Enabling Outcome Based Compliance in Health and Social Care

A practical guide to the implementation and the ongoing management of Care Quality Commission regulation within healthcare enterprises.

by David Winders, Senior Consultant, iGrafx

Enabling Process Excellence.
Due to longer live spans and increased success of medical treatment the growing institutional provision of long term care, is high in the minds of many; as society realises that long term residential care is an inevitable life stage and prospect for many of us.

The reality of busy modern lives, with their growing financial demand for multiple incomes in families accentuated by an increasingly mobile working population, causes widespread geographical dispersion of the extended family. Twenty or thirty years ago families of several generations lived close together, often in the same village or town. Caring for ones elders by families at home was widespread, today this is diminishing social feature.

Long term care in the UK has come under increasing media focus in recent times. Earlier this year the BBC investigative journalism programme, Panorama “Behind Closed Doors”, presented to the public an image of systemic abuse and neglect. This is at a time when headline cases, including the Winterbourne and Orchid View incidents, were still fresh in the public mind.

Although recognising that the industry contains much good practice with committed individuals that work within it, and the fact that the occurrence of abuse and inappropriate behaviours are rare, the matter remains in the public eye with the media campaigning robustly towards more vigorous regulation. In response to public pressure, arising from these well publicised cases of unacceptable performances in the both the residential care sector and hospital care trusts, the government passed The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. In recent months the Government has put further pressure on The Care Quality Commission (CQC) to do more and to increase its regulatory activities across the sector.

The Care Quality Commission is the independent regulator for health and adult social care in England and regulator for those who care for people whose rights are affected by the Mental Health Act; it has jurisdiction over the NHS, local authorities and private providers. It covers a broad scope of regulated activities across 28 coded services: mental, medical, dental, residential and community care within both public and private sector organisations. The regulatory requirements vary according to a combination of: service type, size and complexity of the services provided, the range of staff that are employed and the nature of systems and governance structures in place. The CQC puts forward 28 individual outcomes and cross references regulations to these outcomes. The sets of regulations are: Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009, the outcomes vary according to category of the provider.

This regulatory body is tasked to ensure that the care people receive meets “Essential Standards of Quality and Safety”. The regulator will audit through inspection that essential standards of quality and safety are in place and use its powers of enforcement where necessary. The regulator positions the regulation as being outcome based rather than being based on systems and processes. This view that outcome is more important than the process that creates the outcome is worth exploring in more detail; what is being said here is that the regulator will not inspect to see if prescribed processes are in place but see if the results reflect the standards being required.
It stresses that the views of the people who use the services will be used as a prime source of evidence of success or failure. This approach is not uncommon in regulation, but it does make it more difficult to comply because there is not a list of specific things you must do and demonstrate. The thinking behind it is probably to avoid the problem of “measures create behaviours” where people focus on ticking boxes to comply with rules rather than looking at the consequences, or in the language of the CQC, outcomes. In interpreting the statement of intent not to specifically focus on process on suggests superficially that process design, capture and management is not of interest and by definition business process solutions are not a key focus. The problem at hand is to create consistently compliant outcomes that are measured by the experiences of the service consumer. Doing this without standard and consistent activity aligned to the measures that the people who use the services deem important is problematic to say the least. So, although the CQC state that process is not their focus you can’t create consistent outcomes without consistent processes. Process management is therefore just as essential as a means to manage quality as if the regulator had said it wanted to audit specific process. Process management is the key to consistent outcomes.

If you look at the scope of regulated entities the range is large and the exposure to process management techniques will vary substantially. There will be organisations who manage through the day to day embedded knowledge in their staff with little formal process documentation and design through to large enterprise environments where procedures are well documented and developed. There will be organisations that need a lot of help in developing CQC compliance and others less so, but they will all have to consider a similar path to being compliant whatever their starting their position is on outset.

The ten step path to outcome based compliance

There is a set of things that have to be considered when addressing any compliance requirement and this follows a logical process of evaluation of the compliance requirement and cross mapping to operations and the management to risks, controls and measures. We recommend a ten step approach to developing an outcome based compliant framework.
### 10 steps to outcome based compliance:

<table>
<thead>
<tr>
<th>Step</th>
<th>Summary</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Understand and list the regulatory requirements</td>
<td>Take the QCC compliance sections and create a list of regulatory requirements.</td>
</tr>
<tr>
<td>2</td>
<td>Define outcomes</td>
<td>Define outcomes appropriate to the services you provide and create goals to represent them then link outcomes to regulatory requirements.</td>
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<tr>
<td>3</td>
<td>Document what you do</td>
<td>Understand your current operation and map your activities.</td>
</tr>
<tr>
<td>4</td>
<td>Map compliance requirements through outcomes via goals to processes</td>
<td>Look to see where compliance requirements touch your activities, this will identify gaps where your current activity does not fulfil compliance needs. If gaps exist revisit step 3 and design in new activities.</td>
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<tr>
<td>5</td>
<td>Define governance</td>
<td>Assign roles and responsibilities to activities and the risks to demonstrate governance and accountability.</td>
</tr>
<tr>
<td>6</td>
<td>Identify potential risks</td>
<td>Identify where risks of compliance failure sit in the processes.</td>
</tr>
<tr>
<td>7</td>
<td>Create controls and measure those controls to manage risk an outcomes</td>
<td>Introduce business rules and controlling activities into your processes to manage risks. Create measures that relate to service consumer outcomes.</td>
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<tr>
<td>8</td>
<td>Manage compliance</td>
<td>Measure Outcomes through appropriate process performance. Record operational performance through the use of measures on the effectiveness of controls.</td>
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<tr>
<td>9</td>
<td>Demonstrate compliance</td>
<td>Provide reports that show traceability from regulatory requirements through owners of risks/processes to controls, and measures of compliance outcomes.</td>
</tr>
<tr>
<td>10</td>
<td>Continuous improvement</td>
<td>Continuously improve processes aligned to measured client outcomes. Review activities against measures and manage and mitigate risks. (Go to step 3)</td>
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The iGrafx Ten Step Path
Source: iGrafx
The model that arises by following the steps above is potentially complex. The model may well have items nested in hierarchies, as the items become broken down into lower levels of granularity and detail and there will be many multiple links between items. This requires a dual capability of modelling complexity whilst not making the model a barrier to being able to extract the right information to inform the right people. The capability needed a combination of a need to model in a structured way with a necessity to effectively report on that model. Stakeholders need to look into the model from different perspectives or viewpoints, with the model being represented in a way they want to see in a view which is aligned to their individual needs. This view and viewpoint reporting is vital for communication as a model that no one understands is ineffective.

Each unique item: a compliance requirement, risk, measure, person or outcome is represented as a building block, we call this a business object. Each business object has one or many relationships with other objects these connections are what defines the structure the “business architecture”. By going through the ten steps as described in the table above the model is built by a combination of defining objects and then linking them together. Let us explore the steps in more detail.

**Step 1: Understand and list the regulatory requirements**

In an outcome based regulatory framework the outcome headers of the regulation are created as strategy objects whilst the elements of the outcomes that can be measured against are defined as goals.

**Step 2: Define outcomes**

With the goals in place the actual documented regulation (The clauses in legislation) can be created as separated requirement objects which when linked to strategies and outcomes creates the linkage and traceability back to the underlying legislation. This provides you with your regulatory foundation.

**Step 3: Document what you do**

Working from the top down breaking activities down in levels of detail map what you do, this is traditional process mapping.

**Step 4: Map compliance requirements through outcomes via goals to processes**

What you do today may well not offer the outcomes that the regulation requires so there is a need to cross reference the processes to the requirements and the outcomes. This will identify gaps where changes may well have to be introduced.
Step 5: Define governance
Define who is responsible for the activities, how does the accountability collect up to senior leaders in the organisation; this is done by allocating roles of accountability and responsibility to processes.

Step 6: Identify potential risks
Identify where compliance may fail by conducting a risk assessment to see where things might go wrong; list those risks and where they lie in your processes.

Step 7: Create controls and measure them to manage risk and outcomes
Discuss the risks with accountable owners and then with their agreement and collaboration create controls to prevent those risks from happening and adapt your processes and activities as appropriate.

Step 8: Manage compliance
This is the ongoing management of compliance over a timed period. It measures the effectiveness and informs the management of gaps, failings and where improvements need to be made.

Step 9: Demonstrate compliance
Provide reports that communicate the right information to the right people through the use of views and viewpoints.

Step 10: Continuous improvement
Using information from step 8 and feedback from the regulator this shows that compliance is an ongoing event not just a one off exercise. It requires a loop back to steps 3. To record changes in the operation via change control of to step 4 through regular risk reviews.
In summary recent media attention has resulted in heightened focus on regulation and the Care Quality Commission has a programme to improve and inspect the provision of health care through the implementation of an outcome based compliance regime. For many of these providers; some of whom this type of approach and thinking is new territory, it presents a significant challenge ahead. It needs an approach to satisfying the regulator and the general public as a whole but without becoming too onerous. It is recognised that this sector is about providing excellent safe care not bureaucracy and to ensure that public funds are spent in the right way and on the right things.
In terms of achieving a sensible balance between the time and cost of being compliant and delivering “Essential Standards of Quality and Safety”. The ten step approach to making your organisation Care Quality Commission compliant will show how your organisation achieves its outcomes through measurement and appropriate risk management but hopefully in a pragmatic manner.

About the author

A seasoned Financial Services sector expert and consultant of iGrafx, David Winders mentors clients on the development of business architecture, incorporating an enterprise-wide view into all levels of the organisation to communicate a vision and baseline for business change. David specialises in training, customer experience development and process

About iGrafx

iGrafx process management and analysis solutions empower organisations to achieve maximum performance. iGrafx captures and communicates the alignment of strategy, people, processes and technology, and unites the entire organisation around delivering business value. iGrafx delivers strategic and operational decision support to enable our customers to become and remain world class competitors. For over 20 years, iGrafx products and services have been helping companies of all sizes across the globe manage their processes and optimise their business.

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