



QUESTIONNAIRE FOR INITIAL FACTORY ASSESSMENT

0. NOTE

- 0.1 This document shall be completed by the applicant and shall be returned together with the application form STA/1 and/or covering letter
0.2 Supplements may be included where it is necessary to expand any statements.
0.3 A separate document shall be completed for each factory involved.
0.4 The statements shall relate to the facilities available as of the date of completion of the form.
0.5 The information given in this document shall be treated in Confidence.

1. FACTORY ORGANIZATION

1.1. PROCEDURES/PAPER WORK

Please give the following information

- a). Do you produce against Orders or for Stock?

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- b). Do you issue a work Order or equivalent?

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- c). If so does this identify a batch as separate entity?

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- d). Do products and/or containers carry works order identification in manufacture?

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- e). If not how does system allow for products to be isolated in case of doubtful quality?

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1.2. QUALITY CONTROL/INSPECTION STAFF

Please give the following information on factory QC staff organization:

- a). Head of Quality Assurance, Qualifications, Training etc.

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Reporting to:

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b). Is there a separate Quality Control Inspection Department?

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c). If so indicate if staff are aware of the tests in the relevant standard(s).....

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d). Are Storemen/Production Operations responsible for inspection and test on

i). In-coming materials?

ii). In process operations?.....

iii). Final Products?

e). If so are they monitored by Quality Control Staff?

f). Are Quality Audit checks carried out and by whom?

g). Please give any other information on quality Control Staff Organization.....

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2. MATERIALS OR COMPONENTS:

2.1 PURCHASE SPECIFICATION/MATERIALS QUALITY ASSURANCE

a) Please detail main materials purchased, specification(s) used and major supplies involved.

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b) Please also give quality assurance method adopted on receipt of materials, or components indicating action taken on rejects.

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c) What storage facilities exist for in-coming materials and finished products?

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3. MANUFACTURE

3.1 SYSTEM

a) Please detail various steps in manufacture – A production schedule and /or supplement in chart form showing stages, which may be advantageous.

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3.2 MAINTENANCE SYSTEM – PLANT AND EQUIPMENT

a) What maintenance system is in operation?

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4. QUALITY CONTROL AND TESTING

4.1 SYSTEM

a) Please detail Quality Control System, including sampling followed with particular reference to the tests in the relevant Standard. A quality Control Schedule or supplement cross-reference to Chart required in 3.1 is advantageous.

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- b) Please attach a copy of the Quality Manual or instructions on Quality Control issued to staff.

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a) TEST EQUIPMENT/INSTRUMENTS, GAUGES AND TOOLS.

- a) Please detail test equipment used and if any of the production or test equipment are calibrated?

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- b) Indicate External arrangement for testing if any.

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5. **RECORDS AND DOCUMENTATION**

5.1 COMPLIANCE TO SPECIFICATION

- a) Please indicate level of defectives found in past six month. If tests in accordance with the relevant standard(s) have already been carried out attach copies of test reports if available.

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b) Please indicate the level of claims/complaints made under warranty and/or otherwise and also give as a percentage of total out put.

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c) Have independent tests been made on products against the standard? By whom? Please attach copies if available.

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6. AFFIXATION ON MARK OF CONFORMITY

a) Please attaché an illustration and indicate method e.g. special label, Embossing etc. which will be used to affix the Mark of Conformity. Please indicate at which stage of manufacture the Mark of Conformity will be affixed.

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