Annex 7
Guidelines for the preparation of a procurement agency information file

Introduction
A procurement agency information file (PAIF) is a document prepared by the procurement agency (PA) that contains specific and factual information about the operations carried out at the named site including any closely integrated operations of the PA.

A PAIF should be succinct and, if possible, should not exceed 25 A4 pages.

The PA should give a short description of its activities under each of the following headings. Where appropriate, supportive documentation should be appended.

1. General information
1.1 Brief information on the PA (including name, address and contact details).
1.2 Activities of PA as licensed by the national authority (including those listed below). (Attach a copy of the licence. Where a licence is not available, please state reasons.)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Performed by agency itself (mark X)</th>
<th>Contracted to: (give name and address of contractor)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-qualification of products and manufacturers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchasing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Storage</td>
<td></td>
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<tr>
<td>Distribution</td>
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</tbody>
</table>

1.3 Short description of the quality management system of the PA.
2. **Documentation**

2.1 Brief description of procedures for the preparation, revision and distribution of necessary documentation for pre-qualification, purchasing, quality control, storage and distribution.

2.2 Any other documentation related to product quality that is not mentioned elsewhere in this file.

2.3 Any other activities carried out on the site.

3. **Personnel**

3.1 Number of employees engaged in the following activities:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-qualification</td>
<td></td>
</tr>
<tr>
<td>Purchasing</td>
<td></td>
</tr>
<tr>
<td>Quality control</td>
<td></td>
</tr>
<tr>
<td>Storage</td>
<td></td>
</tr>
<tr>
<td>Distribution</td>
<td></td>
</tr>
</tbody>
</table>

3.2 Organization chart showing the arrangements for all departments (e.g. quality assurance, including pre-qualification, purchasing and quality control).

3.3 Qualifications, experience and responsibilities of key personnel.

3.4 Outline of arrangements for basic and in-service training and how records are maintained.

4. **Pre-qualification**

4.1 Brief description of general policy for pre-qualification of products manufactured by specific manufacturers.

4.2 Brief description of the pre-qualification procedure followed. Where possible, flow sheets and charts specifying important steps and standards for assessment of dossiers, suppliers and manufacturers, should be provided.
5. **Purchasing**
   5.1 Brief description of general policy for purchasing.
   5.2 Brief description of purchasing operations and procedures.
   5.3 Description of tender system used.

6. **Storage**
   6.1 Simple plan or description of storage areas, with indication of scale, including receiving, quarantine, returned goods, rejected goods, storage, staging and dispatch (architectural or engineering drawings not required).
   6.2 Nature of construction and finishes.
   6.3 Brief description of ventilation systems for storage areas with reference to control of temperature and relative humidity.
   6.4 Brief description of special areas for the handling of highly toxic, hazardous and sensitizing materials.
   6.5 Brief description of planned programmes for preventive maintenance of premises and of the system for recording these activities.

**Equipment**
6.6 Provide a list of equipment used in activities.
6.7 Brief description of computer systems used in all operations including quality control where relevant.

**Sanitation**
6.8 Brief description of procedures for cleaning.
6.9 Brief description of procedure for rodent and pest control.

7. **Handling of materials**
   7.1 Types of products stored on the site and information about any specifically toxic or hazardous substances handled.
   7.2 Brief description of the site (including access control, size, location, immediate environment and other activities carried out on the site).
   7.3 Brief description of procedures for the handling of products (e.g. receiving, quarantine, storage, stock rotation and issue of products).
   7.4 Brief description of procedure for release of products for storage after receipt and prior to distribution.
7.5 Brief description of procedure for the handling of rejected products.

7.6 Brief description of procedure for the handling of returned products.

8. **Distribution**
   8.1 Brief description of procedure and recording system for distribution of products (including packing for dispatch, handling of hazardous materials, cold chain management etc., where relevant).
   
   8.2 Brief description of procedure for release of products for dispatch.
   
   8.3 Brief description of procedure to verify that the recipient is authorized to receive the product(s).

9. **Complaints and product recall**
   9.1 Brief description of procedures for the handling of complaints and product recalls.

10. **Contract operations and activities**
    10.1 Brief description of the way in which the compliance with standards for activities that are contracted out is assessed.
    
    10.2 Brief description of the quality control system. (This could include, where relevant, the activities of a quality control laboratory, pre-shipment sampling and testing etc.)

11. **Self-inspection**
    11.1 Brief description of the self-inspection system.