

ROYAL GOVERNMENT OF BHUTAN

ROYAL GOVERNMENT OF BHUTAN MINISTRY OF HEALTH BHUTAN FOOD AND DRUG AUTHORITY



INSPECTION SERVICES

PROCEDURE FOR MAINTAINING CONFIDENTIALITY OF DATA AND INFORMATION

1. PURPOSE

To enforce strict regime of confidentiality of data and information during the operation of Inspection.

2. SCOPE

This procedure covers all Inspection activities operated by BFDA-IS in accordance with ISO/IEC 17020:2012.

3. RESPONSIBILITY

- **3.1** Director is responsible defining the responsibilities and obligation of the BFDA and the clients.
- **3.2** Respective Chiefs, PABD and FQSD is responsible to ensure implementation of this procedure.
- **3.3** Technical focal Officer is responsible to ensure that confidentiality of information is maintained by its personnel, staffs, Committee Members, Inspector and subcontracted Inspectors.

4. PROCEDURE

- **4.1** BFDA-IS requires personnel to safeguard the confidentiality of the information obtained or created during the performance of Inspection activities. Except for information that the client makes publicly available, or when agreed between BFDA-IS and the client, all other information is considered proprietary information and shall be regarded as confidential. BFDA-IS shall inform the client, in advance, of the information it intends to place in the public domain.
- **4.2** When BFDA-IS is required by law or authorized by contractual arrangements to release confidential information, the client or person concerned shall, unless prohibited by law, be notified of the information provided.
- **4.3** Information about the client obtained from sources other than the client such as complainant, regulators during the process of Inspection, is treated as confidential.
- **4.4** BFDA-IS is responsible for ensuring that confidentiality of information is maintained by its personnel and those of its subcontractors concerning all information obtained as a result of their contacts/interaction with the clients. For ensuring adherence of this provision, BFDA-IS takes signed confidentiality statement from all its personnel on payroll and subcontractors including committee members, during each inspection or committee meeting.

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<u> २५०१.५४.५च्यामबिरः। गङ्ग्याज्ञेषामम</u> उर्चेग्याच्याःक्रन्यःस्थ्रेषःमुग्यान्यरः यह्न्यी

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- **4.5** BFDA-IS has arrangements for securing, handling, storage and transmission of confidential information through:
- a) restricted access to Inspection division and providing lockable arrangement to the division,
- b) all computers used by officers have passwords to avoid access to information therein by others,
- c) all cabinets and cupboard containing files and information are kept under lock and key,
- d) files move under confidential cover from one place to another
- **4.6** When confidential information is made available to other bodies such as accreditation body and agreement group of a peer assessment scheme, BFDA-IS shall inform its client of this action, in advance, through agreements, etc.

5. REFERENCES

Food Act of Bhutan, 2005

Food Rules and Regulations of Bhutan 2017

BFDA-IS-PR-16 Procedure for Control of Records

BFDA-IS- PR-14 Procedure for Publicly Available Information

BFDA-IS-FM-02 Form: Confidentiality and Impartiality Statement from Officer/Inspector/Staff

BFDA-IS-FM-01 Form: Confidentiality Statement from Committee Members

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