QUALITY &
EFFICIENCY

ANALYTICAL & REGULATORY CHEMISTRY

OUR SOLUTIONS FOR YOUR SUCCESS

CAPABILITY MANUAL

INTRODUCTION

This manual is designed to introduce you to our laboratory, instrumentation, and the scope of services we offer. Analytical & Regulatory Chemistry (ARC) is a laboratory that provides exemplary EPA GLP compliant chemistry & formulation services to clients worldwide while delivering significant cost savings. Operating under a stringent quality system, our processes assure regulatory compliance with U.S. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practices (GLP).

ARC is a privately owned laboratory located in Sumter, South Carolina. The lab has a long history of providing a fast, efficient process for obtaining EPA registrations. The facility has been GLP-compliant since 1998, conducting product-chemistry studies and other EPA-related research projects.

We have maintained an exceptionally high acceptance rate at the EPA. We offer full analytical and reporting capabilities. We do this at reasonable prices and with excellent turnaround.

SCOPE OF SERVICES

Analytical Chemistry

- Regulatory (GLP)
  - EPA Product Chemistry
  - 5-Batch Analysis of Pesticides
  - Physical, Chemical, and Technical Characteristics of Pesticides
  - Storage Stability of Pesticides and OTC Pharmaceuticals
  - Batch Release of Pesticide Products
  - Method Validation

- Analytical Capabilities
  - GC
  - GC/Mass Spectrometry
  - GC – Headspace Analysis
  - High Performance LC
  - LC/Mass Spectrometry
  - Ultra High Pressure LC
  - Atomic Absorption Spectroscopy
  - UV/Visible Spectrophotometry
  - Particle Size Analysis
  - Thermogravimetric Analysis
  - Karl Fischer (Volumetric and Coulometric)
  - Physical Property Measurements
  - Volumetric Analysis
  - Gravimetric Analysis
  - Inorganic and Elemental Analysis
  - Pesticide Active Ingredients

Formulation

- Formulation Development
  - Aqueous Suspensions
  - Emulsifiable Concentrates
  - Granular Products
  - Micro-Emulsions
  - Wettable Powders
  - Solutions

- Formulating Operations
  - Coating
  - Extrusion
  - Fluid Bed Granulation
  - Spray Drying
  - Milling

Wood Treating

- Formulation Development
- Laboratory Treating Studies
- Leaching Studies
- Corrosion Studies

Quality Policy Implementation

Analytical & Regulatory Chemistry, Inc (ARC) provides a broad range of technical and analytical services for customers and government compliance and is intent on the delivery of those services in a time efficient manner. The Laboratory is committed to meeting the Quality Objectives summarized below.

Quality Objectives

- To guarantee the commitment of management, the organization, and employees to the Quality Program.
- To ensure a Quality Program that is documented and that incorporates adequate review, audit and internal quality control.
- To ensure personnel are adequately supervised and are able to carry out the assigned tasks.
- To ensure test methods and related procedures are validated and incorporate adequate quality control.
- To ensure all equipment, supplies and services are functioning properly and/or meet required specifications.
- To ensure facilities are adequate to carry out the testing activity.
- To ensure sample management, data management, and workload management procedures incorporate adequate measures for the security, receipt, identification, checking, routing, storage and disposal of all samples.

Commitment of Management

The policy of Analytical & Regulatory Chemistry, Inc, and thus, ARC is delineated in five operating categories.

- Safety – We are committed to providing a safe injury-free and healthful workplace for all employees. We believe that all accidents and environmental incidents are preventable and our goals for both are zero.
- Environmental/Legal – We will comply with or exceed relevant environmental legislation and regulations and other requirements to which we subscribe. We are dedicated to the prevention of pollution, reduction of waste, conservation of energy

and the continual improvement of our environmental systems. We will ensure that every employee understands and is responsible and accountable for incorporating environmental considerations in daily business activities.

- Quality – Our products and services provide value to our customers and reflect the pride we take in our work. We will continually strive to improve the quality of our products and services, and to anticipate and fulfill our customers' needs. Quality is defined as minimal variation around a target. Quality improvement is achieved by reduction in variation.

- Throughput – We will continually strive for higher throughput of key processes to better meet customer needs. Once gains are made, additional gains will be sought. There is no finish line.

- Continual Improvement – We will assure our success as a profitable business through continual improvement by all. We will use good management practices, statistical methods, and employee involvement to continually improve processes and EH&S systems, reduce costs, reduce wastes, and improve quality. There is no finish line.

Management and the employees are strongly committed to the ideas of Quality and Quality improvement. Meeting or exceeding customer needs is tantamount to the success of any organization. We are intent on being successful and helping our customers do the same.

Documentation, Review, Audit and Quality Control

A well-developed system of documentation and document control forms the tangible basis for the quality system. Formalized documentation or Standard Operating Procedures (SOP's) define all aspects of the system including responsibilities and customer requirements. The SOP is a set of instructions (procedures) that must be rigorously adhered to in the execution of a project or task. For example, SOP's are available for instrument maintenance and calibration, analytical procedures, record keeping, and report writing. An SOP for an analytical procedure details or references the standard material requirements and sample preparation, the step-by-step method, the calculations of the analytical procedure, the quality control necessary for the procedure, and the reporting requirements. All SOP's involving analytical procedures also reference safety issues specific to the procedure. SOP's are updated on a biannual basis.

Training

Every employee of ARC is engaged in some aspect of quality. ARC employs scientists and clerical workers at several levels of educational and practical experience. However, whether an employee is a Ph.D. in his/her discipline or a laboratory technician they are required to receive training in pertinent aspects of quality. Prior to execution of any SOP

an employee must have the necessary skills for that procedure and then receive training in that procedure. When it is demonstrated that the employee is competent in that SOP, certification in that SOP becomes a part of the training record of the employee.

Employees in ARC are involved in several professional organizations and quality councils. The continuation of formal education is encouraged and sponsored by ARC. Participation in outside seminars and courses has been beneficial in maintaining a high knowledge base in areas such as quality and analytical training.

Method Integrity

The choice of procedures and the validation of those procedures follow specific guidelines. ARC uses techniques for measurement and employs methodologies recommended by groups such as USEPA, USFDA, USP, AOAC, NIST, OECD, CIPAC, AWPA, and ASTM. Where standard methods are unavailable literature searches are instituted and methods are chosen based on sound scientific judgment. Where methods must be developed, in-house validation of the method occurs using accepted validation procedures.

Equipment, Supplies and Services

The integrity of data can be no better than the methods, tools and supplies utilized in the generation of that data. ARC has a well-stocked and well-maintained inventory of standard instrumentation that is used in the analysis of samples. Instrumentation used in the generation of data is generally dictated by the analyte to be tested and the recommendations of several standard-testing organizations such as AOAC, USP, USEPA, USFDA, NIST, AWPA, and ASTM are consulted. Where well-defined standard methods are not readily available, a literature search is implemented and methods are chosen based on the results of the search. The use of these “non-standard” methods is accompanied by validation of the method. The SOP’s define choice of reagent and the standards used for those reagents as well as any associated equipment and chemicals. SOP’s are available that define preventative maintenance schedules of all major laboratory equipment. Associated equipment, such as analytical balances, undergoes a rigorous calibration and maintenance schedule.

Facility

ARC Labs is housed in air-conditioned structures containing over 3000 square feet of laboratory floor space. The buildings contain all the necessary safety equipment such as fire extinguishers, safety showers, and eye wash stations. Safety equipment is inspected on a monthly basis. ARC operates under a Chemical Hygiene Plan as defined by OSHA in 29 CFR 1910.1450. Locked, fire-resistant storage areas are available for records. Sample preparation and workup areas are maintained in separate labs and away from instrumentation areas.

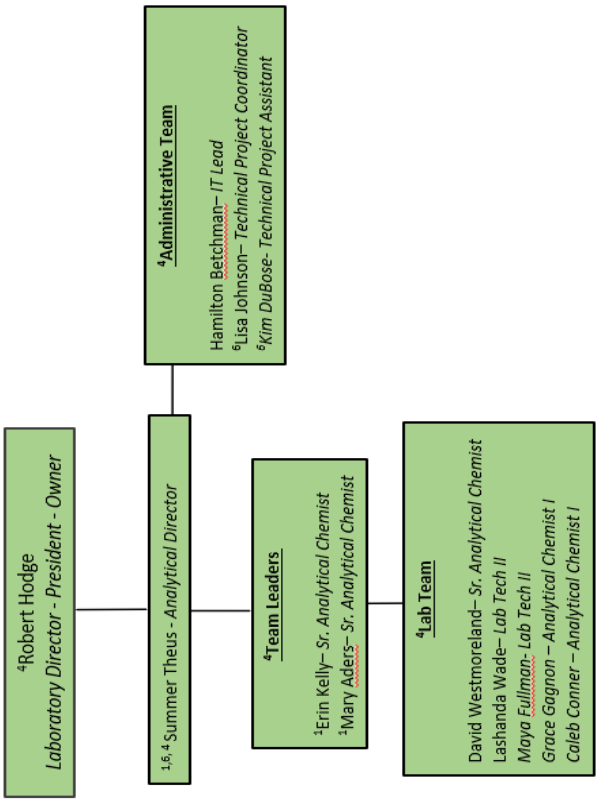
The facility operates under Good Laboratory Practice standards (GLP) as defined by USEPA in 40 CFR 160 and Good Manufacturing Practice standards (cGMP) as defined by USFDA in 29 CFR 210.

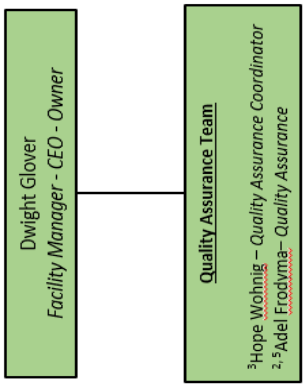
Data and Sample Management

Samples are received into ARC Labs through a variety of routes. On receipt, each sample is logged in the LIMS System and given a laboratory number that is unique to that sample. Samples are maintained in a temperature-controlled sample room in the laboratory under lock and key.

The original instrument data are maintained in computer readable format. The data system is backed up and tapes are maintained for long-term availability. All data are treated as confidential with only limited access. The official GLP Archives are maintained in a digital format at ARC.

Organization Chart





[1]Qualified to act as a Study Director.
[2] Archivist (Document Control Coordinator)
[3] Back-up Archivist.
[4]Technical staff.
[5]Training Coordinator.
[6]Study and Electronic Archivist.

Instrumentation

Instrumentation on the following list is operated and maintained under full compliance to GLP regulations and ARC quality procedures.

Spectrometers

- Perkin-Elmer AAnalyst 300 Atomic Absorption Spectrometer, with mercury/hydride vapor system
- PerkinElmer Lambda 35 UV-Visible Spectrophotometer
- Agilent Technologies Cary 630 FTIR

Chromatography

- 2 Waters Acquity ULC, H Class with PDA Detector
- 3 Agilent Technologies 1290 UPLC with PDA Detector
- PerkinElmer Autosystem XL GC, with FID and NPD detectors
- Agilent Technologies 7890B GC System, with FID and ECD
- Agilent Technologies 8890 GC System, with FID and NPD
- Agilent Technologies 7697A Headspace Analyzer
- Agilent 5977A GC/MS
- Agilent 1200 Series LC with diode array detector, 6520 Q-TOF dual mass spectrometers, and Mass hunter data system

Balances

- 2 Mettler Toledo - Model XS204 analytical balances
- Mettler Toledo - Model XP205 analytical balance
- Mettler Toledo - Model XPE205 analytical balance
- Mettler Toledo – Model XPR225DR analytical balance
- Ohaus Model TS4KD top loading balance
- Denver Instrument Model SI-402 top loading balance
- Mettler-Toledo Model XS6002S top loading balance
- A&D Model FG-30K top loading balance
- PerkinElmer TGA-4000 thermogravimetric analyzer

Ovens & Incubators

- Fischer Scientific 725F Oven
- Fischer Scientific 750F Oven
- VWR Scientific Model 414004-604 Incubator
- Binder Model KB ECO 1020 Incubator
- VWR Scientific Model 10753-894 Incubator
- Thermolyne 1400 muffle furnace
- VWR Refrigerated Model 3734 Incubator
- VWR Scientific Model 89511-422 Incubator

Titrators

- Metrohm 907 Titrando Potentiometric Auto Titrator
- Metrohm 907 Titrando Volumetric Karl Fischer
- Mettler-Toledo C30X Karl Fischer Coulometer with Stromboli oven sample changer

Miscellaneous Instrumentation

- QuantaChrome Multi-Pycnometer
- VWR Symphony pH Meter, Model SB70P
- Brookfield RVTD viscometer
- J. Engelsmann A.-G. volumeter
- Quantachrome Autotap Model AT-2
- Fisher Model 21 Tensiomat
- StanHope Seta Flash Point Tester Model 30000-0
- Fisher-Johns melt point apparatus
- Gilson SS-8R Sieve Shaker
- Microtrac S3500 Particle Size Analyzer

Sample Preparation Equipment

- Burrell Wrist Action Shaker
- New Brunswick Model G10 Orbital Shaker
- New Brunswick Model G24 Incubator Shaker
- IKA Ultra-Turrax T25 Homogenizer
- Ultrasonic baths

Formulation Equipment

- Strea-1 Benchtop Fluid Bed Granulator
- LCI Benchtop Extruder
- Teledyne-Readco 17-inch Pan Granulator
- Retcsh ZM-1000 Hammermill
- Accu-Rate Dry Solids Feeder
- Dyno-Mill Multi-Lab Horizontal Mill
- Red Head Vertical Wet Mill
- Wiley Mill

Other

- Two pilot-scale pressure wood treating cylinders

Physical and Chemical Characteristics (OPPTS 830 Series)

Color (OPPTS 830.6302)	direct observation
Physical State (OPPTS 830.6303)	direct observation
Odor (OPPTS 830.6304)	direct observation
Stability to Normal and Elevated Temperatures, Metals, and Metal Ions (OPPTS 830.6313)	Assay method
Oxidation/Reduction: Chemical Incompatibility (OPPTS 830.6314)	direct observation, 5 reactants
Flash Point (OPPTS 830.6315)	SetaFlash (CIPAC Method MT 12.2)
Storage Stability (OPPTS 830.6317)	25 °C; simulated warehouse
Miscibility (OPPTS 830.6319)	similar to CIPAC Method MT 23
Corrosion Characteristics (OPPTS 830.6320)	conducted in small scale packaging; also coupon corrosion
pH (OPPTS 830.7000)	electrometric
UV/Visible Absorption (OPPTS 830.7050)	neutral, acidic, and basic conditions
Viscosity (OPPTS 830.7100)	kinematic (capillary) viscometry; Brookfield viscometer
Melting Point (CIPAC 830.7200)	Fisher-Johns
Boiling Point (OPPTS 830.7220)	OECD Guideline 103
Density/Relative Density/Bulk Density (OPPTS 830.7300)	hydrometer; tap densitometer; liquid pycnometer; gas pycnometer; free-flowing densitometer

Dissociation Constant (OPPTS 830.7370)	potentiometric titration
Particle Size Distribution (OPPTS 830.7520)	Microtrac S3500
Partition Coefficient, n-octanol/ water (OPPTS 830.7550)	Estimation by LC
Solubility (OPPTS 830.7840)	Shake flask method

Technical Characteristics (91/414/EEC)

Attrition Resistance	CIPAC Method MT 178 / ASTM E 728
Dilution Stability	CIPAC Method MT 41
Dispersibility	CIPAC Method MT 174
Dissolution Degree	CIPAC Method MT 179
Dustiness	CIPAC Method MT 171
Emulsification Characteristics	CIPAC Methods MT 20 & MT 36.1.1
Flowability	CIPAC Method MT 172
Non-Dispersible Residue	CIPAC Method MT 59.3
Particle Size Analysis	CIPAC Method MT 170
Persistent Foaming	CIPAC Method MT 47
Pourability and Rinsed Residue	CIPAC Method MT 148
Spontaneity of Dispersion	CIPAC Method MT 160
Suspensibility	CIPAC Methods MT 15, MT 161, and MT 168
Wettability	CIPAC Method MT 53.3

General Tests Available

Acidity	pH, titration
Alkalinity	pH, titration
Ash	gravimetric
Bioavailability	atomic absorption
Density	hydrometer, tap densitometer, pycnometer, free-flowing densitometer, gas pycnometer
Particle Size Analysis	Microtrac; sieve
Surface Tension	OECD Guideline 115
Viscosity	kinematic (capillary) viscometry; Brookfield viscometer

Inorganic and Elemental Analysis

Aluminum	flame atomic absorption
Ammonia	
Barium	flame atomic absorption
Borates and Boric Acid	titration; flame atomic absorption
Boron	flame atomic absorption
Cadmium	flame atomic absorption
Calcium	flame atomic absorption
Carbonate	precipitation/titration
Chloride	gravimetric; titration; ion selective electrode
Chromium	flame atomic absorption
Cobalt	flame atomic absorption
Copper	iodometric titration; EDTA titration; flame atomic absorption
Copper (I)	redox titration
Cyanide	distillation/titration
Fluoride	ion selective electrode
Hydrogen Peroxide	redox titration
Hypochlorites	iodometric titration
Iron	flame atomic absorption
Iron (II)	redox titration
Lead	flame atomic absorption
Lithium	flame atomic absorption
Magnesium	flame atomic absorption
Manganese	flame atomic absorption
Nickel	flame atomic absorption; gravimetric; EDTA titration
Phosphate	spectrophotometric; gravimetric
Phosphite	iodometric titration
Potassium	flame atomic absorption
Silver	titration; flame atomic absorption
Sodium	flame atomic absorption
Sulfate	gravimetric
Sulfur	iodometric titration
Tin	flame atomic absorption

Titanium	flame atomic absorption
Water	Karl Fischer titration; gravimetric
Vanadium	flame atomic absorption
Zinc	flame atomic absorption; EDTA titration

Organic Analysis –Methods Available

Abamectin	Fenoxyprop-ethyl	Phenoxy herbicides
Acephate	Fipronil	2-Phenylphenol
Acetamiprid	Flonicamid	Pinoxaden
Acetic Acid	Florasulam	Piperonyl Butoxide
Acifluorfen	Fluazifop-p-butyl	Prallethrin
Aldicarb	Fluazinam	Prodiamine
Allethrin	Flucarbazone-sodium	Prometon
Alkyl and Aryl Phenols	Fludioxonil	Propanil
Aliphatic Alcohols	Fluensulfone	Propargite
Aminopyralid	Flumetsulam	Propiconazole
4-t-Amylphenol	Flumeturon	Propyzamide
Asulam	Flumioxazin	Pymetrozine
Atrazine	Fluometuron	Pyrethroid Insecticides
Azoxystrobin	Fluopyram	Pyrethrum
Benalaxyl	Fluridone	Pyriproxyfen
Benoxacor	Fluroxypyr ester	Pyraclostrobin
Bentazon	Fomesafen	Quaternary Amines
6-Benzylaminopurine	Forchlorfenuron	Quinclorac
Bifenthrin	Fosamine Ammonium	Quizalofop
Bifenazate	6-Furfuryladenine (Kinetin)	Rabon (Tetrachlorovinphos)
2,2-Bipyridyl	Gamma-Cyhalothrin	Rimsulfuron-Methyl
Bispyribac-sodium	Gibberellic acid GA3	Sevin
Bromacil	Gibberellins GA4/GA7	Sodium Dichloroisocyanurate
Bromadiolone	Glufosinate/Glufosinate Ammonium	Spinosad
Bromoxynil heptanoate	Glyphosate	Spiromesifen
Bromoxynil octanoate	Halosulfuron-methyl	Streptomycin
Butoxyethanol	Hexachlorobenzene	Sulfentrazone
Brutralin	Hexazinone	Sulfometuron-methyl
Buprofezin	Hexythiazox	Sulfonylureas
Captan	Hydantoins	Sumithrin
Chitosan	Imazamox	Tebuconazole

Chlorantraniliprole	Imazapyr	Tebuthiuron
Chlorimuron-Ethyl	Imazethapyr	Thianaphthene
Chlorobenzenes	Imidacloprid	Thidiazuron
Chlorfenapyr	Indole-3-butyric Acid	Thifensulfuron-methyl
Chlorsulfuron	Indoxacarb	Thiobencarb
Chlorothalonil	3-Iodo-2-propynyl N-butylcarbamate	Thiophanate-methyl
Cinnamaldehyde	Iprodione	Thiram
Citric Acid	Isoxaben	Toluene
Citronellal	Isoxadifen-ethyl	Triadimefon
Clethodim	Isoxaflutole	Tralkoxydim
Clodinafop-Propargyl	Kiralaxyl	Triacontanol
Clofentrazine	Lactofen	Triazole
Clomazone	Lambda-Cyhalothrin	Tribenuron-methyl
Clopyralid	Limonene	Triclopyr
Cloquintocet-mexyl	Linalool	Triclopyr BEE
Cloransulam-methyl	Linuron	Trichloroisocyanuric Acid
Cumyluron	Malathion	Trifluralin
Cyazofamid	Mancozeb	Triphenyltin Acetate
Cyanamide	MCPA	Triphenyltin Hydroxide
Cyantraniliprole	MCPA Esters	
Cyclanilide	Mecoprop-p	
?-Cyfluthrin	Mefenoxam/Metalaxyl	
Cyflumetofen	Mepiquat Chloride	
Lambda-Cyhalothrin	Mesotrione	
Cymoxanil	Metamitron	
Cypermethrin	Metolachlor	
Cyprodinil	Methomyl	
2,4-D	Methylated Seed Oil	
2,4-D BGE	Methoxyfenozide	
2,4-D EHE	Methoprene (S-Methoprene)	
Dazomet	Methyl Anthranilate	
Deltamethrin	Methyl Isothiocyanate	
Diazinon	Metribuzin	
Dicamba	Metsulfuron-methyl	
1,4-Dichlorobenzene	Methylcyclohexane	
Dichloromethane	Myclobutanil	
Dichlorprop-p	1-Naphthaleneacetic Acid	
Diethyl-m-toluamide (DEET)	Naphthalene	
Diflubenzuron	Nicosulfuron	
Dinotefuran	Nitroso-imidacloprid	
Diquat	Novaluron	
Dithiocarbamates	Oryzalin	

Dithiopyr	Oxadiazon
Diuron	Oxamyl
Dodine	Oxyfluorfen
Emamectin benzoate	Oxytetracycline
Endothal	Paclobutrazol
Esfenvalerate	Paraquat
Ethofumesate	Pendimethalin
Etoxazole	Penoxsulam
Etofenprox	Pethiopyrad
Eugenol	Permethrin
Fenopyryoximate	Peroxyacetic Acid

Note: Method Development available for compounds not listed.