



དཔལ་ལྷན་འབྲུག་གཞུང་། གསོ་བ་ལྷན་ཁག་འབྲུག་བཟའ་ཆས་དང་སློན་རིགས་དབང་འཛིན།

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



PROCEDURE FOR MANAGEMENT OF IMPARTIALITY AND CONFLICT OF
INTEREST

1. PURPOSE

To provide a framework for operation of Inspection Schemes in an objective and impartial manner.

2. SCOPE

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

2. RESPONSIBILITY

Director is responsible for management of impartiality in the Inspection operation.

Respective Chiefs, PABD and FQSD is responsible to ensure implementing management of impartiality in the Inspection operation.

The Technical focal officer is responsible for calling Impartiality Committee meeting, preparing the minutes and taking follow up actions.

4. PROCEDURE

4.1 BFDA-IS has the status of regulatory body in Bhutan and thus a non- profit government organization and so does not have commercial and financial pressure.

4.2 BFDA-IS undertakes Inspection activities in an impartial manner without any discrimination.

4.3 BFDA-IS is responsible for the impartiality of its Inspection activities and do not allow commercial, financial or other pressures to compromise impartiality.

4.4 BFDA-IS identifies risks to its impartiality at least on an annual basis (See BFDA-IS FM-26) or any changes in the structure or any incident. This includes those risks that arise from its activities, from its relationships, or from the relationships of its personnel. But such relationships do not necessarily present BFDA-IS with a risk to impartiality and mitigation measures provided.

4.5 Risk analysis conducted has taken into account relationship that threatens the impartiality of BFDA-IS based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new clients, etc. It is a continuous process to identify risk to impartiality as and when it occurs on account of changes/ incidents taking place or annually basis and it is demonstrated how BFDA-IS eliminates or minimizes such risks. This information is made available to the Impartiality Committee.

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4.6 BFDA-IS has top management's commitment to impartiality and has made a public statement to adhere to impartiality:

STATEMENT OF IMPARTIALITY

The Management of Bhutan Food and Drug Authority Inspection Services (BFDA-IS) recognizes and understands the importance of being impartial.

While carrying out all its inspection activities, the commitment to impartiality is upheld through:

- Identification and elimination of any potential conflict of interest
- Ensuring impartiality of inspection personnel
- Maintaining objectivity of management system of BFDA-IS

Director
Bhutan Food and Drug Authority

4.7 BFDA has the board, the highest policy making body and other supporting systems such as Inspection committee and the Head to assure impartiality and independence of inspection activity. BFDA's Impartiality Committee, on which a broad-spectrum of interests is represented without any predominance by any one's interest, monitors the functioning of Inspection activity with respect to Impartiality of the functioning of BFDA's Inspection schemes.

4.8 BFDA-IS under its organizational control shall not:

- a) be the designer, manufacturer, installer, distributor or maintainer of the inspected product,
- b) be the designer, implementer, provider or maintainer of the inspected service,
- c) be the designer, implementer, operator or maintainer of the inspected process,
- d) offer or provide consultancy to its clients related to the inspected products, services or processes,
- e) offer or provide management system consultancy or internal auditing to its clients where the inspection scheme requires the evaluation of the client's management system.

This does not preclude:

- the possibility of exchange of information (e.g. explanations of findings or clarifying requirements) between BFDA-IS and its clients and

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- the use, installing and maintaining of inspected products which are necessary for the operations of the BFDA-IS.

4.9 BFDA-IS ensures that activities of separate legal entities with which the BFDA forms a part, do not compromise the impartiality of its Inspection activities. This situation is not visualized in the BFDA's set up and this has been ensured while constituting Impartiality Committee.

4.10 When the separate legal entity in future offer or produce the inspected product or offers or provides consultancy related to the inspected product, BFDA-IS's management personnel and personnel in the review and inspection decision making process are not involved in the activities of the separate legal entity. The personnel of the separate legal entity are not involved in the management of BFDA-IS, the review, nor inspection decision.

4.11 BFDA-IS's activities are not marketed or offered as linked with the activities of an organization that provides consultancy. BFDA-IS do not state or imply that inspection activities would be simpler, easier, faster or less expensive if a specified consultancy organization were used.

4.12 BFDA-IS does not allow personnel for two years to review or make an inspection decision for a product for which they have provided consultancy. The period of two years has been specified in the inspection scheme which has been considered long enough to allow personnel to review or to take decision and will not compromise impartiality.

4.13 BFDA-IS takes action to respond to any risks to its impartiality arising from the actions of other persons, bodies or organizations associated with it, when it becomes aware.

4.14 All BFDA-IS personnel, either internal or external, or committees, who could influence the Inspection activities, act impartially. The Impartiality statements are required to be signed during each inspection or committee meeting.

4.15 The personnel involved in BFDA-IS inspection activities shall not be remunerated in a way that influences the results of inspections.

5. REFERENCES

BFDA-IS -PR-15 Procedure for Operation of Impartiality Committee

BFDA-IS -FM-26 Form: Risk Assessment of Conflict of Interest.

BFDA-IS-FM-02 Form: Confidentiality Statement from Audit Team Members.

Annexure A: Requirement for Inspection Bodies

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