र्नाता.र्जेष.पर्विधा.यार्थेटा. वार्जु.च.र्जेष.ायवा पर्विधा.यज्ञप.क्रश.रेटः.श्रेष.द्रवाल.रेचटः.पह्नुषी

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



PROCEDURE FOR OPERATION OF IMPARTIALITY COMMITTEE

1. PURPOSE

To ensure that decisions taken on the inspection are impartial and free from any conflict of interest.

2. SCOPE

This procedure covers how to safeguard impartiality in the operation of inspection activities operated by BFDA-IS in accordance with ISO/IEC 17020:2012.

3. RESPONSIBILITY

Director is responsible for composition of Impartiality Committee representing concerned stakeholders.

Respective Chiefs, PABD and FQSD is responsible to develop this procedure and ensure its implementation.

Technical Focal Officer is responsible for convening the meeting and maintaining records.

4. PROCEDURE

4.1 Composition

- **4.1.1** BFDA-IS has constituted an impartiality committee well represented by the stakeholders for safeguarding its impartiality.
- **4.1.2** Although every interest cannot be represented in the committee, BFDA identifies and invites key interest and feedback from clients of the BFDA-IS, customers of organizations whose products are inspected, manufacturers, suppliers, users, and conformity assessment experts, representatives of industry trade associations, representatives of governmental regulatory bodies or other governmental services, or representatives of non-governmental organizations, including consumer organizations, administrative institutions. These interests are limited depending on the nature of the inspection scheme.
- **4.1.3** The Committee members vote to elect the Chair from among themselves annually.

4.2 Terms of Reference

4.2.1 This committee provides:

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- a) the policies and principles relating to the impartiality of its inspection activities,
- b) periodic review of the schemes including confirmation that it is fulfilling its objectives and it is operated in a consistent manner,
- c) counteracting any tendency on the part of IS to allow commercial or other considerations to prevent the consistent impartial provision of inspection activities,
- d) advise on matters affecting impartiality and confidence in inspection, including openness and public perception.
- e) conduct a review, as least once annually, of the impartiality of the inspection and decision making processes of BFDA-IS.
- f) approve the conflict of interest analysis and the mitigation measures prepared by BFDA IS to ensure impartiality.
- **4.2.2** The impartiality Committee oversees impartiality in the operation of inspection services proved by BFDA.

4.3 Committee Deliberations

- **4.3.1** The committee is formally documented to ensure a balanced representation of significantly interested parties such that no single interest predominates and access to all the information necessary to enable it to fulfil all its functions.
- **4.3.2** The meeting of the committee is held at least once in a year and notice of 7 working days is given for convening the meeting. In case of emergency, meeting may be held within 24 hours' notice.
- **4.3.3** All decisions are taken by majority vote and third-third of the member will form the quorum.
- **4.3.4** If the top management of the BFDA-IS does not follow the advice of this committee, the chairman has the right to take independent action of informing authorities, accreditation bodies, stakeholders, etc. In taking appropriate action, the confidentiality requirements relating to the client and BFDA shall be respected.

4.4 Post meeting actions.

- i) The minutes of the meeting are prepared and after obtaining approval from the chairman circulated to the members of the Committee.
- ii) Follow up actions are initiated and concerned members/areas involved are informed to take action arising out of the meeting.

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PROCEDURE FOR OPERATION OF IMPARTIALITY COMMITTEE 5. REFERENCES

Food Act of Bhutan, 2005
Food Rules and Regulations of Bhutan 2017
BFDA-IS-PR-02 Procedure for Management of Impartiality and Conflict of Interest
BFDA-IS-PR-03 Procedure for Maintaining Confidentiality of Data and
Information BFDA-IS-FM-21 Minutes of meeting

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