

# **Russian-American BioIndustry Initiative Integrated Toxicology Testing (RABIITT)**

*Arkadi N. Murashev*

## **BIOLOGICAL TESTING LABORATORY**

**BRANCH  
of Shemyakin & Ovchinnikov  
INSTITUTE OF BIOORGANIC CHEMISTRY  
Russian Academy of Sciences**

Electronic Code of Federal Regulations

*e-CFR*  
TM

THIS DATA CURRENT AS OF THE FEDERAL REGISTER DATED JULY 29, 2003

**40 CFR**

**Protection of Environment**

**CHAPTER I**

**ENVIRONMENTAL PROTECTION AGENCY (CONTINUED)**

**SUBCHAPTER R - TOXIC SUBSTANCES CONTROL ACT (CONTINUED)**

**PART 799 - IDENTIFICATION OF SPECIFIC CHEMICAL SUBSTANCE AND  
MIXTURE TESTING REQUIREMENTS**

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CHAPTER I  
ENVIRONMENTAL PROTECTION AGENCY (CONTINUED)  
SUBCHAPTER R - TOXIC SUBSTANCES CONTROL ACT (CONTINUED)

PART 799 - IDENTIFICATION OF SPECIFIC CHEMICAL SUBSTANCE AND MIXTURE TESTING  
REQUIREMENTS

## Subpart H - Health Effects Test Guidelines

<u>799.9110</u>	TSCA	acute oral toxicity
<u>799.9120</u>	TSCA	acute dermal toxicity
<u>799.9305</u>	TSCA	repeated dose 28-day oral toxicity study in rodents
<u>799.9310</u>	TSCA	90-day oral toxicity in rodents
<u>799.9355</u>	TSCA	reproduction/developmental toxicity screening test
<u>799.9370</u>	TSCA	prenatal developmental toxicity
<u>799.9380</u>	TSCA	reproduction and fertility effects
<u>799.9410</u>	TSCA	chronic toxicity
<u>799.9620</u>	TSCA	neurotoxicity screening battery
<u>799.9630</u>	TSCA	developmental neurotoxicity

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ENVIRONMENTAL PROTECTION AGENCY (CONTINUED)

## **PART 792 - GOOD LABORATORY PRACTICE STANDARDS**

### **Subpart A - General Provisions**

**792.15 Inspection of a testing facility**

### **Subpart B - Organization and Personnel**

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### **Subpart C - Facilities**

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**792.81 Standard operating procedures**

### **Subpart F - Test, Control, and Reference Substances**

### **Subpart G - Protocol for and Conduct of a Study**

### **Subpart J - Records and Reports**

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ENVIRONMENTAL PROTECTION AGENCY (CONTINUED)

## PART 792 - GOOD LABORATORY PRACTICE STANDARDS

### Sec. 792.15 Inspection of a testing facility

(a) A testing facility shall permit an authorized employee or duly designated representative of EPA or FDA



U.S. Food and Drug Administration  
Office of Enforcement  
Division of Compliance Policy HFC-230

**James F. McCormack, Ph.D.**  
Director of Nonclinical Laboratory Compliance

5600 Fishers Lane  
Rockville, MD 20857  
Phone (301) 827-0425, Fax (301) 827-0482  
Email [james.mccormack@fda.gov](mailto:james.mccormack@fda.gov)



# BIOLOGICAL TESTING LABORATORY

## BIOMEDICAL RESEARCH FACILITY



**Total area - 2450 sq.m**  
**13 animal rooms**  
**17 laboratory rooms**

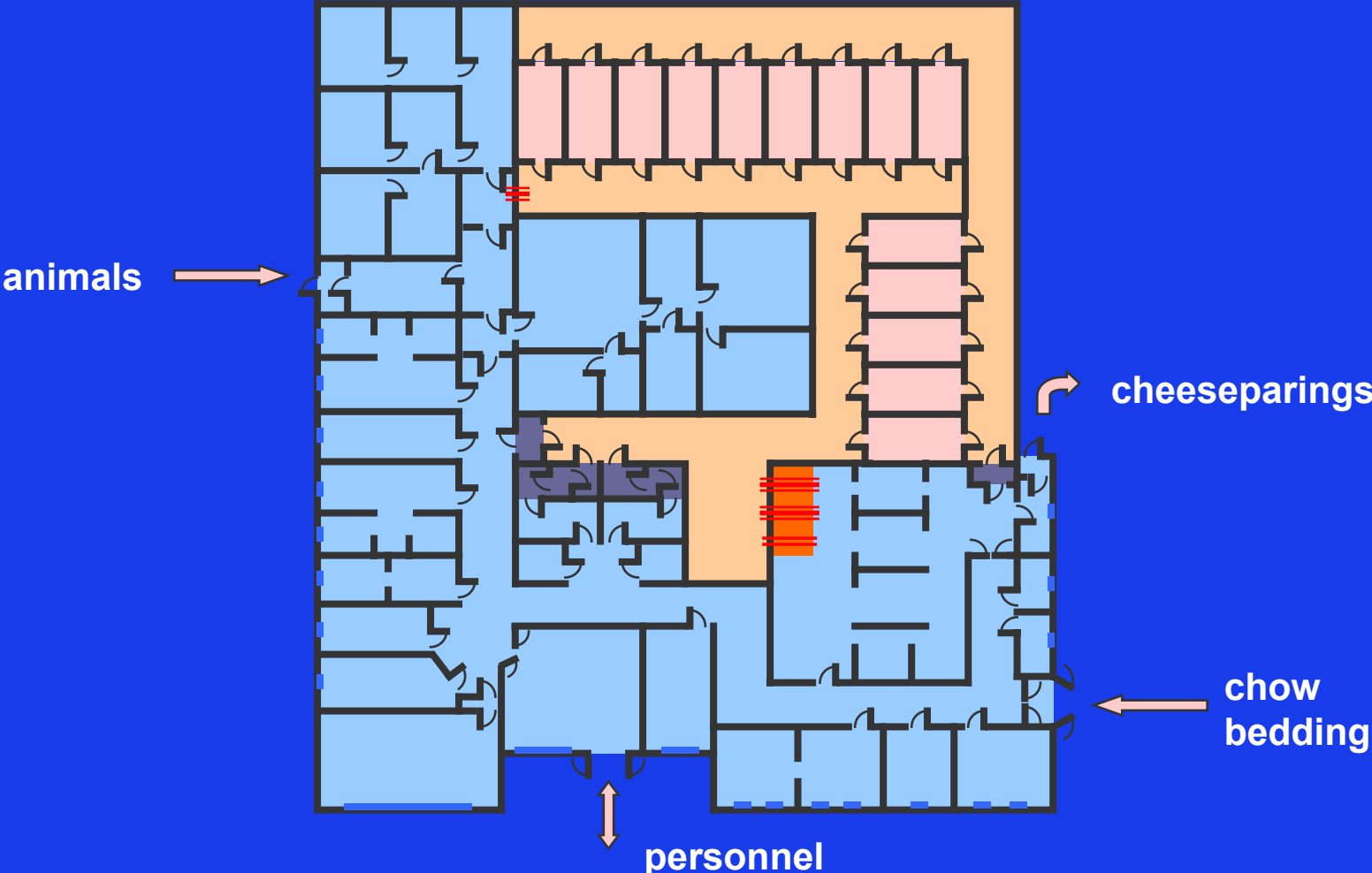
**The animal rooms**  
**are supplied with 100% outside air,**  
**HEPA filtered**  
**are maintained at a positive pressure**

**Temperature (18-24°C) and humidity (30-70%) are controlled**

**12-hour cycle of light is synchronized**

**Animals are given a standard chow and water ad libitum.**

# PLAN OF BIOMEDICAL RESEARCH FACILITY



# PERSONNEL OF BIOLOGICAL TESTING LABORATORY



**Scientific personnel:**  
PhD - 9  
Investigators - 12  
Technicians - 15

**Personnel Training Program is implemented in the Laboratory on a regular basis**



## Head of laboratory

*Мурашеев А.Н.*

### Scientists (SD)

*Хохлова О.Н.  
Шибеев Н.В.  
Кравченко И.Н.  
Кравченко Н.Н.  
Новикова Н.И.  
Захаров М.В.  
Рассказова Е.А.  
Ржевский Д.И.  
Лобанов А.В.  
Лобанова Н.Н.  
Кустанова Г.А.  
Туробов В.И.  
Огай А.Я.  
Дьяченко И.А.  
Пужалин А.Н.  
Захарова Л.А.  
Мурашева Г.В.*

### Technical Staff

*Бородина Г.И.  
Булгакова Л.Н.  
Буторина Е.Е.  
Калабина Е.А.  
Маштакова А.В.  
Мураткина О.А.  
Муратова А.К.  
Орлова С.В.  
Осипова Г.А.  
Остапюк О.А.  
Печникова Т.Н.  
Ситикова В.А.  
Фоменко С.А.  
Шешелева М.А.*

### QAU

*Заргарова Т.А.  
Жармухамедова Т.Ю.  
Садовников В.Б.  
Горелкова Т.Ф.*

### Service for drug preparation

*Пономарева Т.И.  
Туховская Е.А.*

### Engineers Service

*Ватолин В.И.  
Хаустов Р.В.*

### Veterinary Service

*Семушина С.Г.  
Пахомова И.А.*

### Service of the labour SAFETY

*Шпилько О.С.*

### ARCHIVE

*Ледовская Л.А.*

# TECHNOLOGICAL EQUIPMENT

**DOUBLE-ENDED  
AUTOCLAVE**



**MILLIPORE "Elix 10"**



**WASHING MACHINE**



# BIOMEDICAL RESEARCH EQUIPMENT

## EQUIPMENT FOR CLINICAL BIOCHEMICAL STUDY



# BIOMEDICAL RESEARCH EQUIPMENT

## EQUIPMENT FOR CLINICAL HEMATOLOGICAL STUDY



# ANIMAL BREEDING FACILITY



GLP EPA

792.90 Animal and other test system care

*At the initiation of a study, test systems shall be free of any disease*

**CHARLES RIVER LABORATORY**

**JACKSON LABORATORY**

**HARLAN**

**TACONIC FARMS**



SITE VISIT EXIT BRIEFING  
AND  
POST SITE VISIT COMMUNICATION

ORGANIZATION: ANIMAL BREEDING FACILITY / INSTITUTE of BIOORGANIC CHEMISTRY

SITE VISIT DATE(s): 28-29 July 2004 FILE #: 1093

# STUDY ORGANIZATION

## GLP STANDARDS

1. Designate a study director before the study is initiated
2. The study director has overall responsibility for the technical conduct of the study
3. Each study have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study
4. A testing facility have standard operating procedures in writing, setting forth study methods
5. A testing facility have a quality assurance unit which shall be responsible for monitoring each study
6. All raw data, protocols, reports are retained