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TECHNICAL SURVEILLANCE OF THE CLINICAL LABORATORY

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The Law of July 1975 on clinical laboratories has made health inspectors (who are physicians or pharmacists) responsible for surveillance of the technical performance of clinical laboratories. Such surveillance is referred to as control of the proper conduct of clinical tests and will apply, as do the quality control activities of the National Health Laboratory, both to hospital laboratories and to private ones.

A decree is now being prepared in consultation, as provided by the Law of July 1975, with biologists. It begins by stating the purpose of surveillance of technical performance, which is to ascertain that:

- tests are in fact being performed by the laboratory;
- proper facilities exist for the collection of specimens when this is done at the laboratory, or for acceptance of specimens for further testing;
- the rules imposed by the procedures used in the laboratory are respected;
- results are expressed in a proper fashion.

The draft decree next lists the information or documents the clinical pathologist must make available to the health inspector, as follows:

- information on the procedures used;
- invoices for the purchase of reagents or the starting materials used in their preparation;
- the paper work relating to the performance of tests and to the methods used within the laboratory for supervision of its own work;
- the results of the quality control carried out by the National Health Laboratory on the laboratory's tests.

Elsewhere, the decree provides that in addition to checking the facilities for proper performance of tests, the health inspector may ask for tests of one or more specimens provided by the National Health Laboratory to be carried out in his presence under normal laboratory operating conditions.

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Lastly, the health inspector may call on the technical assistance of consultants designated by the Ministry of Health on the basis of their technical competence.

The Ministry of Health, in collaboration with the National School of Public Health, is already running one-week courses in hospital laboratories to give "refresher" training in biology to a number of health inspectors with special responsibility at departmental or regional level for the technical surveillance of clinical laboratories.

This is an ambitious scheme in view of the large number of public and private laboratories in France and the relatively small number of health inspectors. However, the link with the National Health Laboratory will allow health inspectors to concentrate their efforts on the laboratories that the quality control scheme has shown to be particularly weak.

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