

# In-House Reagents and the IVD-MD Directive

*Beware of false  
interpretations!*

Des Kenny, IEQAS Conference,  
16 October 2003  
(updated 13 November)

## IVD Directive (1998)

For the regulation of IVD devices (including reagent kits, analysers ... )

### Three exemptions:

1. Ordinary lab equipment not intended by the manufacturer for diagnostic testing
2. EQA materials
3. In-house reagents

# Directive on In-Vitro Diagnostic Medical Devices (IVD-MD)

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL  
of 27 October 1998  
on *in vitro* diagnostic medical devices

## *Article 1*

5. This Directive shall not apply to devices manufactured and used only within the same health institution and on the premises of their manufacture or used on premises in the immediate vicinity without having been transferred to another legal entity. This does not affect the right of Member State to subject such activities to appropriate protection requirements.

## Article 1, paragraph 5:

This Directive shall not apply to devices manufactured and used only within the same health institution or used on premises in the immediate vicinity without having been transferred to another legal entity.

## Does this mean what it says?

In the 5 years since the Directive was published, this was everyone's understanding

However, in July 2003, the UK Competent Authority, the MHRA\* came up with a new interpretation:

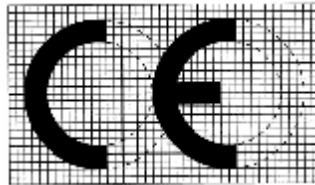
This Directive shall not apply to devices manufactured and used only within the same health institution, **but by “within” we mean “used only to test samples from patients who are within the same institution” [!]**

\*Medicines and Healthcare Products Regulatory Agency (incorporates the former MDA — Medical Devices Agency)

This is contrary to the clear wording of 1.5 which says nothing at all about the source of the samples tested and refers only to the location in which the device is used.

If the device is used to test a sample from an outside patient, the only thing which leaves the institution is the test result, and a result is not a device.

Under the MHRA interpretation, in-house reagents would have to be subjected to the full process of testing and inspection that applies to commercial kits, and would have to receive the CE mark



Essentially all in-house reagents would be involved, since with few exceptions every laboratory tests at least a few samples from outside (other hospitals or GPs)

*So, Article 1 paragraph 5 becomes meaningless!*

This is obviously contrary to the intention of those who wrote the directive — if this paragraph has no meaning why is it in the directive?

To me, and many others, this interpretation is contrary to both logic and common sense, and cannot be allowed to stand.

The Royal College of Pathologists and other bodies have explained to the MHRA how damaging this will be to specialised medical laboratory services, but the response is on the lines of “we’re sorry that you will be inconvenienced, but this is based on a legal opinion, so we have no choice but to follow it”

“Many tests such as virus isolation by cell culture, detection by electron microscopy and a wide range of molecular techniques would be almost impossible to CE mark”  
(UK virologists submission)

Some existing commercial kits are being withdrawn from the market because of cost or difficulty of CE-marking them (in-house tests may be needed to replace them!).

This interpretation must be challenged, and is being challenged.

It seems to be based on a false analogy with medical devices used directly on the patient or attached to the patient, which leave the institution when the patient does (and so, no longer “used within”)

But, with in-house reagents the device (the set of reagents) is only used within the institution. **The only thing which leaves the institution is the result, and**

**the result is not a device!**

This issue was to be discussed at a meeting in Brussels on 27-28 October of the Medical Devices Expert Group (MDEG), but has now been postponed until the next MDEG meeting on 15-17 December

I am not a member of that group, but I was given the opportunity of submitting papers in advance of the meeting

I expect to attend the December meeting to present the documentation

## Documents submitted from

- UK Clinical Virology Network (includes VRL Dublin)
- UK Health Protection Agency
- UK Supraregional Assay Service
- EC4 (European Clinical Chemistry)
- Swedish Committee for Standardisation in Laboratory Medicine
- Clinical Molecular Genetics Society (UK and Ireland)

*see file DKenny-MDEG.doc (647 KB)*

**Health warning:**

**Bureaucratic misinterpretation can  
be hazardous to your patients'  
health!**