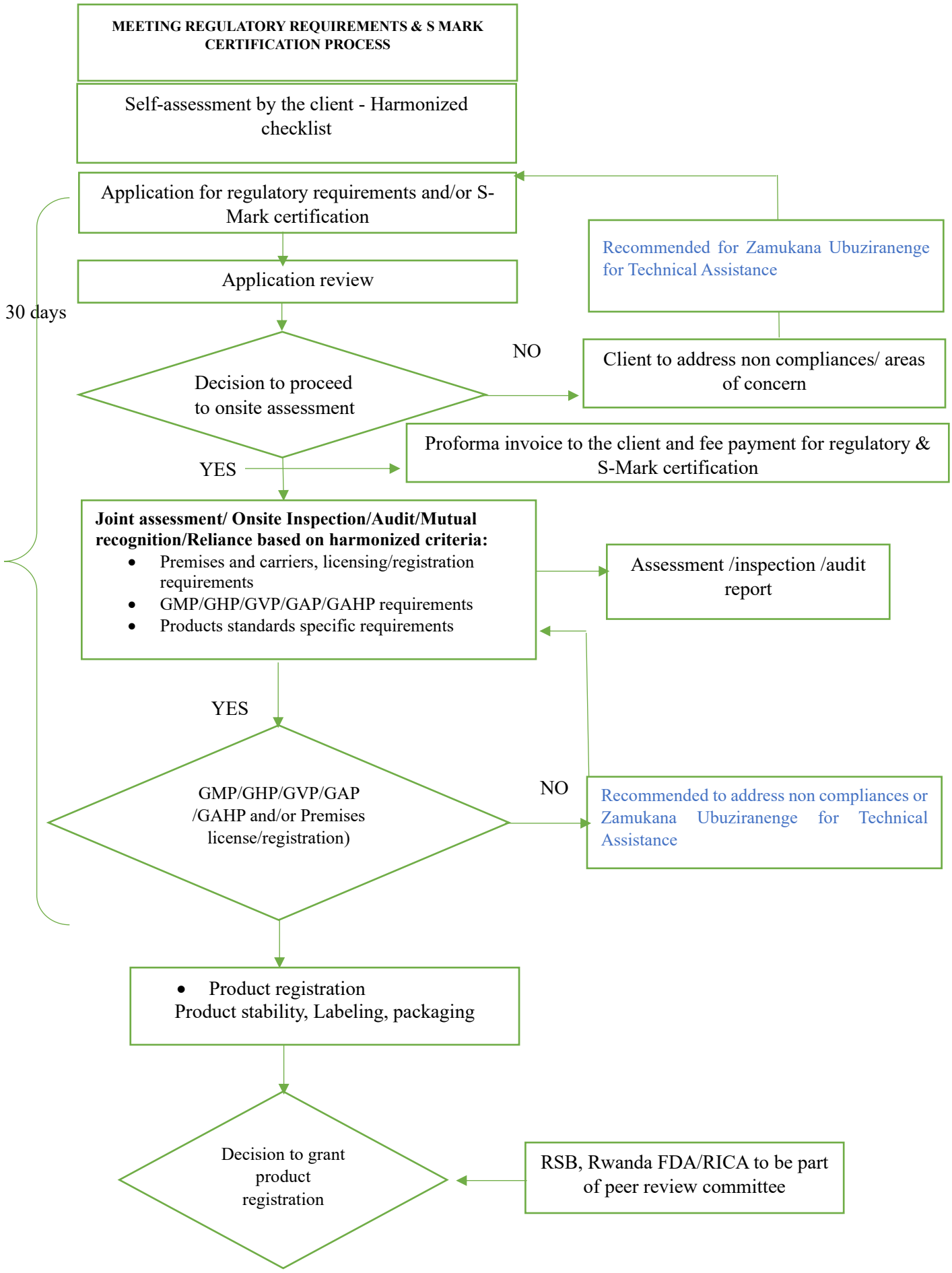
HARMONIZED FLOW DIAGRAM FOR REGULATORY REQUIREMENTS & S MARK CERTIFICATION REQUIREMENTS



HARMO ORY REQUIREMENTS & S MARK EMENTS

- Statutory requirements (EAC regulation on Products Certification)
- Standards specific requirements (ISO IEC 17065 & ISO IEC 17067)
- S-Mark certification requirements specific to the Certification Body

30 days

Decision to grant S-Mark

RSB, Rwanda FDA/RICA to be part of the CDC for products under their respective mandates

Granting certification of conformity, S-Mark valid for 5 years renewable+ issuance of certification documents+ Listing on Directory of S-Mark certified products

Joint Surveillance audits/inspections at the company premises

Joint Market surveillance/ inspections, sampling of the products for testing

Re-certification/ renewal of regulatory licenses (3 months prior the expiration of certificate of conformity/ registration certificate)