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Achieving ISO 9001 accreditation and the role of the NAFEMS QSS, from the perspective of a small consultancy

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Agenda

- Introduction
- ISO 9001 and NAFEMS QSS
- Assessors and consultants
- High-level and low-level
- Save time and effort at point of use
- Keep it simple
- Summary
- Questions

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Introduction

- Abercus is a small independent consultancy specialising in advanced engineering simulation within the energy sector – CFD, FEA, the development of bespoke software tools and teaching/training
- Abercus was founded in 2010 when a number of former colleagues reunited with the aims of providing open simulation consultancy, together with supporting software and training to allow us to share our experience and capabilities with our clients and wider industry
- Abercus has been a member of NAFEMS since early 2011 – it was the first organisation that Abercus joined.

Introduction

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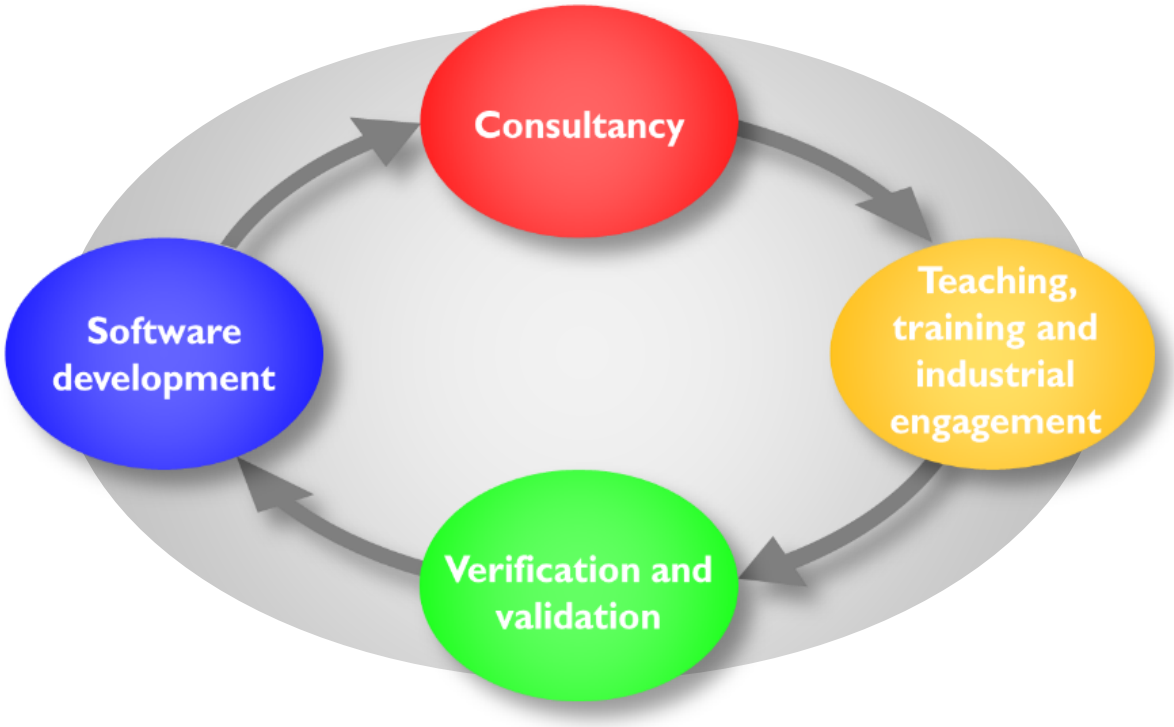

Introduction

- The members within our team have worked in a variety of organisations previously including small, medium and large consultancies, and universities
- We all had an understanding of what ISO 9001 is and how it can be implemented but none of us had actually implemented an ISO 9001 previously
- As a small consultancy, Abercus was initially hesitant to pursue formal ISO 9001 certification because of the investment required in terms of both time and money
- Instead, Abercus implemented a quality management system (QMS) designed in line with our understanding of ISO 9001.

Introduction

- In 2015 Abercus took the strategic decision to become formally certified to ISO 9001 by the end of that year
- Having now achieved ISO 9001 accreditation, Abercus realises that this is something that could, and perhaps should, have been achieved earlier
- The purpose of this presentation is to share some of the lessons from Abercus' journey to becoming accredited, particularly from the point of view of a small company
- It is hoped that by sharing Abercus' experiences, other small companies may be encouraged to pursue a similar route towards formal ISO 9001 certification.

Introduction

Lesson 1

Take the first positive step and formally make the business decision to become ISO 9001 certified

- Operating a quality system designed *in line* with ISO 9001 is not the same as being ISO 9001 certified
- The process of being interrogated by an independent assessor necessarily requires the company to consider ISO 9001 in its entirety, and in Abercus' own experience a certified QMS is likely to be more robust than an in-house QMS designed in line with an understanding of ISO 9001 that may be incomplete.

ISO 9001 certification is not just for big companies – it's for small companies too!

Introduction

- QMS – quality management system
- QSS – quality system supplement (by NAFEMS)
- SDM – simulation data management

- IMS – integrated management system
- JET – job execution tool (an SDM tool, by Abercus).

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ISO 9001 and NAFEMS QSS

- The ISO 9000 family of standards provide guidance and tools for companies/organizations that want to ensure that their products/services consistently meet customers' requirements and that quality is **continually improved**
- There are three standards:
  - ISO 9000 covers the basic concepts of quality management and the associated language
  - ISO 9001 sets out the requirements of a QMS
  - ISO 9004 focuses on how to make a QMS more efficient and effective
  - (The ISO 9002 and 9003 standards were incorporated into the ISO 9001 standard in 2000.)
- ISO 9001 is the only standard in the series for which companies can achieve certification.

ISO 9001 and NAFEMS QSS

- The ISO 9000 and 9001 standards were first released in 1987 and were most recently updated in 2015
- Companies certified against the previous version of ISO 9001 (released in 2008) have a three-year window in which to adapt their QMS to bring them in line with the 2015 standard
- Abercus is certified against ISO 9001:2008 and plans to update to the 2015 standard by the end of 2017.

ISO 9001 and NAFEMS QSS

- The ISO 9000 series is based upon eight principles:
  - Customer focus
  - Leadership
  - Involvement of people
  - Process approach
  - System approach to management
  - Continual improvement
  - Factual approach to decision making
  - Mutually beneficial supplier relations.

ISO 9001 and NAFEMS QSS

ISO 9001:2008

4 QMS
4.1 General requirements
4.2 Document requirements

5 Management responsibility
5.1 Management commitment
5.2 Customer focus
5.3 Quality policy
5.4 Planning
5.5 Responsibility, authority and communication
5.6 Management review

6 Resource management
6.1 Provision of resource
6.2 Human resources
6.3 Infrastructure
6.4 Work environment

7 Product realisation
7.1 Planning of product realisation
7.2 Customer-related requirements
7.3 Design and development
7.4 Purchasing
7.5 Production and service provision
7.6 Control of monitoring and measuring devices

8 Measurement, analysis and improvement
8.1 General
8.2 Monitoring and measurement
8.3 Control of non-conforming product
8.4 Analysis of data
8.5 Improvement

ISO 9001 and NAFEMS QSS

- The ISO 9000 standards are necessarily general – they have been designed to be used by any business, in any industry sector, in any part of the world
- Since 1989, NAFEMS has published and maintained a quality system supplement (QSS) to ISO 9001 which interprets the requirements of the ISO standard in the particular context of engineering simulation
- The NAFEMS analysis management working group (AMWG) is currently revising the QSS to bring it in line with ISO 9001:2015.

ISO 9001 and NAFEMS QSS

- To complement the formal QSS document, NAFEMS has also published a supporting *primer* document, designed to assist in the development and implementation of a quality management system for engineering simulation
- Another NAFEMS document which focuses upon quality assurance procedures for engineering analysis
  - This was published in 1999 to supplement the 1994 version of ISO 9001 and, while it has not been kept up to date, Abercus found this to be an extremely valuable resource
  - In particular, Appendix D of this document includes a set of rudimentary example forms which can be used as a starting point for a QMS
  - (Note that the forms in Appendix D have an FEA bias.)

ISO 9001 and NAFEMS QSS

- **The NAFEMS QSS**

  Engineering simulation, Quality management systems, requirements,
  Quality system supplement NAFEMS QSS:2008, 2014
  (https://www.nafems.org/publications/browse_buy/browse_by_topic/qa/nafems_qss_2008_/)

- **The NAFEMS QSS primer**

  Quality management in engineering simulation, a primer for NAFEMS QSS,
  NAFEMS R0116, 2014
  (https://www.nafems.org/publications/browse_buy/browse_by_topic/qa/nafems_qss_primer_2014_-_r0116/)

- **QA procedures for engineering analysis**

  NAFEMS quality assurance procedures for engineering analysis,
  NAFEMS R0064, 1999

  (https://www.nafems.org/publications/browse_buy/browse_by_topic/qa/r0064/).

ISO 9001 and NAFEMS QSS

Lesson 2

If you haven't already done so, download the latest revision of the NAFEMS QSS and its associated primer from the NAFEMS website – they're free to all NAFEMS members. Also look for the quality assurance procedures for engineering analysis – the sample forms in Appendix D are worth reviewing.

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Assessors and consultants

- Having set the goal of achieving formal certification by the end of 2015, the first step was to appoint an ISO 9001 assessor
- At our first meeting, Abercus learned that the assessor cannot also be engaged in the development of the QMS, since this could represents a conflict of interest
- Whilst the team at Abercus had collective experience of working within a number of different ISO 9001 certified QMSs over the past 20 years, we chose to appoint a separate independent consultant to assist in the development of the Abercus QMS.

Assessors and consultants

- The appointment of an independent consultant was certainly worthwhile, and Abercus' certification would not have been achieved as speedily without their support
  - It was not essential – Abercus' pre-certification QMS already incorporated most of the requirements of ISO 9001
  - There is no substitute for experience and without engaging a separate consultant the journey towards formal certification would have taken longer and would have been more tentative
  - Uncertainty about the unknown is the issue – something could be missed when interpreting the ISO 9001 standard.
- Whilst there was a financial overhead associated with the appointment of the ISO 9001 consultant, it saved us in the long run and we had the peace of mind that our QMS was compliant ahead of the formal assessment.

Assessors and consultants

Lesson 3

Unless you already have experience of successfully implementing a certified ISO 9001 quality system, consider appointing an external independent ISO 9001 consultant to support the QMS development activities.

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High-level and low-level

- ISO 9000 covers two aspects: high level managerial activities and lower level technical activities.
- Abercus' pre-certification QMS had concentrated on the technical aspects of the system, using simulation data management (SDM) tools to automate CFD/FEA workflows
- It had not captured some of the managerial aspects.

High-level and low-level

- Many ISO 9001 consultancies (including those engaged by Abercus) offer an off-the-shelf quality manual and core procedures documents and templates which can be used as the starting point for a certified QMS
- These systems are quite general and tend to focus on the high level managerial aspects
- The certified Abercus QMS is a consolidation of our technical pre-certification QMS and a customised version of an off-the-shelf system covering the high level managerial aspects
- Actually, Abercus' system is an IMS – this allows for future expansion to capture environmental management (ISO 14001) and health and safety (ISO 18001).

High-level and low-level

Quality policy statement

Abercus is committed to providing consistent, reliable and flexible services that meet the needs of customers, and to continually improve the business based upon customer feedback.

Our quality commitments

We will demonstrate our commitment to quality by:

- providing a focus on customer requirements
- compliance with legal and other relevant requirements
- actively engaging in a programme of continuous improvement of the management system to ensure its continuing suitability and effectiveness.

Our quality objectives

Our objectives will be delivered through a program of quality targets.

- monitoring and improving the satisfaction of our customers
- managing our processes carefully to maximize the benefits to our clients
- adoption of best practice in our activities
- train and develop personnel to increase their understanding, efficiency and competency
- the identification and management of critical and business activities
- development and maintenance of a quality management system conforming to ISO 9001.

Who is this policy statement for?

Copies of this quality policy statement will be made freely available to all those with an interest. This statement will be promoted to employees, customers and representatives of the local communities in which we operate.

High-level and low-level

IMS Manual

Content

High-level and low-level

IMS Manual

CORE IMS ELEMENTS

C/1 INTRODUCTION

This section of the manual describes those elements of the IMS that are core to quality management. These common elements are represented by a C/number and address specific clauses in the standard listed in the purpose section. Please note the current certification extends to quality only, however provision has been made for safety and the environment should the need arise.

Core procedures (C/numbers) are used where possible in the management system to stream-line systems and reduce documentation for example where two standards may have a similar requirement.

Specific topics are represented by Q/number for Quality, E/numbers for Environment and S/numbers for Safety.

C/2 POLICY STATEMENTS

Abercus has a quality policy statement and a health and environmental statement in place which describe commitments to act responsibly to our customers, our people, our neighbours and the environment ([BPS-001] and [BPS-002] respectively).

We are committed to customer satisfaction, prevention of pollution, legal compliance and continual improvement in all areas of our services, processes and activities.

C/3 OBJECTIVES, TARGETS AND MANAGEMENT PROGRAMMES

We have established and maintain a management programme that incorporates objectives and targets. Objectives are described in the policy (C/2) and are derived from the mission statement and from consideration of regulatory requirements (C/3) and business risks.

Objectives are broad organisation wide goals framed within the context of the policy statements while targets are measurable, responsibilities are defined and time-scales set. In order to ensure full understanding among colleagues of the objectives and targets these are communicated at least annually. In order to ensure the targets are progressing according to plan management programmes are produced containing project milestones,

High-level and low-level

Conformance audit of IMS against ISO 9001:2008

CLAUSE		REQUIREMENT	DOCUMENTS WITHIN IMS			
			Manual	Procedure	Work Instruction	Other
5		**MANAGEMENT RESPONSIBILITY**				
	5.1	MANAGEMENT COMMITMENT				
		Has top management provided evidence of its commitment to the development and implementation of the quality management system and continually improving effectiveness:				
	a)	communicating to the organisation the importance of meeting customer as well as statutory and regulatory requirements?				
	b)	establishing the quality policy?				
	c)	ensuring that quality objectives are established?				
	d)	conducting management reviews?				
	e)	ensuring the availability of resources?				
	5.2	CUSTOMER FOCUS				
		Has top management ensured that customer requireme the aim of enhancing customer satisfaction (see 7.2.1 an				
	5.3	QUALITY POLICY				
		Has top management ensured that the quality policy:				
	a)	is appropriate to the purpose of the organization?				
	b)	includes a commitment to comply with requirements an effectiveness of the quality management system?				
	c)	provides a framework for establishing and reviewing qua				
	d)	is communicated and understood within the organizatio				
	e)	is reviewed for continuing suitability?				

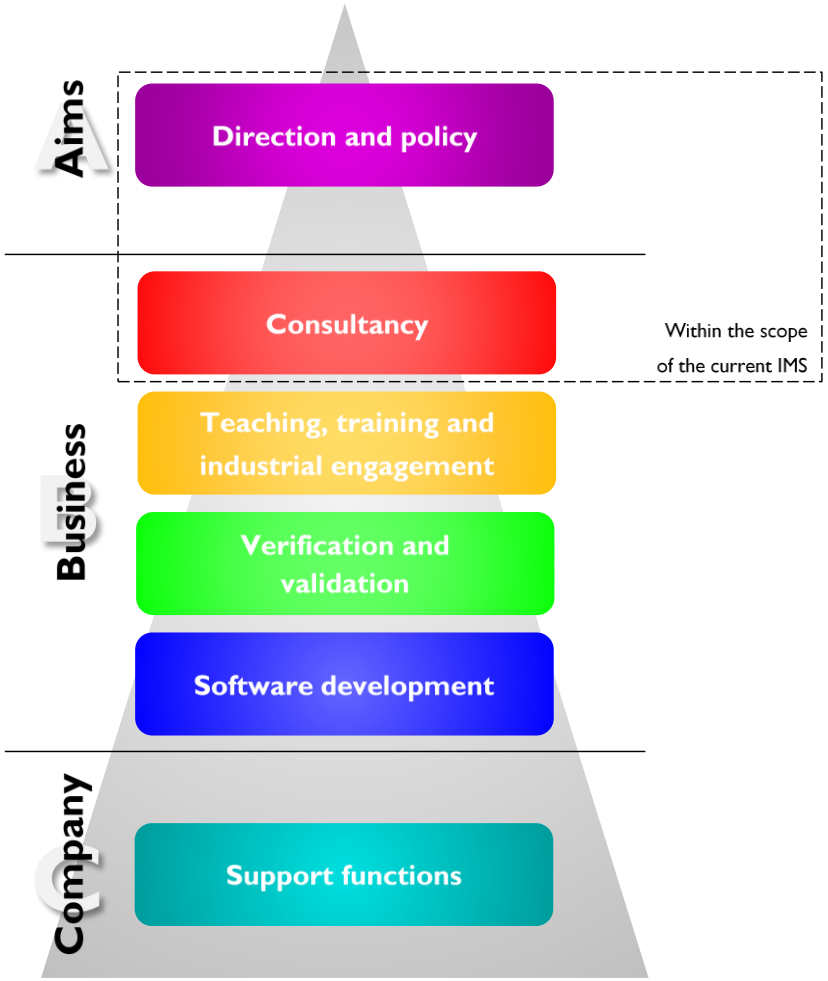
CLAUSE		REQUIREMENT	DOCUMENTS WITHIN IMS			
			Manual	Procedure	Work Instruction	Other
	5.6	MANAGEMENT REVIEW	C/15	CP 05		
	5.6.1	GENERAL				
R		Is top management reviewing the quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness? Does the review include assessing opportunities for improvement and the need for changes to the quality management system, including quality policy and quality objectives? Are the records from management reviews maintained (see 4.2.4)?				
			---	---	---	---
	5.6.2	REVIEW INPUT	-	CP 05	-	
		Does the input to management review include information on:				
	a)	results of audits?				
	b)	customer feedback?	-	CP 05	-	
	c)	process performance and product conformity?	-	CP 05	-	
	d)	status of preventive and corrective actions?	-	CP 05	-	
	e)	follow-up actions from previous management reviews?	-	CP 05	-	
	f)	planned changes that could affect the quality management system?	-	CP 05	-	
	g)	recommendations for improvement?	-	CP 05	-	
			---	---	---	---

High-level and low-level

- Some of these managerial aspects, with hindsight, now seem obvious
- For example, the formalisation of a business map
  - Abercus had operated its business for five years without formalising exactly what the company does. The process of formalising our activities provided the opportunity to review and question our business activities, and this has led to a new data structure underlying the whole of the business.

High-level and low-level

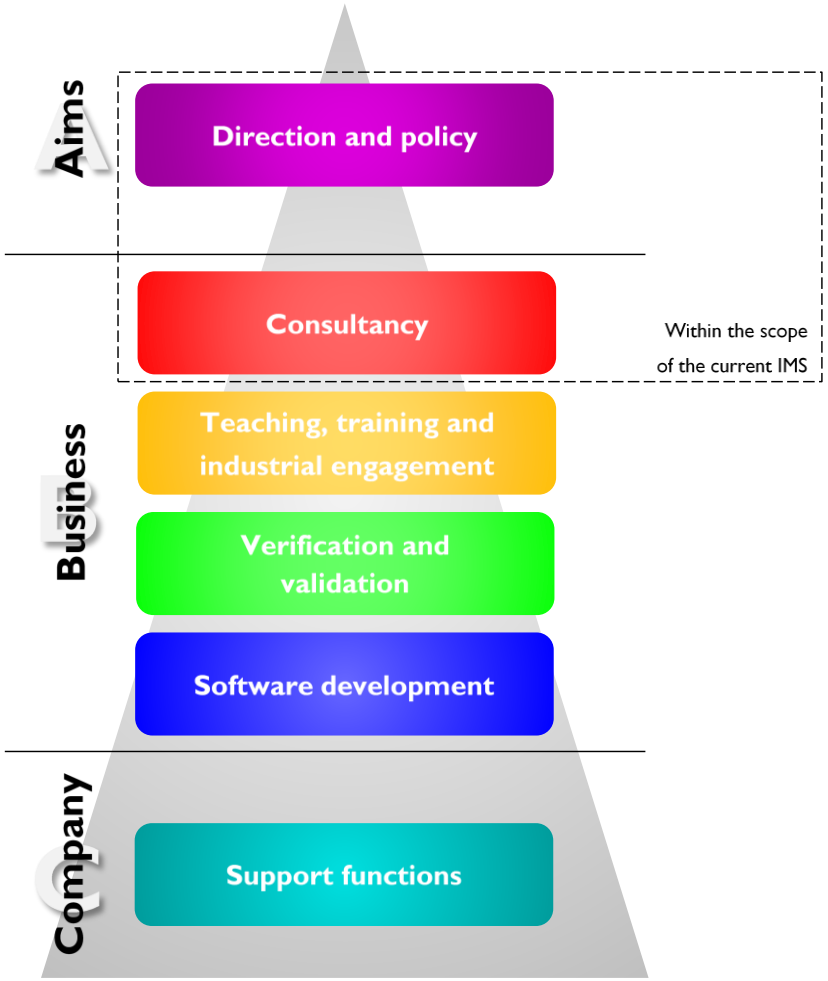
BUSINESS MAP



BUSINESS MODEL

High-level and low-level

BUSINESS MAP

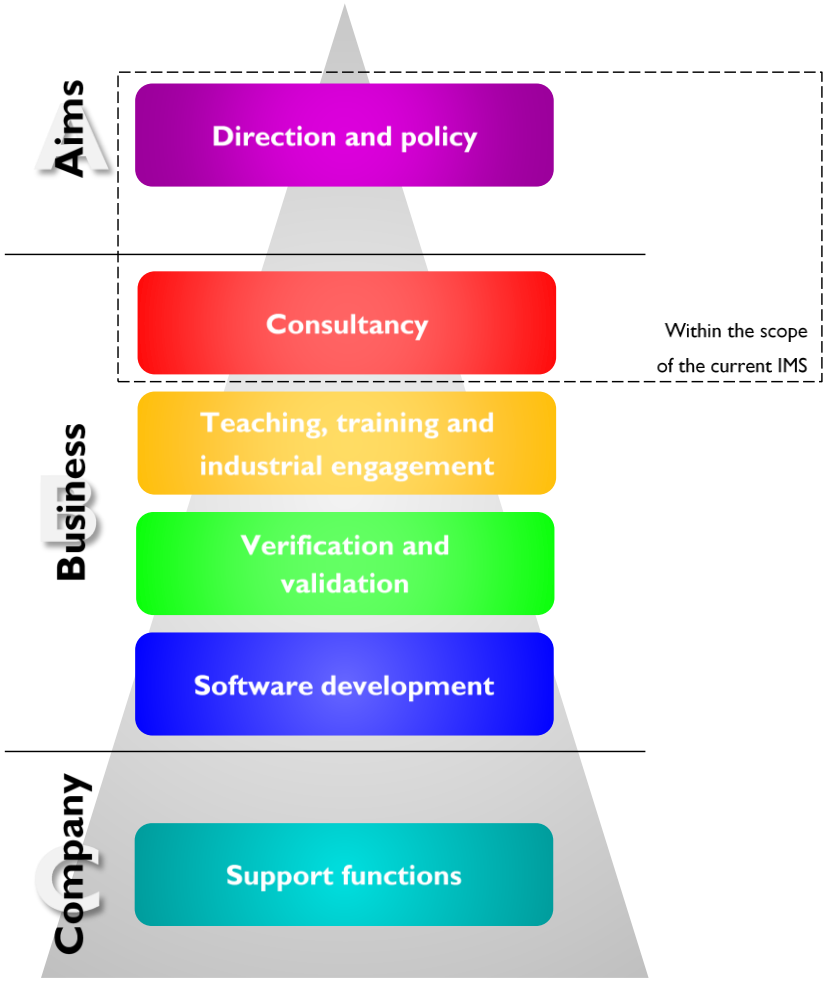


BUSINESS STRUCTURE

- Abercus
  - Aims
    - IntegratedManagementSystem
      - CurrentIssue
      - SupportingDocumentation
  - Business
    - Consultancy
    - SoftwareDevelopment
    - TeachingTrainingEngagement
    - VerificationValidation
  - Company
    - Clients
    - CustomerFeedback
    - Resources
    - Suppliers
    - Support

High-level and low-level

BUSINESS MAP

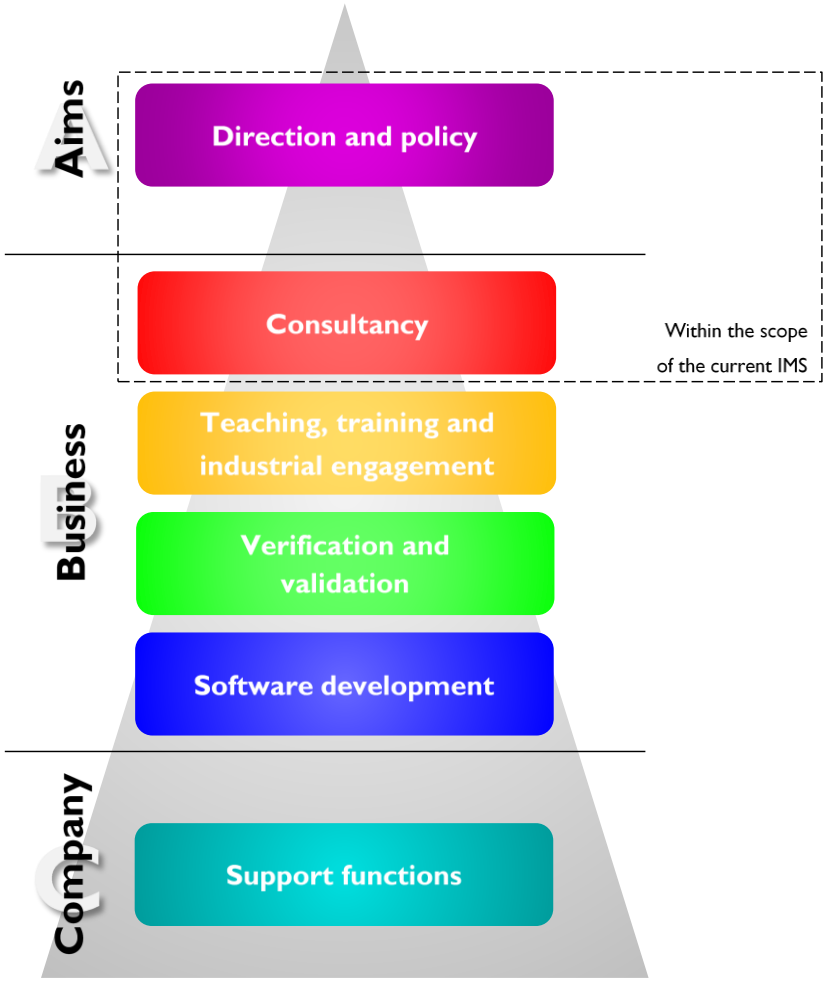


BUSINESS STRUCTURE

- Abercus
  - Aims
  - Business
    - Consultancy
      - 150802_********** DispersionCfd
      - 151201_CavitasGeneratorCfd
      - 151202_GabesPigging
      - 151203_PrioritiConsultancy
      - 151204_********** /eterApitr6afVerificationFea
      - 160101_********** leaseModelling
      - 160201_********** sDispersionCfd
      - 160202_CieErosion
      - 160301_CalciumCarbonateDeposition
      - 160302_TeesDockFlowBehaviour
      - 160303_HydrogenExplosionCfd
      - 160401_DarcyFea8

High-level and low-level

BUSINESS MAP

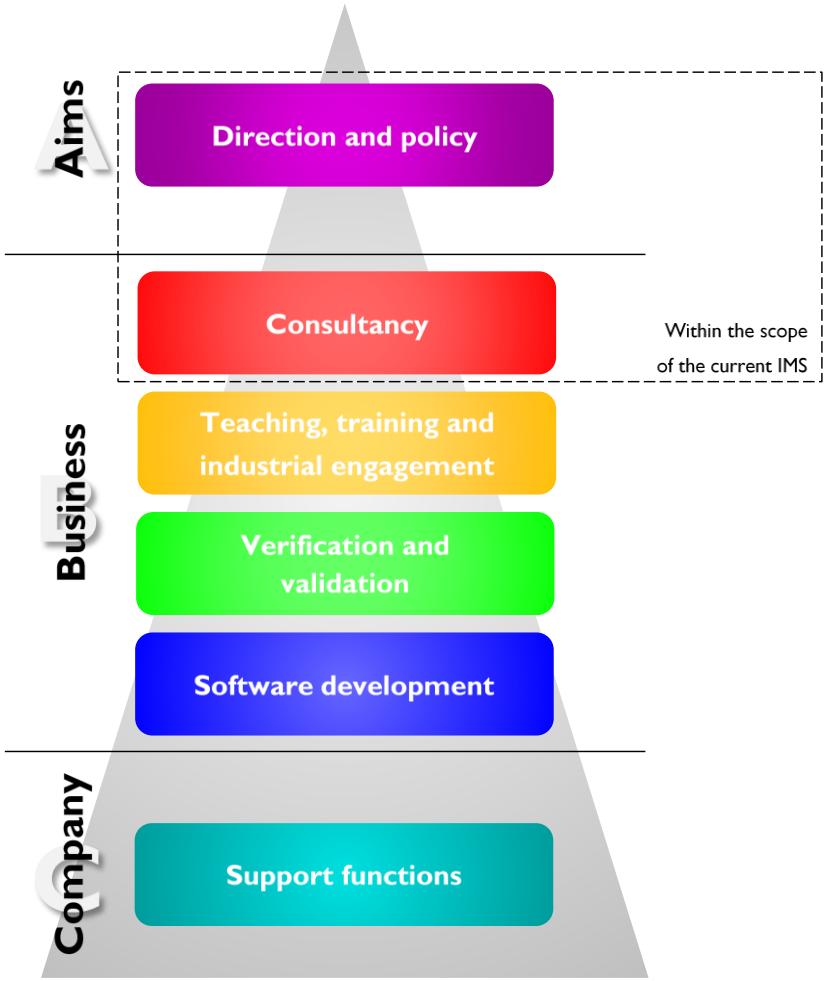


BUSINESS STRUCTURE

- Abercus
  - Aims
  - Business
    - Consultancy
      - 150802_********** DispersionCfd
        - Correspondance
        - Documents
        - Information
        - Studies
          - phase-000
            - study-000
            - study-001
              - batches
              - input
              - library
      - 151201_CavitasGeneratorCfd
      - 151202_GabesRigging

High-level and low-level

BUSINESS MAP



BUSINESS STRUCTURE

- Abercus
  - Aims
  - Business
    - Consultancy
    - SoftwareDevelopment
    - TeachingTrainingEngagement
      - TT150901_IntroductionToCfdForSubseaEngineering
      - TT151201_I***nFlowAssuranceCourse
      - TT151202_NafemsUkTelford
      - TT160101_***** ProbabilisticCfdFea
      - TT160102_ErcoftacOilAndGas
      - TT160201_BenchmarkHpc
      - TT160301_NafemsCfdPrimer
      - TT160302_NsriSubseaStorage
      - TT160501_NafemsCfdV&v
      - TT160502_BenchmarkAmwg
      - TT160503_Flug201605

High-level and low-level

Lesson 4

Formalise a business map – capturing and understanding the current practices within the business is the first step in improving those practices.

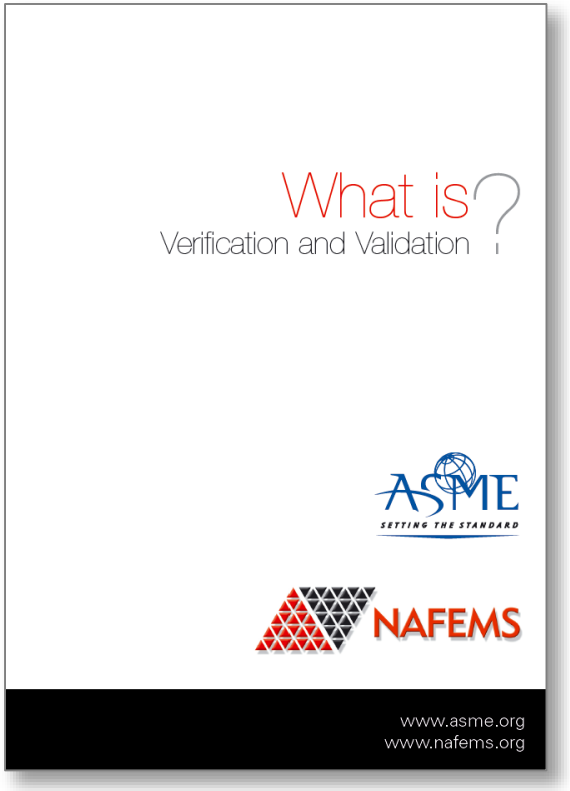
One of the underlying principles of ISO 9001 is that of continual improvement. Without knowing where the business is currently, it is impossible to improve effectively.

High-level and low-level

- NAFEMS QSS has simulation specific requirements, including a risk assessment:
  - Vital
  - Important
  - Advisory
- May influence what is fit for purpose, and the level of validation activity that is undertaken.

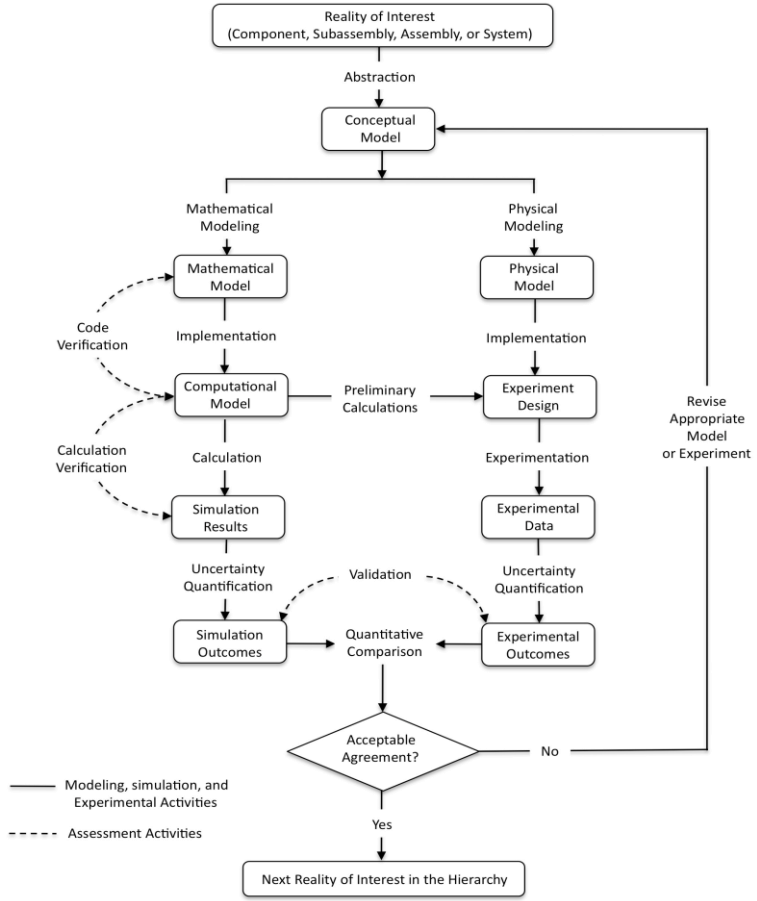
High-level and low-level

- ASME and NAFEMS have published a *What is?* guide that is freely available:
  http://www.nafems.org/publications/browse_buy/browse_by_topic/qa/verification_and_validation/



High-level and low-level

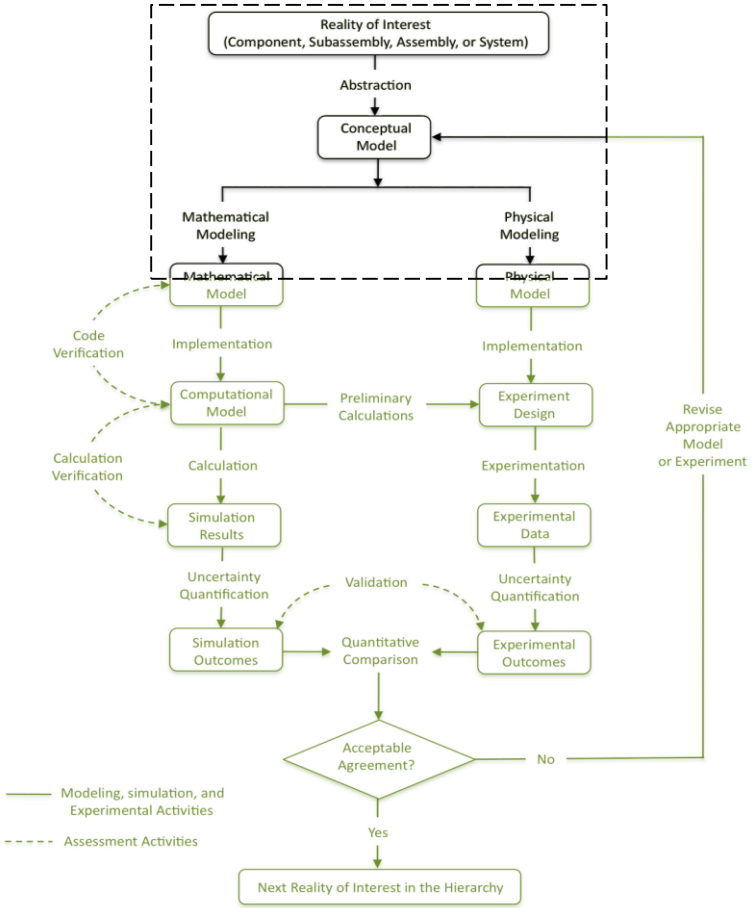
VERIFICATION AND VALIDATION

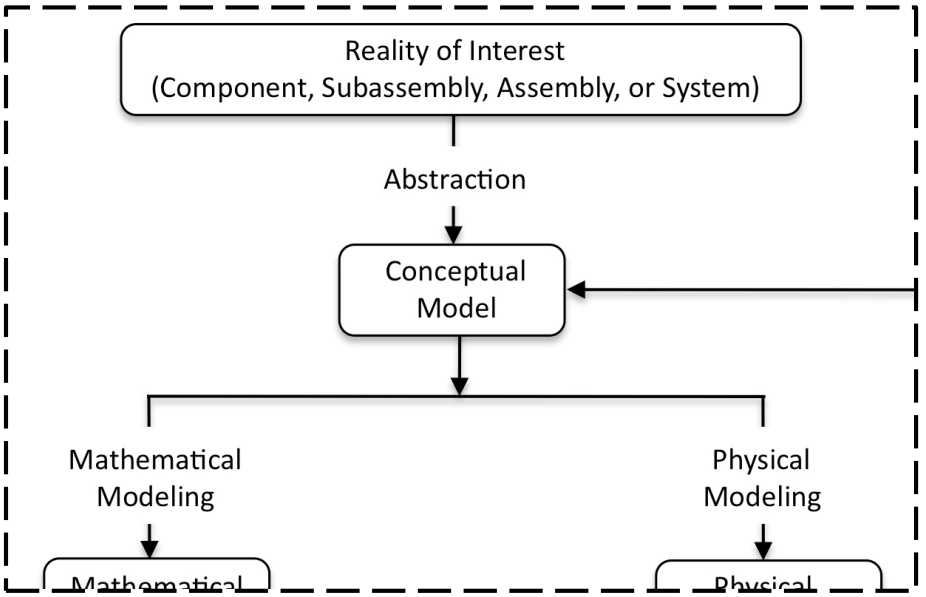


From ASME/NAFEMS *What is?* Guide.

High-level and low-level

VERIFICATION AND VALIDATION





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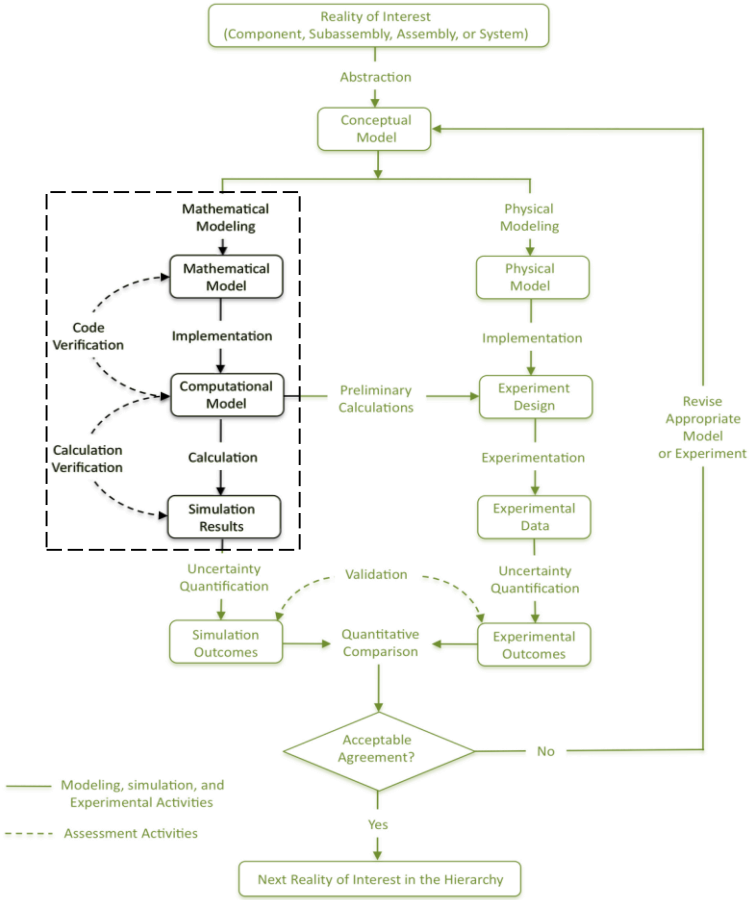
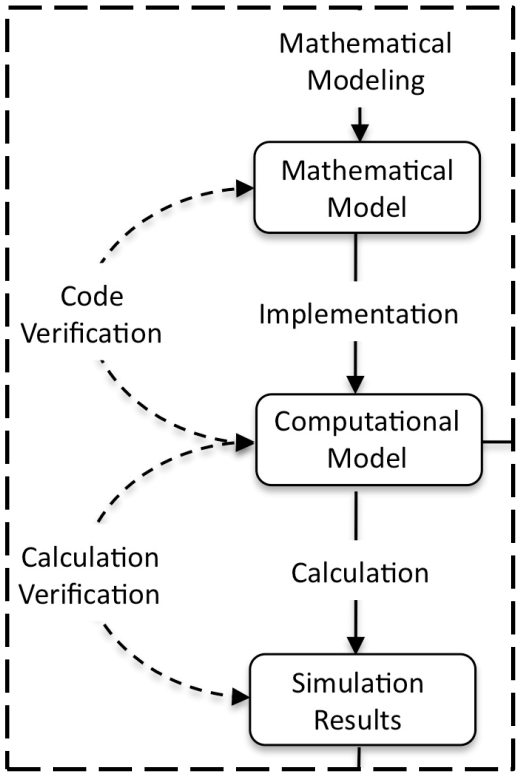
High-level and low-level

VERIFICATION AND VALIDATION





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High-level and low-level

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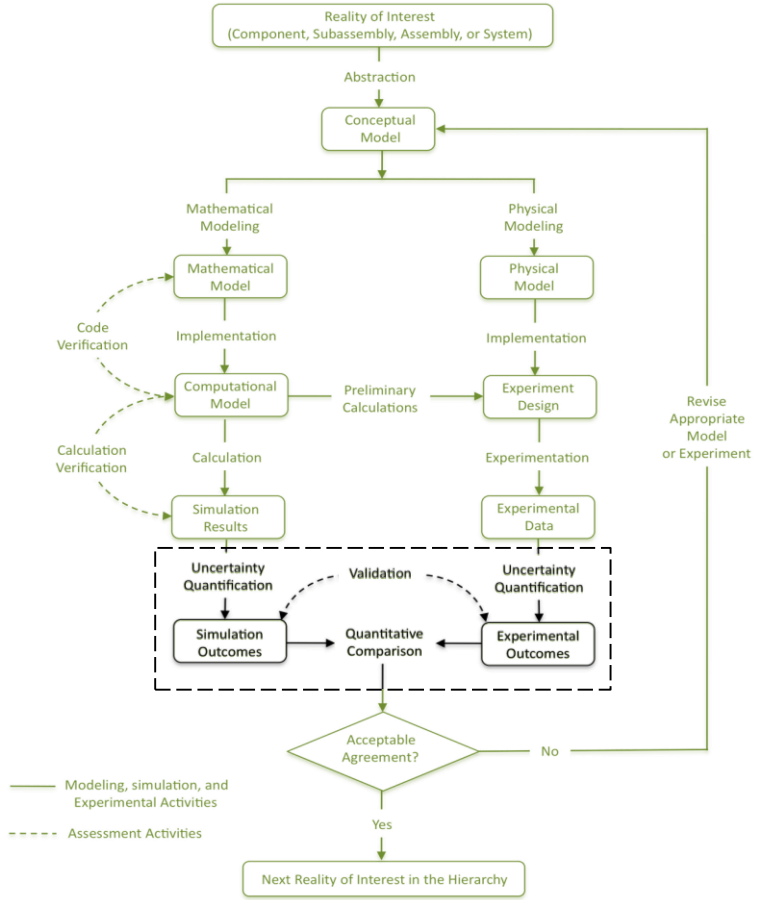

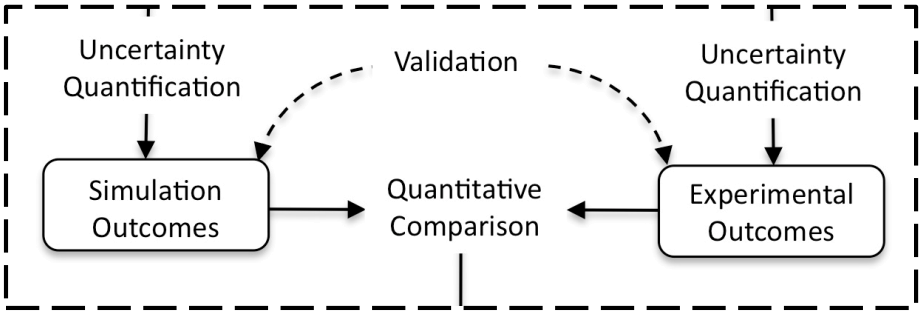

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Saving time/effort at point of use

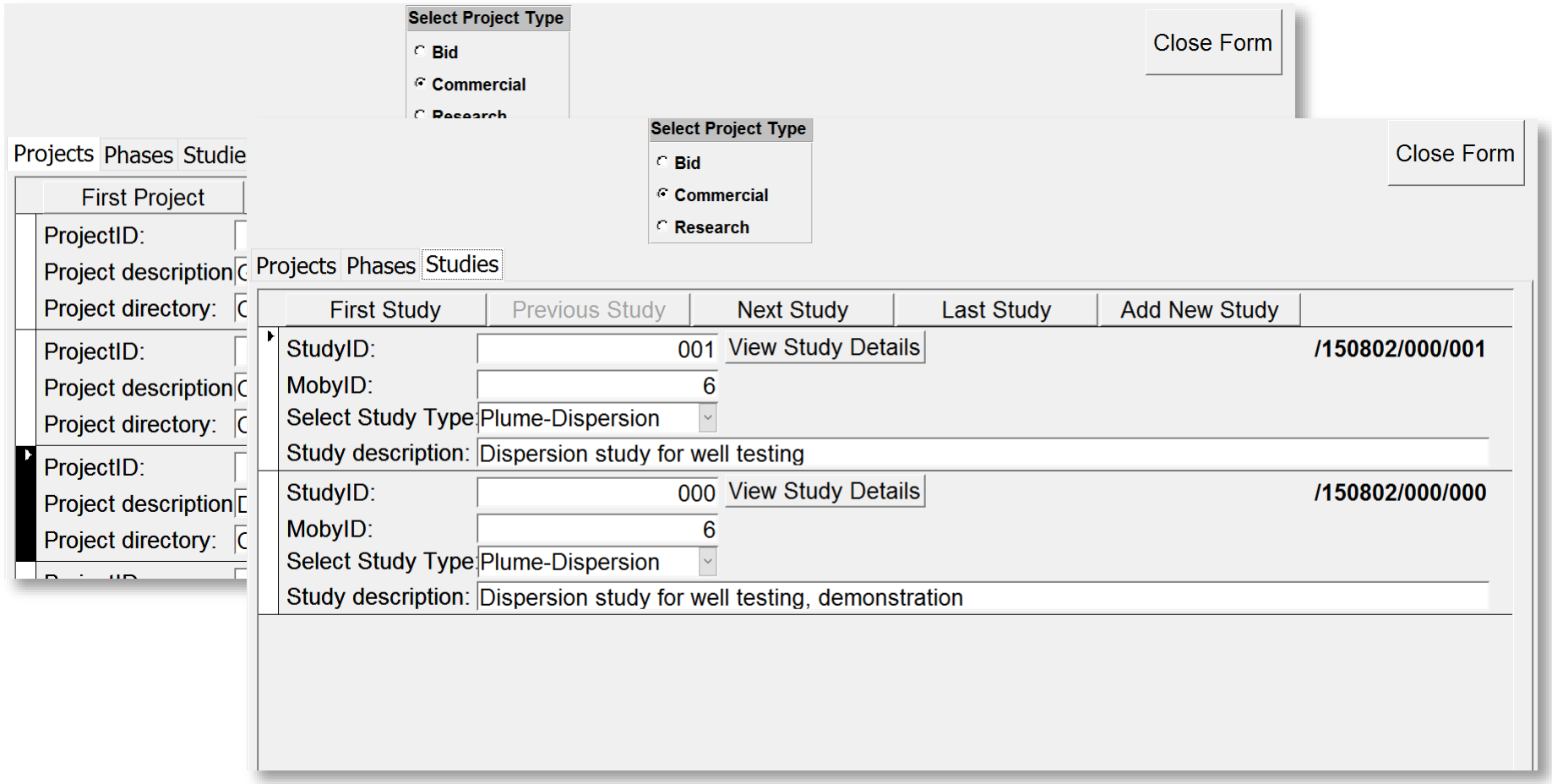
- The completion of QMS records to document the details of engineering simulations is essential to allow projects to be revisited
- However, this often constitutes a separate additional physical task which can be perceived negatively since it can distract from the immediate task of getting a simulation running
- A successful QMS should be designed to save time and effort at the point of use.

Saving time/effort at point of use

- Engineering simulation is well suited to process automation and the use of SDM tools
- Every simulation undertaken within Abercus is scripted so that a precise record of the simulation is stored
  - Each simulation is run as a background process without needing to interact with the GUI of the simulation tool
  - Abercus uses JET, an in-house SDM tool that was originally developed in 2002 to automatically create the simulation scripts
  - Over the years, the use of JET has saved time and effort at the point of use – the act of entering simulation specific information into JET to create the simulation scripts also acts to provide the information required for the QMS record, minimising duplication of effort
  - Work is consistent, efficient, and follows a validated workflow.

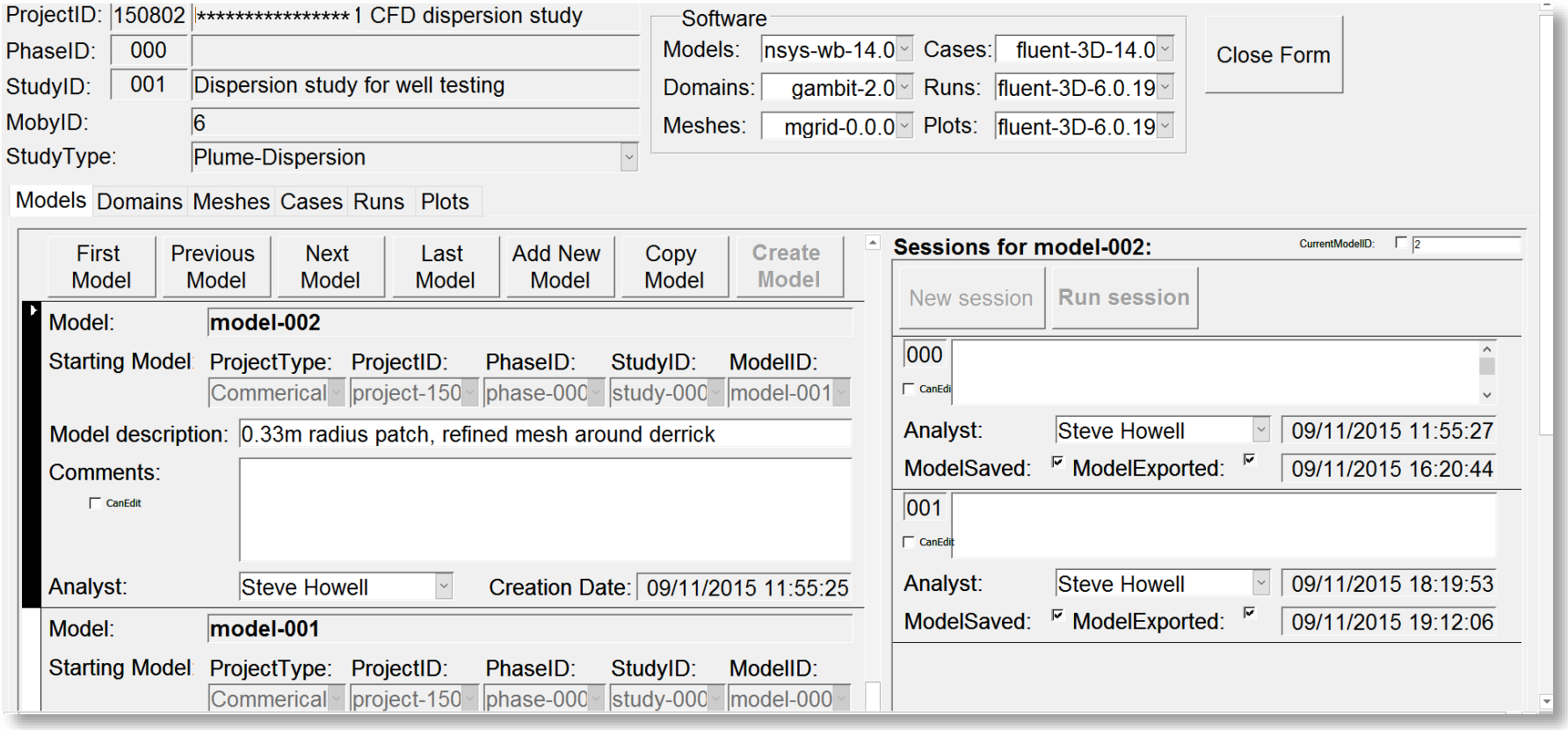
Saving time/effort at point of use

JET – AN SDPM TOOL



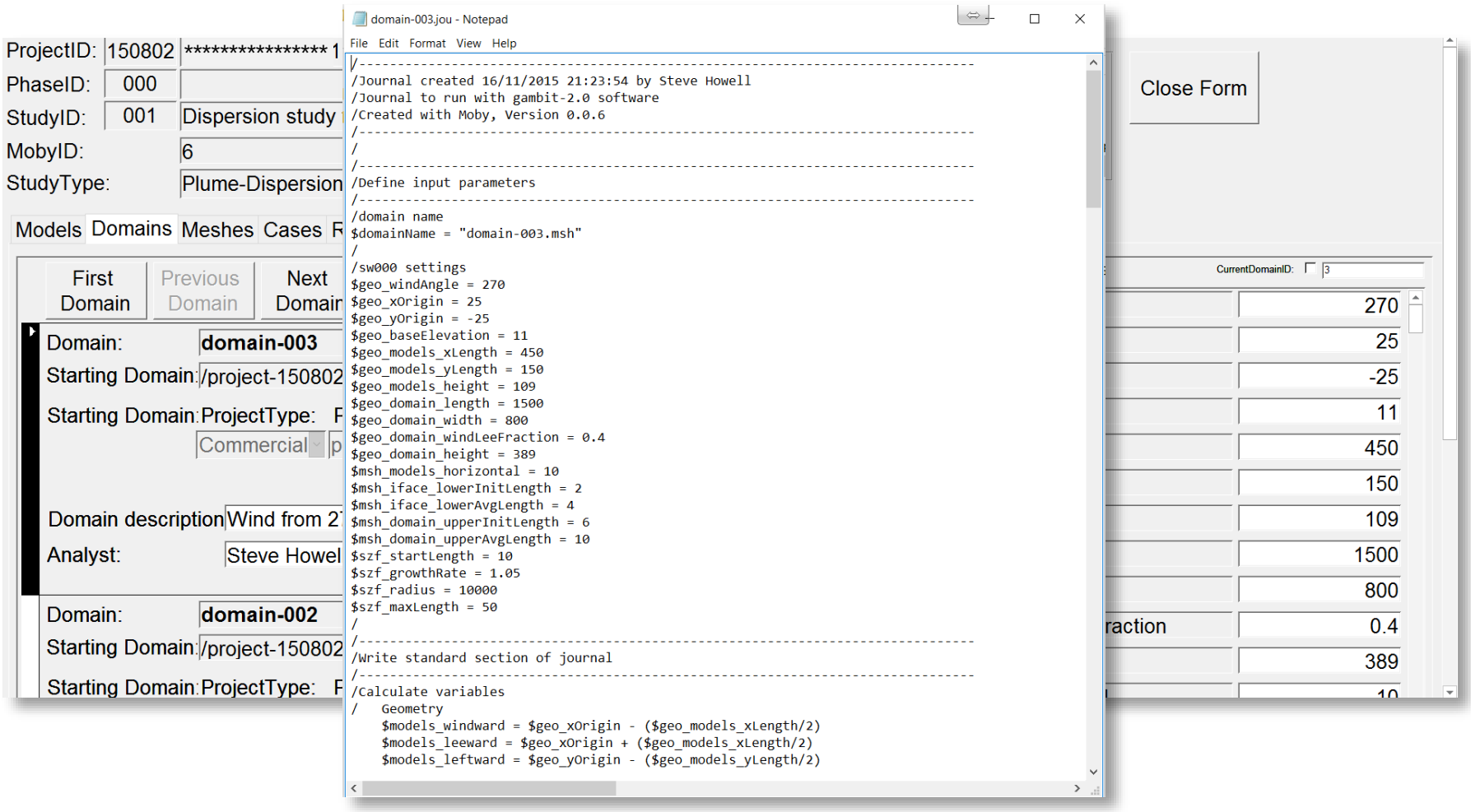
Saving time/effort at point of use

JET – AN SDPM TOOL



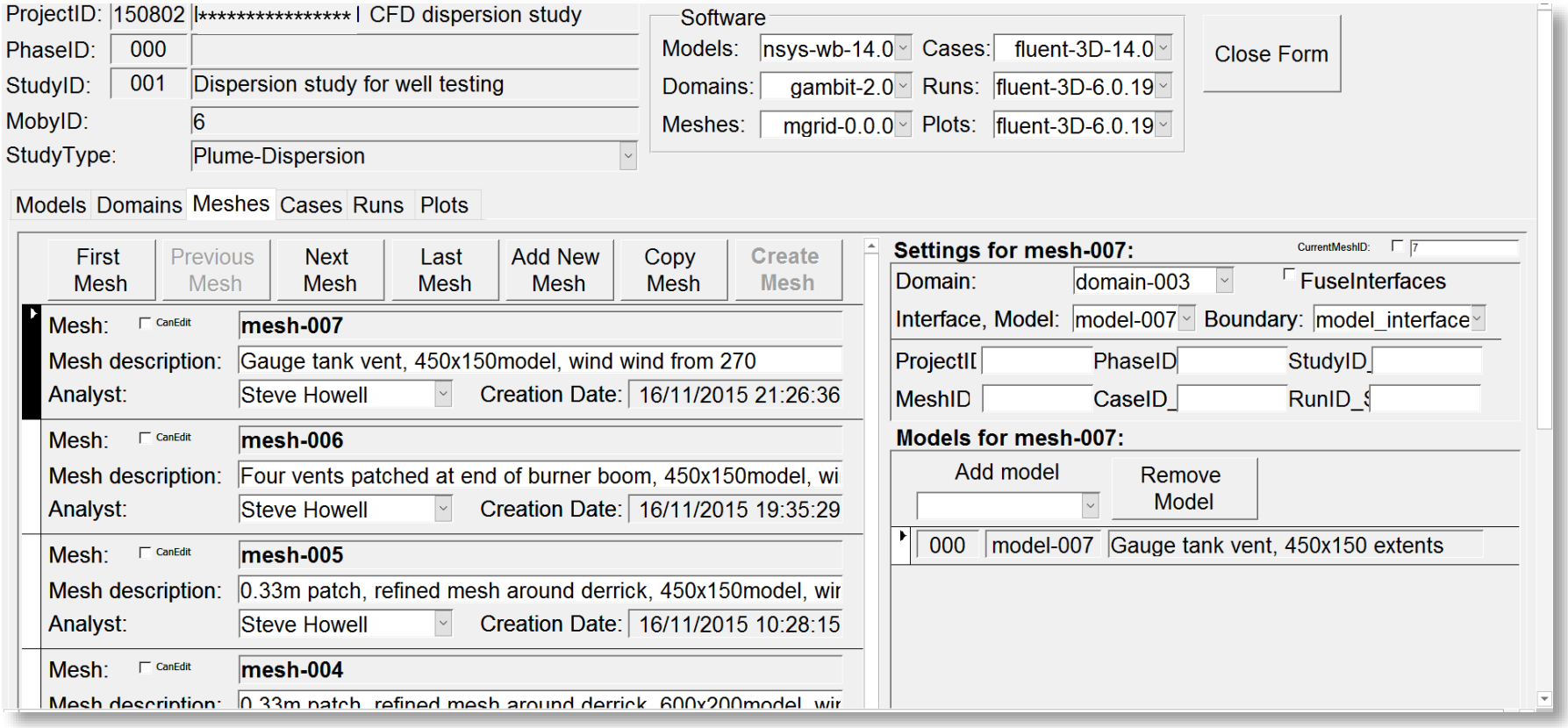
Saving time/effort at point of use

JET – AN SDPM TOOL



Saving time/effort at point of use

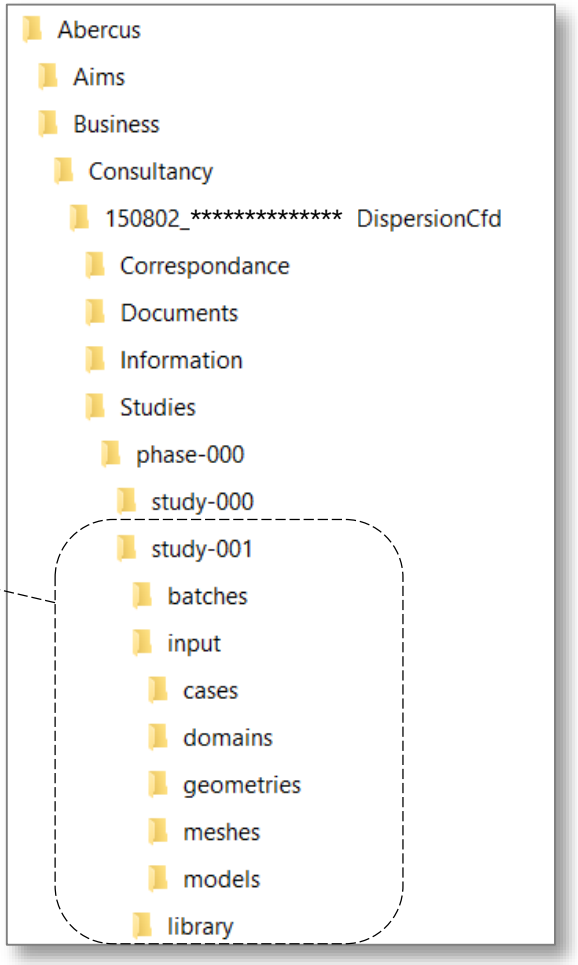
JET – AN SDPM TOOL



Saving time/effort at point of use

JET – AN SDPM TOOL

Underlying file structure is automatically created



Saving time/effort at point of use

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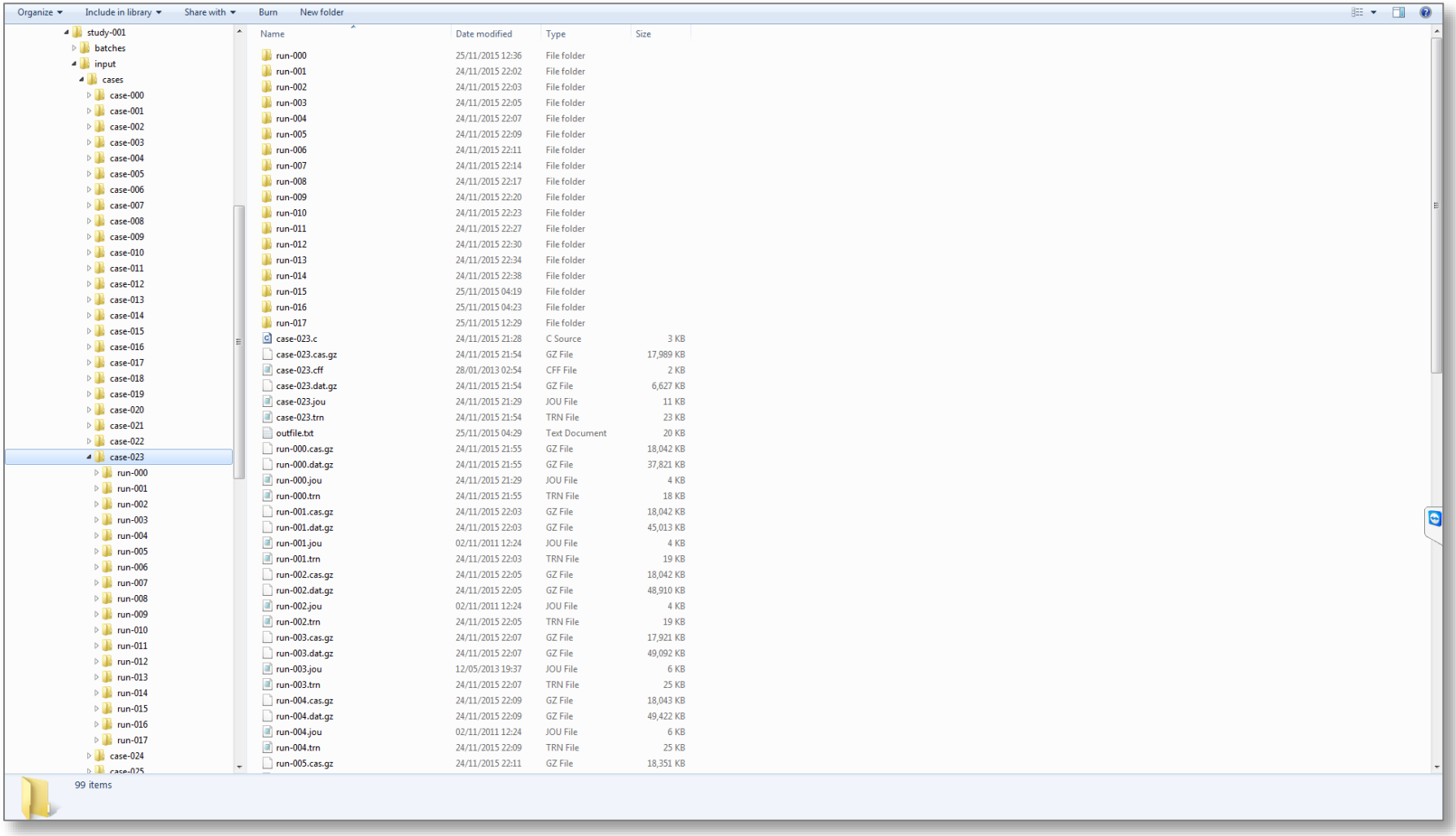

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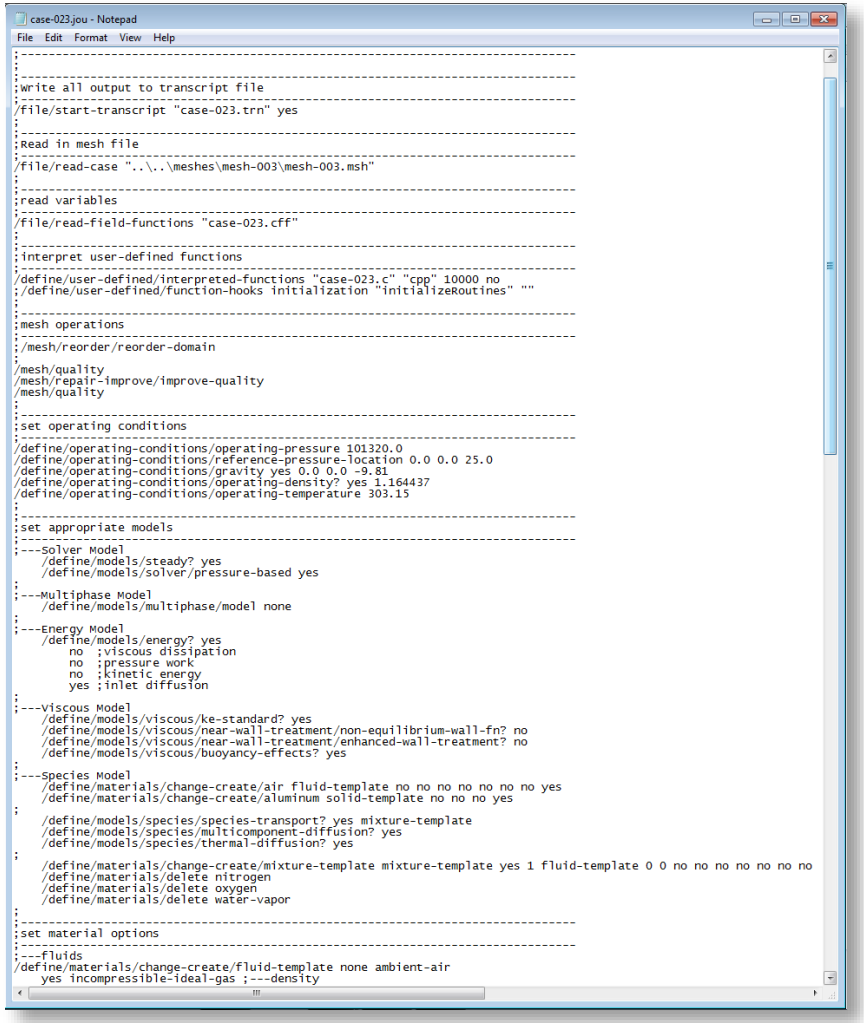

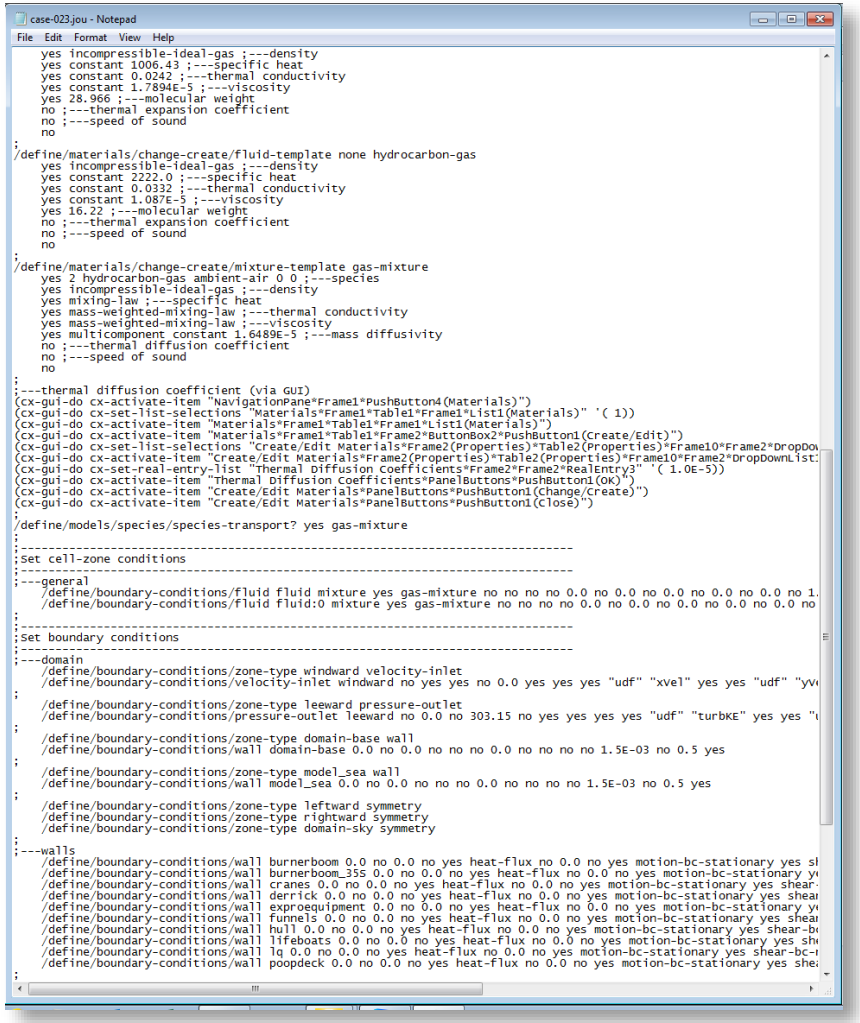

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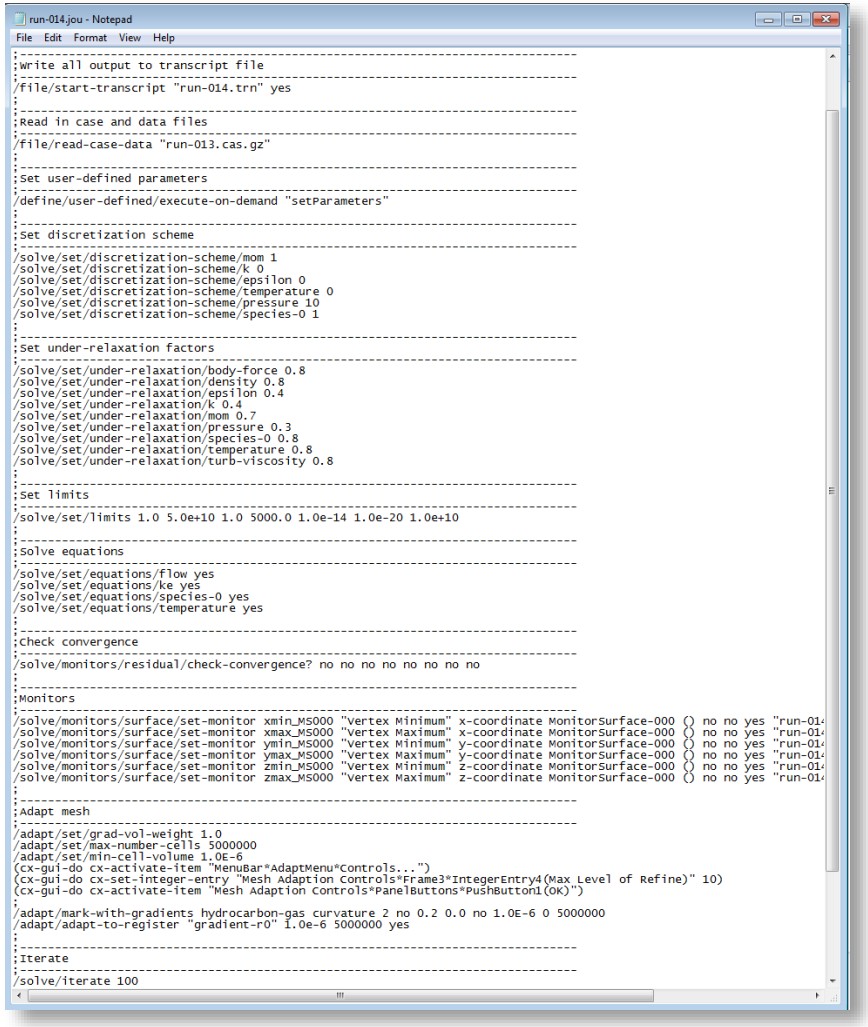

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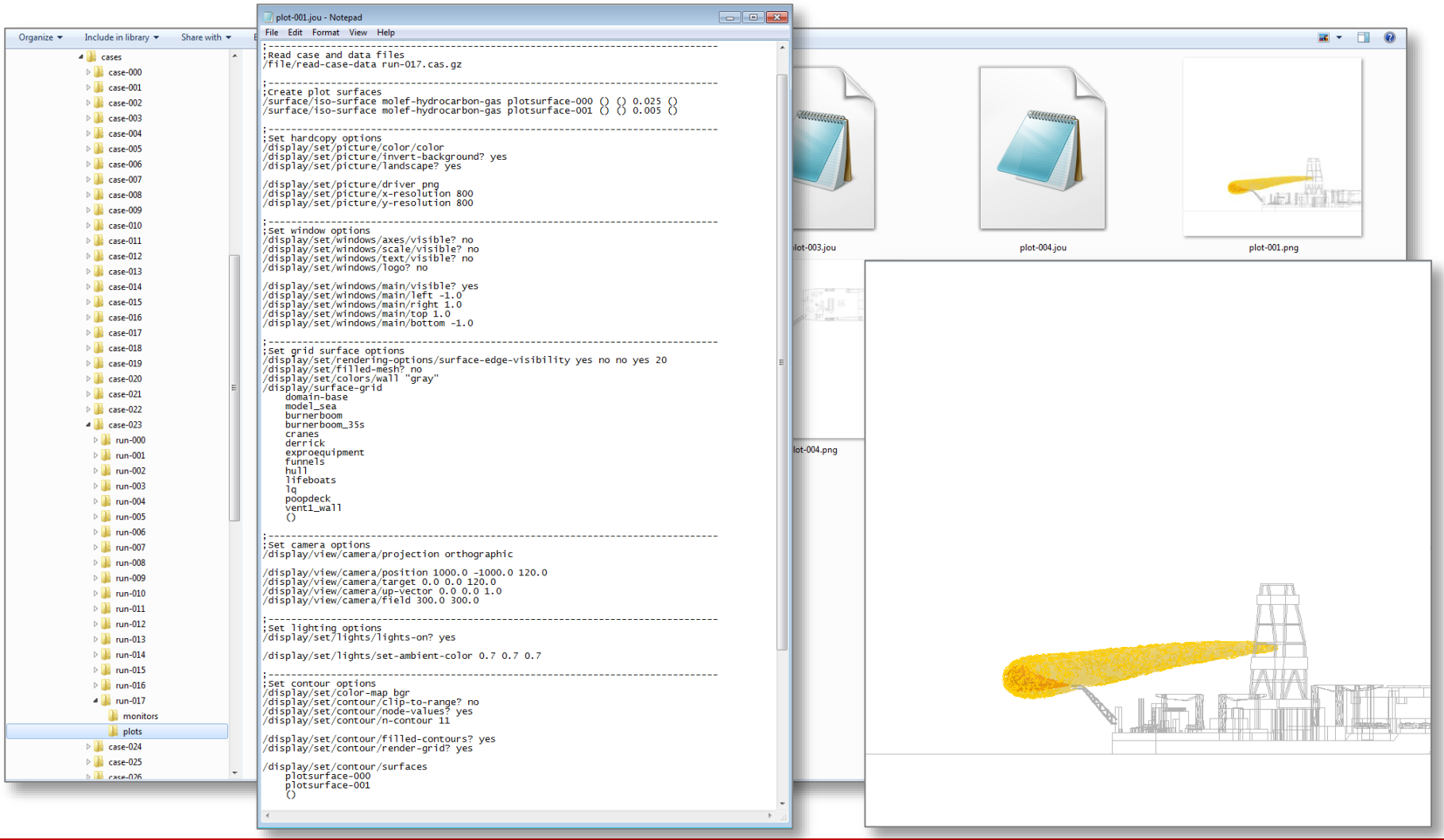

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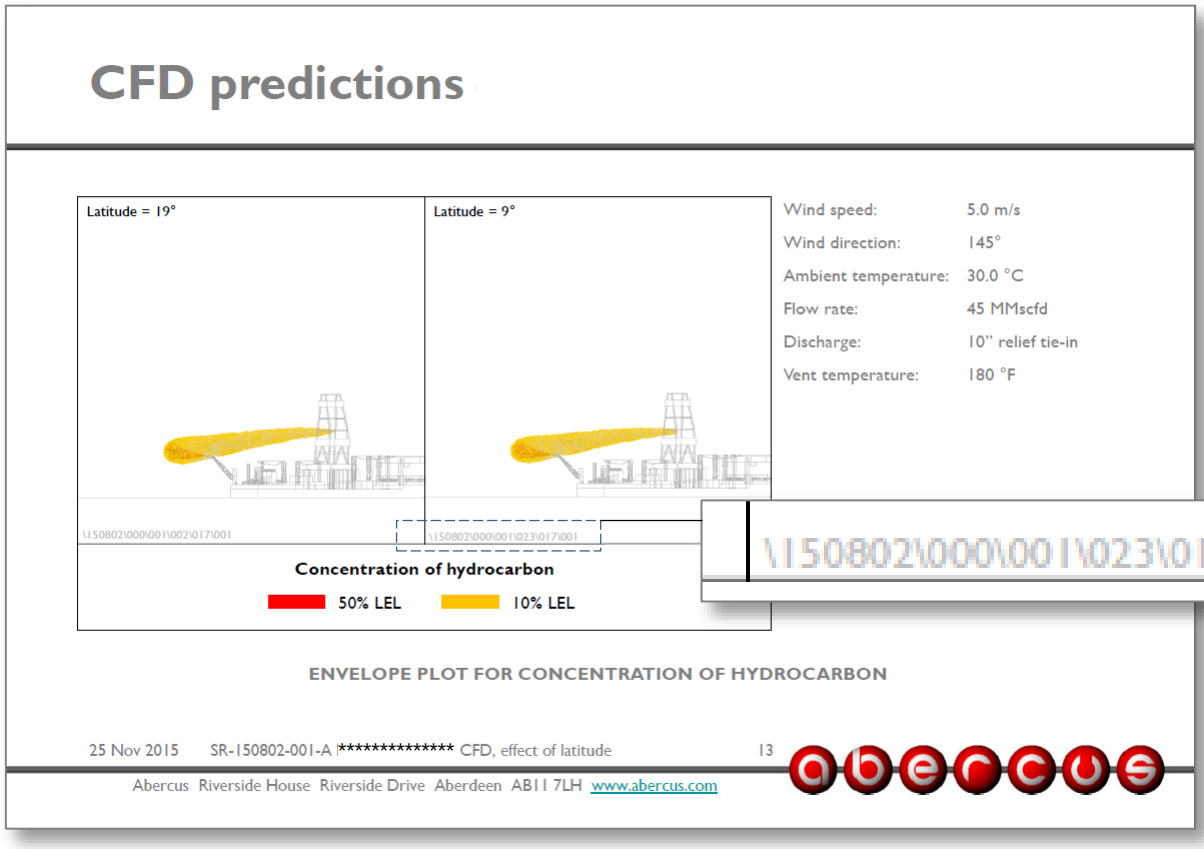

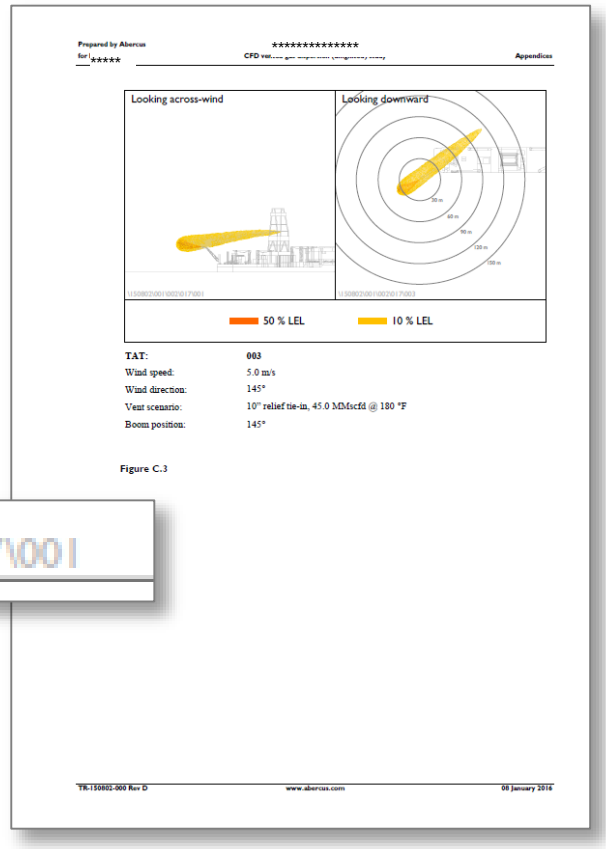

Saving time/effort at point of use

Lesson 5

Consider using an SDM tool to automate the simulation workflow. This provides a consistent framework for undertaking routine simulations whilst automatically compiling the information required for the QMS.

Agenda

- Introduction
- ISO 9001 and NAFEMS QSS
- Assessors and consultants
- High-level and low-level
- Save time and effort at point of use
- Keep it simple
- Summary
- Questions

Keep it simple

- The ISO 9000 standards are generic and there is no right or wrong solution – each QMS is a custom solution that is defined by the users of the QMS, since they know their own business best
- Beware of making a QMS excessively comprehensive from the start:
  - If something is included within the QMS, make sure that it does actually add value and will get done
  - Don’t include any new activities within the QMS just because they seem like a good idea if they are not likely to be completed
  - If you do that, you may have unnecessarily created an opportunity for a non-compliance which could ultimately lead to the loss of certification.

Keep it simple

Lesson 6

Keep the QMS as simple as possible and ensure that it reflects the business process maps outlining the current activities within the business

Don’t wait to design a perfect comprehensive QMS before trying to get certified:

- The whole point of ISO 9001 is that it’s a framework for continual improvement
- The journey towards ISO 9001 certification starts from where the company is now, not from somewhere else that it would ideally like to be
- The important point is to recognise this and start on the journey towards accreditation without delay.

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Summary

- Take the strategic business decision to become ISO 9001 accredited – it's not just for big companies, it's for small companies too
- Make full use of your NAFEMS membership and download the QSS, the QSS primer and the sample forms from the QA procedures (1999)
- Unless you already have experience of ISO 9001, consider appointing an external consultant to support the QMS development activities
- Formalise a business map
- Consider using an SDM tool to automate
- Keep the QMS as simple as possible, and don't wait to design a perfect comprehensive QMS.

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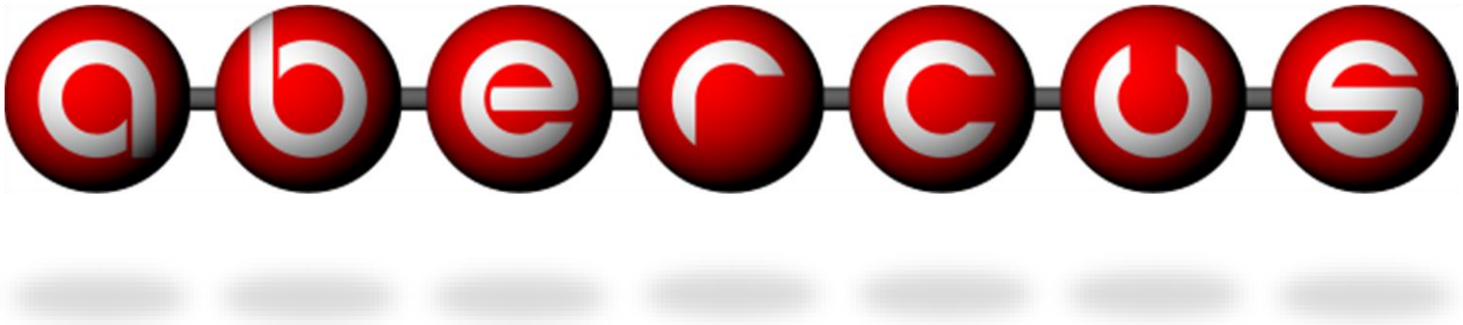
Questions

- Abercus is ISO 9001 accredited and its system is in line with the NAFEMS QSS. Is it possible to achieve formal NAFEMS QSS accreditation too?
- The NAFEMS AMWG is currently updating the QSS and associated primer to bring it in line with the 2015 version of ISO 9001. Would it be a good idea to bring the 1999 document up to date too? Possibly as a sample QA system? (Which could be written as a simple SDM database to create simple simulation scripts.)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