ANNEX B

General Guidelines in Accomplishing the Assessment Forms (AF) for Self-Assessment

1. Applicants shall download the applicable AFs at the FDA website - *Downloadables* Section (https://www.fda.gov.ph/downloadables/) for Self-assessment.

2. Documentary evidence, attachments, and supporting files to the AF used for self-assessment shall be required for **virtual pre-licensing inspections only**, applicants shall upload the AF and its attachments to an online cloud folder before the conduct of inspection.

3. Applicants shall accomplish and submit the AF used for self-assessment through the email used for notification before the conduct of Pre-Licensing Inspection.

4. The facility shall write/encode all necessary details in the AF used for self-assessment. Important details such as serial numbers and brand names shall reflect the same details provided in the applicant's License Application Form (LAF).

5. Use a check (✓), (X) or N/A mark in filling out the checklist and provide necessary details in writing where applicable.

6. Attach to the General AF, all Specific AF per machine being applied for as outlined in the machine list provided.

7. The copy of accomplished and verified AF shall be kept by the facility to be used for every conduct of regulatory inspection to check for continuous compliance.