Buildings need to perform more efficiently. The need to increase competitiveness, leads to the necessity to be able to do things within buildings faster, cheaper and better. The building has to optimally facilitate the core process of clients. At present it is difficult to define the performance of buildings, in our case Operating Theatres, in an objective way to efficiency and as a facilitator for the ‘production’ process. Needed is a new design approach, which enables to simplify the complexity of the design process structure to focus more effectiveness of the resulting production process. A derived supportive framework, based on the Validate-model, structures the design process and also forms the basis for validating the process performance. The focus of the new approach is on interpretation of the client’s intentions, formulated in the design brief as starting point, within the design process. The formulation of production related demands and wishes should be supported, in such a way that decisions about fulfilling ‘production’ aspects, related to the operating theatres, are made transparent for all stakeholders within the design process.

**Keywords:** V-model, design performance measurement and management

**INTRODUCTION**

Organizations can be described as complex systems, in which value-adding activities take place and necessary governance is predominantly achieved by managing processes (Coenen et al. 2011). This applies to goods producing organizations, such as manufacturing, as well as to service organizations, such as health care institutions. For facilities management (FM), the main task is to engage in value-adding activities that support and improve the effectiveness of the core business (EN 15221-1: 2006). These supporting activities often take shape in processes as well. Thus, knowledge of processes has a great importance for modern facilities management.

A comprehensive literature review by Meng and Lines (2011) shows that various models have been developed to measure the performance of organizations, which may include the Balanced Scorecard (BSC), the Business Excellence Model (BEM), the key performance indicators (KPI), the Capability Maturity Model (CMM), etc. Although these models come from different backgrounds various efforts are made by researchers and practitioners to apply these models in their own fields (Meng and Lines 2011). However, still there is a lack of a systematic investigation of performance measurement in the context of Facilities Management of health care facilities and especially of Operating Theatres.

During the last years, aspects of used technology for comfort, as well as environmental process conditions and energy control within the building industry became more important. Especially investments for heating, cooling, ventilation and electricity installations and their control technology has risen from less than 10% up to now sometimes more than 30% of the overall initial building costs. In special buildings like hospitals the percentage of the building Services component of the overall initial building costs is even more than 50%. As a result of this growing part of building services the complicatedness of buildings has increased enormously and as a result of this complexity more and more things go wrong. Within the Dutch building practice present estimated costs of failures are around 10 percent of the annual turnover (USP 2004): this means already around 8 billion Euros in such a small country as the Netherlands! Some of these costs, according to various researches, are caused / created during the building design processes. As complexity and scale of design processes of buildings increase, the traditional approaches may no longer suffice (van Aken 2005).

In the last year the facilities management of healthcare facilities, especially the facilities management of operating theatres became more than once front-page news in the Netherlands. More than once Operating Theatres had to be closed due to unsatisfactory indoor air quality within the operating area. Besides the damage to the image for the healthcare institution there is a direct effect for the whole sector as counter measures often are quickly applied to all institutions to reassure the public opinion with all side effects connected to it. Recent reports from the inspection for the Heath care in the Netherlands show that the management of
Operating Theatres (OT’s) in Dutch hospitals could be improvement on a large number of aspects. Infection prevention and the services management of the air-handling systems of the operating theatres are the major aspects for improvement.

OT’s are the “heart” of any major surgical hospital, with the patient as the centre point of a functioning OT complex. The flow of the patients, staff and materials within these operating and procedure rooms, affect the design layout. Because of the variety of specialized procedures and equipment, operating rooms will vary in layout, size and equipment needs (Assem et al. 2011). The design and establishment of OT’s is not a simple straightforward design job, but involves sophisticated work by architects and engineers. These projects need specialized planning and execution effort from all architectural and engineering specialists driven and coordinated by the needs, preferences and safety of the medical/surgical team (Assem et al. 2011). Evidence from clinical outcome, social studies of patient satisfaction and design field, proves that a well designed OT improves patient outcome and reduces staff costs significantly (Ruddock and Aouad 2011). This shows the possible added value of the development of new design approaches and demonstrates as such the business case for good design.

Only measuring conditions at the commissioning moment of the building services is not enough, it is important to already check the design brief and look into the implicit assumed perfect operational handling by the operating team. Unfortunately the human behavior is often far from perfect when looked from the infection prevention point of view. The results of these imperfections have large influence on the actual performances of the air-handling systems.

A facilities management control plan, for the air-handling of an operating theatre, offers a good starting point, to make a connection between the actual use by the doctors and the possibilities of the technical systems installed. Systematic use of the structures from the system approach of Validation-V makes it possible to reach an integral level of operational quality that maximizes infection prevention within an operation ward. The actual behavior of the operating team should be taken in consideration. Measurements and validations become then really relevant for the actual results on infection prevention.

At the moment, there are no demands on micro-biological purity parameters to control the outcome of the air-handlings process, in real action during operating patients. Still, it is very important to work on these demands and to register specific parameters during the real process. Learning from these trends is important and could be a major support for the design and possible optimized facilities management of air-handling systems in hospitals. The added value of the V-Validation design process is explained for facilities management of Operating Theatres.

INFLUENCE-KNOWLEDGE CONTRADICTION

Design can be viewed as an articulate process composed of phases, where each phase represents a combinatorial action on the parts the composite object is constituted of (Colombo et al. 2007). However the conceptual design stage is especially vague. It often starts with rough initial ideas about the situation in which the building has to be placed and rough initial ideas about the function that the building should have (Aliakseyeu 2003). The design process starts from making/reading the brief by the architect. The brief is a very important way of communicating between the architect, design team and client (see Figure 1).

![Figure 1. Role of the design brief in the conceptual design stage (Aliakseyeu 2003)](image)

The white boxes are the action subjects and the grey boxes are the underlying and implicit knowledge and structural steps that are needed for the interpretation. Work done in later phases of the design process may change one's understanding of the design problem and new information may become available. Therefore modification and refinement of the initial specification should be undertaken.
regularly. The design specification is best further developed, in strong interaction with all stakeholders, through successive iterative cycles, until design requirements and decision criteria fit one another. At the early design stages, usually only conceptual sketches and schematics are available, often rough and incomplete. Architects tend to develop their designs in a drawing-based, graphical way. Building design is a creative process based on iteration: it consists of continuous back-and-forth movements as the designer selects from a pool of available components and control options to synthesize the solution within given constraints.

As the design proceeds, more information and detail will be developed (Holzer 2009). However the main part of the project performances are determined in the early conceptual phase of product development, still in this phase only few resources (manpower, money) are actually spent on the project (Buur and Andreasen 1989). By the dichotomy of this design process at the early stages of design there is little information, even though nearly all the important decisions have to be made at this time, see Figure 2 in analogy with representation by den Hartog (2003).

The effectiveness of decisions, defined as the relation between the impact of the decision on the final building performance and the cost of the action needed to implement the decision, declines during the various stages of the life of a building. The decisions made early have the greatest impact on the performance and the efficiency of a building for its entire life, while the cost is minimal (Heiselberg 2007) (see Figure 3).

Figure 2. Relation between allocated and actually spent costs during a design project

The construction industry is in the early stages of a revolution to reinvent the design process that was used before the large-scale application of HVAC systems (Heiselberg 2007). Building design is conducted more and more in multi disciplinary design teams with a view towards integrating all aspects of the life cycle aspects of a building. Collaboration between architects, engineers, construction managers and owners is difficult as each group has different world views and different modes of practice that are almost incompatible with each other (Kalay 1998). All this makes design a highly complicated process (Hendrickson et al 2008) in which already at the beginning of projects, design teams have to include both architects and engineers. It is necessary to transfer building design into an iterative collaborative process, right from the conceptual design ideas to the final detailed design.
FROM DESIGN TO THE PRACTICE OF MANAGING OPERATING THEATRES: VALIDATION “V”

At the moment in the Netherlands, there are no requirements on micro-biological purity parameters to control the outcome of the air-handlings process in real action during operating patients. In fact, there is no regulation at all, on the operational performance of an Operating Theatre (OT). Most important is the general law on quality in healthcare establishments (Kwaliteitswet zorginstellingen, 1 April 1996). This general legislation dictates that healthcare establishments should monitor, manage and improve their quality. In the management plan for air-handling in the Operational department (Beheersplan Luchtbehandeling Operatieafdeling, maart 2005), this is made more specific for the operational department and follows the risk based approach of the HACCP (Hazard Analysis Critical Control Points) (NACMC 1997). These result in a number of technical parameters to be controlled, monitored or validated on a continuous or intermittent basis. In normal practice, the term validation is used when parameters are measured and reported like the flow, room pressure, filter integrity and microbial parameters.

In nearly all cases, this is done without proper reference of design specifications or defined operational performances. So a clear discrimination, between acceptable results or results to be rejected, becomes difficult. Assuming the result identifies a non-conformity, it is quite difficult to determine the exact cause. A defect can be the result of some mechanical components, it can be the result of problems in the balancing of the air flows, the control system can be incorrectly programmed or the design itself can be erroneous. However, even when measured parameters are reported to be acceptable, it does not necessarily mean there is no error or misbalance in the system. This is the reason why validation is useful: Validation is defined as “establishing documented evidence which provide a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes ” FDA 1987).

This definition emphasizes the following aspects: documented evidence, high degree of assurance, specific process and predetermined specifications and quality attributes. To handle the terms two methods are needed: A systematic approach to the lifecycle of an OT, and a more object oriented approach to the infection prevention mechanisms. A useful systematic lifecycle approach is provided by the V-model, coming from the ict world (Forsberg and Mooz 1991, Forsberg and Mooz 1998) and adopted in the pharmaceutical industry (see Figure 4).

![Figure 4. V-model to describe a systematic lifecycle approach (Forsberg and Mooz 1998)](image)
The V-model is a system development model designed to simplify the understanding of the complexity associated with developing systems by a graphical representation of the systems development lifecycle. Forsberg and Mooz (1998) describe the process as requirements-driven, and starting with identification of user requirements. When the user requirements are fully understood and agreed to by all people involved, they are then decomposed into system concepts from which are developed the system specification. The decomposition process is repeated over and over, until ultimately, single parts are identified.

Agreement is needed at each level, and the decisions are made all together by the stakeholders before proceeding to the next level. When the lowest level is reached, the process proceeds upward through the integration and verification process on the right leg of the V, to ultimately arrive at a complete verified and validated system. At each level there is a direct correlation between activities on the left and right sides of the V – the rationale for the shape. Everything on the left and right legs of the V are sequentially placed under configuration control, and is the “core” of the V” (see Figure 5).

The right side of the V-model describes the steps in the commissioning and qualification process which will verify that the facility and system were installed and operate as intended and that they produce the desired results. The basic difference between commissioning and qualification is that the former is concerned with good engineering practice, whereas the latter primarily verifies facility and systems aspects that can affect product quality (Butterfiled 2005).

Commissioning is a methodical, documented process to ensure that facilities, systems, and equipment meet established design requirements and stakeholder expectations. The commissioning process verifies the following: what was specified was installed; that it functions properly; and that it was successfully turned over to the user. Qualification is a process that extends beyond commissioning because it is primarily concerned with verifying facility and system aspects that can affect product quality. Starting point are always the intended use and the process and product parameters required. The User Requirement Specifications need to lay down, the way the OT is intended to be used, material and personnel logistics, equipment needed, infection prevention, and as specific as possible, the operational specifications and quality attributes needed. Because there will be a lot of information and documents, having relevance to any degree for the documented evidence, a separate framework is found useful to specify the handling and authorization of documents. Also an impact assessment on process parameters and quality attributes needs to be done to determine which are critical and have impact on the product. This information is usually called Validation Master Plan (VMP).

With a structured life cycle approach, the objects of the design process can be used to provide infection prevention mechanisms. These can be defined in the contamination control zones. The operating table is the primary protection area. By the flow of clean HEPA-filtered air the wound of a patient is protected from ingress of microorganisms. However, rigidity of this area is challenged in various ways. Not only by personnel and material used in this zone, but also influenced by the modesty of air movement and thermal balance. The air flow is strongly affected by the position and thermal characteristics of operating lighting, medical panels and
monitors. This explains the need to discuss the way the OT is operated: the number and nature of lighting and panels, the place of the instrument tables, the personnel and material flows and necessary thermal comfort. The next design step, Basic Design, will provide the technical solutions to fulfill the required conditions in the OT. Essential is that the Basic Design clearly specifies the functionality and the technical parameters on which the operational performance of the OT is based. This means solid design efforts as well as proper documentation and description of the design.

To ensure that the design meets the requirement and is an adequate solution, a check is needed. This is usually referred to as design qualification. In the design qualification the design team will be compare the design outcome with the requirements and check it per specification. In many cases no major non-conformities will be detected, but both the User Requirements Specification and the basic design could have been formulated more precise. Sometimes, as the design is reviewed in its final and complete form, as opposed to presentations in design meetings on specific aspects, the client for the first time gets a clean view of the consequences of his requirements and way of operation. This may lead to a wish for adjusting the process conditions. At the end of the design qualification process, the design quality report and the modified basic design documents are approved and ready to be released for detail design.

The basic design needs to incorporate the way the system is put into operation and the way the final system can be tested. During detail design, the basic design is made more in depth within the functional specification and envelop of performance, specifying actual system dimension and components put on construction drawings and component lists.

The actual construction will be done, using appropriate work methods and using the approved construction drawings. When construction of (sub) systems is completed, they can be tested and verified. This can be referred to as installation verification. Performances and quality attributes of the (sub) systems can be checked: strength, air tightness, cleanliness, completeness, accordance to drawings etc. When all is checked and defects are resolved, the next phase can be entered: operational verification. During the operational verification, the systems are balanced and put in operation. Verified is whether the system is able to operate on the specified levels from the basic design. All functionality can be tested: all operating statuses of systems and the functioning of alarms. Sometimes this involves a single system, however in many situations this involves the combined functionality of different systems. This interaction must have been specified in the functional design of the Basic design. When this operational verification is accomplished and all defects are dealt with by the contractors, the system is ready to be put in use by the actual users. Here comes in, the operational procedures of the end user, the cleaning, the personal discipline, etc. Finally it is necessary to inform, instruct and train the end user to understand and behave in accordance with the way the OT is specified in the user requirements specification. When the OT is in full operation, the final and most decisive measurements can be performed to check if the OT does perform correct to all aspects.

**DISCUSSION**

Using the V-model has great advantages: the various levels of abstraction and the distinct phases provide a built up of documented evidence, as well as make explicit how the system was conceived, designed, built and tested. When, after years of operation and proper maintenance, a supposed problem occurs, it can be more easily determined by re-validation, whether the system still performs within specs.

The biggest challenge of using this model for the OT is the lack of clear directives on the performance quality of the OT. The most recent directives have no specifications on air quality and sedimentation of micro-organisms on the critical places. A lot of emphasis is given to the description of functionalities on basic design level. That implies practically, that nearly all hospitals “validate” their OT when not in use and do the testing, only based on conditions specified in the technical performance brief. The effect of behavior and movements of the OT-team, in normal working conditions, are not taken into account! Which is strange, as actions of the operating team can disturb the protecting air flows and thus reduce the perceived air quality. As recent reports and actions by the health care inspection made very clear, there is a substantial problem with awareness and discipline of personnel. Therefore to get a clear idea of the achievable level of indoor air quality, how the actions by the operating team affect the perceived air quality must be included in testing. In addition to all this in many existing OT’s, the technical infrastructure is not controlled and managed adequately: essential functional performance of the technical infrastructure are not specified, checked or maintained. Furthermore and even worse: the use of an OT will often be out of the range of performance of the designed and constructed system. For example, sterile instruments are not placed in a protected down flow zone or lighting and technical shuttles are obstructing the intended down flow of clean air. So clearly the OT should be tested in ‘real’ working conditions.
RECOMMENDATIONS AND CONCLUSIONS

Buildings and thus building design processes are necessary to facilitate the core processes of organizations. To cope with the risen complexity of the technology used in the buildings, multi-disciplinary approaches were needed. Failure costs as a result of inadequate cooperation between the different evolved disciplines in the design process are large. Synergy between the different disciplines involved in present building design processes and the experiences of the actual users is necessary to reach the best designs to be able to optimize facilities management of complex (medical) buildings like Operating Theatres. A first step towards improving design for facilities management of OT’s, is to increase knowledge on how an OT actual performs in practice. This can be done by frequent monitoring with micro-biological settle plates close to the open area and on the sterile instrument tables. This will help to find a practical range based on the most relevant parameter: the actual chance a micro-organism falls in the wound or on a sterile instrument and thus will be transported in the wound also. The second step is the monitoring of the performance of the OT technical system. Is the system still in its range of performance? If not, a variation in microbial fall-out can be explained as a result of operating outside the specs, else it will caused by some other aspects such as the hygienic performance of the operating personnel. Validation supports both stakeholders and design team members, by supplying more information on the tasks and decisions. For the client, this abstract ordering of the design process should be made clear, by presenting it as the direct decomposition of the client's intention. The integrally working design team, should not only design the building, but first of all the design process itself, so that the results can be used to improve on the facility management process of the client. The structure of V-design helps to structure the process as well as the communication and is therefore a useful approach to improve facilities management of highly complex medical facilities such as OT’s.

REFERENCES

Aken J.E. van, 2005, Valid knowledge for professional design of large and complex design processes, Design Studies, 26(4), pp 379-404.
Buur J., Andreasen M.M., 1989, Design models in mechatronic product development, Design Studies 10(3)
FDA, 1987, Guideline on General Principles of Process Validation, Food and Drug Administration, Federal Register of May 11, 1987 (52 FR 17638)
Forsberg K., Mooz H., 1998, System Engineering for Faster, Cheaper, Better, Center for Systems management
Hartog J.P. den, 2003, Designing indoor climate, a thesis on the integration of indoor climate analysis in architectural design, PhD thesis, Delft University, Delft
Holzer D.C.C., 2009, Sense-making across collaborating disciplines in the early stages of architectural design, PhD thesis, RMIT University
Kalay Y.E., 1998, P3: Computational environment to support design collaboration, Automation in Construction 8(1); 37-48
Ruddock S., Aouad G., 2006, Creating impact in health-care design assessment through design evaluation, Proceedings 3rd International Built and Human Environment Research Week, Delft
USP, 2004, bouwsector, wie durft?, USP Marketing Consultancy, juni 2004 (Dutch)