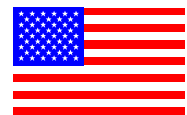


Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report

This document provides guidance on steps to be taken by the clinical laboratory to be prepared in the event of an emergency.

An NCCLS report for national application.



NCCLS...

Serving the World's Medical Science Community Through Voluntary Consensus

NCCLS is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related healthcare issues. NCCLS is based on the principle that consensus is an effective and cost-effective way to improve patient testing and healthcare services.

In addition to developing and promoting the use of voluntary consensus standards and guidelines, NCCLS provides an open and unbiased forum to address critical issues affecting the quality of patient testing and health care.

PUBLICATIONS

An NCCLS document is published as a standard, guideline, or committee report.

Standard A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

Guideline A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

Report A document that has not been subjected to consensus review and is released by the Board of Directors.

CONSENSUS PROCESS

The NCCLS voluntary consensus process is a protocol establishing formal criteria for:

- the authorization of a project
- the development and open review of documents
- the revision of documents in response to comments by users
- the acceptance of a document as a consensus standard or guideline.

Most NCCLS documents are subject to two levels of consensus—"proposed" and "approved." Depending on

the need for field evaluation or data collection, documents may also be made available for review at an intermediate (i.e., "tentative") consensus level.

Proposed An NCCLS consensus document undergoes the first stage of review by the healthcare community as a proposed standard or guideline. The document should receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

Tentative A tentative standard or guideline is made available for review and comment only when a recommended method has a well-defined need for a field evaluation or when a recommended protocol requires that specific data be collected. It should be reviewed to ensure its utility.

Approved An approved standard or guideline has achieved consensus within the healthcare community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (i.e., that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional consensus documents.

NCCLS standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following NCCLS's established consensus procedures. Provisions in NCCLS standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

COMMENTS

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the NCCLS committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are responded to by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any NCCLS document. Address comments to the NCCLS Executive Offices, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

VOLUNTEER PARTICIPATION

Healthcare professionals in all specialties are urged to volunteer for participation in NCCLS projects. Please contact the NCCLS Executive Offices for additional information on committee participation.

X4-R

ISBN 1-56238-510-0

Volume 23 Number 29

ISSN 0273-3099

Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report

Thomas L. Hearn, Ph.D.

J. Rex Astles, Ph.D., FACB

Lawrence A. Kaplan, Ph.D., FACB

Anthony R. Sambol, MA, SM(NRM), SV(ASCP), CBSP

Thomas L. Williams, M.D., FACB, FASCP, FCAP

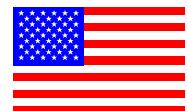
Abstract

NCCLS document X4-R—*Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report* was written for use by laboratory managers, directors, and supervisors, and is intended to provide a checklist of considerations to be used to assess preparedness and begin planning for continuance and redirection of clinical laboratory services during emergency situations. Emergency situations that are associated with large numbers of injured or dead (which will require an acute demand for laboratory services) may also result in catastrophic disruptions in laboratory services. The emergency may be associated with a variety of very different causes: natural, accidental, or terroristic. In each case, emergency operational procedures are necessitated by loss or degradation of infrastructural elements, upon which routine laboratory operations are dependent. Sample infrastructural insults include: interrupted access to utilities (electrical power, clean water, and refuse disposal), climate control, transportation of clinical specimens, and electronic test ordering and reporting. In both natural and man-made disasters, including events such as hurricane, flood, earthquake, and explosion, it is likely that more than one infrastructure element will be lost. In other instances, including accidental or terroristic exposure to infectious, chemical, or radiological agents, it is likely that utility infrastructure will remain operational, but there may be breakdowns in system components, possibly including quality assurance for clinical specimen testing and reporting, as well as reporting public health issues. All of these issues are complicated by the possibility that some laboratory staff may be unable or unwilling to report to work.

This report is written in an expanded checklist format. It outlines the important considerations laboratory professionals must make to identify infrastructure and systems that may be at risk of failure during natural and man-made disasters.

NCCLS. *Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report*. NCCLS document X4-R (ISBN 1-56238-510-0). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.

THE NCCLS process, which is the mechanism for moving a document through two or more levels of review by the healthcare community, is an ongoing process. Users should expect revised editions of any given document. Because rapid changes in technology may affect the procedures, methods, and protocols, users should replace outdated editions with the current editions of NCCLS documents. Current editions are listed in the *NCCLS Catalog*, which is distributed to member organizations, and to nonmembers on request. If your organization is not a member and would like to become one, and to request a copy of the *NCCLS Catalog*, contact the NCCLS Executive Offices. Telephone: 610.688.0100; Fax: 610.688.0700; E-Mail: exoffice@nccls.org; Website: www.nccls.org



This publication is protected by copyright. No part of it may be reproduced, stored in a retrieval system, transmitted, or made available in any form or by any means (electronic, mechanical, photocopying, recording, or otherwise) without prior written permission from NCCLS, except as stated below.

NCCLS hereby grants permission to reproduce limited portions of this publication for use in laboratory procedure manuals at a single site, for interlibrary loan, or for use in educational programs provided that multiple copies of such reproduction shall include the following notice, be distributed without charge, and, in no event, contain more than 20% of the document's text.

Reproduced with permission, from NCCLS publication X4-R—*Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report* (ISBN 1-56238-510-0). Copies of the current edition may be obtained from NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA.

Permission to reproduce or otherwise use the text of this document to an extent that exceeds the exemptions granted here or under the Copyright Law must be obtained from NCCLS by written request. To request such permission, address inquiries to the Executive Director, NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA.

Copyright ©2003. The National Committee for Clinical Laboratory Standards.

Suggested Citation

(NCCLS. *Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report*. NCCLS document X4-R [ISBN 1-56238-510-0]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.)

Report

Approved by Board of Directors

September 2003

Published

October 2003

ISBN 1-56238-510-0

ISSN 0273-3099

Committee Membership

Working Group on Emergency Response

Thomas L. Hearn, Ph.D.

Chairholder

Centers for Disease Control and Prevention

Atlanta, Georgia

J. Rex Astles, Ph.D., FACB

Centers for Disease Control and Prevention

Atlanta, Georgia

Lawrence B. Kaplan, Ph.D., FACB

Department of Pathology,

New York University

Bellevue Hospital Center

New York, New York

Anthony R. Sambol, MA,
SM(NRM), SV(ASCP), CBSP
Nebraska Health and Human
Services System

University of Nebraska Medical
Center

Nebraska Public Health Laboratory
Omaha, Nebraska

Thomas L. Williams, M.D., FACB,
FASCP, FCAP

Methodist Hospital
Omaha, Nebraska

Staff

Geraldine L. Barnes, M.T.(ASCP),
M.S.

Project Manager

NCCLS

Wayne, Pennsylvania

Donna M. Wilhelm

Editor

NCCLS

Wayne, Pennsylvania

Melissa A. Lewis

Assistant Editor

NCCLS

Wayne, Pennsylvania

Acknowledgements

NCCLS would like to acknowledge the participation of the following persons in the review of *Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report*:

Judy Dye, M.A.
Univ. of Arizona Medical Center
Tucson, Arizona

Barry Elkins, Ph.D.
St. Vincent Catholic Medical
Centers - Manhattan Campus
New York, New York

Harvey T. Holmes, Ph.D.
Centers for Disease Control and
Prevention
Atlanta, Georgia

David Huelsmann, MA,
MT(ASCP)DLM
Methodist Hospital
Omaha, Nebraska

Patricia A. Lenaghan RN, MS,
CEN, FAAN
Methodist Hospital
Omaha, Nebraska

Donna M. Meyer, Ph.D.
CHRISTUS Health
Houston, Texas

J. Michael Miller, Ph.D.
Laboratory Response Branch
Centers for Disease Control and
Prevention
Atlanta, Georgia

Janet K.A. Nicholсан, Ph.D.
National Center for Infectious
Diseases
Centers for Disease Control and
Prevention
Atlanta, Georgia

John Osterloh, M.D.
National Center for Environmental
Health
Centers for Disease Control and
Prevention
Atlanta, Georgia

Jared N. Schwartz, M.D., Ph.D.
Presbyterian Healthcare
Charlotte, North Carolina

Peter R. Teahen, President
International Mass Fatalities
Center
Cedar Rapids, Iowa

Tolmie Wachter, S.L.S.(ASCP)
AVP, Director of Corporate Safety
ARUP Laboratories
Salt Lake City, Utah

Sheila M. Woodcock, ART, M.B.A.
QSE Consulting
Nova Scotia, Canada

Raymond A. Zilinskas, Ph.D.
Center for Nonproliferation
Research
Monterey Institute of International
Studies
Monterey, California

Contents

Abstract..... i

Committee Membership..... iii

Foreword..... vii

1 Scope..... 1

2 Introduction..... 1

3 Definitions 2

4 The Environment of Response to Disasters 4

4.1 Categories of Incidents 4

4.2 The Responding Community 5

4.3 The Responding Hospital 7

4.4 The Role of Public Health During a Disaster 8

5 Communications 9

5.1 Communication Systems 9

5.2 Designating a Backup Communications System 10

6 Challenges to Laboratory Operations During Disasters..... 11

6.1 Considerations for Disaster Planning 11

6.2 Human Resource Challenges 14

6.3 Communications Challenges 16

6.4 Failure of Utilities..... 18

6.5 Laboratory Supplies and Inventory 19

6.6 Mass Fatalities Planning 20

6.7 Reference Laboratory Relationships..... 21

7 The Laboratory Response Network 23

7.1 The Laboratory Response Network for Bioterrorism 23

7.2 The Laboratory Response Network for Chemical Terrorism 25

7.3 Reporting of Results 25

8 Special Attributes of Incidents of Terrorism..... 26

8.1 Cooperation with Law Enforcement Officials..... 26

8.2 Cooperation with Public Health Officials..... 26

8.3 Chain of Custody 26

9 The Responding Laboratory: Developing an Emergency Response Plan..... 27

Appendix A. Category A and B Biological Agents 30

Appendix B. Chain of Custody Log Sample Form 31

Websites 32

Website Resources 34

The Quality System Approach 36

Related NCCLS Publications..... 37

Foreword

Recent events have dramatically worsened our perceptions of the likelihood, severity, and types of emergencies to which our communities and healthcare resources may be susceptible. While the laboratory capacity to perform emergency clinical and public health testing has received considerable attention, proportionately little guidance has addressed the logistical, nonanalytic challenges of laboratory operation during large-scale disasters. This document seeks to reasonably balance concepts and completeness, in an effort to urgently field information specifically addressing logistical (nonanalytic) challenges of laboratory operations during an emergency of very large scale. Users of this document are apprised that the challenges it seeks to address are, above all, evolving. National, state, local, and facility emergency response plans and infrastructures are presently under intense scrutiny and revision. Given the complexity of the "emergency response" topic, deficiencies in this limited report are inevitable. The authors and reviewers hope the contents are found useful to laboratorians in considering and planning for these challenges wherever they live and work.

Key Words

Communications, disaster, local emergency operations plan, preparedness, public health, terrorism

Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report

1 Scope

This guide provides direction for assessing nonanalytic (operational) system components of both clinical and public health testing that may be impaired or at risk of failure in various natural and man-made disasters. Although certain aspects of the report focus upon emergency operational challenges confronting hospital-based laboratories, guidance for clinical laboratories residing in physicians' offices, medical centers, and reference (independent) laboratories is also provided. With this document, these institutions have a framework to implement a team responsible for reviewing the infrastructures that support both clinical and public health laboratory testing and result reporting. System components that may be affected include:

- test ordering and receipt by the laboratory/phlebotomy team
- patient specimen acquisition and identification
- computer functions
- specimen transportation to the laboratory
- staffing
- analysis
- test result reporting
- reagents and supplies
- usual internal institutional partners for testing support
- test referral, specimen packaging and transportation, and communication to external reference laboratories
- reporting tests of public health importance
- transportation of isolates for public health testing
- communication with the public health laboratory for epidemiologic surveillance
- morgue operations

2 Introduction

Recent events have emphasized an urgent need to expand laboratory, facility, community, state, and national preparedness to include realistic considerations of the types and magnitudes of emergency incidents heretofore thought impossible. Although beneficial, intense planning is proceeding within the government, law enforcement, public safety, public health, and medical sectors, this document seeks to recognize and address those preparedness and operational challenges unique to the clinical laboratory. Both detrimental and beneficial potential effects related to the clinical laboratory's relationship with selected aspects of local community disaster planning are also explored.

Disaster planning and preparedness requires dedicated people, time, and money. Of these three, the first is by far of greatest importance. It is important to understand that much can be accomplished collaboratively and/or voluntarily without direct resource expenditures. For example, virtually expense-free backup emergency communications systems are possible in cooperation with local volunteer communicators using their own equipment. Networking among the participants and potential stakeholders (to be described in this document) during plan development ensures a robust and flexible plan, and also enhances aspects of routine clinical laboratory practice, such as relationships with local public health personnel.

Funding will be required at most facilities to achieve suitable preparedness. While the situation is evolving, funding for hospital and laboratory preparedness may be available through state health