Brief EU regulatory Update

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The political timetable

*slide provided by the MHRA*

- **January 2014**
  - Greeks chair Member State meetings

- **Spring 2014**
  - European Parliament campaigns

- **May 2014**
  - European Parliament elections

- **July 2014**
  - Italians chair Member State meetings

- **October 2014**
  - New European Commissioners

- **January 2015**
  - Latvians chair Member State meetings
Progress!

Slide provided by the MHRA
Proposed Classification

In the new classification system, IVDs will be divided into four classes of risk:
A (lowest risk), B, C and D (highest risk)

The conformity assessment procedure for class A devices will be carried out, as a
general rule, under the sole responsibility of the manufacturer

For devices of classes B, C and D an appropriate level of involvement of a Notified
Body is compulsory proportionate to the risk class

Devices of class D will require explicit prior approval of the design and of the quality
management system before they may be placed on the market
In the case of class B and C devices, a Notified Body is required to check the quality
management system and additionally, for class C, the technical documentation of
representative samples.
Clinical evidence requirements

Covered in Annexes XII and XIII
Extended from analytical validity to
Scientific validity
ie association to a clinical condition or a physiological state
(from existing tests; literature; expert opinion; results of proof of concept studies; results from clinical performance studies)

Requirement for clinical evidence report
Analytical & scientific validity + performance studies
‘Living’ document expanded and amended with post marketing data
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"You're fired, Jack. The lab results just came back, and you tested positive for Coke."