— the quality records provided for in that part of the quality system concerned with manufacture, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

3.3. The notified body shall conduct periodic audits to make sure that the manufacturer is maintaining and applying the quality system; it shall provide the manufacturer with an audit report. The frequency of the periodic audits shall be such that a full reassessment is carried out every three years.

3.4. Moreover, the notified body may pay the manufacturer unannounced visits. The need for these additional visits and their frequency will be determined on the basis of a visit monitoring system managed by the notified body. In particular, the following factors will be taken into account in the visits monitoring system:

— the results of previous surveillance visits;

— the need to monitor remedial measures;

— where appropriate, special conditions attaching to approval of the system;

— significant modifications in the organisation of the manufacturing process, measures or techniques.

On the occasion of such visits, the notified body may, if necessary, carry out tests or have them carried out in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if a test was carried out, with a test report.

4. The manufacturer or his authorised representative shall keep available for the national authorities, for a period of ten years from the last date of manufacture:

— the documentation referred to in point 2.1;

— the decisions and reports of the notified body referred to in point 2.4, third and fourth subparagraphs, and in points 3.3 and 3.4.

ANNEX XI

MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES FOR THE NOTIFICATION OF BODIES

1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of machines which they inspect, nor the authorised representative of any of these parties. They shall not become involved, either directly or as authorised representatives, in the design, construction, marketing or maintenance of the machines. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.

2. The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.

3. For each category of machinery for which it is notified, the body must possess personnel with technical knowledge and sufficient and appropriate experience to perform a conformity assessment. It must have the means necessary to complete the technical and administrative tasks connected with implementation of the checks in an appropriate manner; it must also have access to the equipment necessary for the exceptional checks.

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4. The staff responsible for inspection shall have:

— sound technical and vocational training,

— satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,

— the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.

5. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.

6. The body shall take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.

7. The staff of the body shall be bound to observe professional secrecy with regard to all information obtained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.

8. Notified bodies shall participate in coordination activities. They shall also take part directly or be represented in European standardisation, or ensure that they know the situation in respect of relevant standards.

9. Member States may take all necessary measures they regard as necessary in order to ensure that, in the event of cessation of the activities of a notified body, the files of its customers are sent to another body or are made available to the Member State which has notified it.

ANNEX XII

CORRELATION TABLE

This table indicates the relation between parts of Directive 98/37/EC and the parts of this Directive that deal with the same subject. However, the content of the correlated parts is not necessarily identical.

Directive 98/37/EC	This Directive
Article 1(1)	Article 1(1)
Article 1(2)(a)	Article 2(a) and (b)
Article 1(2)(b)	Article 2(c)
Article 1(3)	Article 1(2)
Article 1(4)	Article 3
Article 1(5)	-
Article 2(1)	Article 4(1)
Article 2(2)	Article 15
Article 2(3)	Article 6(3)
Article 3	Article 5(1)(a)
Article 4(1)	Article 6(1)
Article 4(2), first subparagraph	Article 6(2)
Article 4(2), second subparagraph	-
Article 4(3)	-