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4.2.1 Scope of Boundaries

Based on an analysis of the above issues of concern, interests of stakeholders, and in consideration of our Products and Services, BAI has determined the scope of the management system as follows:

- **Veterinary Laboratory Testing Services for animal diseases, feeds, veterinary drugs and biologics**
- **Issuance of permits, licenses, clearance and certificates on veterinary quarantine services**
- **Issuance of permits, licenses, registration/accreditation certificates on animal facilities/farms, animal shows/organizers/veterinarians, good animal husbandry practice, livestock handlers/transport carriers**
- **Issuance of permits, licenses, registration/accreditation certificates for feeds, veterinary drugs and biologics**
- **Production of veterinary vaccines and pharmaceutical products**
- **Laboratory Animal Production for Vaccine Testing**
- **Livestock Research and development**

4.2.2 Facilities Within the Scope

The quality system applies to all processes, activities, and employees of the following locations within the company:


BUREAU OF ANIMAL INDUSTRY	Visayas Avenue, Diliman, Quezon City
Laboratory Animal Production Unit	Lagalag, Tiaong, Quezon Province

4.2.3 Permissible Exclusions

The company claims no exclusions from the ISO 9001:2015 standards.

The following sites are excluded from the company quality system at this time. In the future, these stations and centers may be incorporated into the company QMS and this manual will be updated accordingly.

Regional Veterinary Quarantine Stations (12)
National Beef Cattle Research and Development Centers (NBCRDC)
National Swine and Poultry Research and Development Center (NSPRDC)
National Feed Resources Research Development (NFRRDC)
National Small Ruminant Research Development (NSRRDC)

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4.2.4 Scope of the BAI Processes

This manual is prepared for the purpose of defining the company's interpretations of the ISO 9001:2015 international standard, as well as to demonstrate how the organization complies with that standard.


This manual follows the numbering structure of ISO 9001:2015 standard.

All the activities performed by the BAI at the Central Office shall be included in the QMS except those excluded above.


CORE PROCESS
1. Animal Feeds Veterinary Drugs and Biologics Control Division
1. Registration of Animal Feed, Veterinary Drugs and Biological Products
2. Licensing of Animal Feeds, Veterinary Drugs, Biological Product Establishments
3. Accreditation of Rendering Plants (Local and Foreign)
4. Issuance of SPS import clearance
5. Issuance of Import and Export Commodity clearance
2. Animal Health and Welfare Division
1. Registration of Animal Facilities for compliance to Animal Welfare Act
2. Good Animal Husbandry Practices Certification of Animal farms
3. Accreditation of Animal facilities for Local Transport (in support for NVQSD)
4. Registration of Transport carriers and Handlers
5. Disease control, prevention and eradication
6. Accreditation of Animal Breeder Farms
7. Issuance of Permit on the use of Animals for Laboratory Procedures
8. Accreditation of Animal Shows/Organizers/Veterinarians
3. Livestock Research and Development Division
1. Conduct of Seminars on Livestock and Poultry Production
2. Availment of Biogas Technology Demonstration Unit
3. Conduct of Research
4. Preparation of Research Proposal
5. Technical Assistance on BAI Developed Technologies
6. Production of IEC Materials
7. Conduct of Seminar on Organic Agriculture
8. Animal Stocks Distribution Through NOAP
4. National Veterinary Quarantine Services Division
1. Issuance of Local Shipping Permit
2. Issuance of Export Commodity Clearance
3. Issuance of SPS Import Certificate/Veterinary Quarantine Clearance

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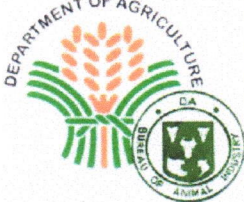
4. Issuance of International Veterinary Certificate
5. Accreditation of Foreign live animal establishments
6. Inspection of Veterinary Quarantine Site (pre-border)
7. Inspection of Veterinary Quarantine Site (during 30 days upon arrival)
8. Issuance of Quarantine Policies and Guidelines
9. Accreditation of Animal products importer
5. Veterinary Laboratory Division
<u>Bacterial Veterinary Biologics Production Laboratory</u>
1. Production of Hemorrhagic septicemia vaccine
2. Production of Anthrax spore vaccine
3. Preparation of Anthrax Master Seed Lot
<u>Viral Veterinary Biologics Production Laboratory</u>
1. Production of Newcastle disease vaccine
2. Production of ND disease antigen for HIT
3. Production for Infectious Bursal Disease (IBD) antigen for APT
4. Production for Reovirus antigen for AGPT
5. Production of Egg-Drop Syndrome (EDS) antigen for HIT
6. In-House Quality Control Testing for Vaccine and Concentrate
7. Test Procedure for HA, HI and AGPT
<u>Laboratory Animal Production Unit</u>
1. Production of piglets
2. Production of Poultry foundation stock
3. Production of embryonated eggs
4. Production day-old and 4-week old chicks
5. Production of Laboratory Mice
6. Production of Rabbits
7. Animal Management Matrix
<u>Veterinary Drug Production Section</u>
1. Production of injectable products
2. Production of topical products
<u>Chemical Feed Analysis Section</u>
1. Receiving and Preparing of Samples for Analysis
2. Preparing and Releasing of Certificate of Analysis Report (CAR)
3. Crude Protein Analysis
4. Crude Fat Analysis
5. Moisture Analysis
6. Ash Analysis
7. Calcium analysis
8. Phosphorous Analysis
9. Sodium Chloride Analysis
10. Trace Mineral Analysis

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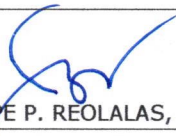
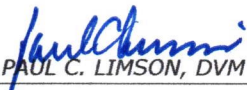
11. Fluorine Analysis
12. Urease Analysis
13. Protein Solubility
14. Gross Energy
15. Lysine HCl
16. L-Methionine, L-Threonine, L-Tryptophan
17. pH-value
18. Free fatty Acids
19. Lactose Analysis
20. Feed Microscopy
21. Water soluble Vitamins – B1, B2, B3, B6 and C
22. Fatsoluble Vitamins - Vit. A, D, E (HPLC Method)
23. Vitamin C Analysis
24. Doxycycline HCl/Hyclate, Chlortetracycline HCl, Oxytetracycline HCl, Ciprofloxacin HCl, Amprolium (UV-Vis Method)
25. Norfloxacin HCl, Enrofloxacin HCl (UV-Vis Method)
26. Amoxicillin Trihydrate, Florfenicol, Cephalexin (UV-Vis Method)
27. Sulfa drugs (UV-Vis Method)
28. Ivermectin (UV-Vis method)
29. Trimethoprim (UV-Vis Method)
30. Amoxicillin (HPLC Method)
31. Lincomycin HCl (HPLC Method)
32. Calcium Gluconate (Titrimetry Method)
33. TMPS (HPLC Method)
34. Albendazole (Titrimetry method)
35. Acetic acid, Citric acid and Phosphoric acid (Titrimetry method)
36. Benzalkonium Chloride (Titrimetry method)
37. Calcium Gluconate (Titrimetry method)
38. Dimetridazole (Titrimetry method)
39. Fenbendazole (Titrimetry method)
40. Tiamulin and Tiamulin Hydrogen Fumarate (Titrimetry method)
41. Glutaraldehyde (Titrimetry method)
42. Iodine (Titrimetry method)
43. Propionic acid (Titrimetry method)
44. Sodium Bicarbonate (Titrimetry method)
45. Choline Chloride (Gravimetric Method)
46. Chloramphenicol (HPLC, ELISA Methods)
47. Salbutamol (HPLC Method)
48. Furazolidone (HPLC Method)
49. Tetracycline (ELISA Method)
50. Aflatoxin Analysis

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51. Method Validation
52. Levamisole
53. Moisture-Free Analysis
54. Fiber Analysis (Tea Bag Technique)
55. Biotin (Titrimetric Method)
<u>Veterinary Biologics Assay Section</u>
1. Safety Test for Veterinary Biologics
2. Potency Test for Inactivated Egg Drop Syndrome (EDS) and ND
3. Hemagglutination-Hemagglutination Inhibition Test
4. Potency Test for Poultry Viral Live Vaccine
5. Potency Test of Anthrax Spore Vaccine by Viable Spore Count
6. Potency test for Hemorrhagic Septicemia Vaccine
7. Preparation and Computation of 100 mouse LD50 challenge HS organism
8. Sterility Test for Veterinary Biologics
<u>Animal Disease Diagnosis and Reference Laboratory</u>
1. Gross Pathology
2. Histopathology
3. Clinical Pathology
4. Viral Isolation and Identification
5. Agar gel Precipitation Test/AGID for AI and EIA
6. ELISA Test – Brucella, AI virus, Trichinella, Toxoplasma, Babesia, Blue Tongue virus, Lentivirus, CSF virus/antibody, PCV2, PEDV, PRRSV, PRV, and FMDV
7. Direct Fluorescent Antibody Testing (FAT)for Rabies
8. HA-HI Test for ND, AI, EDS, IB
9. Antibiotic Susceptibility Test
10. Bacterial Isolation and Identification Test
11. Fungal Isolation and Identification
12. Salmonella Isolation in Feeds
13. Rapid Plate Test for Brucella, Salmonella, Mycoplasma
14. Blood Parasite Examination
15. Fecal Examination
16. Artificial Digestion Method
17. Skin Scraping
18. Mice Inoculation Test
19. Isolation and Identification of Larva
20. Parasite Identification
21. AGID Test for AI,
22. RT-PCR for AIV, CSFV, PEDV, PRRSV, RESTV, SIV, ILTV and NDV
23. Accreditation of Veterinary Animal Disease Diagnostic Laboratories

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SUPPORT PROCESSES
1. Top Management
2. QMR
3. Purchasing Process
4. Internal Audit
5. Document Control
6. Supplies Inventory
7. Inspection of Delivered Raw materials, Supplies and Equipment
8. Calibration and Preventive Maintenance of Equipment, Vehicles
9. Recruitment, Selection, Promotion and Placement
10. Rewards and Recognition
11. Training Program and Development
12. Issuance of requested Documents
13. Other Human Resource Activities (OHRA)
14. IT Management

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