



# COUNTY OF SAN DIEGO

## INTER-DEPARTMENTAL CORRESPONDENCE

January 11, 2008

**TO:** Kathy Wagner, Quality Assurance Manager

**FROM:** Steve Guroff, Supervising Criminalist, Forensic Biology Section  
Michelle Hassler, DNA Technical Manager

**CC:** Byron Sonnenberg, CODIS Manager

**SUBJECT: Response to 2007 Forensic Biology Section audit findings**

With regard to the findings expressed in our 2007 Forensic Biology Section audit:

3.1 A review of the Crime Laboratory Manual was completed in December 2007 (see attachments 1 and 2).

10.2 The Lab is in the process of purchasing an automated temperature monitoring system which will replace the thermometers currently used to monitor the temperatures of refrigerators and freezers. We should therefore be able to avoid issues of this type in the future.

The Lab's calibration program for thermometers used to monitor heat blocks used in DNA analysis procedures is described in manual section 9.8.11.2.3 (the Lab no longer uses hot shakers in any DNA analysis procedure).

The NIST-traceable thermometer used to calibrate glass thermometers used in analysis equipment is itself a glass thermometer. Its calibration certificate has no expiration date. We are not aware of any requirement, either in this standard or in applicable regulations, that necessitates recalibration of glass thermometers (see response to finding under standard 10.2.1 below).

10.2.1 The NIST-traceable reference thermometer used to calibrate the thermometers used to monitor heat blocks used in DNA analysis procedures is a glass thermometer. Its calibration certificate has no expiration date. The calibration certificate includes the statement: "As a general guideline, certification/calibration of instruments once yearly is considered acceptable in most manufacturing and laboratory practices, but each organization must set its own policies". The manufacturer of the thermometer, H-B Instrument Company, has confirmed that their calibration certificate does not have a defined expiration date, and that the governing body to

which they refer, NIST, recommends, but does not require, that traceable thermometers should be recalibrated yearly.

It is our contention that a glass thermometer remains accurate indefinitely unless subjected to specific stresses. The relevant NIST document, publication SP250-23 (NIST Measurement Services: Liquid-In-Glass Thermometer Calibration Services), states, in part:

“With better grades of thermometer glasses the change [in temperature reading] will not exceed 0.1 °C over a period of many years, provided the thermometer has not been heated to temperatures above approximately 150 °C”.

“Permanent changes in the bulb volume [of the thermometer’s indicator reservoir bulb] have also been observed when thermometers have been repeatedly cycled at low temperatures (between -30 and +25 °C)”.

As the thermometers mentioned in the finding are not subjected to temperature extremes, or repeated cycling, we believe it is not necessary to recalibrate them periodically. We consequently believe there is no substance to the assertions that our thermometers are not NIST-traceable, or that they require recalibration. There appears to be an overarching assumption that NIST requires yearly recalibration, but there is no basis we could find to establish that is more than a recommendation. We therefore believe this finding is a result of the inspectors using a false preconception in place of fact.

However, we are in the process of purchasing a temperature monitoring system that will replace the glass thermometers we currently use. This system will use electronic monitors that will be recalibrated annually, thus avoiding this issue in the future.

10.3 The acceptable temperature ranges for all refrigerators and freezers used to store critical DNA reagents have been adjusted to conform to the manufacturer’s recommended storage conditions for the reagents. We are acquiring new NIST-traceable thermometers for each refrigerator and freezer used to store reagents, which will allow us to verify these ranges are maintained until our temperature monitoring system arrives.

The temperature ranges for the refrigerators were originally set at 0°C to 10°C, which is two degrees higher and lower than the manufacture recommends for reagent storage. The temperature ranges for the freezers were originally set at -10°C to -30°C, which is 5 degrees higher and lower than the manufacture recommends for reagent storage. Most of the recorded temperatures from the refrigerators and freezers that contained the critical reagents did not fall outside the manufacturer’s recommendations. The reagents have worked properly as demonstrated by all controls and proficiency samples analyzed with these reagents.


10.3.1 The ‘repair’ described in the finding involved tightening a threaded fitting on a piercing unit, which in no way affected the performance of the extractor. We also note that the discussion for this standard states that “Standard 10.3.1 does not apply to instruments and equipment that cannot be calibrated by laboratory personnel.” As the EZ-1 falls into this category, we do not feel this finding is justified.

10.3.2 The Lab has purchased a service agreement for the 7000 instrument, which includes an annual preventative maintenance. In addition, the forensic biology section has created a calendar in which the schedule of all maintenance can be documented and maintained. This calendar will ensure that all appropriate maintenance is done on instruments in a timely manner.

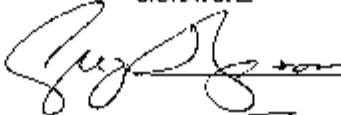
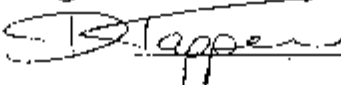
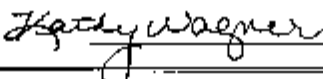
The preventative maintenance was performed three months behind schedule (January 2007). The next preventative maintenance is scheduled for January 2008.

16.1 A review of the Lab's safety programs was completed in December 2007 (see attachment 3).

**SAN DIEGO COUNTY SHERIFF'S CRIME LABORATORY  
CRIME LABORATORY MANUAL REVIEW 2007**

|   |   |                               |
|---|---|-------------------------------|
|  | <b>SAN DIEGO<br/>SHERIFF'S<br/>CRIME<br/>LABORATORY</b> | <b>GENERAL LAB<br/>MANUAL</b> |
| <b>SECTIONS REVIEWED: 1-6, 8-9</b>  |   |                               |

EFFECTIVE DATE: DECEMBER 31, 2007  
REVISIONS WRITTEN BY: MARTY FINK  
REVIEWED BY: STEVE GUROFF  
SUPERCEDES: JANUARY 2005 VERSION

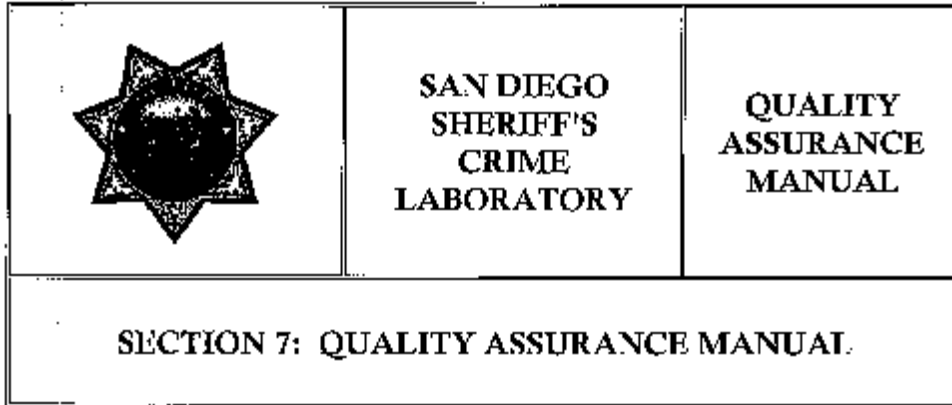
| APPROVALS:                              | SIGNATURE   | DATE              |
|---|---|-------------------|
| DIRECTOR OF FORENSIC SERVICES           |  | December 31, 2007 |
| ASSISTANT DIRECTOR OF FORENSIC SERVICES |  | December 31, 2007 |
| QUALITY ASSURANCE MANAGER               |  | December 31, 2007 |

**SAN DIEGO COUNTY SHERIFF'S CRIME LABORATORY**

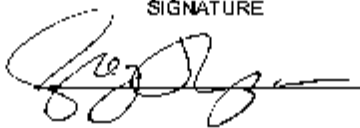

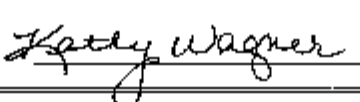
CRIME LABORATORY MANUAL

Section 7.1


**7 QUALITY ASSURANCE MANUAL**




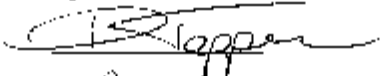

EFFECTIVE DATE: DECEMBER 31, 2007  
 REVISIONS WRITTEN BY: KATHY WAGNER  
 REVIEWED BY: DEBLYEC, DEMARIA, FINK,  
 GYROFF, LIKOMSKI, TAPFER  
 SUPERCEDES: JANUARY 13, 2006, VERSION

| APPROVALS:                              | SIGNATURE   | DATE              |
|---|---|-------------------|
| DIRECTOR OF FORENSIC SERVICES           |  | December 31, 2007 |
| ASSISTANT DIRECTOR OF FORENSIC SERVICES |  | December 31, 2007 |
| QUALITY ASSURANCE MANAGER               |  | December 31, 2007 |

**SAN DIEGO COUNTY SHERIFF'S CRIME LABORATORY  
SAFETY DOCUMENTS REVIEW 2007**

|   |   |   |
|---|---|---|
|    | <p align="center"><b>SAN DIEGO<br/>SHERIFF'S<br/>CRIME<br/>LABORATORY</b></p> | <p align="center"><b>SAFETY<br/>DOCUMENTS</b></p> |
| <p><b>DOCUMENTS REVIEWED: Bloodborne Pathogens Exposure Control Plan, Chemical Hygiene Plan, Injury and Illness Prevention Program, Medical Waste Management Plan, Protocol for Ordering and Receiving Chemicals and Chemical Inventory, Respiratory Protection Program, Safety Contact List, Safety Program Org Chart.</b></p> |   |   |

EFFECTIVE DATE: DECEMBER 31, 2007  
 REVISIONS WRITTEN BY: DEBEVEC, DEMARIA, FINK,  
 GITROFF, LUKOMSKI, TAPPER  
 REVIEWED BY: DEBEVEC, DEMARIA, FINK,  
 GITROFF, LUKOMSKI, TAPPER  
 SUPERCEDES: 2000 - 2004 VERSIONS

| APPROVALS:                              | SIGNATURE  | DATE              |
|---|--|-------------------|
| DIRECTOR OF FORENSIC SERVICES           |   | December 31, 2007 |
| ASSISTANT DIRECTOR OF FORENSIC SERVICES |  | December 31, 2007 |
| ASSISTANT SAFETY MANAGER                |   | December 31, 2007 |