

SUBJECT:	Fermilab Corrective & Preventive Action Plan – Form 1 - Simple	NUMBER:	1004.1001 FORM 1
RESPONSIBILITY:	Quality Assurance Manager	REVISION:	000 C3
APPROVED BY:	Head, Office of Quality and Best Practices	EFFECTIVE:	04/03/09

CAP INITIATION

This section to be completed by the person requesting simple corrective / preventive action		
Requestor Name: Tim Miller	Organization: ES&H	Phone: 3019
Problem/Opportunity To Be Addressed: The Calibration Records in the Instrument Lab do not have a Supervisor signature as stated in the FRCM requirements.		
Unique Tracking Number: DD-MM/DD/YYYY-x: ES-03/19/2009-1		
(DD=Div or Sec, MM/DD/YYYY= Date Opened, x=1, 2, ...n)		
Responsible Person: Don Cossairt	Organization: Radiation Protection	Phone: 3465
**Responsible Person Acceptance: Don Cossairt 		Date: 4/9/09
*Comments: FRCM Ch. 7, Part 1, item 713, Record Keeping Standards, identifies general requirements for record keeping.		

CAP DEVELOPMENT

This section to be completed by the Responsible Person	
Describe the Actual Problem/Opportunity, and What Caused it (Simple Root Cause): The calibrations are documented using electronically generated forms. Past practice has been for the supervisor to informally spot check the results to be sure that proper calibrations are being performed by the technicians having primary responsibility for doing the work according to written procedures that are signed by the supervisor.	
Remedial/Compensatory, Corrective, and/or Preventive, actions being taken and (where applicable) Initial Lessons Learned: The supervisor will revise the procedures to review and approve the calibration forms. Electronic approval methodologies will be investigated. If this is not feasible, paper forms with signatures will be implemented	
Planned start date (format MM/DD/YYYY): 4/20/09	
Key milestones and Dates: Investigate possible electronic alternatives and make decision by 8/1/09	
Estimated date for completion: 8/31/09	
Who will complete the work, Butch Hartman	Phone: 5514

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Who will perform verification and/or validation, Tom King	Phone: 6474
**Responsible Person: Don Cossairt	Date: 041309
*Comments:	

CAP APPROVAL, & CONCURRENCE

This section to be completed and signed by persons identified below	
** Approval Head D/S/C: Nancy Grossman	<i>Nancy Grossman</i> Date: 5/28/09
*Comments:	
***OQBP Concurrence: Jed Heyes	<i>Jed Heyes</i> Date: 6/2/09
*Comments:	

CAP CLOSURE

This section to be completed and signed by persons identified below	
Description of actions taken to implement:	
**Implemented By:	<i>Bob Hill</i> Date: 8/21/2009
**Verified By: Tom King	<i>John Martzel for John Martzel</i> Date: 8/10/2011
*Comments:	
** Acceptance Requestor: Tim Miller	<i>John Dawson for Tim Miller</i> Date: 8/10/2011
*Comments:	
**Acceptance Head D/S/C: Nancy Grossman	<i>Nancy Grossman</i> Date: 8/10/2011
*Comments:	

See Fermilab Corrective Action Plan Guide to Form 1 for directions and a completed example

SUBJECT: Fermilab Corrective & Preventive Action Plan – Form 1 - Simple	NUMBER: 1004.1001 FORM 1
RESPONSIBILITY: Quality Assurance Manager	REVISION: 000 C3
APPROVED BY: Head, Office of Quality and Best Practices	EFFECTIVE: 04/03/09

CAP INITIATION

This section to be completed by the person requesting simple corrective / preventive action		
Requestor Name: Tim Miller	Organization: ES&H Section	Phone: 3019
Problem/Opportunity To Be Addressed: The logbooks for documenting the calibration and documenting the results of surveys for the Mobile Environmental Radiation Lab (MERL) have entries made in pencil, entries crossed out with no initials and dates, do not have a Supervisor signature, and in general do not meet FRCM records keeping requirements.		
Unique Tracking Number: DD-MM/DD/YYYY-x: ES-03/19/2009-2		
(DD=Div or Sec, MM/DD/YYYY= Date Opened, x=1, 2, ...n)		
Responsible Person: Don Cossairt	Organization: Radiation Protection	Phone: 3465
**Responsible Person Acceptance: Don Cossairt 		Date: 4/09/09
*Comments: FRCM Ch. 7, Part 1, item 713, Record Keeping Standards, identifies general requirements for record keeping.		

CAP DEVELOPMENT

This section to be completed by the Responsible Person	
Describe the Actual Problem/Opportunity, and What Caused it (Simple Root Cause): The MERL has been in use for over 35 years. The logbooks observed with these deficiencies in the assessment include archival logbooks created in an era when document control procedures such as those set forth in FRCM Article 713 were not so clearly defined. These logbooks remain useful for reference purposes.	
Remedial/Compensatory, Corrective, and/or Preventive, actions being taken and (where applicable) Initial Lessons Learned: The logbooks in current use do follow the FRCM Article 713 practices, therefore this finding is invalid with respect to current practice. A memo from supervision will be inserted into the logbook to make these expectations clear.	
Planned start date (format MM/DD/YYYY): 04/20/09	
Key milestones and Dates: Insertion of the memo on 5/01/09	
Estimated date for completion: 5/01/09	
Who will complete the work, Don Cossairt	Phone: 3465
Who will perform verification and/or validation, Tom King	Phone: 6474

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****Responsible Person:** Don Cossairt  _____ **Date:** 041309

***Comments:** | |

CAP APPROVAL, & CONCURRENCE

This section to be completed and signed by persons identified below

**** Approval Head D/S/C:** Nancy Grossman  _____ **Date:** 5/28/09

***Comments:** | |

*****OQBP Concurrence:** Jed Heyes  _____ **Date:** 6/2/09

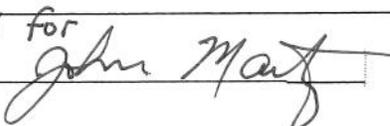
***Comments:** | |

CAP CLOSURE

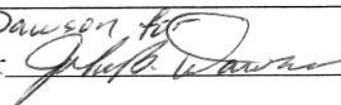
This section to be completed and signed by persons identified below

Description of actions taken to implement: | |

****Implemented By:**  _____ **Date:** 8/21/2009

****Verified By:** Tom King ^{John Martzel for}  _____ **Date:** 8/10/2011

***Comments:** | |

**** Acceptance Requestor:** Tim Miller ^{John B. Dawson for}  _____ **Date:** 8/10/2011

***Comments:** | |

****Acceptance Head D/S/C:** Nancy Grossman  _____ **Date:** 8/10/2011

***Comments:** | |

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APPROVED BY: Head, Office of Quality and Best Practices	EFFECTIVE: 04/03/09

CAP INITIATION

This section to be completed by the person requesting simple corrective / preventive action

Requestor Name: Tim Miller **Organization:** ES&H Section **Phone:** 3019

Problem/Opportunity To Be Addressed: The “Mobile Environmental Radiation Monitoring Laboratory” (MERL procedure?) document is not approved or controlled, and does not meet FESHM 1051, Control of ES&H Documents.

Unique Tracking Number: DD-MM/DD/YYYY-x: ES-03/19/2009-3

(DD=Div or Sec, MM/DD/YYYY= Date Opened, x=1, 2, ...n)

Responsible Person: Don Cossairt **Organization:** Radiation Protection **Phone:** 3465

****Responsible Person Acceptance:**  Don Cossairt **Date:** 4/9/09

***Comments:** FESHM 1051, Control of ES&H Documents identifies requirements for the control of documents.

CAP DEVELOPMENT

This section to be completed by the Responsible Person

Describe the Actual Problem/Opportunity, and What Caused it (Simple Root Cause):

The present document was developed over a period of years as a set of informal procedural notes as the use of the MERL developed over time. This is a natural results of the nature of MERL usages as, in part, a development of experimental techniques to measure the unique radiation fields near a high energy particle accelerator.

Remedial/Compensatory, Corrective, and/or Preventive, actions being taken and

(where applicable) Initial Lessons Learned: These operational notes will be rewritten as a procedure in conformance with FRCM Chapter 7 and FESHM Chapter 1051 requirements. From time-to-time, this procedure may require amendment as new/revised experimental measurement techniques are developed. The techniques may be developed using standard laboratory documentation methods first, then incorporated into procedures.

Planned start date (format MM/DD/YYYY): 5/1/09

Key milestones and Dates: Complete writing of procedures

Estimated date for completion: 10/31/09*

Who will complete the work, Kamran Vaziri & staff members **Phone:** 3457

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Who will perform verification and/or validation, _____ **Phone:** _____

****Responsible Person:** _____ Don Cossairt  **Date:** 041309

***Comments:** _____

CAP APPROVAL, & CONCURRENCE

This section to be completed and signed by persons identified below

**** Approval Head D/S/C:** _____ Nancy Grossman  **Date:** 5/28/09

***Comments:** _____

*****OQBP Concurrence:** _____  **Date:** 6/2/09

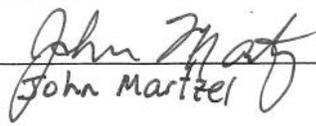
***Comments:** _____

CAP CLOSURE

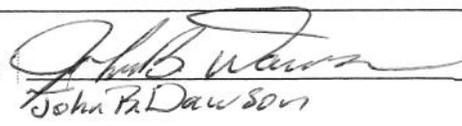
This section to be completed and signed by persons identified below

Description of actions taken to implement: _____

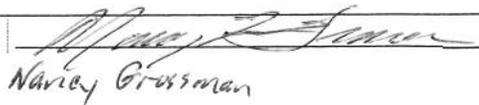
****Implemented By:** _____  **Date:** 8/20/09

****Verified By:** _____  **Date:** 8/10/2011

***Comments:** _____

**** Acceptance Requestor:** _____  **Date:** 8/10/2011

***Comments:** _____

****Acceptance Head D/S/C:** _____  **Date:** 8/10/11

***Comments:** _____

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This section to be completed by the person requesting simple corrective / preventive action		
Requestor Name: Tim Miller	Organization: ES&H Section	Phone: 3019
Problem/Opportunity To Be Addressed: The monthly “Instruments Due For Calibration” report and “Instruments Due for Calibration in AD” report for 2/27/09 indicate that 50-60% of the instruments are “Past due” for calibration. A process or control for addressing the issue of “Instruments Overdue For Calibration” is not documented.		
Unique Tracking Number: DD-MM/DD/YYYY-x: ES-03/31/2009-1		
(DD=Div or Sec, MM/DD/YYYY= Date Opened, x=1, 2, ...n)		
Responsible Person: Don Cossairt	Organization: Radiation Protection	Phone: 3465
**Responsible Person Acceptance: Don Cossairt		Date: 4/9/09
*Comments: A documented process should be established for identifying requirements and for identifying any actions to be taken when instruments are overdue for calibration.		

CAP DEVELOPMENT

This section to be completed by the Responsible Person
Describe the Actual Problem/Opportunity, and What Caused it (Simple Root Cause): Instruments are issued by the RPCF team to other organizations. The present database does not track separately those instruments in actual use and those that might be in storage pending return for calibration or repair. Thus one cannot distinguish between instruments that are in actual use for which their calibration has expired and those that await return for calibration for which their calibration has expired. All Fermilab ES&H training emphasizes verification of instruments having current calibrations.
Remedial/Compensatory, Corrective, and/or Preventive, actions being taken and (where applicable) Initial Lessons Learned: The database will be modified to correctly label instruments awaiting calibration, repair or modification within the ES&H Section. A program of increased vigilance in assuring that the line organizations to which instruments have been issued correctly remove instruments from service, identify them, and assure that they are not being used without current calibrations will be instituted.
Planned start date (format MM/DD/YYYY): 4/20/09
Key milestones and Dates: Program features identified and communicated to parties of concern by 8/1/09

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Estimated date for completion: 8/31/9

Who will complete the work, Butch Hartman, Don Cossairt **Phone:** 5514, 3465

Who will perform verification and/or validation, Tom King **Phone:** 6474

****Responsible Person:** Don Cossairt *[Signature]* **Date:** 041309

***Comments:** | |

CAP APPROVAL, & CONCURRENCE
 This section to be completed and signed by persons identified below

**** Approval Head D/S/C:** Nancy Grossman *[Signature]* **Date:** 5/28/09

***Comments:** | |

*****OQBP Concurrence:** Jed Heyes *[Signature]* **Date:** 6/4/09

***Comments:** *Checked to verify that pre-allocated was not used. ESHH assured that equip. not used.*

CAP CLOSURE
 This section to be completed and signed by persons identified below

Description of actions taken to implement: | |

****Implemented By:** Butch *[Signature]* **Date:** 8/21/2009

****Verified By:** Tom King *[Signature]* **Date:** 8/10/2011

***Comments:** | |

**** Acceptance Requestor:** Tim Miller *[Signature]* **Date:** 8/10/2011

***Comments:** | |

**** Acceptance Head D/S/C:** Nancy Grossman *[Signature]* **Date:** 8/10/2011