National Human Exposure Assessment Survey (NHEXAS)

Arizona Study

Quality Systems and Implementation Plan for Human Exposure Assessment

The University of Arizona
Tucson, Arizona 85721

Cooperative Agreement CR 821560

Standard Operating Procedure **SOP-UA-C-7.0**

Title: Batching of Laboratory Data

Source: The University of Arizona

U.S. Environmental Protection Agency
Office of Research and Development
Human Exposure & Atmospheric Sciences Division
Human Exposure Research Branch

Batching of Laboratory Data

1.0 Purpose and Applicability

The purpose of this procedure is to describe the steps involved in batching the physical laboratory data forms generated by NHEXAS Arizona and slated for data entry at the primary NHEXAS ~~Arizona~~ office (currently located at the HRP site). It applies to all physical laboratory data forms entered at this site.

Border and Other Health + Environment

ESC 7.14.97

2.0 Definitions

2.1 DATA = Classified under this word are the following definitions: DATA, ELECTRONIC; DATA, ENTERED; DATA, PHYSICAL; DATA, VERIFIED; DATA CLEANING; DATA PROCESSING BATCH; DATA VALIDATION.

2.1.1 DATA, ELECTRONIC = Data stored on some type of magnetic or optical medium (for example: floppy disk, hard disk, Bernoulli, tape)

2.1.2 DATA, ENTERED = Electronic data entered for the first time into a computer database. Entered data are the product of "data entry."

2.1.3 DATA, PHYSICAL = A datum or data written on a physical data form.

2.1.4 DATA, VERIFIED = Electronic data re-entered into the same table and database into which it was originally entered, and programatically compared against the original entered data. Verified data are the product of "data verification."

2.1.5 DATA CLEANING = The process of locating and correcting data processing errors. They can be individual level errors in the electronic and physical data, or they can be system level errors in the data collection, packaging, coding, entry, and cleaning procedures themselves. This process is also referred to as "data validation."

2.1.6 DATA PROCESSING BATCH (DP BATCH): A collection of household packets or physical data forms reviewed for quality assurance and ready for data entry. Each DP batch is assigned a unique numeric or alphanumeric code that is written on all forms in the DP batch and is entered into the database corresponding to that form.

2.1.7 DATA VALIDATION = See DATA CLEANING.

2.2 DATABASE, MASTER = Accumulative database generated from validated data processing batches. Newly cleaned batches are appended to the master database. Copies of this database are used in analyses. All corrections made to copies of the master are made to the master database itself. Thus, it is the most complete and accurate database of its kind.

2.3 DATABASE, WORKING = A database earmarked for or in the process of cleaning that contains one or more data processing batches. When cleaned, this will be appended to the master database.

2.4 FORM, PHYSICAL [DATA] = The paper or hard copy version of a data form. This is also referred to as a "physical data form."

2.5 FORM ID: The "ID" of a physical data form consisting of the key variable(s).

2.6 HRP SITE = The **H**ealth **R**elated **P**rofessions building, located at 1435 North Fremont Avenue; Tucson, AZ 85719. The HRP site is an annex of the Respiratory Sciences Center and the location of the NHEXAS Arizona office.

2.7 KEY VARIABLE(S) = A variable or set of variables in a data record whose value or combined values make a data record unique from other data records in the same table or file.

2.8 NHEXAS Arizona = Acronym for **N**ational **H**uman **EX**posure **A**ssessment **S**urvey conducted in Arizona by the University of Arizona/Battelle/Illinois Institute of Technology consortium.

2.9 PACKET: A sturdy, envelope-like container that can be fully closed and is large enough to hold the physical data form(s) generated by a study household, laboratory, research site, or data processing batch. One type of packet is used for one type of physical data forms (eg., manila envelopes would be used for all lab forms processed at the HRP site). Packets are either color coded, labeled according to their contents, or both. What are referred to as "lab packets" are relevant to this SOP (see PACKET, LAB below).

2.10 PACKET, LAB: A packet containing a batch of one type of physical data form that was generated either during laboratory analysis or from non-household research sites.

2.11 PRE-BATCH: A collection of completed, QA checked, physical lab forms, in the custody of the Project Data Coordinator, that is too small to be processed efficiently.

2.12 QA = QUALITY ASSURANCE: All those planned and systematic actions necessary for ensuring the validity, integrity, preservation and retrievability of the data.

2.13 QC = QUALITY CONTROL: Those quality assurance actions providing a means to control and measure the characteristics of an item, process, or the establishment of requirements.

2.14 STUDENT DATA PROCESSING: The area of the HRP site in which one or more Student Data Assistants enter, verify, clean, validate, and/or QA check post-field data.

2.15 TRACKING DATABASE: A database system containing information about the custody, transfer, and storage of hard copy data, electronic data, field samples, and field sample alloquats.

3.0 References

None

4.0 Discussion

Batching physical data forms is an organizational procedure that enables data processing at the HRP site to take place in an efficient, manageable, controlled fashion. First, physical data forms have a much greater chance of being misplaced or lost if they are amassed *ad infinitum* or stored in unlabeled folders or envelopes. Unlabeled folders or envelopes tend to blend in too well with the general office scenery.

Lab packets have a distinctive label in both color and design, and they contain the form's name, a run-down of the data processing steps, and an attached slip of paper indicating the data processing status of the forms contained therein. This minimizes misplaced physical data.

Second, the data processing batch code enables a cross-check with data entered in the working and master databases. The total number of physical forms in a batch can be compared with the total entered records in a database.

The batching of lab data forms is less frequent and regular than the batching of field data forms. Whereas field forms are batched and entered on a weekly basis, lab forms are batched when there is either an efficient quantity to process, or when the On-Site Principle Investigator needs the lab data for analyses.

5.0 Responsibilities

5.1 The Project Lab Supervisor is responsible for the following:

5.1.1 Overseeing the laboratory evaluation of samples and the collection of data at non-household research sites
5.1.2 Performing QA checks of completed physical lab forms
5.1.3 Maintaining custody of physical lab forms during QA checks
5.1.4 Delivering QA checked, physical lab forms to the Project Data Coordinator on a certain designated day of each month
5.1.5 Completing the "Lab Form Transfer Log" form for all lab forms transferred to the data section. Or Generating the data as a report from tracking Dating + Initialing it and filing it in the LAB DATA TRANSFER log.

All except the first responsibility listed above may be delegated.

5.2 The Laboratory Technician is responsible for the following:

5.2.1 Completing the physical lab forms
5.2.2 Accumulating completed physical lab forms in a clearly labeled folder or envelope
5.2.3 Delivering the completed physical lab forms to the Lab Supervisor for QA checks
5.2.4 Maintaining custody of the completed physical lab forms prior to their delivery to the Lab Supervisor.

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5.3 The Field Technician is responsible for the following:

5.3.1 Completing the physical forms for research sites
5.3.2 Accumulating completed physical forms in a clearly labeled folder or envelope
5.3.3 Delivering the completed physical forms to the Field Supervisor

for QA checks

5.3.4 Maintaining custody of the completed physical forms prior to their delivery to the Field Coordinator.

5.4 The Project Data Coordinator is responsible for the following:

5.4.1 Receiving completed physical forms from the Lab Supervisor and completing the "Lab Form Transfer Log" form appropriately upon receipt

5.4.2 Storing the completed physical forms in the appropriate lab packets

5.4.3 Storing the lab packets in the area designated for HRP data entry

5.4.4 Assigning a DP batch code to physical lab forms slated for data processing (this task may be delegated)

5.4.5 Describing the physical lab forms contained in a DP batch on a batch description form (this task may be delegated)

5.4.6 Assigning data entry, data verification, and data validation of the DP batches to Student Data Assistants

5.4.7 Ensuring that the physical and electronic DP batches are entered and cleaned

5.4.8 Ensuring that the contents of the lab packets are properly filed

5.4.9 Maintaining custody of the completed physical forms during pre-batch and batch stages, and potentially at data processing junctures (i.e., coding, data entry, verification, validation, QA checking, and filing)

5.4.10 Being the general custodian of all fully processed, filed, physical lab forms.

5.5 The Student Data Assistant is responsible for the following:

5.5.1 Processing the DP batch

5.5.2 Notifying the Project Data Coordinator at the end of data processing

5.5.3 Maintaining custody of the DP batch while processing it

5.5.4 Filing the contents of lab packet after the electronic data has been validated.

6.0 Materials and Reagents

6.1 Materials

6.1.1 "Lab Form Transfer Log" form (may be optionally generated via the tracking database)

6.1.2 Appropriately labeled lab packet(s)

6.1.3 Completed, QA checked, physical lab forms

6.1.4 Binder clip or large paper clip to keep the data forms together

6.1.5 Pen or ink writing utensil

6.1.6 "Batch Description Form"

6.1.7 "Data Entry and Validation Records" (DEVR) notebook for filing the "DP Batch Description" and "Data Entry and Cleaning Record" forms

6.1.8 "Misplaced Data Forms and Packets" form

6.2 Reagents

None

May be optionally generated by the tracking system
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7.0 Procedure

7.1 Preparations

7.1.1 Site Selection Criteria

None

7.1.2 The Lab or Field Technician completes a "Lab Form Transfer Log" form describing the physical lab forms to be transferred to the data section. The lab forms are then given to the Project Lab Supervisor and she or he transfers custody of them to the Project Data Coordinator on a certain day of each month or as needed. The exact day will be determined in a staff meeting once the lab data are being generated.

7.1.3 The person relinquishing the lab forms (Project Lab Supervisor, Lab Technician, or Field Technician) writes his or her initials and current date on the "Lab Form Transfer Log" form.

7.1.4 Pre-batches (i.e., too few physical forms to process efficiently) are placed in a "pre-process lab packet" labeled with the name of the physical form and the phrase "data accumulating."

7.2 Standards and Blanks

None

7.3 Procedure Description

7.3.1 The Project Data Coordinator (or delegate) describes the batch of physical forms using ink on the batch description form. The description must be such that an outsider could precisely identify which physical forms are in the batch. As such, key variables must be listed in most cases. The batch forms are sometimes customized for a particular physical lab form in order to ensure a complete, precise description of the physical forms in the batch.

7.3.2 The Project Data Coordinator (or delegate) assigns the batch the next available data processing batch number or code (usually ascending order) and writes it on the batch description form.

7.3.3 The Project Data Coordinator (or delegate) stamps or writes in ink the data processing batch number or code on all physical data forms in the batch. The stamp should read "DP Batch:##" where ## equals the batch number or code.

7.3.4 The Project Data Coordinator (or delegate) codes the physical forms in the batch if necessary, using purple ink.

7.3.5 The Project Data Coordinator assigns the lab packet to a Student Data Assistant for data entry and thereby transfers custody.

7.3.6 The Student Data Assistant enters the data, initials and dates the appropriate area of the "Data Entry and Cleaning Record" form in ink, and then returns the lab packet to the Project Data Coor-

dinator unless instructed otherwise.

7.3.7 The Project Data Coordinator assigns data verification of the entered lab packet to a Student Data Assistant different than the one who entered it.

7.3.8 The Student Data Assistant verifies the data, initials and dates the appropriate area of the "Data Entry and Cleaning Record" form in ink, and then returns the lab packet to the Project Data Coordinator unless instructed otherwise.

7.3.9 The Project Data Coordinator assigns the verified lab packet to a Student Data Assistant for data cleaning.

7.3.10 The Student Data Assistant cleans the data according to SOP# UA-D-18.0, initials and dates the appropriate area of the "Data Entry and Cleaning Record" form in ink, and then returns the lab packet to the Project Data Coordinator unless instructed otherwise.

7.3.11 The Project Data Coordinator reviews the "Data Entry and Cleaning Record" form for completion. If complete, she or he gives the lab packet to a Student Data Assistant in order to file its contents.

7.3.12 Upon filing, the Project Data Coordinator becomes the general custodian of the physical lab forms; however, authorized NHEXAS personnel may borrow the forms and therefore maintain temporary custody while they are being borrowed (see UA-C-8.0).

7.3.13 The empty lab packet is returned to the stack of other empty lab packets so it can be used for the next batch of physical data.

7.4 Calculations

None

7.5 Special QA Checks

7.5.1 Tolerance Limits

(a) All completed lab forms transferred from the Lab Supervisor to the Project Data Coordinator should be accounted for on the "Lab Form Transfer Log" form. Any discrepancies between forms listed as transferred and forms actually received will be noted on the transfer log and brought to the attention of the Project Lab Supervisor.

(b) Accumulated, completed lab forms should be transferred from the Lab Supervisor to the Data Coordinator on a certain day of each month. A maximum of ten business days beyond the original scheduled day of transfer is allowable.

7.5.2 Detection Limits

(a) For the processes outlined in this SOP that must occur within a certain time frame, all deviations are detectable via the "Lab Form Transfer Log" and the batch custody form.

(b) For the custody transfers of physical data and DP batches, all errors are detectable because the person representing a link in the chain of custody verifies the claim(s) of the person representing the previous link. This is an independent verification of both the key variable(s) and the presence or absence of physical data.

(c) Any error(s) in key variable(s) originating with the Field Team Leader(s) that went undetected by the Project Field Coordinator will unfortunately be passed through the entire chain of custody, unless discovered by field staff.

7.5.3 Corrective Actions

(a) For any misplaced lab data form, a search for it will begin within one business day of it being recorded on the "misplaced forms" sheet (see Figure 6). The searching parties will be the person who currently maintains custody and the person who most recently relinquished custody. In the above situation, the former will notify the latter of the misplacement. If the form(s) have not been located within five business days, then all personnel in the data section will be notified of the misplacement via memo, e-mail, or meeting announcement. If appropriate, all personnel in the field section will be notified as well. At this point, the intensity of the search effort will depend upon the relative importance of the misplaced form(s).

(b) If the transfer of completed lab forms from the Lab Supervisor to the Data Coordinator exceeds ten business days beyond the original scheduled day of transfer, then the reason(s) for lack of transfer will be addressed immediately. If the usual trained personnel are absent, then the On-Site PI will select someone to perform the job. If the forms are problematic and cannot be resolved immediately, then a new date of transfer will be determined in consultation with the On-Site PI. The new date will depend on the nature of the problem(s).

8.0 Records

8.1 Data to Be Recorded from This Procedure

None

8.2 Record Forms (Attached)

8.2.1 Figure 1: "Lab Form Transfer Log" form (example)
8.2.1 Figure 2: "Data Entry and Cleaning Record" form (example)

8.2.3 Figure 3: "DP Batch Description" form (example)
8.2.4 Figure 4: Label attached to "pre-process lab packet" (example)
8.2.5 Figure 5: Label attached to "lab packet" (example)
8.2.6 Figure 6: "Misplaced Data Forms and Packets" form

8.3 Location of Record Forms

8.3.1 The forms for data to be processed, batch tracking, and batch description are filed in the "Data Entry and Validation Records" notebook. This notebook is housed in room 128 of the HRP site.

8.3.2 The "Lab Form Transfer Log" form is filed in the "Lab Batch Custody" notebook. This notebook is housed in room 128 of the HRP site.

8.3.3 The *empty* lab packets and pre-process lab packets are stored in the stacking file labeled "Data Processing Packets: Empty," in room 128 of the HRP site.

8.3.4 *Pre-process lab packets in use* are stored in the stacking file labeled "Data Processing Packets: Data Accumulating," in room 128 of the HRP site.

8.3.5 *Lab packets in use and ready for data entry* are stored in the stacking file labeled "Data Processing Packets: Ready for Data Entry," in room 128 of the HRP site.

8.3.6 *Lab packets in use and ready for data verification* are stored in the stacking file labeled "Data Processing Packets: Ready for Data Verification," in room 128 of the HRP site.

8.3.7 *Lab packets in use and ready for data cleaning* are stored in the stacking file labeled "Data Processing Packets: Ready for Data Cleaning," in room 128 of the HRP site.

8.3.8 *Lab packets in use and ready for filing* are stored in the stacking file labeled "Data Processing Packets: Ready for Filing," in room 128 of the HRP site.

Figure 1: "Lab Form Transfer Log" form (example)

LAB FORM TRANSFER LOG

From Lab to Data					From Data to Lab (as applicable)						Initials:
Key Var(s)	Stage	Date	Lab Init	Data Init	Returned	QA or Inc	Return Date	Data Init	Lab Init	Resubmit Date	Lab/Data
		/ /			Y N	[ ] [ ]	/ /			/ /	/
		/ /			Y N	[ ] [ ]	/ /			/ /	/
		/ /			Y N	[ ] [ ]	/ /			/ /	/
		/ /			Y N	[ ] [ ]	/ /			/ /	/
		/ /			Y N	[ ] [ ]	/ /			/ /	/
		/ /			Y N	[ ] [ ]	/ /			/ /	/
		/ /			Y N	[ ] [ ]	/ /			/ /	/
		/ /			Y N	[ ] [ ]	/ /			/ /	/
		/ /			Y N	[ ] [ ]	/ /			/ /	/
		/ /			Y N	[ ] [ ]	/ /			/ /	/
		/ /			Y N	[ ] [ ]	/ /			/ /	/
		/ /			Y N	[ ] [ ]	/ /			/ /	/
		/ /			Y N	[ ] [ ]	/ /			/ /	/
		/ /			Y N	[ ] [ ]	/ /			/ /	/
		/ /			Y N	[ ] [ ]	/ /			/ /	/
		/ /			Y N	[ ] [ ]	/ /			/ /	/
		/ /			Y N	[ ] [ ]	/ /			/ /	/
		/ /			Y N	[ ] [ ]	/ /			/ /	/
		/ /			Y N	[ ] [ ]	/ /			/ /	/

Form ID: UA-C-7.0-1.0

Electronic output from tracking file may be attached to this form for transfer
1/17/96

Figure 2: "Data Entry and Cleaning Record" form (example)

DATA ENTRY AND CLEANING RECORD
NHEXAS Arizona

PHYSICAL FORM NAME: ______________________

DATABASE/FILE NAME: ______________________

DATA ENTRY FORM NAME: ______________________

DP Batch Description	DATA PROCESSING: Temporary Location	DATA PROCESSING: Data Entry and Cleaning Steps
DP Batch: ______ Comments: ______	m:\workstor\ ______	START DATE: ______ ENT BY: DATE:
		VER BY: DATE:
		RNG BY: DATE:
		ZIP BY: DATE:
		APP BY: DATE:
DP Batch: ______ Comments: ______	m:\workstor\ ______	START DATE: ______ ENT BY: DATE:
		VER BY: DATE:
		RNG BY: DATE:
		ZIP BY: DATE:
		APP BY: DATE:
DP Batch: ______ Comments: ______	m:\workstor\ ______	START DATE: ______ ENT BY: DATE:
		VER BY: DATE:
		RNG BY: DATE:
		ZIP BY: DATE:
		APP BY: DATE:
DP Batch: ______ Comments: ______	m:\workstor\ ______	START DATE: ______ ENT BY: DATE:
		VER BY: DATE:
		RNG BY: DATE:
		ZIP BY: DATE:
		APP BY: DATE:

This information can be obtained through the tracking system. This can be completed by hand. It will be equally valid to generate a report from tracking and append it to this form in the DATA Entry and Cleaning Notebook.
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3/1/96

Form ID: UA-C-7.0-2.0

Figure 3: "DP Batch Description" form (example)

DP Batch#:

DATA PROCESSING BATCH DESCRIPTION

Page ___of___

This form describes:
House Dust Mite Project Lab Evaluation Sheet

TOTAL # OF PHYSICAL DATA FORMS IN DP BATCH: ______

	COLLECTION DATE	HHID	LOC	COMMENTS
1.	/ /			
2.	/ /			
3.	/ /			
4.	/ /			
5.	/ /			
6.	/ /			
7.	/ /			
8.	/ /			
9.	/ /			
10.	/ /			
11.	/ /			
12.	/ /			
13.	/ /			
14.	/ /			
15.	/ /			
16.	/ /			
17.	/ /			
18.	/ /			
19.	/ /			
20.	/ /			
21.	/ /			
22.	/ /			
23.	/ /			
24.	/ /			
25.	/ /			

	COLLECTION DATE	HHID	LOC	COMMENTS
26.	/ /			
27.	/ /			
28.	/ /			
29.	/ /			
30.	/ /			
31.	/ /			
32.	/ /			
33.	/ /			
34.	/ /			
35.	/ /			
36.	/ /			
37.	/ /			
38.	/ /			
39.	/ /			
40.	/ /			
41.	/ /			
42.	/ /			
43.	/ /			
44.	/ /			
45.	/ /			
46.	/ /			
47.	/ /			
48.	/ /			
49.	/ /			
50.	/ /			

Form ID: UA-C-7.0-3.0

replace with scannable form UA-C-4.0-1.1

11/22/95

see Appendix A

Figure 4: Label attached to "pre-process lab packet" (example)

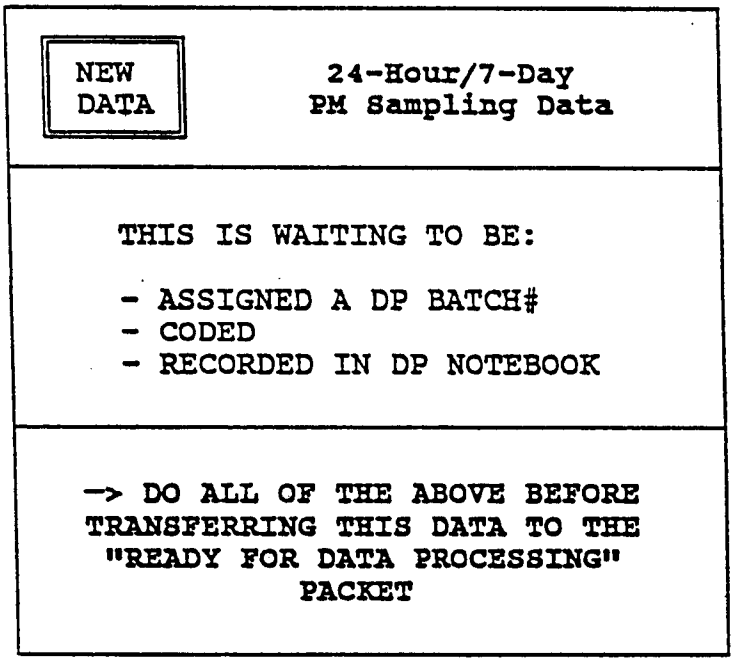

Figure 5: Label attached to "lab packet" (example)

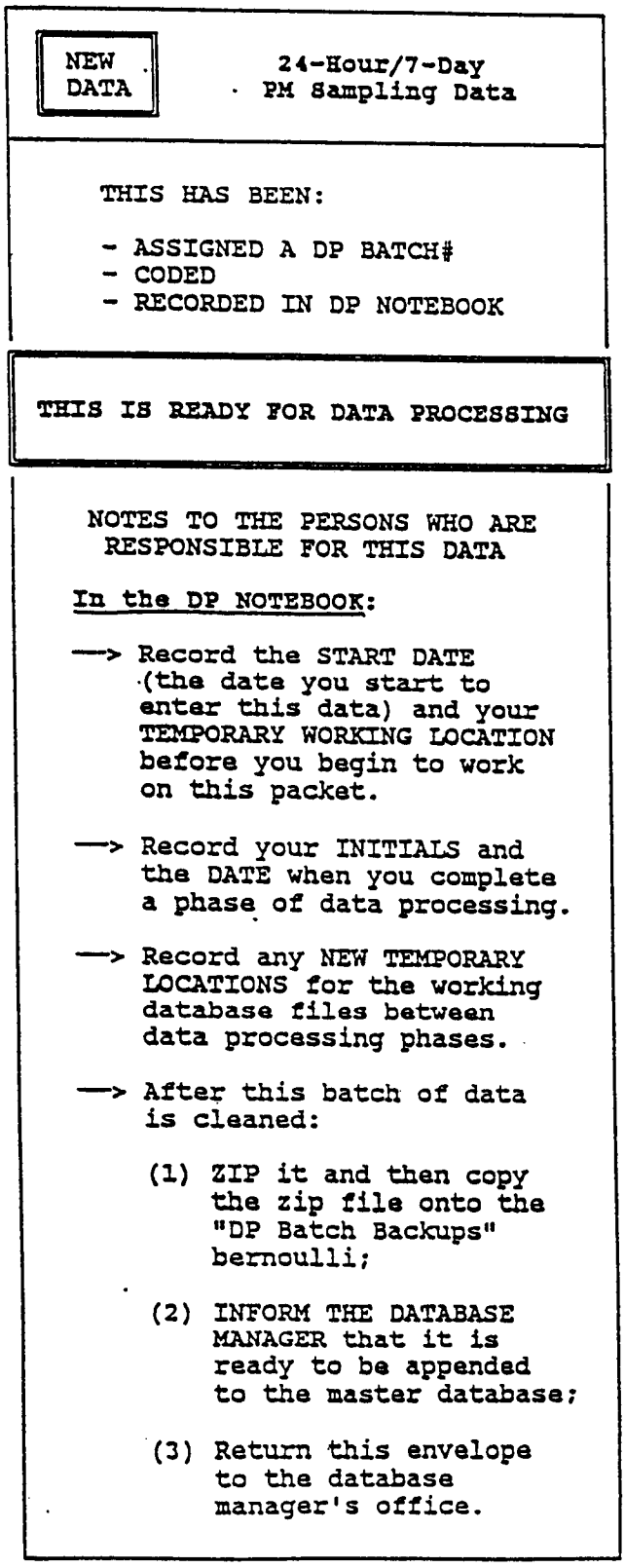

Figure 6: "Misplaced Data Forms and Packets" form

MISPLACED DATA FORMS AND PACKETS

FORM TITLE: _____
STAGE: _____

LOST			FOUND				
Key Variable(s) _____ _____	Date Missing	By	Date Found	By	Where Found	Date Filed	Comments

cereus:\laura\ws2\wkproced\custody\missform.fm
Form ID: UA-C-6.0-3.0

Appendix A: Batch Description and Custody Records

BATCH DESCRIPTION AND CUSTODY RECORD

1. Form : _____

2. DP Batch: ☐☐☐

3. Forwarded to: (Date)

○ Student DP (HRP) ..... ☐☐ / ☐☐ / ☐☐

○ Keypunch (Main Dept.)... ☐☐ / ☐☐ / ☐☐

○ Other..... ☐☐ / ☐☐ / ☐☐

4. Forwarded by: Init. ☐☐ (Tech. ID)

5. Received on: ☐☐ / ☐☐ / ☐☐ by ____ Init. ☐☐ (Tech. ID)

6. Filed on: ☐☐ / ☐☐ / ☐☐ by ____ Init. ☐☐

	HHID	F.S.	Date	IRN (If app.)	To Processing		From Processing		File
					Forward	Receive	Forward	Receive	
1.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
2.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
3.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
4.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
5.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
6.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
7.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
8.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
9.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
10.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
11.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
12.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
13.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
14.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
15.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐

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