

Title: Organization and Facilities

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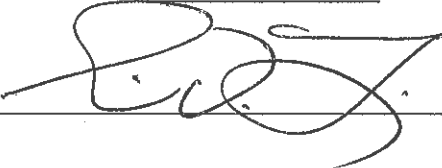

This document does not contain proprietary information.

References: SOP 120: Job Descriptions

<u>Rev. No.</u>	<u>Effective Date</u>	<u>Revision Summary</u>
1.	06-14-94	First Version
2.	09-06-95	Update Org. Chart
3.	02-04-97	Update Facilities and Org Chart
4.	06-16-98	3.0 Organization of laboratory divided into three groups instead of six, updated floor plan, and updated organization chart. The Organics Manager responsible for coordination of GCMS, GC, and Extractions collectively referred to as the Organics Group; IR now under the Chemistry Group.
5.	09-15-98	Update Org. Chart
6.	01-10-00	Update Org. Chart
7.	09-28-01	3.1 Organization of lab divided into five groups instead of three, removed HPLC from Chemistry to form a group and split GC and GCMS into groups from Organics. 5.0 Updated square footage to reflect new building. Removed attached figures and referenced the floor plan and Org. Chart to the QA Manual.
8.	11-12-03	Sec. 3.0: Reformatted. Sec. 3.1.4: Updated to include LCMS. Sec. 3.1.5: Updated to include XRF and HG-CVAFS. Sec. 4.0: Changed Group Leaders to Group Managers and added group leader statement.
9.	06-12-08	Revised throughout to reflect new ownership of lab. 3.0: Changed to reflect current organization of technical groups. 4.0: Changed to add QA Officer position. 5.0: Changed to reflect current size of facilities.
10.	01-13-09	Updated Org. Chart and floor plan.
11.	03-31-09	Updated Org. Chart.
12.	07-16-09	Updated Org. Chart.

<u>Rev. No.</u>	<u>Effective Date</u>	<u>Revision Summary</u>
13.	10-01-09	Updated Org. Chart and revised for rebranding to Exova.
14.	01-25-10	Updated Org. Chart.
15.	09-23-10	Updated Org. Chart.
16.	10-29-10	Updated Org. Chart. Sec. 3.1: CVAFS instrument retired.
17.	12-10-10	Updated Org. Chart.
18.	04-08-11	Updated Org. Chart. Sec. 3.6.1: Scope expanded. Sec. 3.6.4: added. Sec. 4.4 and 4.5: expanded.
19.	05-02-11	Updated Org. Chart
20.	05-25-11	Updated Org. Chart
21.	07-12-11	Updated Facilities Diagram.
22.	SEP 28 2011	Updated Org. Chart

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<u>Prepared by</u>	<u>Date</u>	<u>Technical Review</u>	<u>Date</u>
	09/28/11		09.28.11
QA Approval/Date:		09/28/11	

1.0 SUMMARY

This SOP documents the laboratory's general organizational structure and describes the facilities at the time of this version. It is intended as an introduction for clients and auditors. Both the personnel and the facility are organized by functional groups, i.e. groups of personnel performing separate and defined tasks. Each laboratory group is organized around certain types of analyses.

2.0 RESPONSIBLE PERSONS

The General Manager is responsible for this SOP.

3.0 ORGANIZATION

The laboratory is currently divided into five analytical groups based on similar types of analyses.

- 3.1 Metals: In general, this group performs inorganic analyses using Inductively Coupled Plasma Mass Spectrometry (ICPMS), Inductively Coupled Plasma Optical Emission Spectroscopy (ICPOES), and X-Ray Fluorescence (XRF). This group also performs heavy metals testing per USP <231> and EP 2.4.8.
- 3.2 Wet Chemistry: In general, this group is comprised of UV, elemental analysis, fluorescence, polarimetry, and wet chemistry. A variety of compendial tests are performed for identifying and characterizing bulk materials. Other analyses, using either simple instruments or non-instrumental techniques such as titrations, are also included in this group.
- 3.3 LC/IC: In general, this group is comprised of liquid chromatography (LC) and ion chromatography (IC) for performing both organic and inorganic analyses.
- 3.4 Organics: In general, this group performs organic analyses using gas chromatography (GC), gas chromatography-mass spectrometry (GCMS), and liquid chromatography-mass spectrometry (LCMS).
- 3.5 Spectroscopy: In general, this group performs spectral analysis using FTIR and NMR.
- 3.6 Other non-analytical functions are performed by the support staff and client services groups, which include:

- 3.6.1 Health, Safety, Environmental and Quality (HSEQ): Responsible for assuring compliance with regulatory agency requirements, certifying body standards, corporate policies, and quality agreements with clients. Includes ensuring the health, welfare and safety of all employees and visitors; hazardous waste and controlled substances management; facilities maintenance; metrology and equipment qualification; training and qualification of employees; materials receiving and release; laboratory investigations; change control; corrective and preventative actions; document approval and control, including test methods; quality trending and reporting to management; management of internal and third-party audits and regulatory inspections; and facilitating continuous improvement of management systems. Fulfills the responsibilities of the Quality Unit, as defined in FDA GMP and GLP regulations.
- 3.6.2 Client Services: Responsible for sample receipt, word processing, business development, and project management. Includes tracking jobs, responding to client inquiries, preparing bids and proposals, marketing, documenting the receipt and storage of samples, and distributing paperwork associated with sample analysis.
- 3.6.3 Office Management: Human Resources, Reception, Purchasing, and Accounting.
- 3.6.4 Information Technology (IT): Responsible for maintenance of computer systems.
- 3.7 Refer to Attachment I for the organization chart.

4.0 MANAGEMENT

- 4.1 In 2006, West Coast Analytical Services was purchased by Bodycote Materials Testing. In 2008, the Bodycote Testing Group division was purchased by Clayton, Dubilier and Rice (CD&R), a global private equity firm, and rebranded as Exova in 2009.
- 4.2 This site (Exova Site 400 at 9240 Santa Fe Springs Rd., Santa Fe Springs CA) is headed by a General Manager who supervises all the accounting, finance, personnel, marketing, and general business functions.
- 4.3 Both technical and non-technical managers are used at different levels of management in the company. More detailed Job Descriptions are contained in SOP 120.
- 4.4 The Technical Director is responsible for all technical aspects of the laboratory including analytical problem solving and ensuring the accuracy and quality of data reported by the laboratory. The Technical Director fulfills the role of Laboratory Director, as defined in state, national, and international laboratory accreditation standards.

4.5 HSEQ is headed by the HSEQ Officer, who also reports to the Exova Regional HSEQ Director. The HSEQ Officer is responsible for the implementation and monitoring of the Exova management system and fulfills the Quality Manager function as defined in International Standards. The HSEQ Officer heads the Quality Unit, as defined in FDA GMP and GLP regulations. The HSEQ Officer has the authority to stop work and withhold the issuance of reports and certificates where such activities compromise the integrity of Exova services, the validity of reported data, or management system requirements.

4.6 The analytical groups are managed by Department Managers (Group Leaders) who have overall administrative, technical, and quality control responsibilities for the operation of their groups.

5.0 FACILITIES

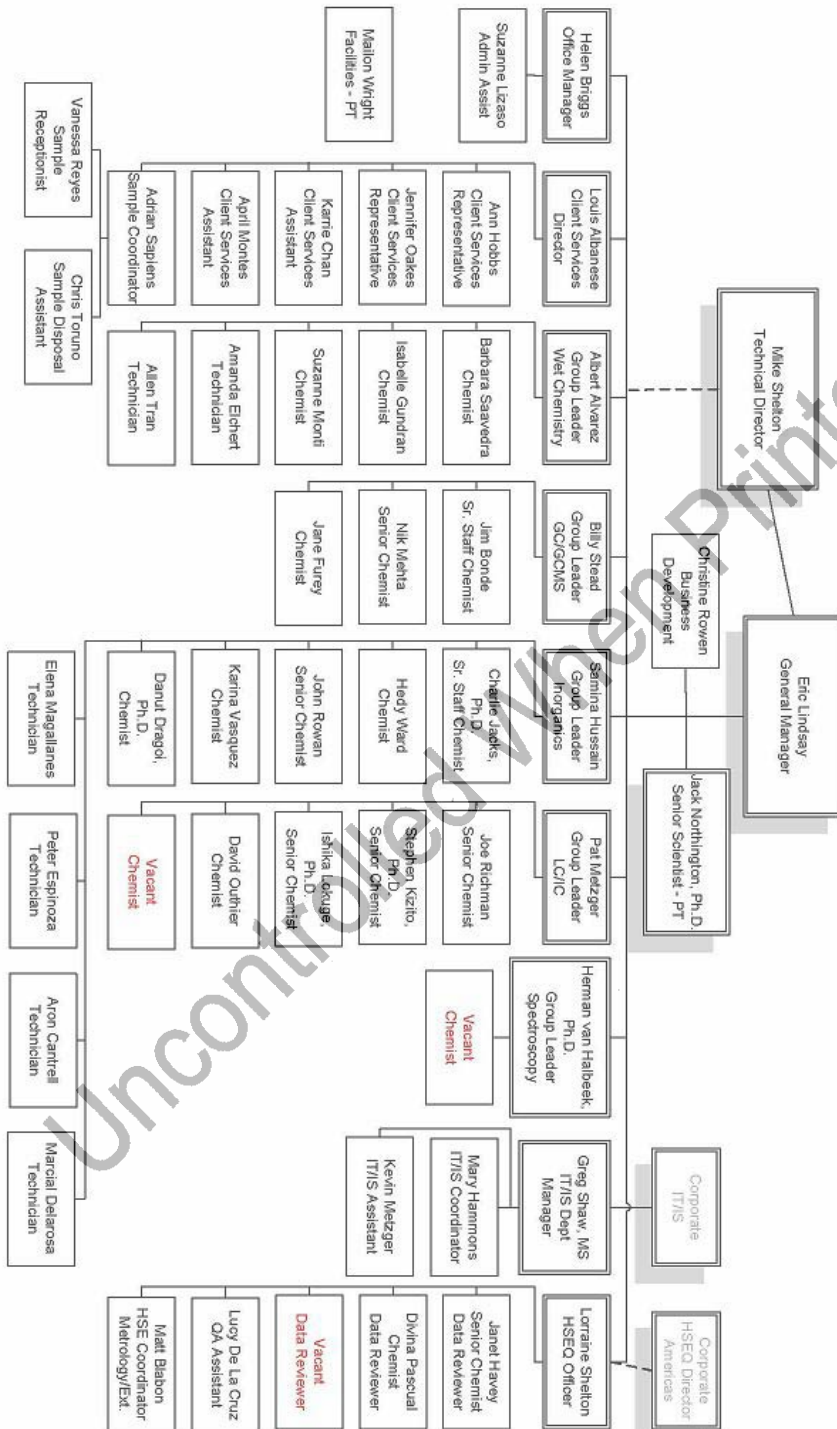
The laboratory is housed in a single stand-alone building of approximately 35,000 square feet. A facilities diagram is included as Attachment II.

6.0 TRAINING

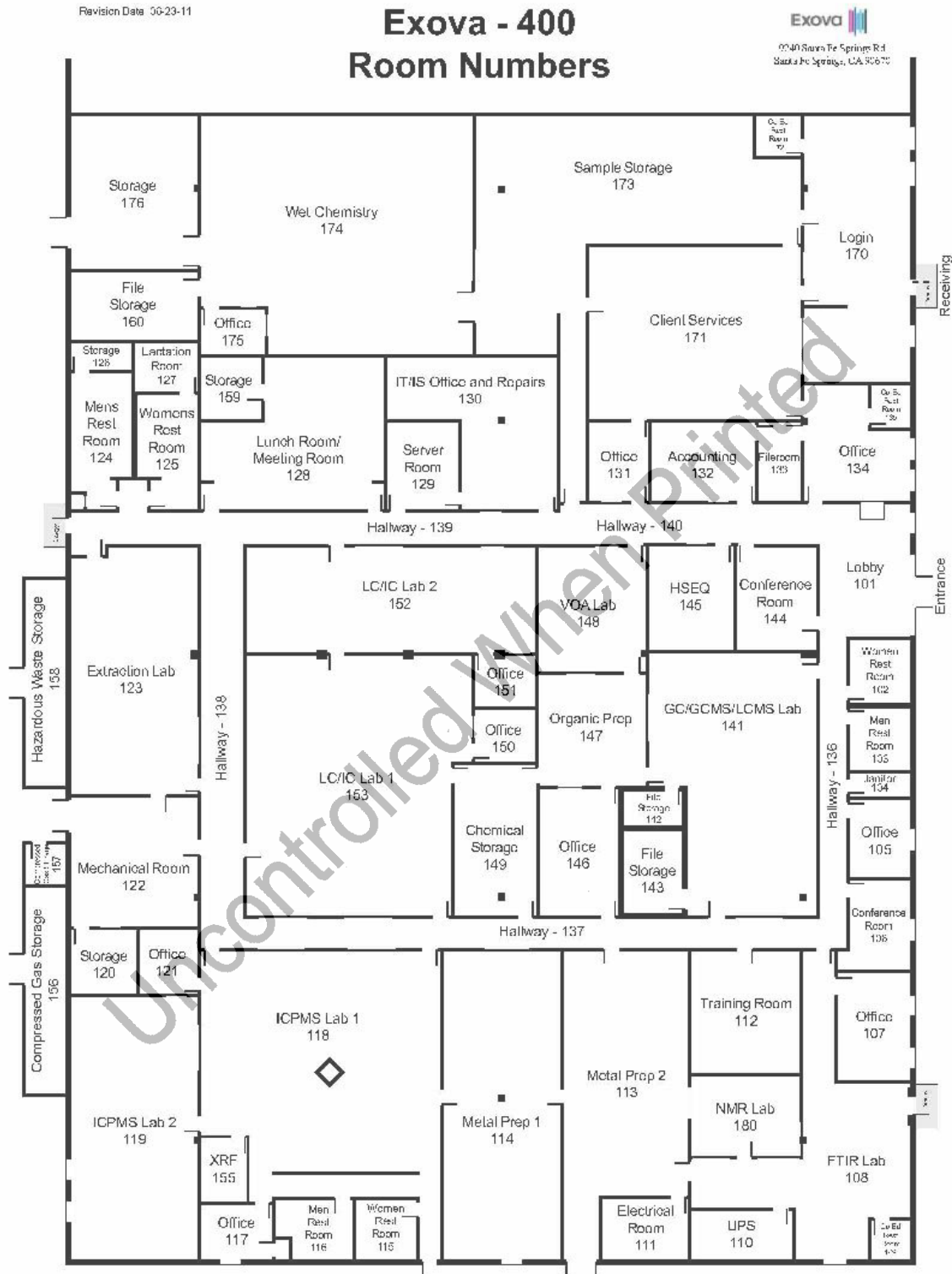
Personnel training is not required for this SOP.



Exova – 400
Health Sciences - Americas
 9240 Santa Fe Springs Road, Santa Fe Springs, CA 90670
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Attachment I - Organization Chart



Attachment II - Facilities Diagram