ANNEX VIII

FULL QUALITY ASSURANCE

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality assurance system.

4.2. The manufacturer must allow the notified body entrance for inspection purposes to the locations of design, manufacture, inspection and testing, and storage and must provide it with all necessary information, in particular:

— the quality assurance system documentation

— the quality records as foreseen by the design part of the quality assurance system, such as results of analyses, calculations, tests, etc.

— the quality records as foreseen by the manufacturing part of the quality assurance system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body shall periodically carry out audits to make sure that the manufacturer maintains and applies the quality assurance system and must provide an audit report to the manufacturer.

4.4. Additionally the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may carry out, or cause to be carried out, tests to verify that the quality assurance system is functioning correctly, if necessary. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.