Establishing a Quality Medical Surveillance Program in your Flavor Company

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Medical Surveillance

- What is medical surveillance?
- Why do medical surveillance in the flavor industry?
- Who should be included in medical surveillance?
- How often should it be performed?
- How to assure it's done properly?
- What to do with abnormal results?
- What are the costs?

What is medical surveillance?

- Medical screening vs. medical surveillance
- Components of medical surveillance program:
  - Clinical evaluation
  - Communication of results and medical referral
  - Trend monitoring and follow-up

Why do medical surveillance?

- Key component of effective respiratory health and safety program in flavor industry.
- Difficult to identify specific causative agent/ exposure.
- Lung function abnormalities or reported symptoms may be the first clue to an exposure-related problem.
- Medical surveillance may identify health issues before progression to serious illness occurs.

Who should be included in your medical surveillance program?

Employees who work in potentially " high risk" areas:

- Heating of flavors
- Manufacture and handling of liquid flavors
- Manufacture and handling of dry and powdered flavors
- Quality assurance and product testing that results in repeated exposures, even if a single exposure is of a smaller quantity

Who else should be included?

- Those for whom environmental sampling points to exposure risk
- Those employees with complaints/ symptoms

How often should surveillance occur?

- Pre-employment, baseline data
- At least annually for laboratory and production employees
- Every 3-4 months for production workers with evidence of obstruction based on spirometry

How to assure surveillance is performed properly

- Spirometry
  - NIOSH certified technician
  - Must follow ATS guidelines for accurate testing
  - Quality control must be performed
- Essential to link questionnaire and spirometry results

What are the costs?

- Medical surveillance, when done accurately, is relatively inexpensive and cost effective.
- Spirometry = $30-$50 per test (compared to chest CT scan at >$800)

Components of a Medical Surveillance Program

- Clinical evaluation
  - Questionnaire
  - Spirometry
- Communication of individual results to employee and appropriate medical referral
- Communication of aggregate results to employer
- Trend monitoring and follow-up

Questionnaire

- Captures information regarding:
  - Demographics (age, race, gender)
  - Medical history
  - Symptoms
  - Medications
  - Smoking history
  - Work history
  - Respiratory protection

Questionnaire

- Self-administered
- Reviewed by physician with individual employee in a private setting
- Translator services may be needed
- Results kept confidential
- Aggregate results (de-identified) provided to employer

Spirometry

- Principles of spirometry
- Indications for spirometry in flavor industry
- Essential components of valid spirometry
- Quality control

Spirometry

Principles of Spirometry

- Most basic and frequently performed test of pulmonary function
- Uses forced expiratory maneuver to measure volume and flow rates
- Accuracy of results are dependent on effort of participant
- Clinically useful measurements are FVC, FEV1 and FEV1/FVC

Indications for Spirometry

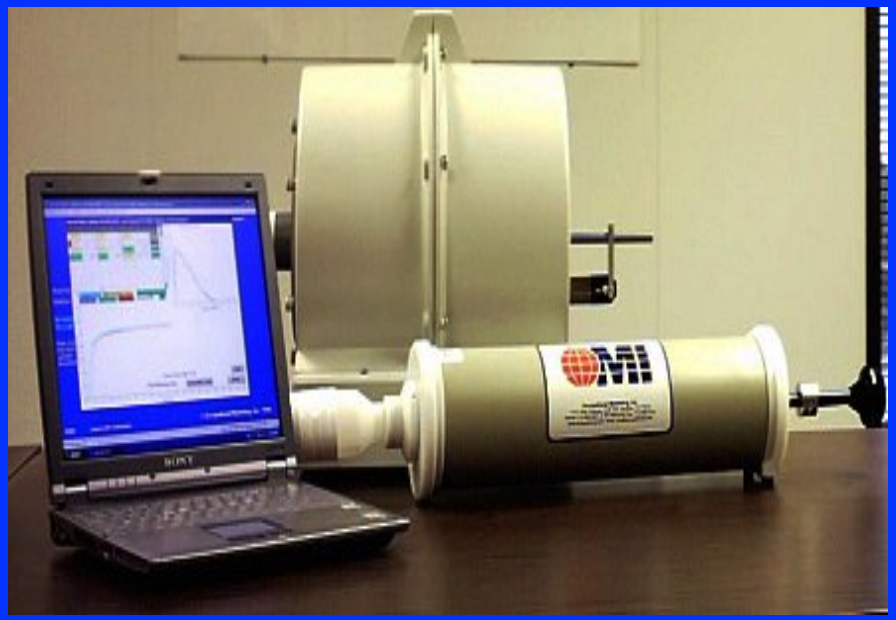
- Pre-employment, baseline data
- Evaluating effects of workplace exposures
- Ongoing monitoring of health status in workers
- Clinical evaluation of symptomatic workers

Essential Components of Spirometry

- Equipment Performance
- Testing Technique
- Measurement and Interpretation of Results
- Technician Training

Equipment Performance

- Daily calibration must be performed
- Maintain log of calibration and maintenance records
- Spirometer provides real-time volume-time and flow-volume curves
- Spirometer provides extensive computer-derived technical quality indicators



Testing Technique

- Based on ATS guidelines for performance of spirometry
- Participant's demographics (age, height, weight, sex, race) entered into computer
- Technician describes and demonstrates test
- Coaches participant through efforts
- Performs at least three acceptable efforts, with up to eight attempts

Measurement and Interpretation of Results

- Spirometry efforts must meet ATS criteria
- Predicted values based on large population studies
- Interpretation completed by physician trained in ATS criteria

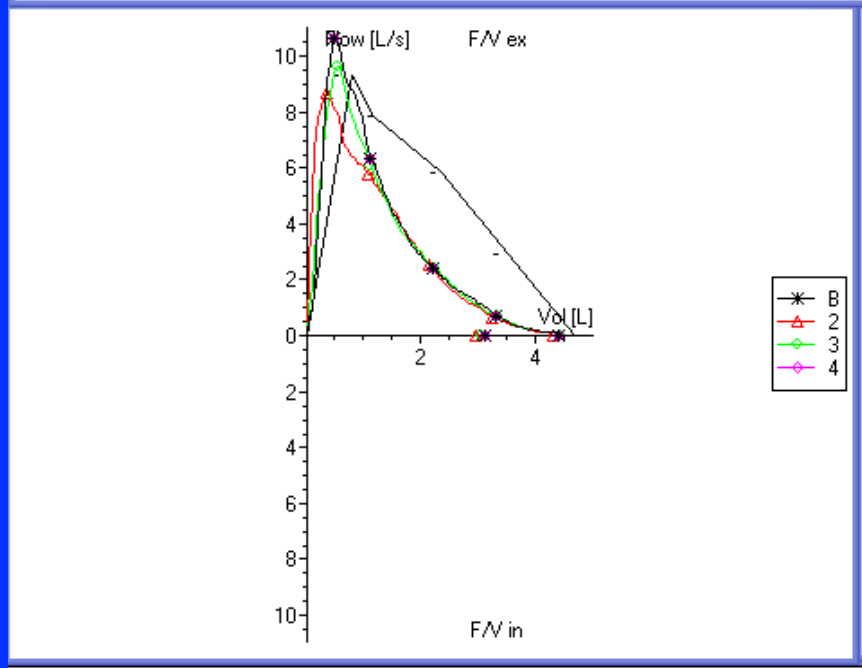
Technician Training

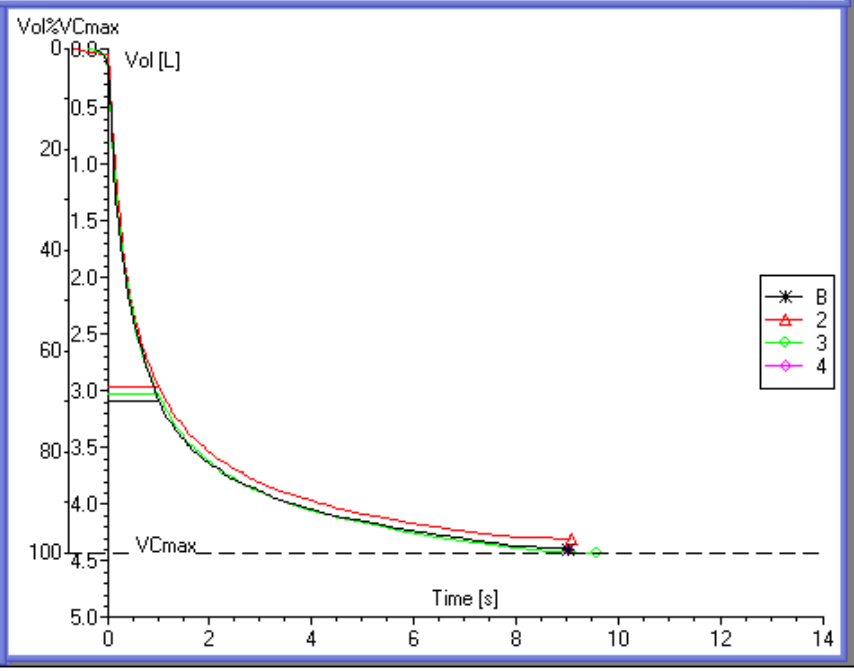
- Spirometry technicians should be NIOSH certified
- Technicians should attend a spirometry refresher course every three years
- Technicians should be provided regular feedback regarding quality of performance

Patient data

Last Name:		First Name:	
Med. Rec. #:		Sex:	male
Age:	54 Years	Date of Birth:	
Weight:	86 kg	Height:	174 cm
Pred. Module:	NJ 2001	Technologist:	Sandra Ulrich
Physician:	Dr. Rose	Placer Order #:	

	Pred	Best	%Pred	Act1	Act2	Act3	Act4	Act5	Act6	Act7	Act8	Act9	Act10
FVC	4.70	4.39	93.5		4.30	4.43	4.39						
FEV 1	3.62	3.10	85.7		2.97	3.04	3.10						
FEV1/F	77	71	91.6		69	69	71						
PEF	9.28	10.60	114.2		8.68	9.60	10.60						
25-75	3.14	1.88	60.0		1.82	1.71	1.88						
PIF	4.88												
FE/FIF	141												
EET		9.05			9.13	9.63	9.05						
VBe/FV		3.28			1.16	3.16	3.28						



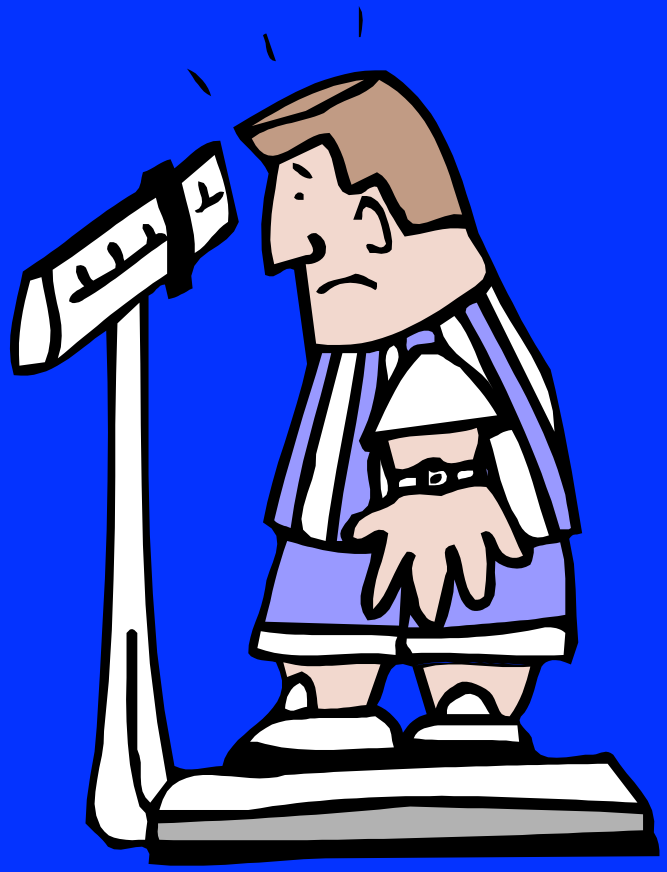


Quality Control

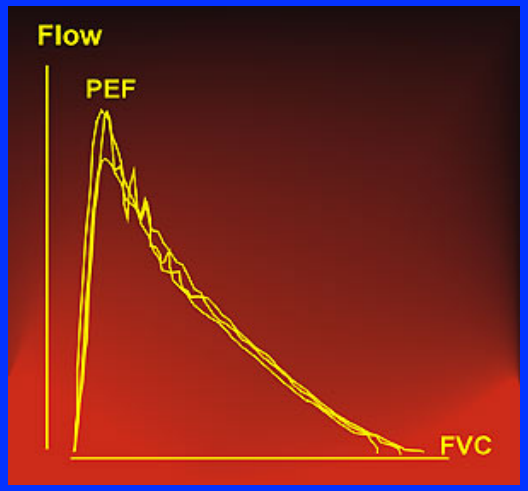
- Quality control can be performed on electronic or hard copy spirometry reports
- Review random samples of reports for adequacy and apply ATS criteria
- Observe technicians performing spirometry
- Accuracy of patient data can affect predicted values

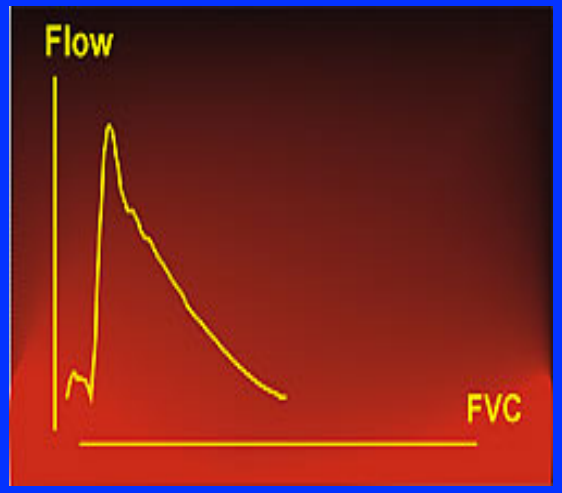
The scale at the doctor's office has a chart showing the desired weight per height. Thanks to it, I now know my problem. I'm not overweight…

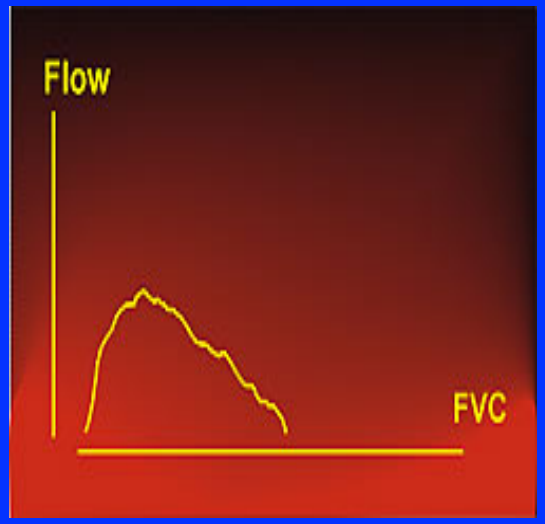
I'm too short !!

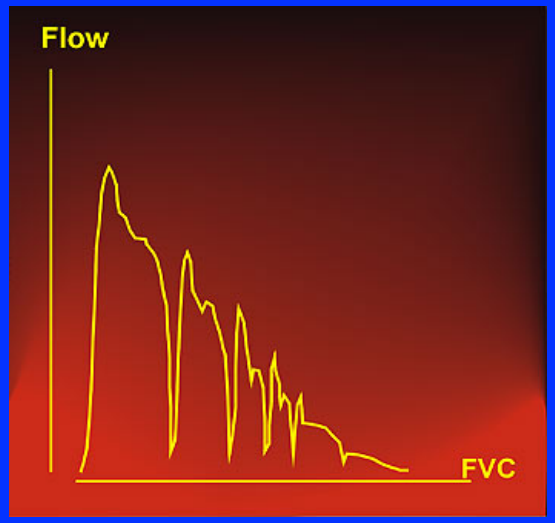


Examples of Spirograms









Communication of Results to Employee and Medical Referral

- Provide written result letter to employee with any recommendations for follow-up
- Provide employee's personal physician the results, with employee's signed permission
- Refer employee for medical evaluation if:
  - FEV1 < 80% predicted
  - FEV1/FVC ratio < 70%
  - Decline in FEV1 > 15% from baseline

Communication of Results to Employer

- Provide aggregate results to employer
- Recommendations for ongoing medical surveillance
- Appropriate work restrictions of employees with abnormal results

Trend Monitoring and Follow-Up

- Correlate abnormal spirometry to questionnaire data (job title, smoking history, previous respiratory problems)
- Compare rates of respiratory conditions to expected rates based on published data

Trend Monitoring and Follow-Up

- Encourage at least annual screening of employees
- Compare individual annual results to previous questionnaire and spirometry data
- Assess for an accelerated decline in lung function, worsening symptoms or excess rates of reported respiratory conditions

Follow-Up

- Continue to limit exposures to respiratory irritants based on environmental sampling.
- Employees should be encouraged to notify employer of new symptoms or worsening respiratory conditions.

Take Home Points

- Medical surveillance is an essential component of an effective respiratory health and safety program.
- Only effective if program meets all quality standards.
- Medical surveillance should be performed at least annually, or more frequently if abnormalities are detected, with defined protocols for referral and diagnosis.
- Essential to perform longitudinal follow-up and analysis to monitor health status of employees.

"The key to reliable pulmonary function testing is the technician's way of guiding the employee through a series of respiratory maneuvers. The most important quality of a pulmonary function technician is the motivation to do the very best test on every employee. The technician must also be able to judge the degree of effort and cooperation of the participant. Test results obtained by a technician who lacks these skills are not only useless, but also convey false information which could be harmful to the employee."

From Preamble to OSHA Cotton Dust Standard, 1978