all

collectively toward a more meaningful architecture that is both responsive to, and reflective of this current crisis and need for change.

Building Codes and Performance

Throughout its service life, the building envelope must continue to protect and maintain all of its functioning services, without redundancy or protection from the forces of the environment. The exterior wall is required by current 2003 International Building Code (IBC) to conform to Chapter 14, part 1403 Performance Requirements and 2003 International Energy Conservation Code, Chapter 8, Section 802 for Commercial Buildings, and ASHRAE/IESNA 90.1. The IBC outlines "the exterior walls shall provide the building with a weather resistant exterior wall envelope."[2] The walls are required to "be designed and constructed in such a manner as to prevent the accumulation of water within the wall assembly by providing a water-resistive barrier behind the exterior veneer …. and a means of draining water that enters the assembly to the exterior of the veneer, unless it is determined that penetration of water behind the veneer shall not be detrimental to the building performance."[3] Further, an exception to this code applies when wall designs demonstrate passing testing in accordance with ASTM E331: Standard Test Method for Water Penetration of Exterior Windows, Skylights, Doors, and Curtain Walls by Uniform Static Air Pressure Difference at a differential pressure of 6.24psf and criteria as noted in 1403.2 Exceptions.

The many environmental factors that can impact in-service performance of the building envelope are immense. The building envelope must be responsive to environment and weather which creates moisture in various forms including water, ice and snow, and vapor (typically in the form of moist air and vapor diffusion). The exterior envelope must prevent and control moisture entry to interior which can occur in the following forms: 1. Penetration of liquid moisture, typically rain, and ground water; 2. Migration of moisture through capillary action; 3. Condensation resulting from vapor in air, relative humidity and surface temperature differentials, and vapor diffusion (being the movement of vapor from an area of high pressure to an area of low pressure through materials and is independent of air flow). In addition, air movement and wind results in pressure differentials on various shape and heights of buildings, and relative to immediate neighboring environment. The influence of wind effect, stack effect, HVAC effects and combined effects all influence the ability the exterior envelope has to prevent uncontrolled moisture migration. Also, related aspects of weather including; temperature through expansion and contraction of materials; radiation and UV light impact varying with orientation; biological attack resulting from local pests; and regional geography including orientation, slope, adjacent buildings, proximity to large bodies of water (fresh and salt) all impact the building envelope in some manner.

The building envelope and the interior environment are interdependent, both separating and connecting the exterior from the interior, and the success of either can be highly dependent upon the integrity of the exterior enclosure. The building envelope thermal continuity, water penetration resistance, and air leakage all combine to influence the interior environment and demands upon the mechanical system, affecting its ability to perform. Although typical minimum guidelines for indoor air quality of commercial buildings are outlined by codes and

industry standards, several specialized building types and facilities require performance levels that exceed these standards - a factor that must be fully considered by the design team and reflected in the design of the building envelope. Specialized and sensitive buildings and facilities are typically more likely to require higher standards of quality, and also require commissioning of various systems. In addition, the need to validate performance may also be required for operation, such as compliance with Federal Drug Administration (FDA) or current Good Manufacturing Practices (cGMP) which have specific demands for the functional use of the space which will influence the requirements of the HVAC and interior air quality. Specialized buildings such as pharmaceutical wet chemical laboratories require typically regulated temperature and humidity, air motion, outside and supply air changes, supply and exhaust air filtration, specific air distribution techniques and specialized pressurization relationships to adjacent spaces. In the event these laboratories are placed concurrent with an exterior wall, the building envelope components must be designed and installed to allow for the mechanical system operation to these precise requirements.

Conversely, activities occurring within the interior spaces of specialized buildings may place non-typical loads on the building envelope and air handling systems which must be understood and accommodated in the design phase. HVAC designs for natatoriums and cold freezer storage spaces for example, require careful examination so as to minimize the potential impact on the exterior envelope. A firm understanding of the science related to the interdependency of the interior air characteristics and the building envelope are critical to the overall buildings' success. High levels of relative humidity in specialized buildings such as natatoriums must be considered in the design phase to ensure the building envelope performs to prevent premature deterioration or increased maintenance of the facility. In the event that breaches in the vapor barrier or excessive air leakage through the building envelope occurs, leading to the development of condensation and excess moisture within the materials, deterioration of the building will be exacerbated, together with increased operating costs due to lost efficiency.

Energy Consumption

The impact of building envelope performance on energy consumption and life-cycle building and maintenance costs has been well documented. A study of air tightness of the building envelope prepared for the U.S. Department of Energy, Office of Building Technologies, "Investigation of the Impact of Commercial Building Envelope Air-tightness on HVAC Energy Use" states a "predicted potential annual heating and energy cost savings for these buildings ranged from 2% to 36% with the largest savings occurring in the heating-dominated climates of Minneapolis and Bismark."[4] Typical commercial buildings have been simulated and failed to provide energy efficient solutions increasing operating costs and overall negatively impacting the environment through the use of diminishing energy sources, especially fossil fuels. To achieve the recommended air tightness of the air barrier component of the building envelope, 0.02 L/s.m2 at 75 Pa (0.04 cfm/ft2 at 0.3 in H2O) the study recognized "additional expenditure would have to be included for quality assurance and quality control (i.e. for inspections and testing)."[5]

A Case for Specialized Building Envelope Commissioning

Understanding the Goal

Often, to achieve a holistically designed and operational building, the highest level of care and quality must underpin the complete design and development process, from pre-design through construction and post-occupancy operation and maintenance. The plan to commission buildings or systems of any type endeavors to achieve this goal by outlining the various roles and responsibilities of individual project team members who will be integral to the development and implementation of the commissioning process. The greater the risk associated with the project (perhaps as a function of building type, use group, location, climate or exposure), the greater the need for confidence in the long-term durability and performance of the system and, consequently, the greater the need for highly specialized design and consulting expertise necessary to effectively develop and implement the process. To understand the interdependency of the various systems and components, and to provide fully integrated "whole-building" approach, our recommendations include; a building envelope commissioning plan developed and implemented with the active participation of a specialized building envelope design and/or construction professional to further reduce the risk of building envelope performance failure; and a detailed understanding as to the standards of performance for each different envelope component and their inter-relationships to assure the overall performance of the building envelope. As architectural functions and forms become more complex, hence forth the construction and components can become more complex, and a lack of specialized knowledge related to design and construction can be traced to the root cause of many a failure to perform

Defining the Process

Without question, numerous knowledgeable professionals design and construct buildings. Unfortunately, we are all human as well, and although each of us strives to perform to the best of our ability, there are occasions in which the necessary knowledge falls short of the necessary abilities and/or implementation. Too often, the inherent complexities of interior and exterior environments and the performance required by the building envelope to meet the basis of design and the expectations of the occupants are not completely understood. To assist in establishing and achieving realistic buildings, that function correctly, are sustainable, durable and maintainable, the NIBS Commissioning Guideline 3 (2006) has been refined to provide project teams with an outline of the commissioning process, defined as:

- *"The Commissioning Process is a quality-oriented process for achieving, verifying, and documenting that the performance of facilities, systems, and assemblies meets defined objectives and criteria. The Commissioning Process assumes that owners, programmers, designers, contractors, commissioning team members, and operations and maintenance entities are fully accountable for the quality of their work. The Commissioning Team uses methods and tools to verify that the project is achieving the Owner's Project Requirements throughout the delivery of the project."*[6]

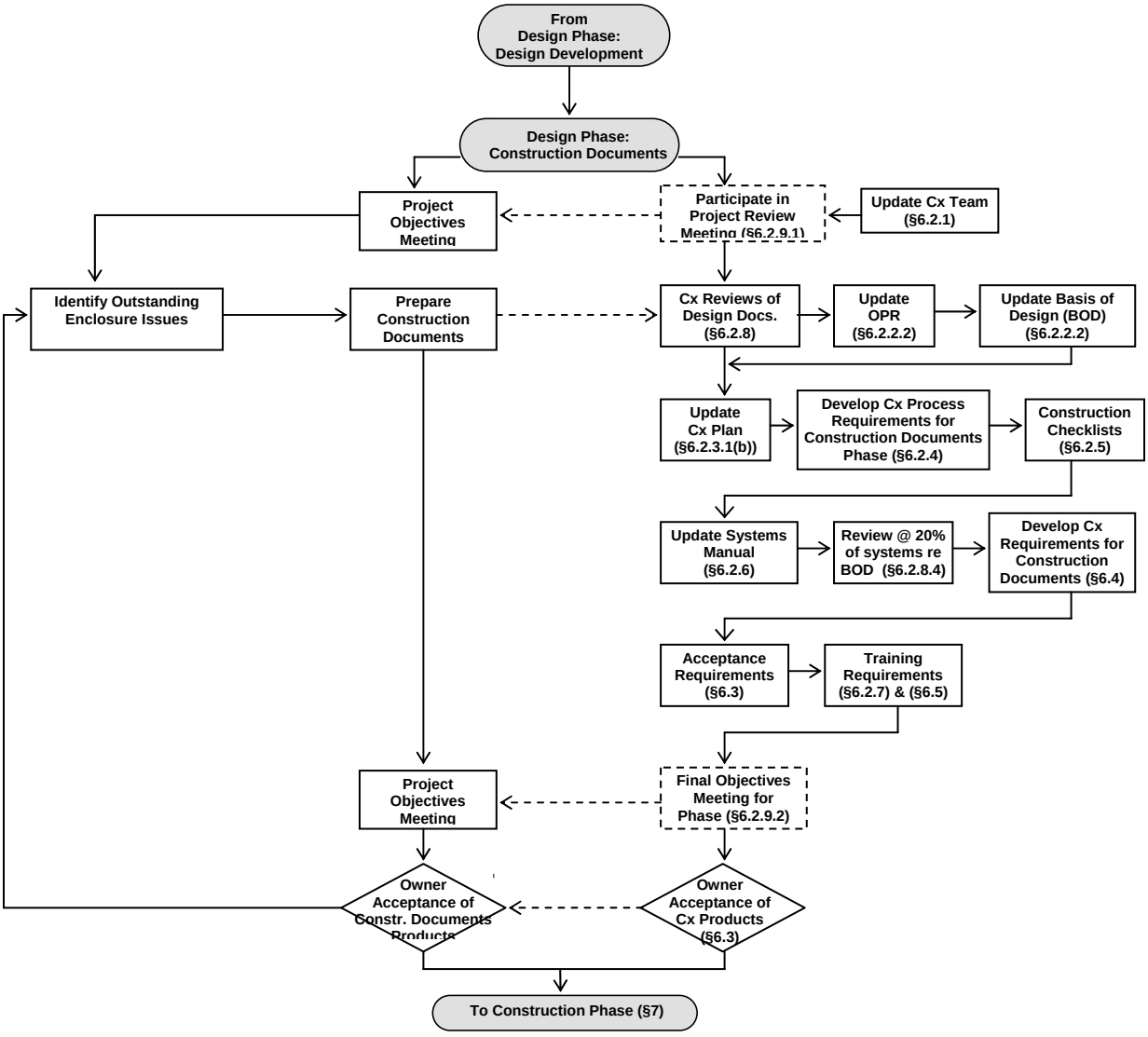
The process, roles and goals commencing with the project inception pre-design phase, followed by schematic design and design development, construction documents, to the construction phase, to occupation and operation are outlined in detail in the Guideline. However, each process must be tailored to fit the individual nature of each individual project, participants and project delivery methodology. Similarly, our recent experience indicates that various projects' teams have adapted with new members, choosing not to assume the quality of the entities involved, and preferring capability to accountability, have retained the services of professional building envelope specialists to augment the design and construction commissioning process

Planning for Success

Typically the services associated with a specialist commence with a peer review of the basis of design, the design development drawings and specifications. However, when introduced earlier into a project, a specialized building envelope professional can comprehensively guide the project specific building envelope design process, integrate the anomalies of the construction process to enhance quality, and reduce the potential for conflict and confusion and associated costs and delays. Today's professionals within the building envelope community provide experience and recommendations which respond to the unique nature and specifics of the design and building program. Our experience suggests that the building envelope specialist provides the missing link between the world of design and the field of construction, and will provide benefits to the commissioning process beyond standardized documentation. As outlined below in the Flow Diagram Process, Annex B, The Design Phase of the commissioning process begins with the "Project Objectives Meeting":

Annex GL3 – B Flow Diagram of Process

Building Development Process Commissioning Process



Throughout the NIBS Guideline 3 commissioning process, the building envelope specialist maintains intimate connections with the overall design development process, providing services in response to practically achieving the Owner and design performance expectations. With knowledge of design objectives, paralleled with construction experience and acute awareness of material durability and operating/serviceability constraints, the building envelope specialist provides a professional and committed resource from which the Owner via the commissioning process and the design and construction team can build confidently.

The role of the building envelope specialist may combine with, or perhaps supplement, the role of the typical Commissioning Agent. Traditionally, the commissioning agent has stood alone to provide independent review, observation and documentation of the building commissioning process which has traditionally focused on the construction phase activities. However, challenges related specifically to the building envelope provide the opportunity to engage the building envelope specialist during the pre-construction phase as both consultant and commissioning agent, under the guidance of the overall building commissioning agent and plan. In particular, the design phase is critical to establishing the performance criteria, basis of design of exterior envelope components and commissioning plans for during construction. Our recommendation is to engage the building envelope specialist to assist in outlining realistic performance criteria and associated products that may form the basis for the detailing and construction document development phase. Such decisions made early in the process provide a firm base for preconstruction budgeting and potential value engineering activities as required. The more clear the performance objectives and relationships between building envelope components, based upon actual industry standards, profiles and characteristics of materials, the better suited the details will be for accurate pricing and quality construction. In our experience, deficiently performing buildings too often result from poor interface detailing, incomplete purchasing of the details, inconsistent installation due to lack of coordination, and poor design respectively. As noted in recent JBED Winter 2007 article, " Commissioning Airtight Building Enclosures: The Importance of the Pre-Construction Phase Commissioning Process" by Knight and Boyle, it is acknowledged that "… many issues that may arise during the construction process, such as inconstructable details and other design issues, material incompatibilities, scheduling or sequencing conflicts with detail assumptions, confusion or disagreements over testing procedures, and a myriad of others, can be eliminated through proper commissioning procedures conducted during the preconstruction phase of the project."[7]

Conclusion

Commissioning of the building envelope, when properly influenced by a building envelope specialist, can provide greater comprehension and structure to the process, translating to a more efficient development of holistic building design and quality of contract documents. The pre and design development phase has the greatest possibilities for creating coordinated and detailed envelope assemblies to facilitate a quality installation. If left to the field installation phase, the building envelope commissioning process will serve only to document, rather than complement the overall design development and commissioning processes.

Case Studies

In all likelihood, the requirement to perform building envelope commissioning will occur on complex facades and/or sensitive building typology such as hospitals and laboratories, and/or unique and specialized building systems, and/or as an overall component of the risk management strategy, such as condominium buildings. The case studies outlined below discuss the commissioning process and the roles of the building envelope specialist in the design and construction of new facilities. Typically, when engaged, the building envelope specialist is retained by the Owner or Developer of the building to provide services beyond the capabilities of the traditional project team, and to enhance the quality of the project.

Case Study #1
Traditional Validation and Commissioning Process - (FDA regulated Laboratory)

The process of validation and commissioning of processes, systems and facilities arguably can be traced to the development of the pharmaceutical industry in the early twentieth century when the first Food and Drug Acts became law in 1906. Subsequent inquiries by the Federal Food Drug and Cosmetics Act into the clearance of new drugs to assure safety in 1938 were followed by the factory Inspection Amendment in 1953, giving the FDA the authority to perform facility inspections after written notification. In the 1960's Drug Amendments further defined the manufacturing and approval process of drugs, followed by the Code of Federal Regulations new controls and validation requirements. Finally in 1986, the FDA issued "Guidelines on General Principles of Process Validation". In 2001, the commissioning process was defined by ISPE as "A well defined, 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."[8] In 1987, the validation process is defined by USDHHS, PHS, FDA as "establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes."[9] Although the validation process is a regulatory requirement, unlike the commissioning process, the objectives of the two procedures share a common mission to ensure the installed system has documented evidence that it operates, and in a manner consistent with the user requirements and specifications.

The mechanical, electrical and plumbing has been the traditional systems validated and commissioned. In addition to the commissioning plan, the contractor quality assurance plans and quality control programs should be fully integrated with the commissioning and validation efforts. The validation efforts have been traditionally undertaken by the Owner, with support from an outside commissioning agent, or on occasion, an experienced contractor. The commissioning plan must be designed into the project from the onset, and the requirements for the system validation integrated into the program of the building. The building designer then can design in accordance with the validation requirements, and the contract documents can identify the commissioning efforts necessary which can be a part of the overall construction contract and subsequently sub-contractor bid-packages. The traditional approach has been focused on the

internal space performance requirements and is undertaken typically during the construction phase whereby the facilities, equipment and processes to be validated are installed. The commissioning is carried out by a team typically comprised of the Owner Engineering department, Operations and maintenance, Quality Control personnel, installer and the commissioning agent, of which each has a specific role and responsibility associated with the commissioning. Upon review of the validation and commissioning efforts, the documented performance of the item is compiled to form the commissioned systems, processes or components. The specialized building envelope professional may play a minor role in the design and construction phase through peer reviews and field testing, however traditional commissioning plans have not directly engaged the specialist.

Traditional commissioning plans have targeted only the mechanical, electrical and plumbing systems, and most commonly the HVAC system. Traditional commissioning outlines only the project specific MEP systems, while the roof and façade systems are typically tested to industry standards, unless more stringent standards are outlined in the testing part of the specifications. Traditional commissioning plans outline exterior envelope quality assurance in each building envelope specification. Under these plans, the building envelope specialist is typically not a participant in the commissioning phase of the building, unless issues are uncovered which can be sourced to the exterior envelope, such as uncontrolled moisture infiltration and/or excessive air leakage. This approach neglects the interdependency of the exterior envelope and the indoor air and comfort of the space.

It stands to reason, then, that if the exterior envelope is allowing air or moisture to pass uncontrolled through the materials, components, and systems of the building envelope, the ability to balance and maintain the air handling system as designed becomes increasingly difficult to control, often subject to operator adjustment outside of design specifications to achieve required interior air standards. The building operates most successfully as a coordinated and integrated whole. The commissioning of the building envelope makes sense for quality and economics by assuring that the “whole” building performs in accordance with the design.

Case Study #2
Owner Directed Peer Review and Construction Observation Plan (Condominium)

The nature of condominium ownership has increased awareness of the vulnerability of the condominium building to class action law suits. As numerous designers have moved towards relinquishing detailing for fear of this litigation, performance specifications and contractual language have added to the confusion, with many contract documents containing voids which typically are not recognized until field installation. The role of building envelope specialist on condominium projects has increased exponentially with risk-adverse developers and contractors responding by engaging building envelope specialists to help mitigate concerns related to poor design and construction, which may lead to the development of mold and reduced serviceability of the building as whole.

Although not specifically outlined as a commissioning plan, numerous condominium projects undertake a process similar to the commission plans in an effort to increase quality. In these situations, the building envelope specialist will perform a peer review of the architectural drawings and specifications related to the building envelope. Unless previously performed, calculations for wind pressure analysis, roof uplift analysis, heat/moisture analysis can be provided to establish the necessary code requirements and conformance for the specific building and schematic design. As the design process evolves, an on-going review and refinement of the details and specifications typically occurs to address the concerns of uncontrolled moisture penetration, air leakage and building durability.

Following the refinement of construction documents, the building envelope specialist can provide assistance to the project team during the pre-bid, bid and contract negotiation phases of the project with items such as review of proposed subcontractors and material substitutions as needed. The building envelope specialist services following a peer review continue throughout the construction process, and include shop drawing and submittal review assistance and coordination in support of the architect-of-record. As activities move towards construction, the specialist is available to review mock-ups and perform testing on mock-ups prior to full scale implementation in the field. All complex or non-typical details are mocked-up to ensure the performance and understanding of the detail by the installers. Typically, building envelope specialist activities will continue throughout the construction period, performing on-site construction observation and field air and water penetration resistance testing. These services are akin to validation efforts, performed under traditional commissioning plans, and serve to ensure the in-service performance of the exterior envelope components as an integrated whole are in accordance with the basis of design.

Case Study #3
Building Envelope Commissioning in Support of a Whole-Building Commissioning Program (Office Building Façade Re-clad and retro-fit non-traditional HVAC design)

Previously untested or new building systems continue to evolve, and while Owners and designers strive to achieve sustainable and unique building designs, the nature of their success is too infrequently measured by the end users. For Owners who cannot afford to risk investment or user dissatisfaction, the engagement of a building envelope commissioning process in conjunction with the overall commissioning process during the pre-design phase is an effort to assure the quality specified.

During the design process, a unique building façade system with high standards of performance was required for the efficiency of the new chilled beam water system and radiant heat systems. The interior HVAC design inspired the development of building envelope commissioning program, due to the extent of the façade glazing system and complexity of building envelope interface conditions, excessive thermal loads, and moisture-laden airflow. The plan was developed and is currently being implemented by building envelope specialists, working within a larger whole building commissioning plan. The building envelope specialists are providing

critical technical insight to design team, however functionally providing services in a support role to the designated Commissioning Agent on the project.

The project is still early in the process by way of overall schedule, and yet the building envelope commissioning plan has shaped the parameters of the performance-oriented detailing, the purchasing and the bid-negotiation phases of the general contractor and subcontractors. During the pre-design and design development phases, the team has overcome integrating the building envelope-specific pre-construction and field performance testing with goals and objectives from the basis of design related to air infiltration; the contractual roles and responsibilities of the commissioning agent for the whole, and the building envelope, relative to "architect-of-record" and construction team; and defined the line between consulting and "design assist" and "architect-of-record".

Looking Ahead…

The complexities that initiate the development of the building envelope commissioning plan are varied; the changing roles of the architect and contractor in the traditional design and construction process; or the management of risk; or the overriding concern for quality and performance. Yet without question; the result of a commissioning plan is to provide a documented, quality performing, reliably operating and efficient built resource for the shelter of the inhabitants' needs and activities. The building envelope commissioning agent and the building envelope specialist are the opportunities for the future; to partner and produce a comprehensive, fully-documented, technically sound and verifiable building envelope commissioning plan that is both cost-effective in the near term and beneficial to the long-term durability and performance of the project.

References

[1] Building Commissioning Association, Purpose of Building Commissioning, Building Commissioning Attributes, 2005.

[2] 2003 International Building Code - Commentary Volume 1, International Code Council, 2004, USA. p. 14-3.

[3] I bid

[4] Steven J. Emmerich, Timothy P. Mc Dowell and Wagdy Anis, "Investigation of the Impact of Commercial Building Envelope Airtightness on HVAC Energy Use" U.S. Department of Energy, Office of Building Technologies, 2005. p.34

[5] I bid. p.20

[6] Exterior Enclosure Technical Requirements for the Commissioning Process, NIBS Commissioning Guideline 3 (2006), p.1.

[7] Knight and Boyle, "Commissioning Airtight Building Enclosures: The Importance of the Pre-Construction Phase Commissioning Process", JBED Winter 2007, p. 27

[8] International Society of Pharmaceutical Engineering (ISPE) Baseline Pharmaceutical Engineering Guide; Volume 5 Commissioning and Qualifications; First edition, March 2001.

[9] General Guideline on Principles of Process Validation, USDHHS, PHS, FDA, May 1987.