

that will record receipts and expenditures of Federal funds in accordance with accounting principles, Federal regulations, and terms of the cooperative agreement.

#### C. Audits

Funds claimed for reimbursement under this cooperative agreement must be audited annually by an independent certified public accountant (separate and independent of the consultant referenced above or recipient's staff certified public accountant). This audit must be performed within 60 days after the end of the budget period, or at the close of an organization's fiscal year. The audit must be performed in accordance with generally accepted auditing standards (established by the American Institute of Certified Public Accountants (AICPA)), governmental auditing standards (established by the General Accounting Office (GAO)), and Office of Management and Budget (OMB) Circular A-133.

#### D. Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations (45 CFR Part 46) regarding the protection of human subjects. Assurance must be provided (in accordance with the appropriate guidelines and form provided in the application kit) to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee.

#### E. Paperwork Reduction Act

Data collection initiated under this cooperative agreement has been approved by the Office of Management and Budget under number 0920-0249, "HIV Prevention Programs in Minority and Other Community-Based Organizations Project Reports," Expiration date 8/31/99.

#### F. Confidentiality

All personally-identifying information obtained in connection with the delivery of services provided to any individual in any program supported under this announcement shall not be disclosed unless required by a law of a State or political subdivision or unless such an individual provides written, voluntary informed consent.

1. Non-personally-identifying, unlinked information, that preserves the individual's anonymity, derived from any such program may be disclosed without consent:

a. In summary, statistical, or other similar form, or

b. For clinical or research purposes.

2. Personally-identifying information: Recipients of CDC funds who obtain and retain personally-identifying information as part of their CDC-approved work plan must:

a. Maintain the physical security of such records and information at all times;

b. Have procedures in place and staff trained to prevent unauthorized disclosure of client-identifying information;

c. Obtain informed client consent by explaining the possible risks from disclosure and the recipient's policies and procedures for preventing unauthorized disclosure;

d. Provide written assurance to this effect including copies of relevant policies; and

e. Obtain assurances of confidentiality by agencies to which referrals are made.

Some projects may require an Institutional Review Board (IRB) approval or a certificate of confidentiality.

#### Application Submission and Deadline

On or before January 6, 1997, submit the original and two copies of the application (PHS Form 5161-1, OMB Number 0937-0189) to Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mail Stop E-15, Atlanta, GA 30305. Faxed copies will NOT be accepted. In addition, CDC strongly recommends that all applicants simultaneously submit a copy of the application to their State HIV/AIDS Directors.

**Deadline:** Applications will meet the deadline if they are either received on or before the deadline of 4:30 p.m. (EDST), January 6, 1997, or sent on or before the deadline date and received in time for submission to the review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks will not be acceptable proof of timely mailing.)

Applications that do not meet these criteria will be considered late and will not be considered in the current funding cycle. Late applications will be returned to the applicant.

#### Where to Obtain Additional Information

To receive the application kit, call (404) 332-4561. You will be asked to leave your name, address, and telephone number, and you must refer

to Announcement Number 704. You will then receive program announcement 704, required application forms and attachments, a current list of SPOCs, a summary of HIV-related objectives, a list of the State health departments contact, and the HERR guidelines. The announcement is also available through the CDC home page on the Internet. The address for the CDC home page is <http://www.cdc.gov>.

If you have questions after reviewing the contents of the documents, business management technical assistance may be obtained from Maggie Slay, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mail Stop E-15, Atlanta, GA 30305, telephone (404) 842-6797, or INTERNET address, [mcs9@ops.pgo1.em.cdc.gov](mailto:mcs9@ops.pgo1.em.cdc.gov).

Announcement Number 704, "Cooperative Agreements for Community- Based Human Immunodeficiency Virus (HIV) Prevention Projects," must be referenced in all requests for information pertaining to these projects.

Programmatic technical assistance may be obtained by calling Tim Quinn or Sam Taveras in the Division of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), Mail Stop E-58, Atlanta, GA 30333, telephone (404) 639-8317. (Technical assistance may also be obtained from your respective State/local health departments.)

Potential applicants may obtain a copy of "Healthy People 2000" (Full Report; Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Dated: September 27, 1996.

Joseph R. Carter,

*Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 96-25313 Filed 10-2-96; 8:45 am]

BILLING CODE 4163-18-P

#### National Institute for Occupational Safety and Health; Draft Document "Engineering Control Guidelines for Hot Mix Asphalt Pavers"

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control

and Prevention (CDC), Department of Health and Human Services.

**ACTION:** Request for comments.

**SUMMARY:** NIOSH is seeking public comments on the draft document "Engineering Control Guidelines for Hot Mix Asphalt Pavers" provided in this announcement.

**DATES:** Written comments to this notice should be submitted to Diane Manning, NIOSH Docket Office, 4676 Columbia Parkway, Mailstop C-34, Cincinnati, Ohio 45226. Comments must be received on or before November 4, 1996.

Comments may also be submitted by email to: dmm2@NIOSDT1.em.cdc.gov, as WordPerfect 5.0, 5.1/5.2, 6.0/6.1, or ASCII files.

**FOR FURTHER INFORMATION CONTACT:** Technical information may be obtained from Joann Wess or Ralph Zumwalde, NIOSH, CDC, 4676 Columbia Parkway, M/S C-32, Cincinnati, Ohio 45226, telephone (513) 533-8319.

**SUPPLEMENTARY INFORMATION:** The following is the complete text of the draft document for public comment "Engineering Control Guidelines for Hot Mix Asphalt Pavers".

#### Background

On July 8-9, 1996, NIOSH convened a public meeting in Cincinnati, Ohio, to discuss the scientific and technical issues relevant to the development of recommendations for controlling exposures to asphalt fume during asphalt paving operations. Representatives from labor, industry, and government knowledgeable of current control technologies for asphalt exposure met to discuss the types of remedial action (e.g., engineering controls, work practices) needed to reduce worker exposures. Participants at this meeting included representatives from the Asphalt Institute (AI), the Federal Highway Administration (FHWA), the International Union of Operating Engineers, the Laborers' Health and Safety Fund, the National Asphalt Pavement Association (NAPA), the Occupational Safety and Health Administration (OSHA), manufacturers of hot mix asphalt (HMA) pavers, and asphalt paving contractors.

The participants provided detailed information on state-of-the-art engineering controls currently in use and discussed a draft document on guidelines for engineering controls in the asphalt paving industry that was prepared jointly by labor and industry. The draft guidelines provided in this announcement represent a recommendation of the participants to minimize asphalt fume exposures by

developing and installing engineering controls on asphalt pavers and by providing training for workers.

#### Purpose

The purpose of the document "Engineering Control Guidelines for Hot Mix Asphalt Pavers" is to provide information on the use of engineering controls for the reduction of worker exposure to asphalt fumes during hot mix asphalt (HMA) paving operations. NIOSH is soliciting public comments on the completeness and feasibility of the recommendations.

#### Document for Comment

##### *Engineering Control Guidelines for Hot Mix Asphalt Pavers*

On July 8-9, 1996, the National Institute for Occupational Safety and Health (NIOSH) convened a public meeting in Cincinnati, Ohio, to discuss recommendations for controlling exposures to asphalt fume during asphalt paving operations. Participants at the meeting included representatives from the Asphalt Institute (AI), the Federal Highway Administration (FHWA), the International Union of Operating Engineers, the Laborers' Health and Safety Fund, the National Asphalt Pavement Association (NAPA), the Occupational Safety and Health Administration (OSHA), manufacturers of hot mix asphalt (HMA) pavers, and asphalt paving contractors. This meeting culminated in the development of these guidelines that provide information about the use of engineering controls (i.e., local exhaust ventilation systems) to reduce worker exposures to asphalt fumes during HMA paving operations.

#### 1. New HMA Pavers

a. Paver manufacturers should develop and install ventilation systems with controlled indoor-capture efficiencies of at least 80% (as determined by the tracer gas method described in Appendix A) on the following equipment:

- All new self-propelled HMA pavers weighing 16,000 pounds or more and manufactured after July 1, 1997.
- All new self-propelled HMA pavers weighing less than 16,000 pounds with slat conveyors or with augers detached from the hoppers and manufactured after July 1, 1998.

b. Paver manufacturers should test the ventilation systems for all HMA paver models and certify that the systems meet the minimum capture efficiency of 80% as specified in Section 1.a. To assure performance of the ventilation systems, manufacturers should install an indicator device on each HMA paver

to monitor the system flow rate. Each HMA paver manufacturer shall provide a plate attached to the paver that shows:

- schematic of the ventilation system;

- acceptable operating range for the indicator device; and
- list of operator maintenance procedures.

c. Manufacturers should develop and implement quality control plans to ensure that ventilation systems on these models comply with the minimum capture efficiency specified in Section 1.a.

#### 2. Existing HMA Pavers

By July 1, 1998, paver manufacturers should make retrofit packages available for all self-propelled HMA pavers weighing 16,000 pounds or more and manufactured after July 1, 1987. These retrofit packages should be installed by July 1, 1999. Retrofit packages for self-propelled pavers weighing less than 16,000 pounds with slat conveyors or augers detached from the hopper should be available by July 1, 1999, and should be installed by July 1, 2000. Manufacturers should test and certify that all retrofit packages installed according to the manufacturer's instructions meet the minimum capture efficiency of 80% for a specific model or equivalent class design configuration (as determined by the tracer gas method described in Appendix A). To assure system performance, manufacturers should include in the retrofit package an indicator device to monitor the system flow rate.

#### 3. Inspection and Maintenance

Owners of HMA pavers with ventilation systems should inspect and maintain the systems according to the manufacturer's recommendations. Each manufacturer should provide an operator manual containing detailed sketches and performance criteria for contractors to use in their annual assessment of ventilation systems. Annual performance inspections should be recorded in the operator's manual.

#### 4. Training Program

The National Asphalt Pavement Association (NAPA), unions, and equipment manufacturers should develop specific training criteria/materials (i.e., separate document) on the operation, maintenance, and repair of HMA pavers.

#### 5. Glossary of Terms

**Asphalt Paver:** A self-propelled construction machine (either rubber-tired or crawler-mounted) specifically designed to receive, convey, distribute,

profile, and compact paving material by the free-floating screed method.

**Auger:** A screw conveyor used to transversely distribute paving material ahead of the screed.

**Automatic Feeder Control:** A system for automatically controlling the flow of paving material to the screed.

**Conveyor:** A device for transferring paving material from the hopper to the auger.

**Conveyor Flow Gate:** A device for regulating the height of paving material being transferred by the conveyor.

**Feeder System:** The combined conveyor and auger components which transfer paving material from the hopper and distribute it in front of the screed.

**Hopper:** That section of the paver which receives the paving material from an external source.

**Material Feed Sensor:** A device used to detect a quantity of paving material in front of the screed.

**Operator:** The person whose primary function is to control the paver's speed and direction.

**Screed:** The device which is towed behind the tractor to strike off, compact, contour, and smooth the paving material.

**Screed Arm:** The attachment by which the screed is connected to and towed by the tractor.

**Screed End Plate:** A vertically adjustable plate at the outboard end of the screed, to retain the paving material and form the edge of the mat.

**Screed Extension:** A fixed or adjustable attachment to the screed for paving at widths greater than the main screed.

**Tow Point:** The point at which the screed arm is attached to the tractor.

**Tractor:** That portion of a paver which provides propulsion and may also receive, convey, and distribute paving material.

**Tunnel:** The passageway through which paving material moves from the hopper to the auger/screed.

## Appendix A

### Laboratory/Factory Test Procedure

Engineering controls (i.e., ventilation systems) for HMA pavers will be evaluated in a laboratory setting (i.e., manufacturers' plant, shop, or warehouse) in which ventilation control efficiency will be measured using smoke and tracer gas tests. The smoke test will be used as a qualitative test to visualize airflow patterns around the paver and ventilation system, and to ensure appropriate testing conditions for conducting the tracer gas tests. The tracer gas test will be used to quantitatively measure the volumetric

airflow rate and capture efficiency of the ventilation system.

Ventilation systems will be evaluated in a large bay area at the manufacturing plant or testing shop. The paver will be parked with the screed and rear half of the tractor positioned in the bay area (referred to as the testing area) and with the front half of the tractor and engine exhaust ducts positioned outside the building. An overhead garage door or other barrier can be used to separate the two areas. A garage door can be lowered to rest on top of the tractor, and the remaining doorway openings around the tractor can be sealed to isolate the paver's front and rear halves. The screed will rest on the ground with edger plates extended one foot on each side of the screed. The flow gates at the back of the hopper should be closed as far as possible and the remaining tunnel opening should be blocked off. During the performance evaluations the idle speed for the paver, which can affect the exhaust rate of the ventilation system, will be set near the typical revolutions per minute (rpm) that are maintained during normal paving operations.

### Safety

Following are safety precautions for each test:

- Handle smoke generating equipment that can be hot with appropriate caution.
- Make sure that the smoke generators do not set off fire sprinklers or create a false alarm.
- Avoid direct inhalation of smoke from the smoke generators because the smoke may act as an irritant.
- Transport, handle, and store all compressed gas cylinders in accordance with the safety recommendations of the Compressed Gas Association.
- Store the compressed cylinder outdoors or in a well-ventilated area.
- Stand back and let the tank pressure come to equilibrium with the ambient environment if a regulator malfunctions or some other major accidental release occurs.

### Smoke Test

A smoke generator is used to produce theatrical smoke as a surrogate contaminant. The smoke is released through a perforated distribution tube traversing the width of the auger area between the tractor and the screed and supported above the ground under the augers. The smoke test helps to identify failures in the integrity of the barrier separating the front and rear portions of the paver. After sealing leaks within this barrier, smoke is again released to verify the integrity of the barrier system, to identify airflow patterns within the test

area, and to visually observe the ventilation system's performance.

The sequence of a typical smoke test is outlined below:

- Position paving equipment within door opening and lower the overhead door.
- Seal the remaining door opening around the tractor.
- Place the smoke distribution tube directly underneath the auger.
- Connect the smoke generator to the distribution tube (PVC pipe, 2-inch diameter, 10 feet long, capped on one end, 1/4-inch diameter holes every 6 inches on-center).
- Activate video camera if a record is desired.
- Activate the ventilation system and the smoke generator.
- Inspect the separating barrier for integrity failures and correct as required.
- Inspect the ventilation system for unintended leaks.
- De-activate the ventilation system for comparison purposes.
- De-activate the smoke generator and wait for smoke levels to subside.
- Disassemble test equipment.

### Tracer Gas

The tracer gas test is designed to: (1) calculate the total volumetric exhaust flow of the prototype design; and (2) evaluate the effectiveness in capturing and controlling a surrogate contaminant under the "controlled" indoor conditions. Sulfur hexafluoride (SF<sub>6</sub>) will be used as the surrogate contaminant. A real-time SF<sub>6</sub> detector should be calibrated in the laboratory prior to the test. There are several methods for calibrating the SF<sub>6</sub> detector. The least labor-intensive method requires the use of multiple compressed gas cylinders with known concentrations of SF<sub>6</sub>. The SF<sub>6</sub> concentrations should include at least four concentrations ranging from zero to 50 ppm SF<sub>6</sub> in nitrogen. An industrial hygiene sampling bag such as a 12-liter Milar® bag can be filled from each cylinder, then the bag can be hooked to the detector, and the response of the detector can be recorded for each concentration.

Another method for calibrating the SF<sub>6</sub> detector requires the use of two compressed gas cylinders, one with pure nitrogen and another with 50 ppm (or higher concentration) SF<sub>6</sub> in nitrogen. Four different concentrations of SF<sub>6</sub> are made by mixing different volumes of fluid from the two cylinders into sampling bags. The bags are mixed, hooked to the detector, and the response of the detector is recorded for each concentration.

The sampling bags should be clearly marked with the appropriate concentration of SF<sub>6</sub> that each contains. Bags can be reused; however, they should be emptied prior to reuse and they should only be filled with approximately the same concentration of SF<sub>6</sub>. A bag used to hold 50 ppm SF<sub>6</sub> in a previous test should not be used to hold the 2 ppm SF<sub>6</sub> sample in the next test because of the possibility of residual gas causing an incorrect calibration point.

Using either calibration method or an equivalent method, a calibration curve, not necessarily a straight line, can then be calculated to fit the data and convert the detector's response to an actual SF<sub>6</sub> concentration.

To increase the likelihood of independence for each SF<sub>6</sub> concentration reading, program the SF<sub>6</sub> detector to a minimum sampling interval of 30 seconds. Larger intervals may be required based on the model of SF<sub>6</sub> detector and the experimental setup.

**100% Capture (to quantify exhaust volume):** A known volumetric flow rate (0.90 liters per minute) of SF<sub>6</sub> is released into the ventilation system. The release point must be upstream of the ventilation system's fan and downstream of the ventilation system's hood to ensure 100% capture of the released gas. The supply tank of pure SF<sub>6</sub> is connected to the release point via a pressure regulator, flow controller, and 1/4-inch tubing.

A 1/4-inch diameter hole is placed in the ventilation system's exhaust duct half way between the fan and the outlet of the exhaust duct. A 12-inch long and 1/4-inch outside diameter stainless steel tube (sampling probe) is inserted into this exhaust-duct hole perpendicular to the exhaust air flow. The sampling probe should be sealed at the end and have several 1/8-inch diameter holes, one inch on-center along one side. The number of holes depends on the diameter of the exhaust duct. An 8-inch exhaust duct would require use of a sampling probe with six 1/8-inch holes. These holes should be positioned perpendicular to the exhaust air flow and must all be inside the duct when sampling. The tubing connecting the sampling probe to the detector should be airtight to ensure that the sample is pulled from within the exhaust duct and not from the surrounding area. The exhaust volume is then calculated using the following equation:

where

$Q(\text{exh})$  = volume of air exhausted through the ventilation system (lpm or cfm) (To convert from liters per minute

(lpm) to cubic feet per minute (cfm), divide lpm by 28.3.)

$Q(\text{SF}_6)$  = volume of SF<sub>6</sub> (lpm or cfm) introduced into the system

$C^*(\text{SF}_6)$  = Concentration of SF<sub>6</sub> (parts per million) detected in exhaust and the \* indicates 100% capture of the released SF<sub>6</sub>.

If there is more than one ventilation system exhaust duct, then the above procedure should be repeated for each. Sufficient time should be allowed between tests for the background readings to drop to below 0.2 ppm SF<sub>6</sub>. Background readings must be subtracted from the detector response before calculating the exhaust volume.

To quantify capture efficiency, SF<sub>6</sub> is released through a distribution plenum located under the augers between the tractor and the screed. A discharge hose feeds pure SF<sub>6</sub> at a flow rate of 0.90 lpm from the pressure regulator, through a mass flow controller (precision rotameter), and into the distribution plenum. Accuracy of the flow controller will greatly affect the accuracy of the test and should be #3% or better. The plenum is ten feet long and is designed to release the SF<sub>6</sub> evenly throughout its length. The same multi-port sampling wand, sampling location, and detector, as used in the 100% capture test, is also used in this test.

At least five consecutive measurements will be taken and an average value will be calculated. If the SF<sub>6</sub> volumetric flow rate is the same for both the 100% capture test and capture efficiency test, then the capture efficiency is calculated using the following equation:

where

$\eta$  = capture efficiency  
 $C(\text{SF}_6)$  = Concentration of SF<sub>6</sub> (parts per million) detected in exhaust

$C^*(\text{SF}_6)$  = Concentration of SF<sub>6</sub> from 100% capture test

If the SF<sub>6</sub> volumetric flow rate is not the same for both the 100% capture test and the capture efficiency test, then the capture efficiency is calculated using the following:

where  $C(\text{SF}_6)$  and  $Q(\text{SF}_6)$  refer to the values obtained during the capture efficiency test and  $Q(\text{exh})$  was calculated from the 100% capture test.

A total of four pairs of the 100% capture tests and capture efficiency tests will be performed with the ventilation system's overall capture efficiency determined from the average of all four trials.

Between each test (after a pair of 100% capture test and capture efficiency test), the paver should be shut down and background SF<sub>6</sub> measurements should be monitored to

determine if any SF<sub>6</sub> had accumulated in the test area. If SF<sub>6</sub> has accumulated (>2.0 ppm), the integrity of the barrier system should be checked and the test area should be well ventilated before proceeding. Sufficient time should be allowed between tests for the background readings to drop to below 0.2 ppm of SF<sub>6</sub>. Background readings must be subtracted from the detector response before calculations are made.

The sequence for a typical test run is outlined below:

- Position paving equipment and seal openings as outlined above.
- Calibrate (outdoors) flow meters at approximately 0.9 lpm of SF<sub>6</sub>.
- Drill an access hole in the ventilation system's exhaust duct for insertion of the detector's sampling probe and position the sampling probe into the exhaust duct.
- With the ventilation system activated, begin monitoring for SF<sub>6</sub> to determine background interference levels.
- While maintaining the SF<sub>6</sub> tanks outdoors or in a well-ventilated area, run the discharge tubing from the mass flow meter to well within the exhaust hood to create 100% capture conditions.
- Initiate flow of SF<sub>6</sub> through the flow meter and allow it to reach steady-state (should take only a minute).
- Continue monitoring until 5 readings are recorded.
- Deactivate the flow of SF<sub>6</sub>.
- Remove the discharge tubing to an outdoor location.
- End the 100% capture test. (Leave the tractor engine running.)
- Initiate monitoring to establish background interference until levels drop to <0.2 ppm.
- Locate an SF<sub>6</sub> distribution plenum under the auger area and connect the discharge tubing of the flow meter.
- Initiate SF<sub>6</sub> flow through the mass flow meters and monitor until approximate steady-state conditions appear (about one minute) and take at least 5 readings.
- Discontinue SF<sub>6</sub> flow and quickly remove the distribution plenum and discharge tubing from the auger area and remove to an outside location.
- Continue monitoring to determine the general area concentration of SF<sub>6</sub> which escaped into the test area.
- Discontinue monitoring when concentration decay is complete.
- Turn off the ventilation system and paver engine; calculate the capture efficiency.
- Repeat four times.

#### Example Test Run and Calculations

The paver was positioned and smoke was used to visually test the system.

Smoke was seen coming in the top of the overhead door. The opening in the overhead door was sealed and the smoke test revealed no other problems.

For simplicity of example, the SF<sub>6</sub> detector was calibrated and adjusted to read directly SF<sub>6</sub> in ppms. The SF<sub>6</sub> flow meter was calibrated using a bubble meter.

Trial No.	Flow rate, lpm
1 .....	0.903
2 .....	0.908
3 .....	0.899
4 .....	0.900

The mean flow rate was  $((0.903 + 0.908 + 0.899 + 0.900) / 4)$  0.903 liters per minute (lpm).

The sampling probe was placed in the exhaust duct of the ventilation system and background samples were registered by the detector. The tubing (pure SF<sub>6</sub> outlet) from the flow meter was placed through the hood and into the duct of the ventilation system (upstream of the fan). Readings were as follows:

Task	Reading No.	Detector reading, ppm of SF <sub>6</sub>
Background .....	1	0.0051
	2	0.0062
	3	0.0048
	4	0.0050
	5	0.0066
	6	0.0062
Start SF <sub>6</sub> .....	7	0.0058
	8	6.3
	9	22.0
	10	21.8
	11	21.9
	12	21.7
End .....	13	21.8
	14	21.9

At least five consecutive measurements are needed; in this case, the last six data points were used. The eighth reading (6.3 ppm) does not reflect steady-state and was not used in determining the average. The mean concentration of SF<sub>6</sub> is 21.85 ppm (the average of those six points). The mean background value is 0.0057 ppm. These values were used to calculate the volumetric flow rate from Equation 1.  $Q(\text{exh}) + 0.903 / 28.3 / (21.85 - 0.0057) * 106 = 1460 \text{ cfm}$ .

The average background value, 0.0057 ppm, was subtracted from the average 100% capture value, 21.85 ppm. In this case, the background value was negligible.

The same flow meter and SF<sub>6</sub> flow rate were used for the capture efficiency test. The tubing was removed from the ventilation system hood and connected

to the 10-foot distribution plenum.

Readings were as follows:

Task	Reading No.	Detector reading, ppm SF <sub>6</sub>
Background .....	1	0.092
	2	0.084
	3	0.078
Start SF <sub>6</sub> .....	4	28.1
	5	18.8
	6	19.6
	7	19.7
	8	20.9
	9	17.3
	10	19.4
	11	18.9
	12	19.6

At least five consecutive measurements are needed; in this case, the last eight will be used. The fourth reading (28.1 ppm) was high; in this case it reflects the flow controller overshooting the set point during the startup of SF<sub>6</sub> flow, and this point is not used in determining the average. The mean concentration of SF<sub>6</sub> is 19.28 ppm; the average background concentration was 0.0847 ppm.

Because we used the same SF<sub>6</sub> flow rate in both the exhaust volume test and the capture efficiency test, the calculations are simplified. From Equation 2, the capture efficiency is  $(19.28 - 0.0847) / (21.85 - 0.0057) * 100 = 87.9\%$ .

This procedure was done four times with the following results:

Trial No.	100% capture, ppm SF <sub>6</sub>	Capture efficiency, ppm SF <sub>6</sub>	Capture efficiency, %
1 .....	21.84	19.20	87.9
2 .....	21.67	19.95	92.1
3 .....	21.74	18.10	83.3
4 .....	21.93	19.01	86.7

#### Statistics

Calculate the overall average of the means:

$$m = (87.9 + 92.1 + 83.3 + 86.7) / 4 = 87.5\%$$

Calculate the estimated standard deviation:

$$s = \{((87.9 - 87.5)^2 + (92.1 - 87.5)^2 + (83.3 - 87.5)^2 + (86.7 - 87.5)^2) / (4 - 1)\}^{0.5} \\ = \{(0.16 + 21.16 + 17.64 + 0.64) / 3\}^{0.5} = 3.63$$

If the number of trials, n, is different from 4, then (n-1) is used in the denominator of this calculation and the numerator is the sum of all n squared differences, rather than just 4. Choose the number t (from the Student's t-distribution table at the 95th percentile) from the following table, based on the value of n:

t: 6.31 (n=2) 2.92 (n=3) 2.35 (n=4)  
2.13 (n=5) 2.02 (n=6) 1.94 (n=7)  
1.90 (n=8) 1.86 (n=9) 1.83 (n=10)

Calculate a test statistic (T):

$$T = m - t * s / n^{0.5}$$

For this example:  $T = 87.5 - 2.35 * 3.63 / 40.5 = 83.2$ .

If  $T > 80.0$ , then decide (with 95% confidence) that efficiency is greater than 80%. In this example, we are 95% confident that the efficiency is greater than 80%.

If  $T \leq 80.0$ , then the conclusion that the efficiency is greater than 80% cannot be made from these data.

#### Equipment

##### Smoke Test

Smoke generator  
2 inch x 10 foot Schedule-40 PVC perforated distribution pipe

##### Tracer Gas Tests

Compressed cylinder of 99.98% SF<sub>6</sub> with regulator  
Flow controller such as a precision rotameter  
1/8-inch ID x 20-foot Teflon tubing and snap valves for SF<sub>6</sub> distribution  
Primary Flow Calibrator  
1/2-inch ID x 10-foot Copper tubing with 1/32-inch holes every 12 inches SF<sub>6</sub> distribution plenum  
Gas monitor calibrated for SF<sub>6</sub>  
Calibration gases, nitrogen and at least one SF<sub>6</sub> concentration in nitrogen  
12-liter Mylar gas sampling bags

##### Ventilation System Evaluation

Air Velocity Meter  
Micro manometer w/Pitot Tube

Dated: September 27, 1996.

Linda Rosenstock,

Director, National Institute for Occupational Safety and Health Centers for Disease Control and Prevention (CDC).

[FR Doc. 96-25314 Filed 10-2-96; 8:45 am]

BILLING CODE 4163-19-P

#### Food and Drug Administration

[Docket No. 94M-0404]

**Thermo Cardiosystems, Inc.;**  
**Premarket Approval of the HeartMate® IP LVAS**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its approval of the application by Thermo Cardiosystems, Inc., Woburn, MA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of HeartMate® IP LVAS. After reviewing