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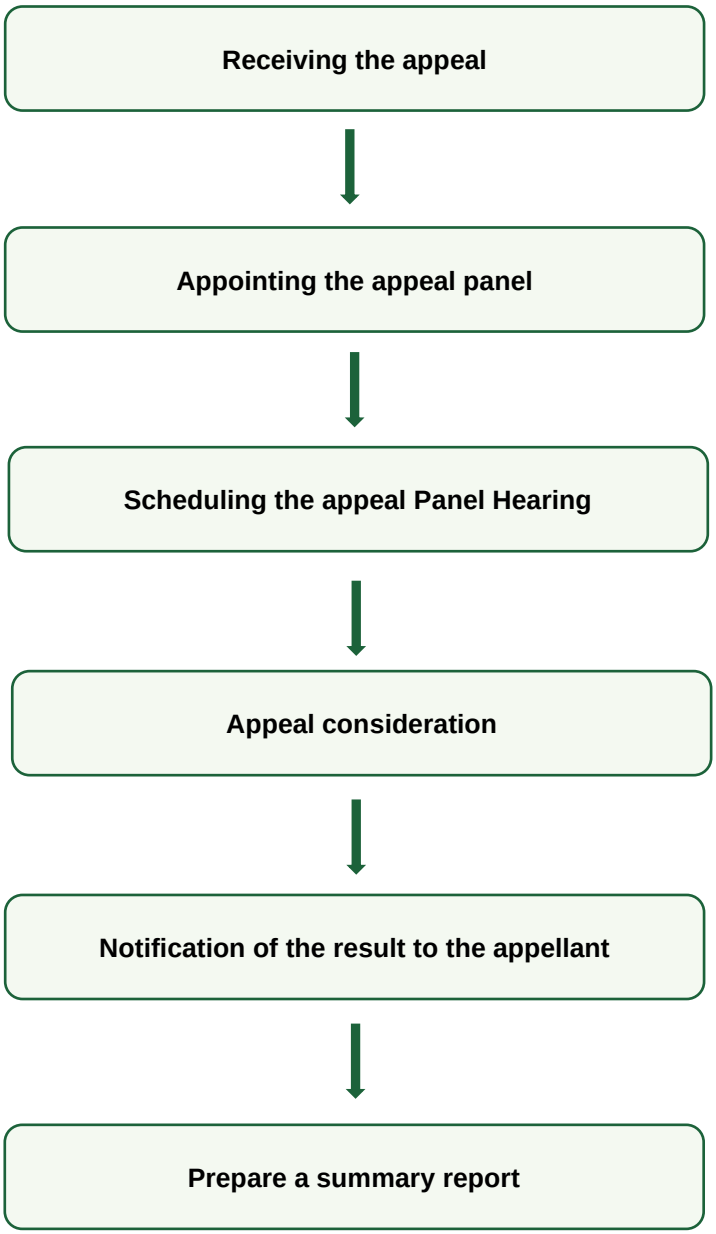
APPEAL PROCEDURE

Roles and responsibilities and appeal handling process.



1. **Receiving the appeal**

   a. Upon receipt of a written appeal, the CEO of NIOSHCert shall task the General Manager or another designated individual to gather and verify all necessary information for evaluation the validity of the appeal. Then, a written appeal shall be given to the Sustainability Division for officially register. The Appellant shall be notified of the receipt of the appeal and that it is being evaluated. The notification shall be sent to the appellant within 7 working days of the date of its receipt.

2. **Appointing the Appeal Panel**

   a. After gathering and verifying all necessary information for evaluation the validity of the appeal, the CEO/GM of NIOSHCert shall appoint minimum 3 people to be members of an Appeal Panel. One of the members of the Appeal Panel shall be appointed as the chairperson. The members of the Appeal Panel shall be independent and have no conflict of interest with the appeal in any way according to CAS 04 Procedure for Independence, Impartiality and Confidentiality.

   b. MSC Manager shall assume the non-voting role of the secretary of the Appeal Panel. The secretary of the Appeal Panel shall notify the appointment of the Appeal Panel to the appellant for concurrence, and inform other concerned parties.

3. **Scheduling the Appeal Panel Hearing**

   a. The secretary of the Appeal Panel shall schedule the Appeal Panel Hearing within 20 working days of the date of an appeal receipt. The appellant shall be notified of the date, time and place of the hearing at least 5 working days before the hearing.

4. **Appeal consideration**

   a. Considering the appeal

      i. The Appeal Panel has the right to hear the explanations from the witness and/or consult with external technical experts and/or take any measure and/or any actions, including arranging meetings as necessary to make right decision.

      ii. NIOSHCert personnel and external technical experts who are related to the appeal shall provide all requested information to the Appeal Panel and shall not withhold or conceal any parts of that information. The members of the Appeal Panel shall hold in confidentiality all information generated during the appeal process related to the appellant’s business/organization.

      iii. The members of the Appeal Panel shall hold in confidentiality all information generated during the appeal process related to the appellant’s business/organization.

b. Judging the appeal

i. The Appeal Panel shall judge the appeal with fairness by using a majority rule voting process. The appeal process shall be completed within 45 working days of the date of an appeal receipt.

ii. Every Appeal Panel member shall sign the appeal decision.

iii. The secretary of the Appeal Panel shall notify the decision with explanation to the President within 5 working days from the date of decision.

5. Notification of the result to the appellant

a. The appellant shall be notified of decision with explanation by the CEO of NIOSHCert or General Manager or MSC Manager Manager within 10 working days from the date of decision.

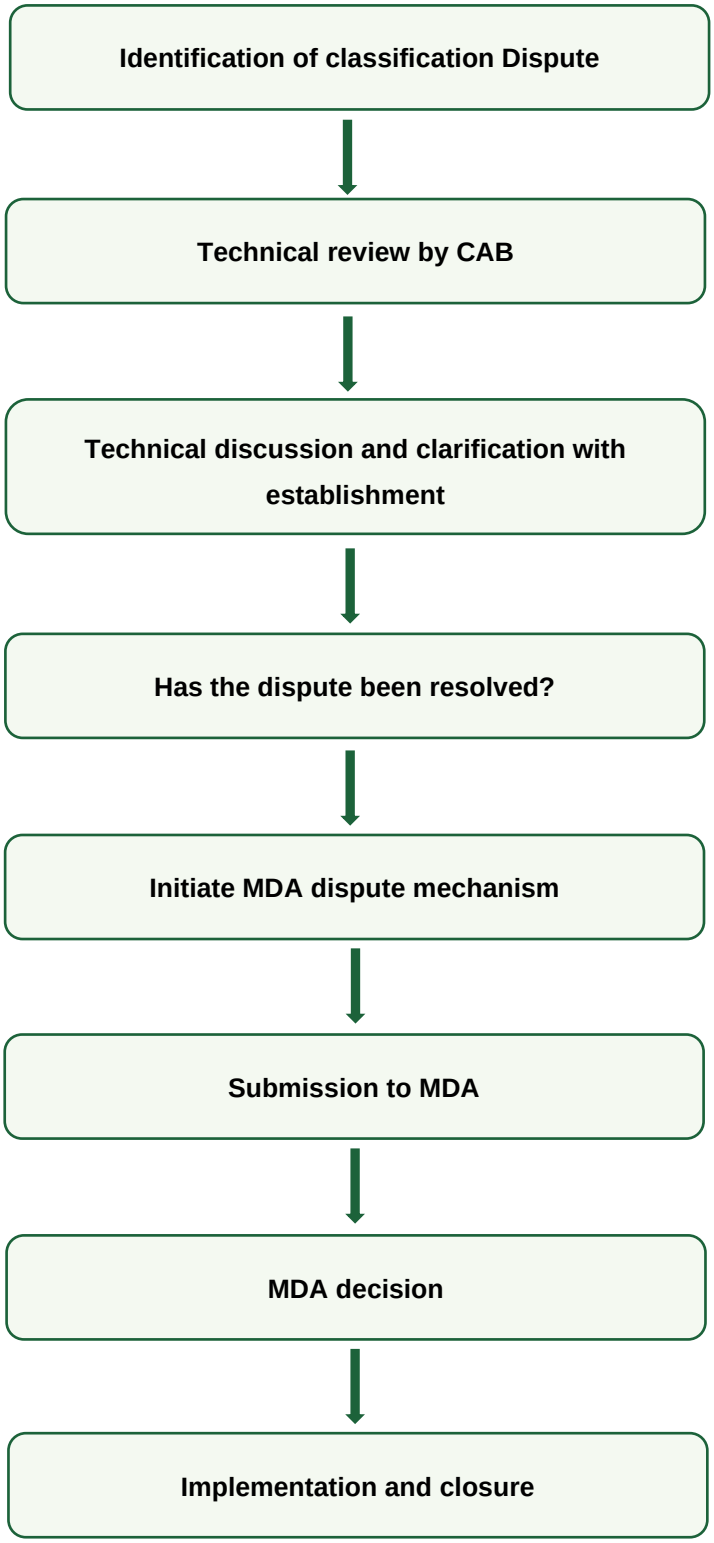
b. In case the appellant is not satisfied with the decision of the appeal panel, NIOSHCert shall inform the appellant that it has an option of complaining to the Appeal Panel.

6. Prepare a summary report

a. The secretary of the Appeal Panel shall prepare a summary report and inform all concerned parties of any actions that need to be taken as a result of the decision.

b. If the investigation points towards a non-conformance, MSC Manager and MSC Technical Officer shall take corrective action according to CAP 09 Corrective and Preventive Action Procedure , and prepare an appeals handling summary report for management review according to CAP 07 Management Review. The cost for conducting an appeals procedure shall be covered by the appellant. The secretary of the Appeal Panel will inform Corporate Division (Finance Unit) for an appeals fee billing except in case the appealing applicant is given right.

PROCESS FLOW FOR HANDLING DISPUTES ON MEDICAL DEVICE RISK CLASSIFICATION



1. **Identification of classification dispute**

Trigger:

A difference of opinion arises between the Establishment and CAB regarding the applicable medical device risk classification and/or classification rule.

Process:

a. The Establishment presents its proposed risk classification and the basis for the classification.
b. The CAB identifies and records the area(s) of disagreement.
c. The dispute should be clearly defined before proceeding to technical review.
d. The relevant device, intended purpose and classification rule under dispute should be identified.

Output:

Documented identification of the classification issue/dispute.

2. **Technical review by CAB**

Process:

The CAB conducts a technical review of the Establishment's proposed classification based on the available information and applicable requirements.

The review should consider, where applicable:

a. intended purpose of the device;
b. device description and function;
c. device configuration;
d. mode of operation;
e. applicable classification rule;
f. characteristics relevant to determining the risk classification;
g. supporting technical documentation/evidence; and
h. rationale provided by the Establishment.

The CAB should document the technical basis supporting its classification position.

Output:

Documented CAB technical assessment and classification position.

3. **Technical discussion and clarification with establishment**

Process:

The CAB and Establishment discuss the respective classification positions to determine whether the difference can be resolved through clarification of the technical information, classification rule or supporting evidence.

The discussion should:

a. clearly identify the basis of each party's position;
b. allow the Establishment to provide additional clarification or supporting evidence, where
c. applicable;
d. allow the CAB to explain the technical basis for its position;
e. identify any misunderstanding, missing information or difference in interpretation; and
f. ensure that the discussion and relevant supporting information are documented.

Important:

This stage is intended to facilitate technical clarification and resolution between the parties. It should not be interpreted as replacing the MDA dispute mechanism where the classification disagreement remains unresolved.

Output:

Documented outcome of the technical discussion.

4. **Has the dispute been resolved?**

If YES:

a. Confirm and document the agreed risk classification and/or applicable classification rule.
b. Ensure the basis for the resolution is supported by appropriate technical evidence.
c. Update the relevant assessment and classification records.
d. Retain the documented resolution and supporting evidence.

If NO:

a. Proceed to the MDA dispute mechanism.

5. Initiate MDA dispute mechanism

Where the Establishment and CAB are unable to resolve the classification dispute through the technical review and clarification process, the matter may be referred through the applicable MDA dispute mechanism.

Process:

a. Obtain and complete MDA/BKPP/DCR/01 – Dispute Classification Risk Application Form.
b. Compile the information and supporting documentation required by MDA.
c. Clearly describe the classification issue and the respective positions of the Establishment and
d. CAB.
e. Provide the technical basis and supporting evidence relevant to the disputed classification.
f. Ensure the submitted information is complete, accurate and consistent with the records
g. available from the assessment.

Purpose of the application:

The form is used to provide MDA with the relevant information for consideration and resolution of the dispute concerning the medical device risk classification between the Establishment and CAB.

Output:

Completed MDA dispute classification application and supporting documentation.

6. Submission to MDA

Process:

Submit the completed dispute application and supporting information to the applicable MDA channel:

- GMD: registration@mda.gov.my
- IVD: ivd.registration@mda.gov.my

The submission and relevant correspondence should be retained as part of the dispute record.

Output:

Documented submission to MDA.

7. MDA decision

Process:

a. Upon receiving the MDA decision:
b. record the decision in the relevant dispute/assessment records;
c. communicate the decision to the relevant parties;
d. review the impact of the decision on the ongoing assessment or certification process; and
e. ensure the MDA decision is implemented accordingly.

The existing draft states that the applicant is required to comply with the MDA decision and that the decision is final.

Output:

Recorded and communicated MDA decision.

8. Implementation and closure

Process:

Following resolution of the dispute:

a. implement the applicable risk classification and/or classification rule; update the assessment records;
b. update relevant technical and classification documentation;
c. revise other affected records, where applicable;
d. ensure consistency of the classification information across relevant documents; and
e. retain the complete dispute record, including the initial dispute, technical review, correspondence, supporting evidence, MDA submission and MDA decision.

Closure:

The dispute is considered closed once the applicable classification has been established and all affected records and processes have been appropriately updated.

Output:

Updated records and documented closure of the dispute.