In vitro diagnostic medical devices: security requirements

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The ESC endorsed the proposal and was pleased that the implementation of the in vitro diagnostic medical devices directive would remain in the hands of the Member States. This was a further indication that the concept of subsidiarity had been correctly understood by the Commission. The ESC noted that control materials for external quality assurance were expressly excluded from the scope of the draft Directive. This should be reviewed, at least in respect of stable control materials, which were frequently in no way different from those used for internal monitoring. In the ESC’s view, the directive should embrace all control materials, irrespective of the way in which they were used in medical laboratories. Exceptions could be made in the case of preparations using fresh blood, which could only be conserved for limited periods. The European standards bodies CEN/Cenelec should establish a standard in order to take account more effectively of the traceability requirement. It was important for users to continue to participate in the work of the working parties concerned on any future further development of the directive on in vitro diagnostic medical devices. The ESC considered that, particularly for self-testing devices, the ‘instructions for use’ should be in the language of the target country so that they could be understood by the users.