2nd International CDIO Conference
Linkoping University
Linkoping, Sweden
13 to 14 June 2006

Towards the Unknown – Developing Students' Abilities in Dealing with Indeterminate Design Tasks

Geoff Tansley & Michael Johnson

School of Mechanical, Materials and Manufacturing Engineering, The University of Nottingham, Nottingham, United Kingdom

ABSTRACT

Early educational experiences (at school and university) do not serve students particularly well when it comes to design tasks. By the second year of an engineering degree students know that there is a correct answer, pre-prepared by their teachers, to every problem they are asked to solve. This is very different from the world view of practicing engineers – especially in the area of mechanical engineering design. So how do we get students to change their world view from 'there is a correct answer to all problems' to 'I will have to determine a suitable answer from a list of possibles or compromise solutions'?

In a recent curriculum redevelopment in Mechanical Engineering Design in our School a new philosophy was proposed and implemented which aims to develop students' confidence in tackling open-ended design tasks. In the course of two semesters, projects are set which get progressively more 'indeterminate', starting with a heavily analytical and determinate machine assembly design, through to a very indeterminate systems design project. On the way, the entire design cycle is introduced but not followed from start (user requirements) to finish (prototype manufacture & testing) in any one project. Instead each project concentrates on developing an understanding of select sub-sets of knowledge and skills which when 'bolted together' yield an understanding of the whole picture.

The overall learning objectives are: confidence on the part of the students to tackle open-ended projects, whilst at the same time have an appreciation of the need for competent analytical design – and all wrapped up in an understanding of the role and responsibilities of the designer.

Early feedback from students is encouraging with a consensus that greater responsibility and more freedom in design work yield greater enjoyment and confidence. The project continues ….

INTRODUCTION

The School of M3 and its Courses

The School of Mechanical, Materials and Manufacturing Engineering (M3) at The University of Nottingham was formed in 1998 when the separate departments of Mechanical Engineering, Materials Engineering and Manufacturing Engineering and Management merged (Engineering Management disassociated in 2002 to join the Business School). M3 is one of the largest Schools in the University of Nottingham with 730 undergraduate students, 210 graduate students (80 taught and 130 research), 53 academic staff members, and 60 support staff. The School offers a variety of undergraduate degree courses which are modular in structure. The main courses are:

- Mechanical engineering (ME) - also available with language, mathematics, Automotive, Aeronautical and Biomedical options
- Mechanical Engineering, Materials & Manufacture (MEMM)
- Product Design & Manufacture (PDM)
- Manufacturing Engineering & Management (MEM) - also available with language options
- Mechanical Design, Materials & Manufacture (MDMM)
- Biomedical Materials Science (BMS)
- Integrated Engineering (IE).

Most of these courses allow ‘stepping-off’ points after three years of study (340 credit points for BEng, 360 credit points for BEng (Hons)) or four years (480 credit points for MEng) of study where 120 credit points constitutes a full years’ load.

Broadly speaking, the structure of the courses aims to put in place engineering sciences in the first two years of study, with the third and fourth years of study aiming to develop these skills in project-based work and in developing advanced knowledge of engineering science and practice. Thus the first two years of study are prescribed whereas the later one or two years allow students to select, 30 to 70 credit points of electives to supplement focused learning in specific areas of engineering. The balance of credits is made up of ‘core’ modules.

All of the degree courses offered by the School are accredited by the appropriate professional institution:

- ME - Institution of Mechanical Engineers (IMechE)
- MEM and PDM – Institution of Electrical Engineers (IEE)
- MEMM and MDMM – Institute of Materials, Minerals and Mining (IoM3).

The standards to which the institutes accredit courses are set by the Engineering Council in the form of the UK Standard for Professional Engineering Competence (UK-SPEC) [1].

Design in the School

Design plays a central, integrative role within the curriculum and is a common to all courses in both first and second year; in both of these years 30 credit points are allocated to design. In their 3rd year, students do a group design project and an individual (major) project (which can take a design focus) and in 4th year a group development project. It is important that design modules in the first two years of study put in place the skills necessary for students to tackle later-year design projects. The emphasis placed on design is to develop an understanding of the design process along with material selection and manufacturing processes. Machine element topics largely act as the medium by which these processes are introduced, and facilitate more analytical design.

Table 1 compares the level to which each group of students studies design, materials and manufacturing processes as core topics in their first three years.

Table 1: Comparison of core studies

Group/studies	ME	IE	MEM/PDM	MDMM	MEMM
Y1 design	✓	✓	✓	✓	✓
Y1 materials	✓✓	✓	✓	✓	✓
Y1 manufacturing	✓✓	✓	✓✓	✓	✓
Y2 design	✓	✓	✓✓	✓	✓
Y2 materials	×	?	×	✓✓	✓✓
Y2 manufacturing	×	?	✓✓	✓	✓
Y3 design	✓	✓	×	×	×

✓ modules of study in this area
✓✓ multiple modules studied in this area.

Design Teaching Background

Previous to the new initiatives, the School of M3 already placed great emphasis on the central role of Design within its engineering programmes and had maintained a design and build project, has a Visiting Professor on the Royal Academy of Engineering scheme, has an industry advisory board and maintained a Design Office based approach. All of these provided a good departure point for the development of the Design curriculum and all have been incorporated into the new syllabuses. The 4 projects run previously (in 2004-2005) were:

- **Indeterminate design:** this project asked students to develop a small air compressor (mass produced) to inflate car tyres. This project challenged students to use their knowledge of materials and manufacturing processes, along with their design skills to produce a small machine for production, and reinforced some of the subject material (e.g. on seals and threaded fasteners). The problem was cast as an indeterminate problem, but there were limited opportunities to develop novel approaches and tutors effectively guided students to a 20 mm diameter piston & cylinder arrangement.

- **Determinate design and build**: in this assignment students were asked to re-design the air compressor for prototype manufacture and testing. The project provided invaluable feedback to students about their design and drawing skills – especially when they are faced with unintelligible drawings in the workshop!

- **Detail design/machine design**: students were asked to design a centrifugal clutch for a weed trimming machine (line cutter). This project gave students the chance to apply engineering science and detailed design skills to a greater depth. The project also helped to cement their understanding of additional elements of machine design.

- **Detail design/machine design**: students were asked to design a gearbox for an agricultural tilling machine. This project was similar in learning objectives to the project above and although it added additional detail knowledge about machine elements, its learning objectives were not significantly different to the previous project.

In reviewing the design syllabus for second year it was felt that learning outcomes were not sufficiently and explicitly stated nor relayed to students, and on closer examination, many of the original exercises had learning outcomes that were indistinguishable from those of other exercises – even though the content (vehicle by which the outcomes were delivered) were quite different.

The challenge posed was to maintain students' abilities in drawing and detailed design whilst improving their overall appreciation of the design cycle and design management. The inclusion of more product design was seen to be an important step since this gave better scope for exploring the entire design cycle; though concern was expressed by a few of the experienced tutors over the possibility that the engineering design content might be diluted or become 'softer' (less rigorous analytical design).

OVERALL PHILOSOPHY

The new syllabuses for 2nd year design were developed using the established good practices within the School as a basis, yet while incorporating the requirements of UK-SPEC and taking guidance from the CDIO syllabus [2] and principles [3].

A new philosophy was developed, the aim of which was to give students a better and more holistic understanding of the roles and responsibilities of a designer. This could be written as: to develop students' understanding of the roles and responsibilities of the engineering designer through familiarity with the design cycle and the management of design, and to develop competence in practical design by moving students' understanding from a deterministic approach through to a holistic approach.

At the same time as this philosophy was implemented, a general updating of the syllabuses was carried out to include: sustainability in design (necessary if a systems-wide view is implemented and also a new requirement of UK-SPEC); inclusive design (part of an increased awareness of user needs and reflecting social and legal changes in the UK as addressed by the Disability Discrimination Act 1995); product design (allowing greater exploration of the entire design cycle than was previously possible with a focus on machine design); and design management (to aid students to define roles within their design teams and to set goals and track progress of their projects).

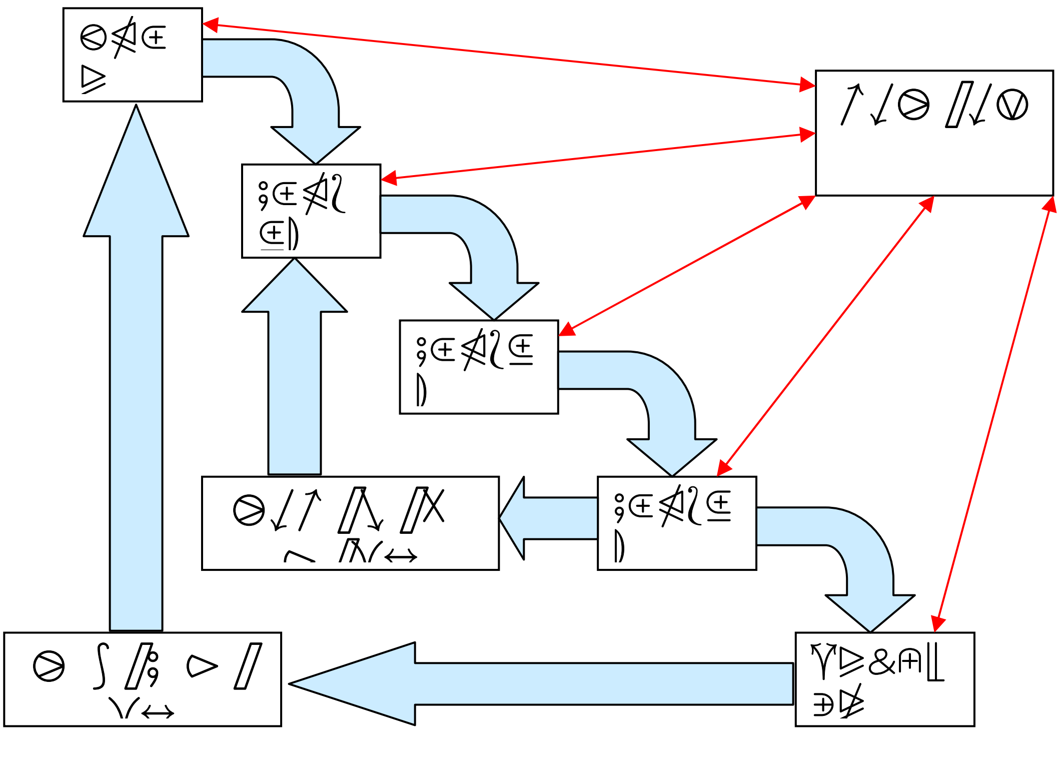

Figure 1: The Waterfall Model of design phases

Design Cycle

Central to a more holistic approach is an understanding of the design cycle and how design is managed/controlled. To emphasise this, the Waterfall Model was made central to the syllabuses. The Waterfall Model is a common tool within the medical device industry [4] for describing the phases of design control but has been surrounded by controversy since its introduction [5] since it can be seen as limiting the ability to iterate within the design process.

Students were encouraged to develop an understanding of the extent of activities within design; the Waterfall Model represents both breadth and depth of activity to the designer:

- The breadth of the activities prescribed by this model represents designers' responsibilities from onset of the project in developing user needs statements through to supporting the product in use and to withdrawal from market.
- The depth of activities prescribed by the model is tied up in each of the design stages (user needs through to product). Included within these activities are the conceptualisation, embodiment, and detail design phases. Underlying this is the iterative nature of design in the requirements for verification, validation and review; each of which can require the design process to loop back to an earlier stage (or stages) to ensure earlier requirements are met or modified.

Determinate to Indeterminate Design

Determinate design is a vital element in any engineering design education and brings a multitude of benefits:

- Limitation of the scope of a design assignment thereby making it easier for students to understand the task set.
- A need/expectation on the part of students to incorporate analytical design.
- An opportunity to develop a design to the detailed level. This gives students experience in producing engineering drawings and forces them to identify which components/assemblies typically are designed, and which ones are "bought in" from specialist suppliers (e.g. seals, bearings, gears, etc.).
- Group support – if all students (as individuals or groups) are set the same determinate problem all are able to 'bounce ideas off each other' and generally support each other. There is also the benefit of more readily understanding others' work and better being able to compare others' outcomes with their own.
- Simplicity in setting and marking the design assignments. If all students work on the same detailed design, then academics can compare submissions against prepared answers at a high level of detail. This is the case even when detailed design solutions vary a little, since the same methodologies are likely to have been followed.

But in itself, deterministic design assignments only allow students to explore a part of the design cycle, namely detailed design and possibly embodiment design (both parts of the stage identified in the Waterfall Model as Design Process) and (parts of) Design Output. Deterministic design allows only limited scope for conceptualisation or choosing between concepts (both of which are also part of the Design Process in the Waterfall Model) or any role in specification of user needs or design input. Typically, within an undergraduate engineering programme, validation is not possible (outside the scope of most programmes) and verification is only possible where a design and build project is incorporated into the module.

To fully explore the role of the designer in all aspects of the design cycle, it becomes necessary to set indeterminate design assignments. Ideally such assignments would follow the design cycle from user needs specification through to validation of a finished product within a single design exercise, but very few undergraduate engineering programmes would have the time and resources available for such a large undertaking.

A NEW APPROACH

The approach taken in the School of M3 at The University of Nottingham allows students to become familiar with the design cycle from start (User Needs) to finish (verification) but, because of time and resource restrictions, not all in one project.

Figure 2 aims to show how the Waterfall Model (with its underlying design cycle) is explored in each of the projects. Necessarily the first design task students undertake is determinate – a familiar approach for students. Because the first project is not a design and build, only the embodiment and detail design processes can be followed here; no artefact may be tested and minimal review is possible against such rigid input specifications. The second project is a reasonably determinate design and build project; again this does not explore input specifications, but embodiment and detail design along with project management, design output, review, and verification are all expected. The third project is an indeterminate design (typically of a product) and focuses heavily on establishing who the users are and what their needs are; a small amount of detail design is required along with embodiment design, review and design control. Design output is in the form of sketches and rough models and verification is therefore very limited. The fourth assignment is a systems design project which focuses less on the design of technology and more on the influences of technology on society or environment. This sort of project does not map well onto the Waterfall diagram which might indicate a project of little scope, whereas in fact the scope is quite extensive, but where the later design steps are not followed. This year the systems design project looked at aspects of providing heat and power to one of the campuses of The University of Nottingham. The remit emphasised sustainability through the “triple bottom line” whereby social, environmental, and financial attributes are balanced.

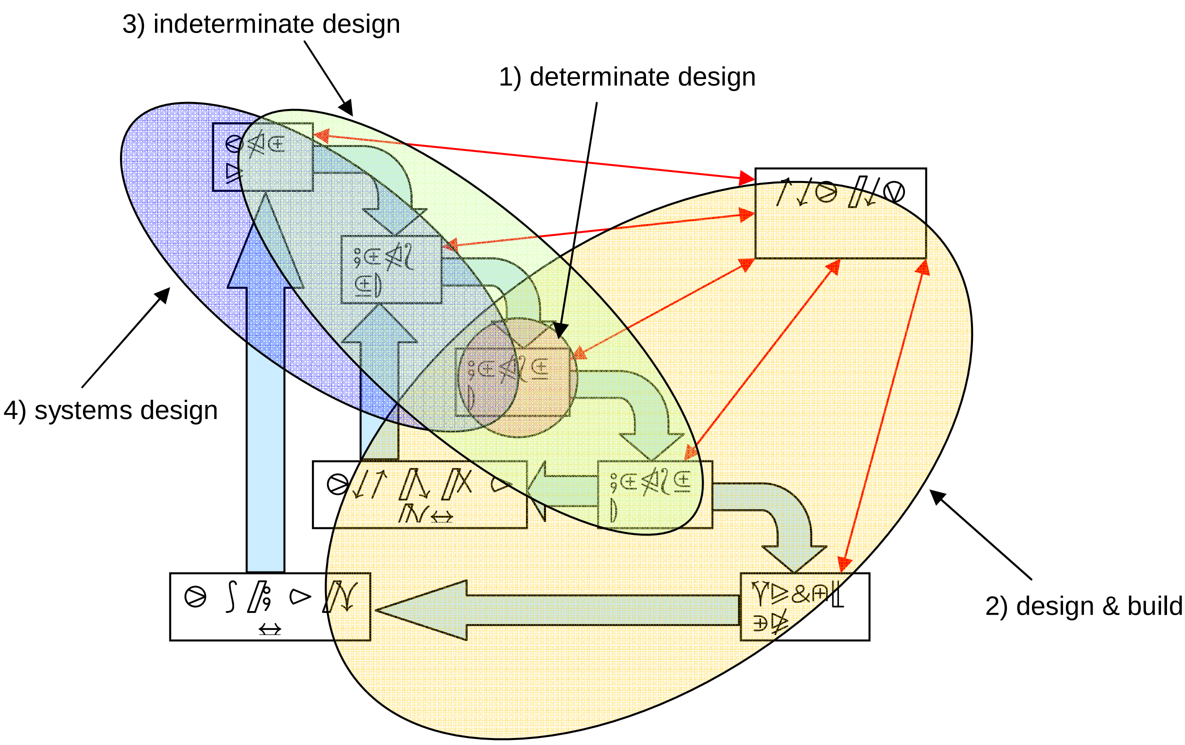

Figure 2: How projects map onto the Waterfall Model

With each successive assignment the projects become more open-ended. Project work is the key to the design syllabus and greatest emphasis on redeveloping the syllabus has been focussed here.

IMPLEMENTATION

The new strategy has been implemented throughout second year design and the material is viewed as a continuum in spite of Design being split across two modules (Design Manufacture and Materials A in first semester and Design Manufacture and Materials B in second semester – each a 15 credit module and each with its own exam).

Delivery

Project work is carried out in the Design Office sessions. These are two hours in duration each week throughout the two semesters. Students are separated into groups of 4 or 5 and are assigned a tutor for each project. About half of the projects are set as individual assignments and the other as group assignments. In group assignments the group must divide the tasks amongst the individuals, produce timelines and manage their project as if in a commercial setting; role play is an important aspect of group work and aids communication. The role of each tutor is to act as 'Chief Designer' for their group. There are also two tutorial sessions per semester wherein students have the opportunity to work though example questions (typical to the exam questions posed at the end of each semester) with the aid of their tutor. In support of the project work are lectures, CAE sessions and Workshop sessions. In addition to the four main projects, in the first week of the 1st semester students were set the task of identifying a successful design and a design failure; they were also asked to justify their choices. This exercise was used as an 'ice-breaker' - to help students to feel more confident in their group and with their tutor.

Given the large number of students (around 180), a reasonably traditional lecture structure has been maintained and students attend two 1-hour lectures per week for the 13 weeks of each semester. However more lecture sessions were less structured, for example giving students chance to work in teams to identify users of products and their needs before formal investigation of these topics.

The lecture series comprises 5 major topics:

1. Machine Element Design: tribology, bearings, brakes, clutches, seals, joints, shafts, fatigue
2. Design Cycle: design management, design control, design input, design output, user needs, validation and verification
3. Products: product design, design successes and failures, inclusive design
4. Concepts: creativity, choosing between concepts, concept evaluation
5. Design Topics: design for manufacture, embodiment design, reliability, risk, sustainable design, systems design.

The lecture topics were scheduled so that they preceded project work which drew upon them.

Each student will have undertaken basic machine-tool training in their first year and will have completed a first-year design and build project using the workshop facilities. This practical nature is furthered in second year with students attending at least 2½ days of workshop practice to enable them to fabricate their design and build project.

Integrated CAE tools, in the form of the Pro/ENGINEER suit were implemented in second year in the 2005-2006 session. This builds on students' Pro/ENGINEER work from first year and is extended to cover FEA analysis using Pro/MECHANICA and model analysis using Pro/MECHANISM. Students attend four 2-hour CAE sessions throughout the year. In future years it is hoped that at least one component of the design and build project will be CNC fabricated by students following tool path generation using Pro/MANUFACTURE. It is felt that the use of an integrated CAE suit aids students' familiarity and allows us to put in place practical skills which students will be able to use in later year design projects.

Assessment

This year's assessment is weighted 50% to formal end-of-semester exams and 50% to coursework including 10% for build and test, 4% for CAE work and the remainder for project work – no marks are allocated for the tutorial sessions. Commencing 2006-2007 session the exam allocation will be reduced to 40% to reflect staff and student concerns that insufficient credit is given for project work, and to further substantiate the importance placed upon project based learning.

A range of assessment methods was used for project work including: (standard) engineering report, Design History File (which pulled together management, design input, output, and review), poster presentation, and verbal reporting as a group. In the indeterminate design exercise students role-played designers from a start-up company and made a 'pitch' to a tutor role-playing a business development manager from an investment house. This reporting method was the most popular with both staff and as it gave time for instant and good quality feedback to students, captured imaginations and helped staff quickly to get a feel for the quality of work and effort applied by each student in the team. Where appropriate an element of competition is added to projects to encourage participation as are incremental marks for setting and meeting task timelines.

Project Work

A brief description of each of the projects follows giving details of the nature of the task, the rational for setting the task, and specific learning objectives. The projects are run in the order presented – from determinate to indeterminate design tasks.

- **Introductory assignment – failures and successes in design**
  This small project is run in the first two weeks of semester 1 as an 'ice breaker' and in conjunction with a lecture which explores what makes a design successful or fail. The stated learning objectives were:
    - Understanding of the breadth and depth of engineering design.
    - Literature searching – finding sources of information on the internet and in libraries and collation of the information into a useable form.
    - Individual learning – gathering information individually and preparing a cogent argument.
    - Critical Thinking – analysing the information found and devising a set of criteria against which to judge designs.
    - Presentation skills –arguing a case and answering others' questions in a tutorial group.

  Assessment is by participation in discussion; students reported back verbally with the use of a couple of graphics to a small peer group and tutor.

- **Determinate design**
  This is necessarily the first design task wherein students are asked to use taught subject material to design a technical object – a gearbox, a clutch, etc. The design process here is very analytical with the intention of confirming to students that theory must back up design practice. This exercise places students on familiar ground (the starting point in their voyage toward discovering open-ended design methodologies). The learning objectives for this project were:
    - Design analysis, material selection, machine element design, and design for manufacture and assembly. The product is to be analysed to ensure its correct function at the design stage. Appropriate materials and supplier components are to be specified. Manufacturing methods are to be considered and reflected within the design.

- Individual design execution. Students work in groups during design office sessions for “brain storming” of ideas and to liaise with their tutor. However, the design must be individual work.
- Solid modelling and drawing presentation. Students develop the design within ProEngineer and produce an assembly drawing, important features of which are: how the product is assembled, limits and fits, general operation, and materials/components used.

This work is assessed via a standard engineering report, since students are familiar with this method of assessment and it is wholly adequate for this project. Four weeks are available for this project.

- **Determinate design and build with project management**
  This is the major project and 5 weeks are allocated to it in design office plus 2½ days in the workshop. Students work in groups to develop a small machine (air motor, pneumatic pick and place machine, tyre pump, etc.). A strong design brief is given including material available and power output and speed required – built products are tested against this at the end of second semester. The groups must allocate roles to each member, identify tasks, plan the project and manage the timelines and deliverables. Quite a degree of technical input is necessary including calculations of torque and power, selection of materials and limits and fits, and good detail and assembly drawings (the drawer is not allowed to make his own components!). Learning objectives are:
    - Hands-on skills in the manufacture of components and assembly of the machine.
    - Integration of other course content – basic thermodynamics, statics, and dynamics are needed to complete the design.
    - The design of a prototype – this is very different from design for manufacture in that high-volume processes such as casting are not used. This influences the choice of materials, tolerances, and manufacturing methods.
    - Team working – the team will need an appropriate management structure which ensures all tasks are done satisfactorily, on time and the load is distributed evenly (and accounted for). Management tools must be adopted at outset: tasks identified, timelines drawn up and load apportioned.
    - CAD/drawing and other communication skills – a product is to be developed, boundaries defined, detail drawings made and an assembly drawing made.
    - Design analysis and component selection – the product is to be analysed to ensure its correct function; appropriate machine elements are to be selected.

  Assessment is via a design history file (DHF) which must fully detail the project management, design process and design outcomes. A competition relating to machine performance helps to motivate students.

- ***Indeterminate Design***
  Students, working in groups, are given a very loose specification, typically for a consumer product. Each group is encouraged to develop a solution independently but to be aware of market ‘competitors’. This project is a good vehicle for exploring user needs, inclusive design, and intellectual property.
  Learning Outcomes are:
    - Group work – project management and intra-group communication skills.
    - The design of a consumer product – this influences the choice of materials, tolerances and manufacturing methods, but also the form and function of the product – it should look like something a member of the public would want to buy, should be easy and safe to use.

- Indeterminate Design - the design brief given is quite loose; it is for the design team to work out what the market wants, develop concepts, choose the best of the concepts, and complete the embodiment and (some) detailed design.
- User Needs and Inclusive Design – the users of a product might have a wide range of varying needs; students are to investigate who might use the product, evaluate conflicting needs, and decide which group of users to aim the product at.
- CAD/drawing and other communication skills – a particular emphasis is placed on hand sketching of concepts and some simple model making.

Assessment is by verbal presentation to a tutor in a role playing exercise. The scenario is a "pitch" to a potential financial backer. In addition a Design History File (DHF) is submitted for assessment so the detailed decision making processes and embodiment design may be assessed.

- ***Systems design***

  This project challenges students not only to look at the detail, but to question their design brief and to look at the bigger issues. Issues such as sustainability, appropriate design, inclusive design, etc. may be explored here. Learning Outcomes include:
  - The Bigger Picture/Systems Design - this is an indeterminate design project, and as a result, students are responsible, in some part, for specifying the problem as well as providing a solution.
  - The designer's role in projects & society – this project is very far-reaching and students are encouraged to understand how their work impacts on society and vice-versa.
  - Communication – students will prepare a poster and must efficiently communicate their objectives and design solutions and outcomes.
  - Research – students are required to use information resources in preparing their solution.

  Assessment is by poster presentation in a conference setting - subjecting students to yet another mode of communication. Students mark each other's work which helps students to gain an insight to effectiveness of communication (the student:tutor ratio of marks is 30%:70%). Also, since this is the last assignment of the year marking is all completed in class and assignment marking does not interfere with impending exam marking.

OUTCOMES

CDIO Objectives

The new syllabus takes the School of M3 further down the path prescribed by the CDIO syllabus through:

- Standard 1: allowing greater scope for conceiving (design, implement and operate were already established)
- Standard 2: better focusing the learning outcomes and making these clearer to students.
- Standard 3: Design teaching at The University of Nottingham is seen as the glue which aids curriculum integration. This new approach helps to bind in some of the management and professional studies material but the more analytical subject material (maths, thermodynamics, etc.) was already well integrated into the determinate design work.

- Standard 5: maintaining two design and build projects in core curriculum – other design and build opportunities are available to students in later projects, but not all projects contain a build element – some, for example, are purely computational.
- Standard 6: the refit and introduction of a new workshop, design studio and project space for students' project work, along with a new 24-hour access Computer/CAE suite stand us in good stead to meet the workspaces requirement, but the design studio is not large enough to accommodate our large class sizes in 1st and 2nd year.

Other standards are met to varying degrees and will be addressed in time as the Design Curriculum (across all levels) is revised in the coming years.

Approach

The taught content was scheduled so that it preceded project work which drew upon it. This has proven to be slightly problematic with topics being interrupted so as to squeeze in taught content just in time for a project and with topics needing to be rearranged each year to accommodate projects with different content. Students have complained that they perceive a lack of structure in the lecture sequence for these reasons. This is compounded to an extent because the modules are team-taught and the programme must be arranged to suit lecturer availability.

Student Feedback

The University of Nottingham runs student evaluations of modules (SEM) and teaching (SET) every other year, but we have chosen to run these each year for both design modules in second year to gain a quicker indication of how effective the new approach is and how well received it is by students. Student evaluations of module provide both a qualitative (open-ended question) section and a quantitative measure (in the form of multiple questions which students should score 1 (excellent) through 3 (neutral) to 5 (very poor)) of how well the modules were received.

Quantitative measures from the SEM indicate better reception in both modules with scores improving by 0.2 points in each semester.

Qualitative comments indicated that:

- Students enjoyed the practical nature of the Design modules
- Students liked the breadth of the Design topics and variety brought by team teaching
- It was felt that excessive marks were allocated to the exam and the amount of work in the assignments was not fairly reflected
- Students enjoyed the integrated approach to CAE and individual CAE exercises
- 'studying maths is justified' by such practical use of mathematics in design classes
- There is a preference for the two 2nd year design modules to be joined into one year-long module.

Tutor Feedback

Response from experienced tutors has been extremely positive. Professor Kirk, our esteemed Royal Academy of Engineering Visiting Professor has endorsed this syllabus and has been involved actively in its implementation. Professor John Dominy – Managing Director of an SME - has commented that the indeterminate and system design projects are what engineers (let alone designers) really do in order to define a product specification. Other tutors who are more traditionally minded have recognised the benefit to students and have been invigorated by the enhanced engagement of students.

Encouraging participation by incrementally awarding marks for setting and meeting task goals was surprisingly well received by students; this meant that work progressed relatively orderly and was not left to the final week (as was common in previous years). It also meant that students got to apply their Design Management skills in a very hands-on way. Experience showed that only 10% of the project mark is needed for this to be effective.

CONCLUSIONS

Design is a complex subject which must be experienced in order to be understood. Determinate design projects play an important role in the learning process in that they allow students to distil their knowledge from theoretical sciences into practical design solutions. However, meaningful solutions to the problems that will be faced by future generations will only be addressed through systems design which, in itself, is entirely indeterminate in nature.

The teaching process to foster systems thinking from a closed form and determinate mindset has been addressed within this paper. The outcomes have been encouraging from the points of view of both student learning and engagement by tutors. Future work will focus on enhancing teaching methods to improve knowledge uptake. Following on, the design curriculum over the full 3-4 year course will be addressed to ensure continuity, whilst meeting the UK specification through greater adherence to CDIO principals.

REFERENCES

[1] Engineering Council UK, “UK Standard for Professional Engineering Competence”, Engineering Council UK, 2004

[2] Crawley, E.F., “The CDIO Syllabus: A Statement of Goals for Undergraduate Engineering Education”, http://www.cdio.org/cdio_syllabus_rept/index.html, 2001, viewed 9th May 2006

[3] CDIO, CDIO “Principles“, http://www.cdio.org/tools/cdio_standards.html, viewed 9th May 2006

[4] Food and Drugs Administration, “Design Control Guidance for Medical Device Manufacturers”, Food and Drugs Administration, page 3, 1997

[5] Royce, W.W., “Managing the Development of Large Software Systems: Concepts and Techniques”, WESCON Technical Papers, 14, A/1-1-A/1-9, 1970. Reprinted in Proceedings of the Ninth International Conference on Software Engineering, Pittsburgh, 328-338, 1989