

Well good morning everyone. It's very good and pleasing to see such a huge turnout. As Shirley said I'm the chief executive of the HTA.

I want to pick up on something that Shirley has just ended up with and that is to say, quite apart from authority members who have been incredibly supportive, quite apart from the stakeholders who've helped us develop so much of our standards, so much of our work.

I want particularly to take this moment to thank the staff, my senior team, all of whom are sitting in the front row here. And of course the others who are dotted around the back and sitting amongst you.

Because the amount of work that they've done and the way in which they've done it is simply commendable. So thank you very much to them.

I'm going to give you as it were a preview of what you'll be reading about in the annual review. This is the opportunity for me, not particularly to wave flags, but to describe to you in summary the sorts of things that we've been doing to satisfy our regulatory remit.

I'd like to start off by putting all of this into context. We've never been ashamed to publicise year after year that our main strategic aim is to operate a regulatory framework that has the confidence of the professionals and the public.

We constantly set out our stall, which is not about regulatory enforcement but one which is designed to improve standards. And thirdly, and terribly appositely in the current climate, we need to operate as efficiency and at low a cost as possible.

And the cost issue applies not only to us operating as a regulator but we want to try to keep the costs for those whom we regulate also as low as possible.

Our statutory remit is prescribed. It is prescribed in two pieces of legislation. The first is the Human Tissue Act which so many of you are familiar with, our historical piece of legislation.

And more lately the Human Tissue Quality and Safety Regulations which emanate from the European Directives. And I'll be saying a little bit more about that because as Shirley has already alluded to, that caused us a little bit, a few sleepless nights.

And what are we here to do? What does the law ask us to do and require us to do? Well, in terms of licensing we have five sectors in which licensable activities take place.

I've listed them there for you in summary and perhaps what might be more of a surprise to you is the number of premises that we are required to licence, 865.

We started out by the way, just to give you some contextual observation here, we started out thinking that we would have around 550 in total. So you understand that the size, quite apart from the complexity, has multiplied.

And what are we required to regulate, also more widely? And the answer is well, the Human Tissue Act here asks us to approve all organ donations from living people and to provide a framework at least for regulation of bone marrow from living people.

Our approach to regulation, I'm not saying this because we have someone from the Better Regulation Executive here, is that we should be, and we've set out our stall from the very outset, we should be a risk based regulator.

By that I mean we don't site visit just because an establishment exists. We site visit according to a risk assessment. We want to be an engaging regulator.

I've already said that we take great pride in the fact that we have engaged you to help us develop standards to develop codes of practice and so on. And that will continue.

The phrase "coach not cop" was coined by someone who was speaking to the authority members at a meeting in 2005, a former chair of the Audit Commission, who characterised the good regulator as being the coach not cop.

That is one who's going to try to drive up standards rather than simply operate the stick wielding approach.

So what does this mean in terms of turning the approach into reality? Well, our generic work is about interpreting the legislation. It's ridiculously complicated.

We've got two lawyers who spend all of their time trying to work out what certain words, phrases, clauses, sections mean. Both in the Human Tissue Act and in the Quality and Safety Regulations.

We offer guidance, and that's in the form of the Codes of Practice. But let's not forget the very extensive licensing standards that we have developed with your help, the stakeholders help.

We collect and analyse data, I'll be explaining a little bit more about that in due course. We need to train the people who are responsible for ensuring compliance in the establishments, in the premises that we licence and we do that in a variety ways as shown there.

And we like to give information to the regulated sectors. I'll expand on that also. But this is all generic contextual stuff. To continue that list we need constantly to find ways of avoiding overlap and duplication with other regulators, or others who touch on our remit.

The abbreviations are there only because I can't fit the whole words onto the slide. This is the Medicines and Health Care Regulatory Products Agency and The National Ethical Service.

Now the answering of written and phone enquiries is something that has grown like [top seed 0:06:32] and we are trying to harness that by logging all of the enquiries we get.

I can't give you numbers at the moment because we've only just started logging it. But I can assure you that in our capacity as an advice and guidance type regulator we put great premium on responsiveness, clarity of response, accuracy of response.

We also, in order to engage you and to train people in the places that we licence and regulate, we run workshops, training seminars, consultations and conferences.

So that's all the list of generic activity that we get on with and are required to get on with from day to day.

I'd like to turn then to key achievements and then move on to some specific activity. Well you've already heard about the codes of practice and Vicky Chapman, the director of policy and strategy, is going to tell you a little bit more about detail.

But you wouldn't expect me to stand up here and talk about key achievements without mentioning the huge task that it was to revise, overhaul all of our codes of practice and indeed to create an entirely new code of practice on research.

Another key achievement is that we sustained a review. We were audited to see whether we adhered to the better regulation principles.

Tim Courtney from The Better Regulation Executive and Sandy Mather will be talking about that in a moment. And we issued the first summary inspection reports, five of them in respect of the five sectors that we licence.

That wasn't an approach to criticise or condemn people who might not quite have been coming up to standard. Much more it was an attempt to provide information and analysis to help people drive up their standards from a point of view of understanding what good practice was.

More key achievements last year, well new licensing requirements were successfully implemented. I'm thinking here of the expanding European remit when we started to licence procurement organisations in July of 2008.

We developed a new fee structure that wasn't at all popular. The responses we got to the consultation suggested that we should approach it a different way. And we've listened. We've had some development workshops, in fact in the New Year, and we're looking at how we might overhaul the fee structure.

We've moved to new accommodation, that's only regrettably temporary accommodation until a place is found for us on the government estate. So we've got more of that coming into place this year.

And finally let's not forget the sort of root and branch stuff. We've got to run this organisation. We've got to respond and react to developing regulatory needs.

And we have done so by engaging in a development plan for our organisation that looked at structure that looked at numbers and so on. And that takes quite a lot of time believe me.

At the moment we're in the middle of implementing that development plan and I imagine we will have completed that by the end of this financial year.

We've had an unqualified audit from the National Audit Office. I want to say that because this is something that's often forgotten and it's a credit to our very small resource team to have achieved that yet again. This is our third unqualified audit.

We continue to search for efficiency. And what I'm referring to here is for example those of you who are from the licensing sectors, or the licensed sectors I should say, may have played a part in one of the many workshops, I think we held four in total, to examine the need for continuous licensing rather than a finite period for licences.

We started last year helter-skelter to overhaul our rather disparate series of IT systems containing information to bring them into one customer relationship management system. That will provide efficiencies.

And thirdly, just by way of example, we created and recently set up, implemented our new enquiries logging system which will provide a much more efficient way of responding to enquiries.

So in those ways we want to continue to be a low cost regulator. On that point I think, I just want to understand in terms of perspective, that for the 860 places, premises that we licence for the organ donation approvals, and I'll be giving you some numbers in a moment, in other words to be a national regulator.

Someone from the Royal College for Surgeons remarked to me with great surprise and bewilderment that she could not understand that we operated on about 60 staff.

I want to try and keep it at that. That may not be possible we'll have to see in time to come. But we need to keep costs as low as possible because frankly I don't want the hassle of going to you for more licence fee income.

Okay, let's look at some baseline activities. On the licensing front this is what we do. I'm not going to go through this line by line, but this was a slide that

was put up at one of the development workshops to look at how we might overhaul fees.

And such was the feedback on this slide that I thought I ought to put it in here. For those of you who weren't at the workshop you should understand that licensing is not site visit inspections. I repeat we do not site visit by rote. Just because an establishment is there doesn't mean to say we visit it.

But what we do do, and part of our regulatory approach remember, coach not cop, advice and guidance, is to spend some 48% in terms of proactive and reactive time on giving advice and guidance.

The rest is admittedly phase 2 inspections which are the site visits 25%. And the remainder is taken up on the other elements that you can see on the slide.

In terms of organ donation we're required to approval all organ donations from living people. And also we need to train independent assessors who act on our behalf to interview donors, potential donors and recipients in order to provide us with a report on which we could base our approval.

Regulatory activity on organ donation seems to keep going up just as the number of licence applications and premises seems to keep going up.

Last year there were 1000. It's gone to 1058 donations to family and friends. There were 22 paired donations, this is the sort of sexy stuff that you read in The Sunday Times and other newspapers.

22 paired pool donations, this is where partners swap with other partners, there were only six last year. That may not seem like mega numbers to you but actually it's a hell of a lot of work.

Because in those sorts of cases and the altruistic cases we have to set up a panel of authority members to adjudicate on these particular cases.

The 1058 figure are decided upon as a delegated responsibility by the executive. 15 altruistic donations, that hit the headlines about three or four weeks ago, which came as a great surprise to everyone. Frankly it came as a bigger surprise to us because we thought we'd have about one or two a year.

So there's quite a lot of increase here. And the next slide is designed simply to create an impression rather than for you to read every single line, that the work we do just does not stand still.

We've, under the European Directive, got to continue to implement new facets and elements of the various Directives. And you can see that slide goes up to September 2010. And the last one by the way is a biggy believe me.

Again on the organ donation side, I beg your pardon, on the increase side, 72 new licence applications were received in 2008/9. Who would have thought in

2005 that we would be receiving 72 new licence applications on top of 800 odd? But there you are.

There's an increase in need for regulatory action because the number, the sheer numbers have generated in one or two cases some pockets of minor non-compliance, or even whistle-blower type non-compliance that I've referred to.

So the police, the Health and Safety Executive, whistle-blowers from within establishments, either with a grievance or who may have a point, have increased in number in terms of the numbers of calls we get about potential non-compliance.

And that of course generates more site visit inspections. We tend to visit immediately we get any hint of non-compliance to investigate.

And of course the requests for advice and guidance multiply. Now what I would like to say, and I keep saying this to the staff but they keep saying "Yeah, yeah, we've heard that one before." Is that this is going to settle down and eventually subside.

I mean there has to come a moment surely when this does abate. But at the moment, and I imagine for the next couple of years, because particularly on the European side things are going to keep running at this pace in terms of the requests for help, support and advice and guidance.

And on the organ donation side you've seen the order of increase. We've no reason to believe that all of the different types of organ donation approvals aren't going to continue to increase.

That means we need more independent assessors. That means we need to train more independent assessors. It also means that we get more enquiries about body donation.

And those of you may remember The Daily Telegraph ran a campaign which resulted in something like 200 to 300, just in one week 200 to 300 enquiries about how to donate a body.

And I put up here as a hostage to fortune the new European Directive on organ donation. We haven't a clue who is going to manage this piece of business but we do need to make sure that we're fleet footed enough to adjust to what the implications of implementing this new Directive will be for the HTA.

So in conclusion, having taken you through helter-skelter the context, the key achievements and the bread and butter stuff, which I hope has given you some broad oversight into not only what we've done in the last year but that there's a continuation of more of the same plus, plus.

I just want to conclude by saying we certainly will continue to apply the

principles of better regulation. We will never let go of that. We want to continue to work with stakeholders to improve our standards.

And we certainly want to continue to be the low cost regulator that we started out and how we're continuing to be. So thank you for listening.