



Advanced Medical Systems, Inc.

1020 London Road
Cleveland, OH 44110
(216) 692-3270

September 6, 1996

Kevin G. Null
Nuclear Materials Licensing Branch
U. S. Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60532-4351

Re: Radiation Safety Procedures for USNRC License No. 34-19089

Dear Mr. Null:

In your letter dated December 5, 1995 you requested the opportunity to review the Radiation Safety Procedures (RSPs) that were referenced in our license renewal application dated October 30, 1995. Although not referenced therein, enclosed is RSP-021, "Changing Exhaust Filters in the Cell Machinery Room". This procedure is being submitted as supplemental information only, to assist in your review of our renewal application. It is not to be considered part of the application package or incorporated as license conditions. However, your comments on this RSP, which has been reviewed and approved by the AMS Radiation Safety Committee, are welcome.

Because our renewal application was originally submitted more than thirty (30) days prior to the expiration date of License No. 34-19089-01, AMS assumes the license will remain in effect, under its existing provisions, until final action is taken on this revised application. Since AMS wishes to institute significant changes in our radiation protection program in order to improve its applicability and auditability, your prompt consideration of our revised application would be greatly appreciated. If you have any questions, please contact me at (216) 692-3270.

Sincerely

Stephen J. Haddock, R.S.O.

cc: D. Cesar
D. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM

C1103

Advanced Medical Systems, Inc.

CHANGING EXHAUST FILTERS IN THE CELL MACHINERY ROOM

Procedure: RSP-021

Revision No.: 000

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Date: September 5, 1996

Approved by (Vice President):

Approved by (RSO):

Approved by (RSC Chair):

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PURPOSE

The purpose of this Radiation Safety Procedure (RSP) is to describe the methodology for changing the HEPA filters in the Cell Machinery Room. Typically, filters are changed after failure is identified, when significant dust loading occurs, or when the RSO deems the action necessary for radiation protection purposes.

1 SCOPE

This RSP applies only to routine exchange of the exhaust filters in the Cell Machinery Room. Exchanges performed under non-routine conditions, or exchange of other filter systems at the London Road facility are exempt from the requirements of this RSP.

2 REFERENCES

- 2.1 U. S. Nuclear Regulatory Commission License No. 34-19089-01 (as amended).
- 2.2 ASTM D 4536-91, American Society of Testing and Materials, "Standard Test Method for Particulate Matter and Determination of Particulate Emissions", 1991.
- 2.3 Operations Manuals for the Hot Cell and Isotope Shop Ventilation System.
- 2.4 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-008, "Instrumentation and Surveillance".
- 2.5 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-007, "Training and Qualifications of Radiation Protection Personnel".
- 2.6 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-010, "Exposure Control".
- 2.7 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-012, "Control of Work".
- 2.8 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-013, "Control of Radioactive Waste".
- 2.9 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-017, "Stop Work Authority".
- 2.10 Advanced Medical Systems, Inc., Isotope Shop Procedure No. ISP-9, "Portable Air Samples".

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3 DEFINITIONS

The definition of terms used in this RSP that may not be commonly understood shall be included in RSP-002, "Definitions".

4 PROCEDURE

4.1 Responsibilities

4.1.1 The Vice President shall ensure adequate resources for performance of this procedure.

4.1.2 The RSO shall:

4.1.2.1 Ensure filters are exchanged as necessary.

4.1.2.2 Confirm that only individuals who have been trained as Radiation Workers pursuant to RSP-007 perform the filter exchange.

4.1.2.3 Confirm that individuals are "current" in the internal and external monitoring requirements of RSP-010.

Note: Monitoring requirements may include but are not limited to baseline or routine urine bioassay, completion of prior exposure history (for contract workers), and respirator fitness.

4.1.2.4 Prepare a Radiation Work Permit (RWP) pursuant to RSP-012.

4.1.2.5 Provide pre-job briefings and participate in planning/staging sessions.

4.1.2.6 Apprise the Radiation Safety Committee (RSC) of actual doses incurred during the work after dose assessments are complete.

4.1.2.7 Secure contract health physics support to serve as the Radiation Protection Technician if required pursuant to License No. 34-19089-01 or RSP-012.

Note: The contractor should have qualifications and experience that are equivalent to that specified in RSP-007.

4.1.3 The Radiation Safety Committee (RSC) shall review and approve the RWP and the personnel exposures estimated at the termination of work.

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4.1.4 Radiation Workers that perform the filter exchange shall:

- 4.1.4.1 Perform work only under the provisions of an RWP.
- 4.1.4.2 Participate in pre-job briefings and "dry runs".
- 4.1.4.3 Remain cognizant of high- and low-dose-rate locations within the work area.
- 4.1.4.4 Stop work when directed to do so by the Radiation Protection Technician or the RSO.
- 4.1.4.5 Maintain exposures ALARA.
- 4.1.4.6 Comply with the requirements of this procedure.

4.2 Pre-operational Activities

4.2.1 The air handling system shall be checked and confirmed to be functioning one (1) time per day for three (3) work days immediately prior to the start of work.

- 4.2.1.1 The air monitor chart shall be inspected and the strip chart reading shall be recorded on the "Filter Change Pre-operational Check Sheet" (Attachment 1).
- 4.2.1.2 The cell manometer shall be inspected, re-zeroed (only on the first of the three days), and the reading recorded on Attachment 1.
- 4.2.1.3 The Panalarm shall be inspected, the lights confirmed to be "dim", and the findings recorded on Attachment 1.
- 4.2.1.4 The Gamalarms shall be inspected, the lights confirmed to be "green" and the findings recorded on Attachment 1.
- 4.2.1.5 The stack monitor shall be inspected, calibrated (only on the first of the three days), and the air flow reading recorded on Attachment 1.

4.2.2 The radiological conditions in the Cell Machinery Room (HEPA Room), its entrance, and environs shall have been determined pursuant to RSP-008 within 30 days of the date of the filter change.

Note: If circumstances that might result in changes to radiological conditions after performance of the survey but before the filter change occur, the survey shall be repeated.

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4.2.3 The expected radiation exposure of workers involved in the filter exchange shall be estimated.

4.2.3.1 The procedural steps described herein shall be refined, as necessary, and choreographed.

4.2.3.2 Measured exposure rates, personnel locations, and stay-times shall be used to estimate exposures.

4.2.3.3 Maximum likely exposure rates in uncontrolled areas shall be determined to ensure they do not exceed two (2) millirem per hour at any location.

Note: If exposure rates in excess of 2 millirem per hour are possible in uncontrolled areas, access to those locations should be controlled through the use of ropes, signs or other passive controls, or by active controls (e.g., gates, fences, guards).

4.2.4 An RWP shall be prepared as described in RSP-012 and submitted to the RSC for review and approval.

4.2.5 The work area in the HEPA Room and the landing shall be covered to prevent the spread of contamination.

Note: Plastic sheeting, craft paper, or other suitable cover material may be used.

4.2.6 Step-off pads shall be placed at locations designated by the Radiation Protection Technician.

4.2.7 All equipment and supplies shall be staged.

Note: Equipment may include, but is not limited to: survey meters, tools, new filters, transport box, communication devices, timers or stop watches, tape, plastic bags, air monitors, duct tape, replacement belts for the air handling system, and grease for the fan motor.

4.2.8 A waste collection location as described in RSP-013 shall be set up in the work area.

4.2.9 Final storage locations for the spent filters shall be identified and prepared.

Note: The Hot Cell filter should be stored in High Level Waste Storage.

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4.2.10 A temporary containment system for the Hot Cell filter housing shall be constructed.

4.2.11 A transport box may be prepared.

Note: The transport box will be large enough to hold a double-bagged Hot Cell HEPA, have handles or grips to aid in transport of the spent filter to its pre-determined storage location, and serve as tertiary containment for the spent filter during transport.

4.2.12 A "dry run" exchange using an inert filter shall be performed in order to confirm exposure estimates, finalize transit routes, confirm the adequacy of equipment and personnel, and optimize the use of "time", "distance" and "shielding".

4.2.13 The AMS security service shall be alerted to the fact that the supply fans will be shut down.

Note: The telephone number of the security service, ADT, is (216) 526-9539.

4.3 Cell Filter Exchange

4.3.1 The main gate to the London Road facility shall be closed and locked.

4.3.2 A minimum of two (2) Radiation Workers, plus one Radiation Protection Technician, shall be assigned to do the work.

4.3.3 The Radiation Protection Technician shall

4.3.3.1 Ensure all workers have met the Protective Clothing (PC) requirements specified in the RWP and that none exhibit exposed skin.

Note: PCs may include, but are not limited to, disposable coveralls, plastic shoe covers, plastic hoods, rubber gloves, and full-face respirators. All seams shall be taped.

4.3.3.2 Ensure all workers have met the personnel monitoring requirements specified in the RWP.

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Note: Personnel monitors may include, but are not limited to, TLD badges (one or more), self-reading pocket dosimeters (SRPDs), extremity dosimeters, breathing zone samplers, alarming dosimeters, and a communication device (if required).

- 4.3.3.3 Ensure proper placement of step-off pads.
- 4.3.3.4 Confirm all staged radiation survey instruments are functional pursuant to RSP-008.

Note: Survey instruments may include, but are not limited to, a frisker (pancake GM), ionization chamber, and teletector.

- 4.3.3.5 Tape the entrance door to the HEPA Room shut after Worker One enters, and remove the tape when Worker One is ready to pass the spent filter to Worker Two.
- 4.3.3.6 Assist Worker One, as necessary, in installation of the temporary containment or removal of the spent filter.
- 4.3.3.7 Continuously monitor exposure rates, alert workers as to radiological conditions, track the time spent in the work area, and assist workers in optimizing "time", "distance", and "shielding".
- 4.3.3.8 Scan the spent filter with a radiation survey instrument to identify locations with maximum and minimum exposure rates.

Note: The results of this survey will be used to determine how the filter should be positioned during transit to the High Level Waste Storage area.

- 4.3.3.9 Instruct Worker Two in the location, methodology and orientation for placing the double-bagged spent filter into the transport box (if used).
- 4.3.3.10 Assist Worker Two in conveying the transport box, if used, to the High Level Waste Storage area.
- 4.3.3.11 Stop work pursuant to RSP-017 if radiological or operational conditions are not consistent with those described in the RWP.

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4.3.4 Worker One shall:

- 4.3.4.1 Enter the HEPA Room with staged equipment, the temporary containment, and an unused filter.

Note: A filter may consist of the HEPA filter, a pre-filter, or a combination.

- 4.3.4.2 Order the Radiation Protection Technician to tape the entrance door to the HEPA Room shut.
- 4.3.4.3 Order Worker Two to shut down the Hot Cell and the Isotope Shop supply and exhaust fans.
- 4.3.4.4 Confirm the dampers have closed.

Note: A loud sound, an alarm and notation on the indicator lights are indicative of closed dampers.

- 4.3.4.5 Remove the long bolts holding the filter between the sheet metal shrouds.
- 4.3.4.6 Seal the temporary containment around the housing.
- 4.3.4.7 Slide the filter into the containment bag.

Note: A filter may consist of the HEPA filter, a pre-filter, or a combination.

- 4.3.4.8 While still mounted, close and seal the containment bag.
- 4.3.4.9 Cut the sealed bag away from the containment and housing.

Note: Assistance from the Radiation Protection Technician may be necessary in order to complete steps 4.3.4.5 through 4.3.4.8.

- 4.3.4.10 Order the Radiation Protection Technician to remove the tape from the entrance door to the HEPA Room.

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- 4.3.4.11 Place the bagged filter into a second plastic bag held by Worker Two.

Note: Worker Two will be positioned outside of the door to the HEPA Room.

Note: Caution is necessary to ensure the outside of the plastic bag is not contaminated by either the filter or Worker One.

- 4.3.4.12 Remove the remnants of the temporary containment.

- 4.3.4.13 Bolt the unused filter into place.

Note: Caution is necessary to ensure the filter orientation is correct with respect to air flow.

- 4.3.4.14 Examine the fan motor and grease as necessary.

- 4.3.4.15 Examine the belts for proper tension and wear and replace as necessary.

- 4.3.4.16 If the Isotope Shop filters *will not be exchanged*, order Worker Two to re-start the Hot Cell and Isotope Shop fans.

4.3.5 Worker Two shall:

- 4.3.5.1 Remain positioned outside of the HEPA Room.

- 4.3.5.2 When instructed to do so by Worker One, turn off the Hot Cell and Isotope Shop supply and exhaust fans.

- 4.3.5.3 Hold a plastic bag in position and accept the bagged spent filter from Worker One into the plastic bag.

Note: Caution is necessary to ensure the outside of the plastic bag is not contaminated by either the filter or Worker One.

- 4.3.5.4 Position the bagged filter so that the Radiation Technician can complete an exposure rate survey.

Note: The Radiation Protection Technician will survey the filter to identify locations of maximum and minimum exposure rate.

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- 4.3.5.5 Securely grasp the spent filter as instructed by the Radiation Protection Technician and place it in the transport box (if used).
- 4.3.5.6 With the assistance of the Radiation Protection Technician, convey the spent filter or transport box (if used) to the designated storage location.

Note: The "distance" between the filter or transport box (if used), Worker Two, and the Radiation Protection Technician should be maximized.

- 4.3.5.7 Return to the work area.

4.4 Isotope Shop Filter Exchange

- 4.4.1 A minimum of two (2) Radiation Workers, plus one Radiation Protection Technician, shall be assigned to do the work.

4.4.2 The Radiation Protection Technician shall

- 4.4.2.1 Ensure all workers have met the Protective Clothing (PC) requirements specified in the RWP.

Note: PCs may include, but are not limited to, disposable coveralls, plastic shoe covers, plastic hoods, rubber gloves, and full-face respirators.

- 4.4.2.2 Ensure all workers have met the personnel monitoring requirements specified in the RWP.

Note: Personnel monitors may include, but are not limited to, TLD badges (one or more), self-reading pocket dosimeters (SRPDs), extremity dosimeters, breathing zone samplers, and alarming dosimeters.

- 4.4.2.3 When directed to do so by Worker One, measure the exposure rate on contact with the filter bank

- 4.4.2.3.1 If the contact exposure rate is less than 10 mR per hour above background, no additional action is necessary.

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4.4.2.3.2 If the contact exposure rate exceeds 10 mR per hour above background:

4.4.2.3.2.1 Secure a temporary containment (enclosure) to the housing prior to its removal.

4.4.2.3.2.2 Assist Worker One in sliding the filters into the temporary containment, sealing the containment, and cutting the containment away from the housing.

4.4.2.4 Continuously monitor exposure rates, alert workers as to radiological conditions, track the time spent in the work area, and assist workers in optimizing "time", "distance", and "shielding".

4.4.2.5 Survey the spent filter to identify locations with maximum and minimum exposure rates.

Note: The results of this survey will be used to determine how the filter should be positioned during transit to the designated storage area.

4.4.2.6 Instruct Worker Two in the location, methodology and orientation for transporting the filters to the designated storage area.

4.4.2.7 Stop work pursuant to RSP-017 if radiological or operational conditions are not consistent with those described in the RWP.

4.4.3 Worker One shall:

4.4.3.1 Enter the HEPA Room with staged equipment and unused filters.

4.4.3.2 If the Hot Cell filter *was not exchanged*, order Worker Two to shut down the Hot Cell and Isotope Shop supply and exhaust fans.

4.4.3.3 Order the Radiation Protection Technician to measure the contact exposure rate on the filter bank.

4.4.3.4 Order the Radiation Protection Technician to tape the entrance door to the HEPA Room shut.

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- 4.4.3.5 Remove the long bolts holding the filter assembly, separate the HEPA bank from the assembly and pull out the cart that holds the HEPA bank.

Note: There are four filters for this fan in a 2-by-2 array. They are mounted on a cart which rolls out from the assembly.

- 4.4.3.6 Remove the tape from between the filters.
- 4.4.3.7 Order the Radiation Protection Technician to remove the tape from the entrance door to the HEPA Room.
- 4.4.3.8 Remove each filter and place into plastic bags.
- 4.4.3.9 Place each bagged filter into a second plastic bag held by Worker Two.

Note: Worker Two will be positioned outside of the door to the HEPA Room.

Note: Caution is necessary to ensure the outside of the plastic bag is not contaminated by either the filter or Worker One.

- 4.4.3.10 Bolt the unused filters into place, place tape between the filters, and re-position the cart and assembly into the housing.

Note: Caution is necessary to ensure the filter orientation is correct with respect to air flow.

- 4.4.3.11 Examine the fan motor and grease, as necessary.
- 4.4.3.12 Examine the belts for proper tension and wear, and replace as necessary.
- 4.4.3.13 Order Worker Two to re-start the Hot Cell and Isotope Shop supply and exhaust fans.
- 4.4.3.14 Confirm the dampers have opened.

Note: Cessation of the alarm and a notation on the indicator lights are indicative of open dampers.

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4.4.4 Worker Two shall:

- 4.4.4.1 Remain positioned outside of the HEPA Room.
- 4.4.4.2 If instructed to do so by Worker One, turn off the Hot Cell and Isotope Shop supply and exhaust fans.
- 4.4.4.3 Hold plastic bags in position and accept the spent filters from Worker One, sequentially, into the plastic bags.

Note: Caution is necessary to ensure the outside of the plastic bag is not contaminated by either the filter or Worker One.

- 4.4.4.4 Position the bagged filters so that the Radiation Technician can complete an exposure rate survey.

Note: The Radiation Protection Technician will survey the filter to identify locations of maximum and minimum exposure rate.

- 4.4.4.5 Securely grasp each spent filter in the manner directed by the Radiation Protection Technician, and transport it to the designated storage location.

Note: The "distance" between the filter and Worker Two during transport should be maximized.

- 4.4.4.6 When instructed to do so by Worker One, re-start the Hot Cell and Isotope Shop exhaust and supply fans.

4.5 Disposition of Spent Filters

Prior to disposal, the RSO shall ensure all filters are characterized by the methodology described in RSP-013.

4.6 Post-operational Activities

- 4.6.1 The security service shall be contacted to confirm that all "trouble signals" for the system have ceased.

Note: During the filter exchange, trouble signals may have been sent for the fire sensor in the ventilation ductwork or other sensors connected to the system.

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- 4.6.2 The main gate to the London Road facility shall be unlocked and opened.
- 4.6.3 The air handling system shall be checked and confirmed to be functioning once immediately after the filter exchange is complete and once per day for the next four (4) consecutive work days.
 - 4.6.3.1 The air monitor chart shall be inspected and the strip chart reading shall be recorded on the "Filter Change Post-operational Check Sheet" (Attachment 2).
 - 4.6.3.2 The cell manometer reading shall be recorded on Attachment 2.
 - 4.6.3.3 The Panalarm shall be inspected, the lights confirmed to be "dim", and the findings recorded on Attachment 2.
 - 4.6.3.4 The Gamalarms shall be inspected, the lights confirmed to be "green" and the findings recorded on Attachment 2.
 - 4.6.3.5 The stack monitor shall be inspected and the air flow reading shall be recorded on Attachment 2.
- 4.6.4 If the air handling system is not certified by the RSO to be fully functional at the end of the five (5) day observation period, or if the post-operational stack monitor readings are significantly higher than the pre-operational readings:
 - 4.6.4.1 Repairs, as necessary, shall be made under the direction and supervision of the RSO.
 - 4.6.4.2 Efficiency testing of the system, pursuant to ASTM D 4536-91, may be performed.
- 4.6.5 Mats, drapes, liners, step-off pads, temporary containment, and other contamination control items in the work area shall be removed, frisked, segregated, and disposed of as described in RSP-013.
- 4.6.6 The radiological conditions in the Cell Machinery Room (HEPA Room), its entrance, and environs shall be determined pursuant to RSP-008 within 24-hours after the work is complete.

Note: If radiological conditions differ significantly from those shown in the pre-operational survey, the area shall be decontaminated until such time as repeat surveys show the pre- and post-operational conditions are similar.

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4.6.7 Personnel radiation exposures shall be estimated as described in RSP-012.

Note: To estimate exposures, SRPDs shall be collected, read and, if deemed necessary by the RSO, TLD badges shall be processed (see RSP-010). Internal exposures from the breathing zone samplers shall be estimated and, as necessary, bioassays shall be performed as described in RSP-010, ISP-9, and RSP-008.

5 EXEMPTION PROVISIONS

Variances and exceptions to the requirements of this procedure shall be permitted pursuant to the written authorization of the RSO and the RSC.

6 DOCUMENTATION

Records generated during the filter exchange shall be maintained pursuant to RSP-004, "Radiation Protection Records"

7 ATTACHMENTS

7.1 Attachment 1 - Filter Change Pre-operational Check Sheet

7.2 Attachment 2 - Filter Change Post-operational Check Sheet.

ATTACHMENT 1
FILTER CHANGE PRE-OPERATIONAL CHECK SHEET

Item	Date of Check			Notes
	Day 2 Before Exchange (insert date):	Day 1 Before Exchange (insert date):	Day of Exchange Prior to Exchange (insert date):	
Air Monitor Chart	Inspected by:	Inspected by:	Inspected by:	
	Strip Chart Reading:	Strip Chart Reading:	Strip Chart Reading:	
Cell Manometer	Inspected and re-zero-ed by:	Inspected by:	Inspected by:	
	Reading	Reading	Reading	
Penalarm	Inspected by:	Inspected by:	Inspected by:	
	Light Intensity:	Light Intensity:	Light Intensity:	
Gamalarm	inspected by:	Inspected by:	Inspected by:	
	Light Color:	Light Color:	Light Color:	
Stack Monitor	Calibrated by:	Inspected by:	Inspected by:	
	Air Flow :	Air Flow:	Air Flow:	

Reviewed by (RSO signature): _____

ATTACHMENT 2
FILTER CHANGE POST-OPERATIONAL CHECK SHEET

Item	Date of Check					Notes
	Day of Exchange Immediately After Exchange (insert date):	Day 1 After Exchange (insert date):	Day 2 After Exchange (insert date):	Day 3 After Exchange (insert date):	Day 4 After Exchange (insert date):	
Air Monitor Chart	Inspected by:	Inspected by:	Inspected by:	Inspected by:	Inspected by:	
	Strip Chart Reading:	Strip Chart Reading:	Strip Chart Reading:	Strip Chart Reading:	Strip Chart Reading:	
Cell Manometer	Inspected by:	Inspected by:	Inspected by:	Inspected by:	Inspected by:	
	Reading	Reading	Reading	Reading	Reading	
Panalarm	Inspected by:	Inspected by:	Inspected by:	Inspected by:	Inspected by:	
	Light Intensity:	Light Intensity:	Light Intensity:	Light Intensity:	Light Intensity:	
Gamalarm	Inspected by:	inspected by:	Inspected by:	Inspected by:	Inspected by:	
	Light Color:	Light Color:	Light Color:	Light Color:	Light Color:	
Stack Monitor	Inspected by:	Inspected by:	Inspected by:	Inspected by:	Inspected by:	
	Air Flow:	Air Flow:	Air Flow:	Air Flow:	Air Flow:	

Reviewed by (RSO signature): _____