Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reference: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

To:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Subject: **Information regarding a Testing Facility requesting extension.**

Organization seeking to extand their area of expertise or testing materials or facilitiy or other according to the GLP-OECD principles is requested to provide ISRAC the following documents:

1. Description of the testing facility, including the structure map and a clear indication of the new GLP areas.

2. Organizational structure and job descriptions that refer to the change:

2.1 GLP testing facility's Management;

2.2 GLP testing facility's Quality Assurance;

2.3 Study Director (SD);

2.4 Archive Manager;

2.5 IT (Information Technology) unit.

3. Officials CV for the personel described above.

4. A comprehensive and updated list of procedures of the testing facility including their versions number and indicating the changes.

As well as a copy of the procedures that describe the following processes:

Receiving, handling and storage of samples, Equipment-maintenance and calibration, Computerized system: validation, operation and their maintenance, Numbering of the studies, Collection procedure of raw data, including the use of computerized systems, Writing a study protocol, Writing a study report, Quality-assurance planning and performing internal audits, and the Quality Assurance plan for the testing facility.

5. Updated list of completed GLP studies. The list shall include at least 3 studies at the time of ISRAC's audit assessment, in each area of expertise.

6. A copy of one study protocol and report for each field of extansion.

7. Please complete the following table detailing the Areas of expertise relavant the this request.

Sincerely,

Head of GLP Division **Definition of the Areas of expertise of testing facilities according to the GLP principles**

|  |  |  |
| --- | --- | --- |
|  | 2Areas of expertise | 1List of Chemicals |
|  | Physical-chemical testing | a) Industrial Chemicals  b) Pharmaceuticals  c) Veterinary Medical Products  d) Pesticides  e) Food Additives  f) Feed Additives  g) Cosmetics  h) Biocides  i) Other Products  j) Medical Devices |
|  | Toxicity studies |
|  | Mutagenicity studies |
|  | Environmental toxicity studies on aquatic and terrestrial organisms |
|  | Studies on behavior in water, soil and air; bioaccumulation |
|  | Residue studies |
|  | Studies on effects on mesocosms and natural ecosystems |
|  | Analytical and clinical chemistry testing |
|  | Other studies, specify |

(1) whether they are prepartions or materials: from GLP agreement

(2) from GLP / OECD documents.

The definition of a research areas of the testing facility, operating in compliance with GLP principles is by defining an area of expertise and a chemical from the table above.

For example: a research facility specializing in analytical chemical studies of pesticides (6-f)

**Using the index above, please fill out the following table with GLP areas relevant to your research facility**:

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| J | I | H | G | F | E | D | C | B | A | Test items |  |
|  |  |  |  |  |  |  |  |  |  | Physical-chemical testing | 1. |
|  |  |  |  |  |  |  |  |  |  | Toxicity testing | 2. |
|  |  |  |  |  |  |  |  |  |  | Mutagenicity testing | 3. |
|  |  |  |  |  |  |  |  |  |  | Environmental toxicity studies on aquatic and terrestrial organisms | 4. |
|  |  |  |  |  |  |  |  |  |  | Studies on behavior in water, soil and air; bioaccumulation | 5. |
|  |  |  |  |  |  |  |  |  |  | Residue studies | 6. |
|  |  |  |  |  |  |  |  |  |  | Studies on effects on mesocosms and natural ecosystems | 7. |
|  |  |  |  |  |  |  |  |  |  | Analytical and clinical chemistry testing | 8. |
|  |  |  |  |  |  |  |  |  |  | Other studies, specify: | 9. |

|  |  |
| --- | --- |
| Testing facility's Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Name of Person of Contact: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |