

Inspections are helpful. Helpful because they show us where we can improve and also what we're doing well. We all experience inspections in our lives.

In our personal lives we choose to go to the dentist for an inspection, a check up, because we know it's helpful.

In our professional lives we're inspected by organisations such as The Human Tissue Authority. The Human Tissue Authority itself, as Tim explained, has been inspected and is inspected by The Better Regulation Executive and also auditors.

So logically we know that inspections are helpful. Although emotionally some of us are a little bit anxious about them, and HTA were anxious about theirs.

I'm going to divide the presentation into three elements. First of all how we prepared for the inspection. So that I can share some tips that may help you when you prepare for an inspection, perhaps by HTA or by other organisations.

Then I'll take you through the areas that the BRE thought we should follow up and improve, and also some areas of good practice.

So how did we prepare for the inspection? First of all we reviewed the statutory code of practice for regulators that was published in 2007 by BRE.

The statutory code of practice brought together the information that Tim talked about from Hampton and [Macraurie] into a set of standards and requirements for regulators to comply with.

Because the recommendations were published originally in 2005 that was the year that HTA was established. So when we set up HTA we set it up firmly based on those recommendations of risk, proportionality and transparency.

So – preparing for the inspection: The statutory code was published in December 2007. It's primarily targeted at the regulation of businesses.

Our view was that we should treat all organisations we licence and inspect in exactly the same way and be consistent with how we treat the burdens of regulation for everyone. So all five sectors have a regulatory framework based on the same principles.

In May 2008 we presented our paper to the Authority that summarised, at a high level, where we thought we were compliant with the statutory code of practice and where we thought we could improve.

The Authority took the decision at that point to advise us to ask the BRE for an early inspection. We consequently did that. In preparation for the inspection I attended some workshops run by The Better Regulation Executive so that I may better understand their methodology and also what standards they expected of regulators and bring that learning back to HTA.

I was also fortunate to be able to attend an inspection of another regulator as a peer reviewer, animal health. and that also offered some helpful learning.

So those of you who are most familiar with HTA will know that we like to use project plans wherever possible. So it was agreed that there would be an inspection in December 2008, and we were told that in September.

So immediately we set up a project and identified a project manager, an experienced inspector from HTA, to plan the process and engage the staff.

The first step was to develop a self-assessment template. So we looked at all the standards in the code of practice and mapped them across onto the template.

We used the same structure as we used for licence applications. So we gave summaries of the evidence of compliance and we also scored ourselves on whether we thought we were compliant or partially compliant, or in some cases not as far as that. That was back in September so we had room to improve.

One of the other elements of the project planning approach was engagement of staff. We worked in teams across the organisation working with the standards from the code of practice and asking staff what their views were about whether we complied with the code or not, what we did well and where could we improve.

It was important to get their engagement and their buy in so that everyone felt ownership of the statutory code of practice. And so that new staff felt as familiar with the regulatory Better Regulation recommendations as the original staff back in 2005.

We then submitted a completed evidence pack to The Better Regulation Executive. This included our self assessment template and some links to the website where there was useful information and other evidence.

Interestingly, at around the same time we knew that we were due for an audit. And so we arranged to have a joint audit and Hampton review at the same time – so two inspection teams on site at the same time.

We had planning meetings with members of staff from the BRE and also from the auditors so that they could agree which interviews they could do jointly and where information could be shared.

So I've told you about how we prepared for the inspection. I'm now going to tell you about the areas for follow up.

One of the areas for follow up relates to legislation. The inspection team felt that we could do more work with stakeholders to help to explain and clarify the perceptions about the legislation, particularly for the research sector.

They felt that we could also work with the Department of Health to influence the legislation so that further improvements can be made when the legislation is revised in due course.

We've produced guidance on interpretation of relevant material and types of tissues and cells. And the review team thought we could do more of that.

They also asked us to look at evaluating more of our guidance material taking a more strategic perspective about evaluating guidance material.

And to look at sharing more of the lessons learned from our surveys of public perception that increase the confidence of the public in donating tissue.

They asked us also to look at activity data and to carry on working with our stakeholders, particularly in the human application sector to revise and review how we collect activity data on behalf of the European Commission so that we may make it as useful as possible for them and as streamlined as possible for them.

They asked us to continue targeting our site visits on the highest risk establishments. And they also asked us to continue our work on collaborative inspections.

And as Adrian said we're planning joint inspections with the Medicines and Healthcare Products Regulatory Agency at the moment.

So I've told you about how we prepared for inspection. I've also explained the areas that Hampton inspection team thought that we could improve on.

Finally here are some of the areas of good practice that the team commented on.

They recognised that the strategic policy decision we made to delay enforcement of legislation was a proportionate one. For clarity we decided to delay enforcement of the Quality and Safety Regulations for those procurement organisations affected by the European Union Tissues and Cells Directive.

We delayed it for one year whilst we sought further policy interpretation from the European Commission itself, from the Department of Health, and also whilst we conducted some workshops with people that represented procurement organisations so we could make sure we got the policy just right.

The implementation team also found that we shared good practice effectively. They acknowledged and recognised that the self assessment methodology for licence applications was a very helpful process to engender ownership by those who are regulated by HTA.

The endorsed the transparent approach that HTA takes to inspection and the information that we provide pre, during and post inspection, including the advice and guidance.

They also commented on the efficacy of our regulatory action panels. These are internal panels that are set up in HTA where we consider whenever we're going to take significant regulatory action such as suspending a licence or revoking a licence. So we can ensure we make the most proportionate, risk based, evidenced and justifiable decision we can.

The inspection team also commended that objectives were very well understood by staff. So from the organisational level objectives they noted that they fit into the directorate level objectives and then were cascaded to individual objectives. And they thought that was good and helpful.

So I've explained to you how we prepared for inspection. Also the areas that the inspection team thought we could improve on and the areas where we do well.

I hope that you're able to take some tips away for your own inspection. Certainly we found the BRE inspection very helpful and motivating for staff.

Helpful because it showed us where we could improve. And it also told us what we were doing well. Thank you.