

LOVELACE RESPIRATORY RESEARCH INSTITUTE

SOP No.: TXP-1258.1	Effective Date: 11/02/04	Page 1 of 5
Title: NERC Data Management		
Approved: <i>For signature see official, signed SOP.</i>		
_____		Date: _____
LRRRI Management		

1 Purpose

The purpose of this standard operating procedure (SOP) is to define the sequence of, and responsibility for, the movement, quality control, and quality assurance of data produced in NERC core studies, and incorporation of the data into the NERC database.

2 Responsibility

NERC Investigators are responsible for measurement of biological and physical-chemical data in NERC core studies, placing the data into tabular form in electronic media suitable for transfer to the database, performing quality control (QC) checks, to ensure the accuracy of the data transferred, and working with the Quality Assurance (QA) Unit as necessary to complete QA audits and remedy deficiencies. Investigators are responsible for ensuring that current SOPs are in place for the measurement procedures used in NERC core studies. Investigators are responsible for ensuring that NERC results published in the peer-reviewed literature are derived only from data in the NERC Final Database. NERC Investigators are also responsible for the timely publication of NERC results so that the database files can be made available to the public in a timely manner.

The **NERC Database Manager** is responsible for creating, documenting, and maintaining the NERC Database, for ensuring adequate back-up of the database, for making changes to data in the Final Database (with case-by-case approval from the NERC Director and with full documentation), for managing the availability of NERC database data to the public (as approved by the NERC Director), and for protecting the Final and Public Databases from internal or external tampering.

The **LRRRI Quality Assurance Unit** is responsible for performing QA audits of NERC data from the Interim Database, interacting with Investigators as necessary to complete the audits and remedy deficiencies, and working with the Database Manager to ensure that changes resulting from audits are incorporated into the files transferred to the Final Database. These functions may be performed by Unit personnel, or by another independent Auditor designated by the Unit. The Auditor will notify the NERC Study Director of all audit findings.

The **NERC Study Director** is responsible for tracking the status of NERC data, providing periodic updates to the NERC Director, prompting the completion of data flow steps, if necessary, tracking the status of peer-reviewed publications of NERC results, and interacting with the NERC Director as necessary to resolve problems.

The **NERC Director** is responsible for the overall management and funding of NERC, resolving major problems, approving core study protocols, approving the submission of peer-reviewed publications by investigators, and approving public access to the database.

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3 Scope and Objectives

The primary purpose of NERC is to create and analyze a high-quality, detailed database of exposure-response and physical-chemical characterization data produced by a series of identically-designed inhalation studies (“core studies”) of complex mixtures of air contaminants, primarily combustion source emissions. To achieve a database of high quality, diverse types of data produced by numerous individual investigators at LRRRI and collaborating institutions during the course of each core study will follow a standardized pathway from the laboratory to the Final Database.

The objective of this SOP is to describe the sequence of steps in the flow of NERC data, and the individuals responsible for each step. The goal of this SOP is to facilitate the quality and integrity of data contained in the Final Database.

4 Precautions

It is essential that the data supporting NERC publications and the analysis of composition-response relationships be of high quality and capable of withstanding rigorous external scrutiny. Peer-reviewed publications of NERC results are to be developed only from data contained in the Final Database. Because NERC data will be released for public access after NERC Investigators have a reasonable opportunity to publish, it is essential that the data in the Final Database and those used to develop publications are identical (i.e., it should be possible to reproduce key published results from data contained in the Public Database).

5 Materials

Not applicable

6 Procedures

The step-wise procedures described in this SOP will follow the flow path illustrated in the diagram below. These steps will be described in general terms in this SOP. It is the responsibility of the participants to develop and follow detailed procedures at each step.

6.1 Definitions and Terms

Database: An electronic data repository maintained by the Database Manager, and having three conceptual sections (i.e., separated by code, but not necessarily by physical location): 1) an “**Interim Database**” serving as a repository for data formatted by the Database Manager from files transferred by Investigators, and the source of data for QA audits; 2) a “**Final Database**,” serving as a read-only repository for QA’d and formatted data, and accessible by Investigators for statistical analysis and publication purposes; and 3) a “**Public Database**” serving as a repository for data accessible to the public via the NERC web site.

Quality Control (QC): A process of checking data to detect and correct problems such that the accuracy and reasonableness of the data are ensured by the Investigator. This process includes ensuring that issues pertaining to outlying data, missing data, duplicate data, implausible results, and mislabeled data are detected and addressed. This step is performed by the investigator or group responsible for generating the data or performing the most recent transformation of the data, and may occur in multiple steps as the data are generated and moved. Whether or not the

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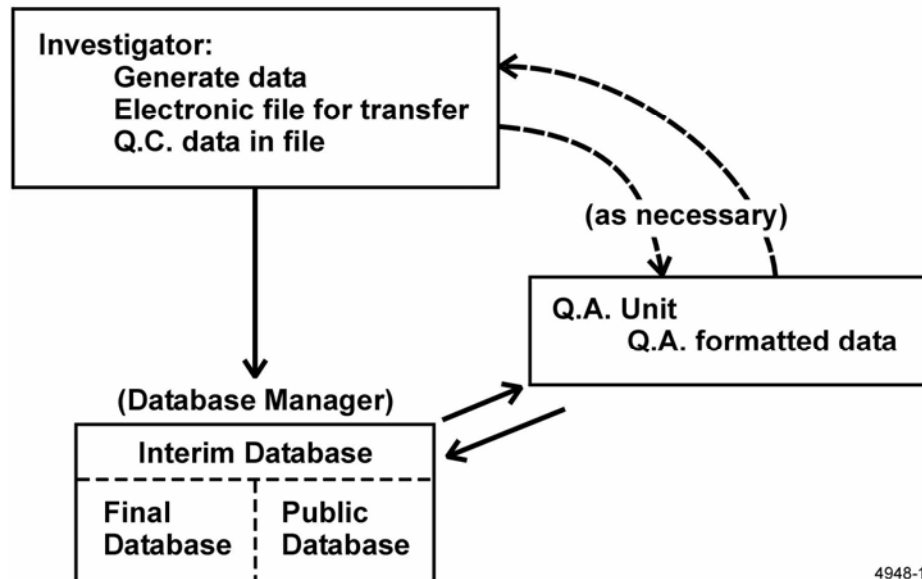
QC process includes previous steps; it should always include examination of the data contained in the electronic file transferred to the Database Manager.

Quality Assurance (QA): A systematic process of confirming that data accurately reflect the results of original observations. This step is performed by the QA Unit or its designees, to maintain independence of the audit from the Investigator. Because the types of data and processes by which data are generated vary considerably across the NERC core protocol, different specific audit strategies may be established for different types of data. The audit will begin with data from the Interim Database, to include the steps of transfer to the database and reformatting for the database within the scope of the audit. The audit will work backward from that point to ensure that the source and accuracy of the data can be tracked back to the original recorded observation. The audit may include confirmation that calculations and transformations were performed correctly. The audit staff will work with the Investigator to track through the data collecting and processing steps, and to resolve discrepancies.

6.2 Step-wise Data Flow

The following figure illustrates the key elements of data flow, as described in subsequent paragraphs.

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6.2.1 Generation of Data

Data will be generated by NERC Investigators according to the NERC core study protocol and by specific methods described in SOPs developed by the investigators. Raw data may be recorded manually in notebooks or electronic media, or may be recorded automatically into electronic media from measurement devices. The Investigator will ensure that raw data, as initially recorded, are retained for QA audit, and that sufficient laboratory records are archived to facilitate audits and allow confirmation of results if they are disputed later.

6.2.2 Submission of QC'ed Data to Interim Database Manager

The Investigator will place the data in electronic spreadsheet form (typically Excel, but possibly in another form as agreed with the Database Manager), confirm that the data file is properly labeled, conduct a final QC check, transfer the file to the Database Manager, and notify the Database Manager and the Study Director of the transfer. Prior to initial transfer of a given type of data (i.e., resulting from the first core study) the Investigator should review the data fields, the nature of the data, and labeling with the Database Manager. Although the Investigator will often perform preliminary data summaries (e.g., calculations of means) and exploratory statistical evaluations by this time, the transferred file will contain only individual data points and no summary data or statistical results. Preliminary statistics from QC'ed data may be used for presentation of interim results (e.g., abstracts for meetings); however, final statistics for publications must only be done using QA'd data from the Final Database.

6.2.3 Formatting of Data from QC File and Entry into Interim Database

The Database Manager will re-format files received from Investigators, enter the data into the Interim Database, and notify the Auditor that the data are available for QA audit.

6.2.4 QA Audit

The QA Unit (Unit personnel or a designated Auditor) will audit the data file using a data-specific strategy. The Auditor will interact with the Investigator as necessary to identify steps used in generating the QC'ed data, locate interim and raw data, and identify and resolve discrepancies. The investigator's SOPs will be an important facilitator of the audit. The Auditor will coordinate with the Database Manager to ensure that changes resulting from the audit are either incorporated into the file in the Interim Database, or that the file in the Interim Database is replaced with a file that has passed audit successfully. The Auditor will notify the Study Director immediately if problems are detected. The Auditor will provide an audit report to the Study Director when the audit is completed.

6.2.5 Entry of Files into the Final Database

After completion of QA audit, the Database Manager will enter the audited and approved data into the Final Database and notify the Investigator and the Study Director when the transfer is completed. Data from the Final database will be open to NERC Investigators on a read-only basis, and will be the source of data for summaries and statistical analyses used by Investigators for publication of results.

6.2.6 Entry of Files into the Public Database

The Study Director will keep the NERC Director apprised of the contents of the Final Database, and the status of Investigator publications. The NERC Director will determine when each type of data will be made public. Upon approval from the NERC Director, the Database Manager will code the data to allow public access, update the list of available data on the NERC web site, and notify the NERC Director when these actions are completed. The NERC Director will determine the mechanism for notifying the public of the availability of data.

7 References

Not applicable

8 Calculations and Formulas

Not applicable

9 Appendices

None