

OFFICE OF REGULATORY AFFAIRS
OFFICE OF REGULATORY SCIENCE
PROGRAM ALIGNMENT UPDATES
AND
IMPACT ON RESEARCH

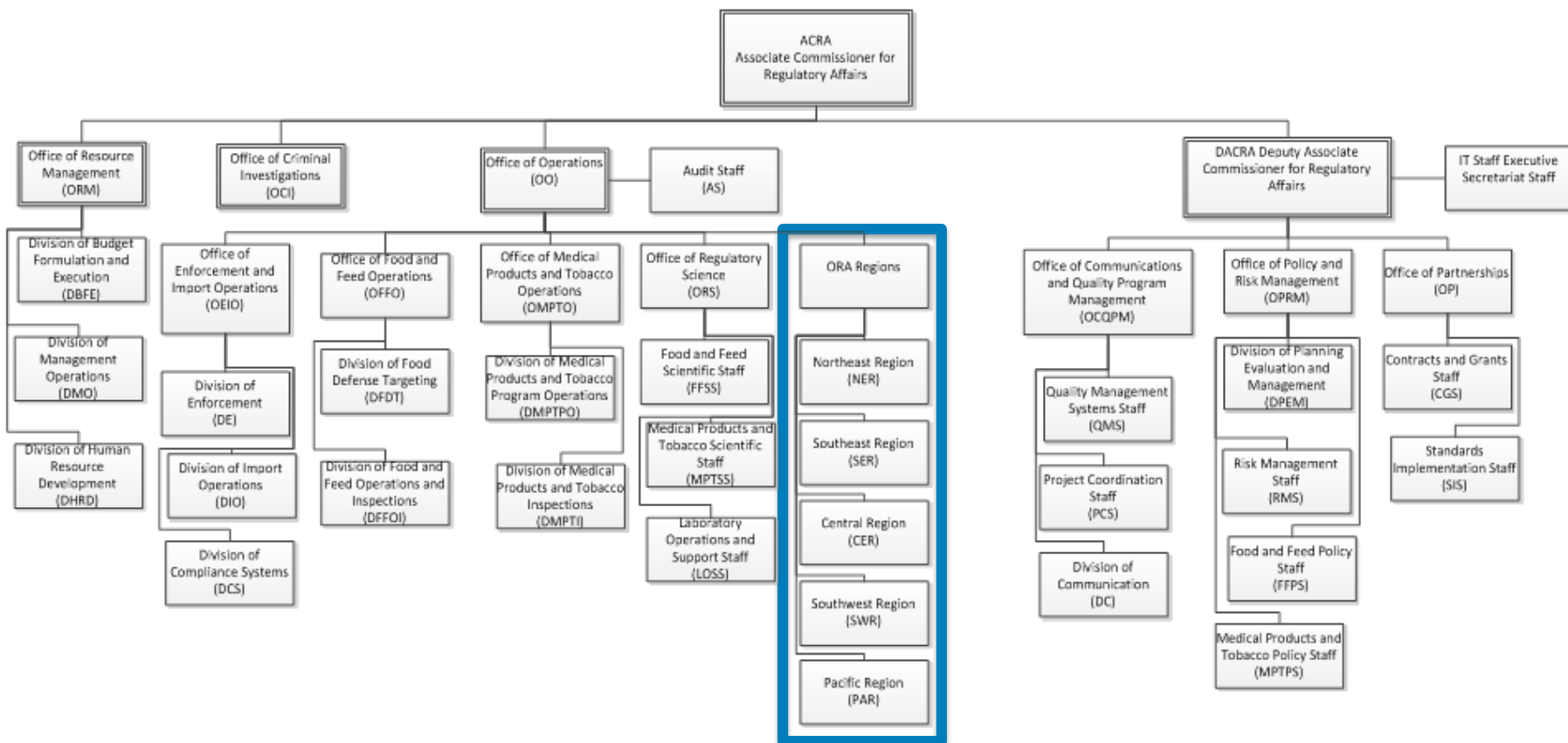
NCTR Science Advisory Board
November 2017

“...Modernize and strengthen the FDA workforce to improve public health response.”

2013 FDA Program Alignment Charge

OLD

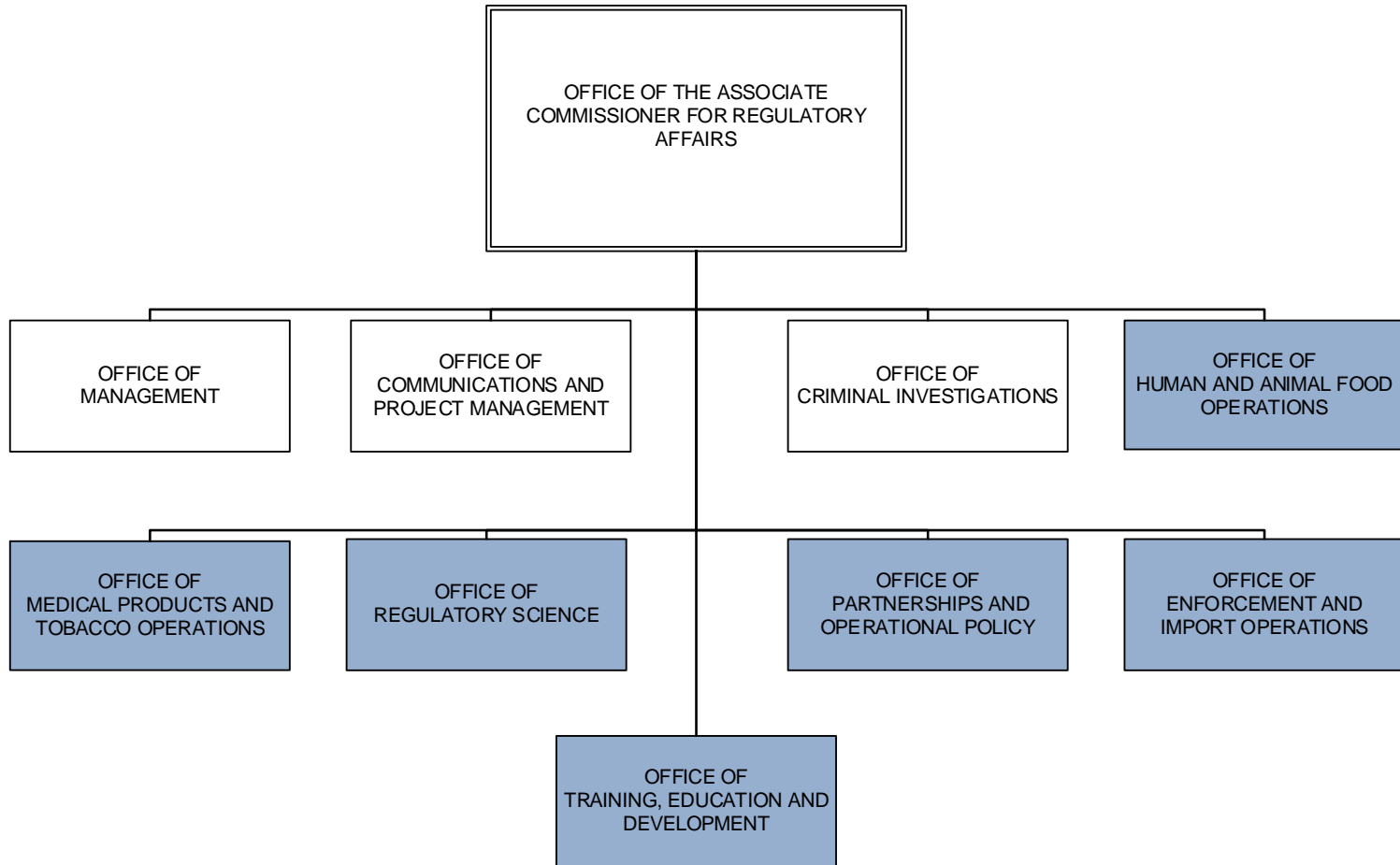
Geographically Aligned Organizational Model



New

Program Aligned Organizational Model

FDA



Office of Regulatory Science



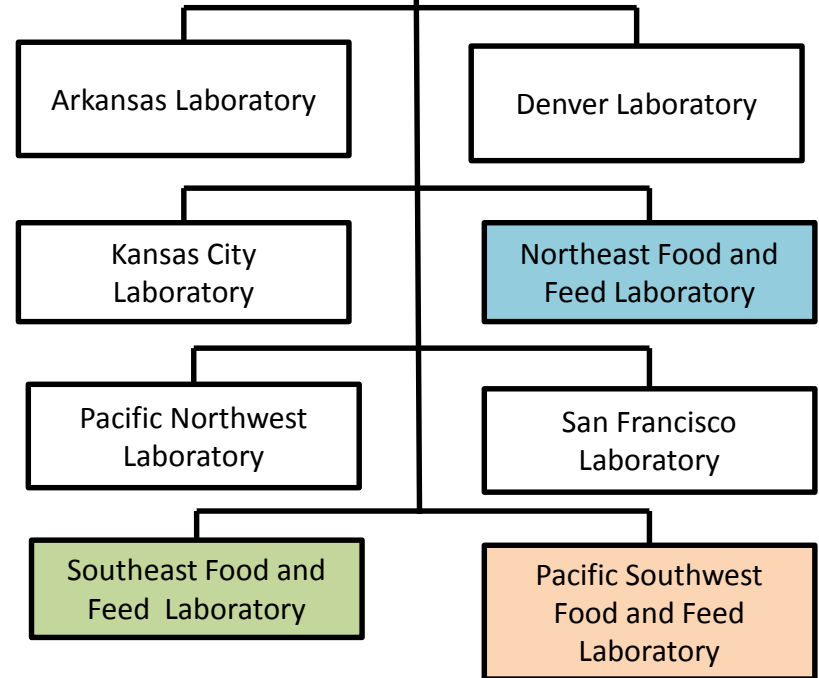
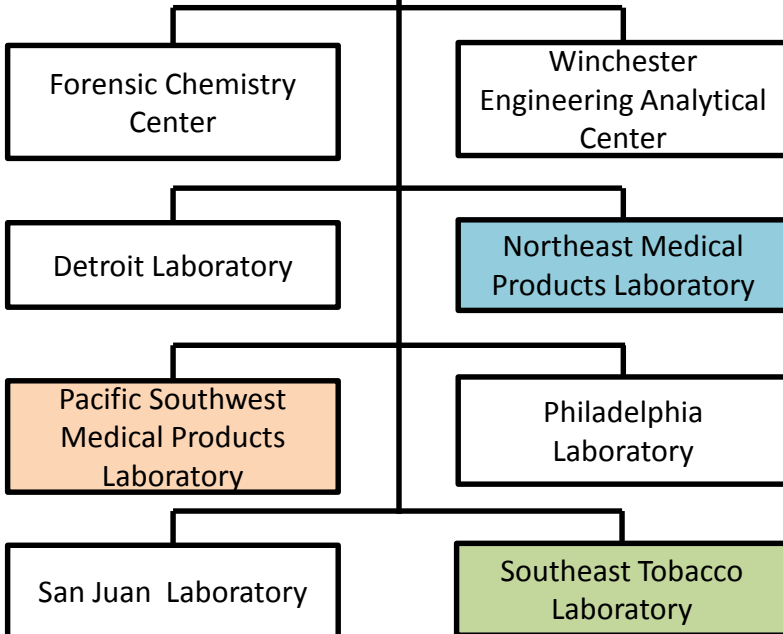
Dr. Paul Norris
Director
Office of Regulatory
Science

Office of Research
Coordination and
Evaluation (ORCE)

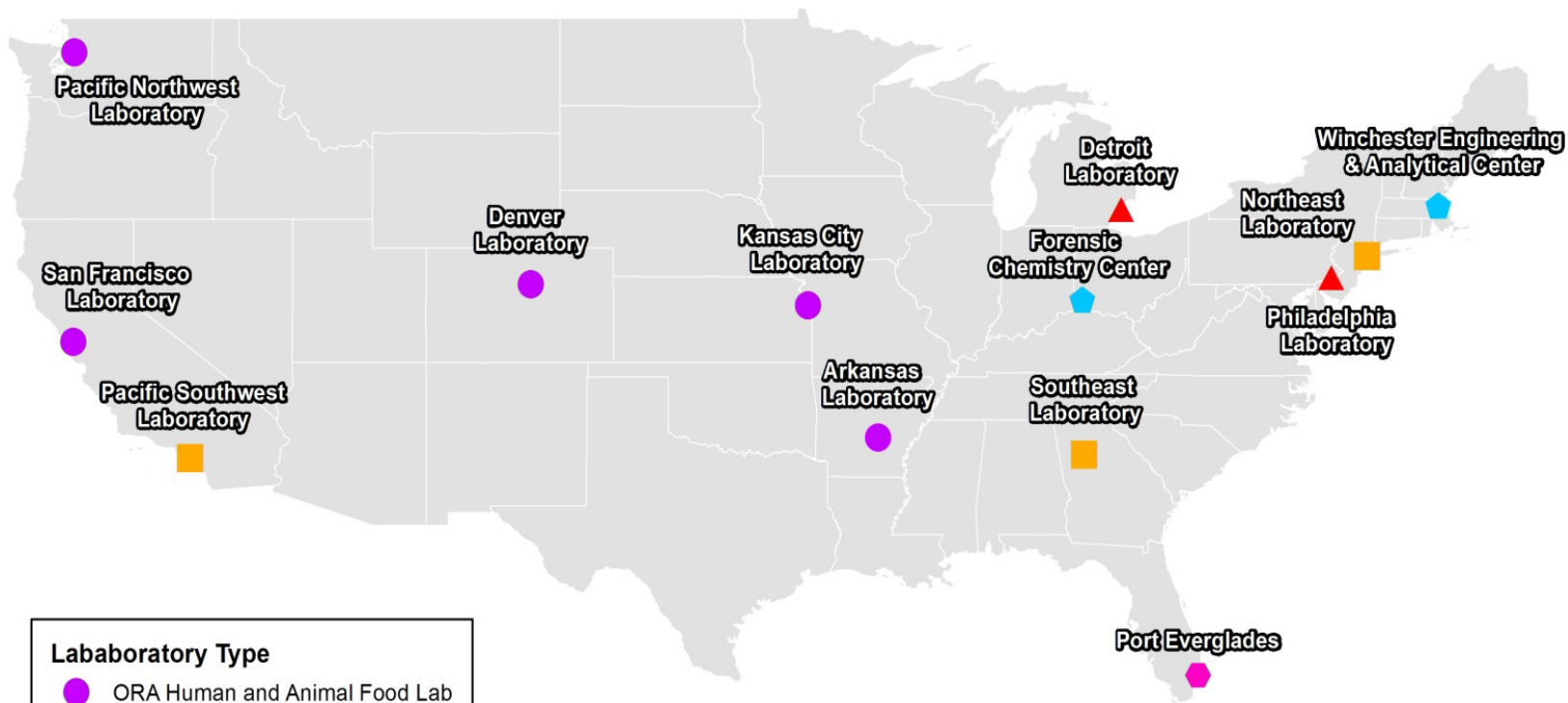
Office of Business and
Safety Operations

Office of Medical Products, Tobacco
and Specialty Laboratory Operations
Medical Products and Tobacco Scientific Staff

Office of Food and Feed Laboratory
Operations
Food and Feed Scientific Staff



Office of Regulatory Science



Laboratory Type

- ORA Human and Animal Food Lab
- ▲ ORA Medical Products Lab
- ORA HAF & MPT (co-located)
- ⬠ ORA Specialty Lab
- ⬡ ORA Screening Station
- State Boundaries

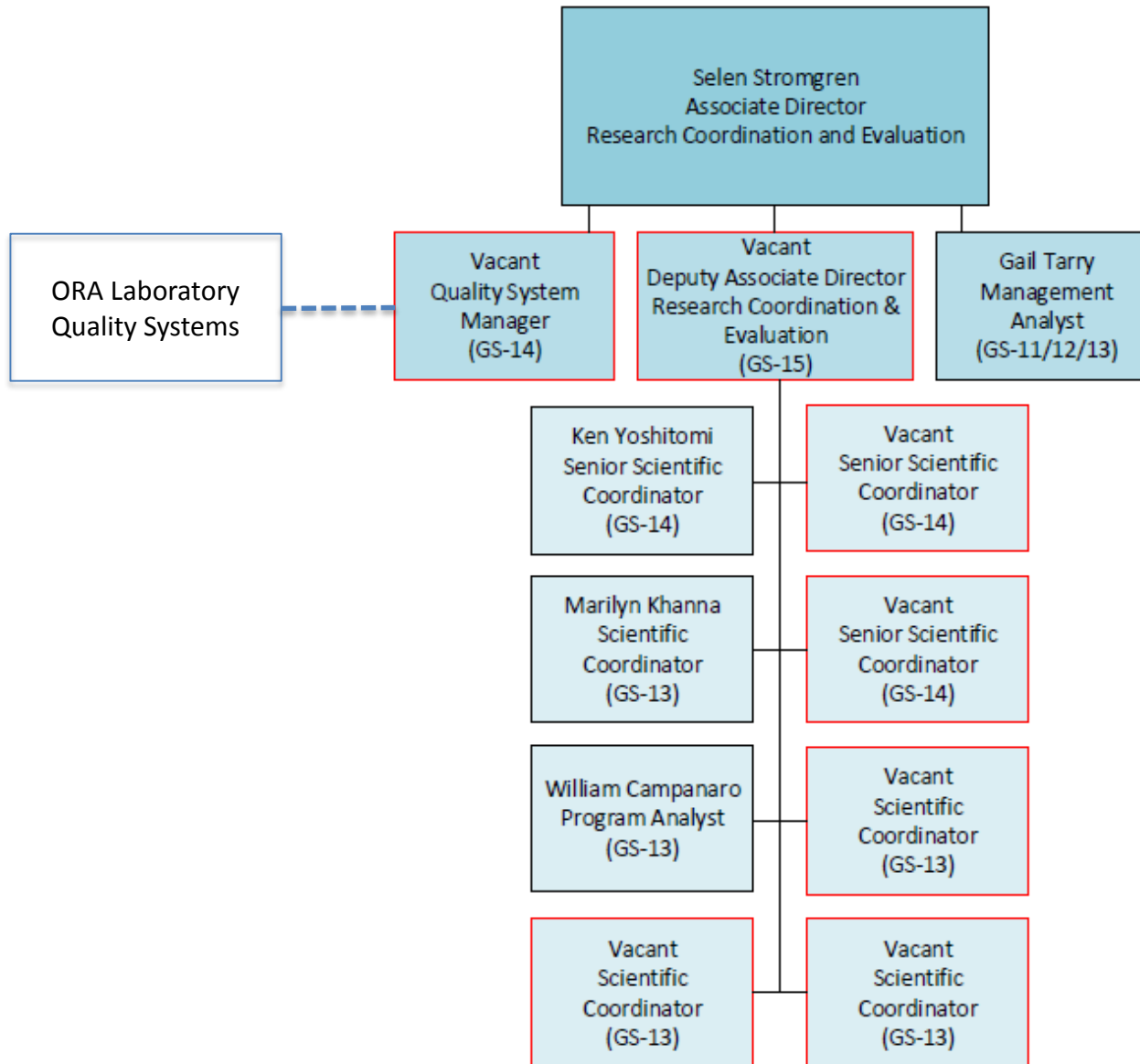
San Juan Laboratory

Puerto Rico - SJN

Office of Regulatory Science

Office/Division	Title	Name
Immediate Office	Director	Paul Norris, DVM, MPA
Immediate Office	Senior Science Advisor	Sean Linder, PhD
Immediate Office/Safety and Risk Management Staff	Associate Director	Sufian Al Khaldi, PhD (acting)
Office of Medical Products, Tobacco and Specialty Laboratory Operations	Associate Director	Debra Barnes, PhD
Office of Food and Feed Laboratory Operations	Associate Director	Dan Rice, DrPH
Office of Research Coordination and Evaluation	Associate Director	Selen Stromgren, PhD

Structure of ORCE



Mission of ORCE

- ***ORCE Immediate Office*** – Leading ORA Science
- ***Research Group*** – Shaping Landscape of Regulatory Research
- ***Quality Group*** – Increasing Confidence in Execution of Core Scientific Mission



Responsibilities of ORCE

- Elevate ORS science, research and quality activities through active leadership, engagement with Center stakeholders, academic collaborators, and sister agencies.
- Define new areas of work for ORS labs, introduce new technology, expertise and continuously expand scientific portfolios to remain mission-relevant, forward-looking, cutting-edge and versatile.
- Establish a framework of harmonized processes that define criteria for generation of scientific publications, external presentations, scientific contracts/agreements, and research proposals.
- Work with ORA's Division of Quality to establish a robust laboratory quality management program, provide rigorous scientific assessment of our lab activities as part of pre-audits, evolve and modernize our proficiency testing program, improve management reviews and promote quality as a key factor in achieving confidence in our lab products.

Landscape of ORA Scientific Research

Area	Topic	SEL HAF	SEL Tobacco	NEL HAF	NEL MP	PSW HAF	PSW MP	AL	DEN	KAN	PNW	SFL	PHI	SJN	DET	WEAC	FCC
Research Areas	Regulatory Method Extension/New Method Validation	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█
	New Capability Development	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█
	Rapid Detection Technologies			█	█	█	█				█		█		█	█	█
	Development of Application for Portable Instrument Platforms			█	█	█	█			█					█	█	█
	Product Assessment at Preapproval Stage														█		
	Field Exam Method Development															█	
Specialty Areas	Devices/Engineering															█	
	Forensic Testing																█
	Counterfeit Detection																█
	Tobacco Testing		█														█
	Novel Microbiological Method Development										█						
	Veterinary Drug Residue Method Development								█								
	Nanotechnology							█									
	Trace Chemical Analysis							█									
Radiochemistry															█		

