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Inspections, Compliance, Enforcement, and Criminal Investigations

Air Velocity Meters

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DEPT. OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION *ORA/ORO/DEIO/IB*

Date: 7/30/76 Number: 24 Related Program Areas: Sterile Drugs, Devices, Foods, and Cosmetics

ITG SUBJECT: AIR VELOCITY METERS

This ITG is written to familiarize Investigators with the numerous uses to which they can put an air velocity meter.

An air velocity meter is particularly useful during inspections of firms that produce sterile drugs or devices, it also has applications in food and cosmetic plants.

Some example applications are as follows:

1. Firms that manufacture sterile drugs or devices
 - A. Determine the direction of air flow into and out of controlled environment areas such as filling rooms, assembly areas, and sterility testing rooms.
 - B. Measuring airflow velocity at the face of HEPA filters and in sterile work areas. (See C.P. 7332.24, Proposed Large Volume Parenterals Good Manufacturing Practices, Part 212.55(d)). Some leaks in HEPA filters can be detected by locating areas of high air velocity, and compliance with applicable standards can be determined.
 - C. The air velocity meter can be used to calculate the number of air changes per hour in a controlled environment area (refer again to the proposed L.V.P.G.M.P.s Part 212.265(e)).

The following method may be used for determining the number of air changes per hour in a controlled environment room.

Area of air Velocity of air at X X 60 min/hr

inlet(s) * \ in ft 2 inlet(s) * \ in ft/min

----- = Air changes

Volume of air in room in cubic feet Per Hour

* \ Outlets can also be used but air loss around doors, through access ports, etc., cannot be discounted.

Applying the above to a room measuring 40 ft. X 20 ft. X 10 ft. with an air inlet measuring 20 ft. X 10 ft. (one wall) and an air velocity of 80 feet/minute would be:

10 X 20) X (80) X (60) ----- = 120 Air changes Per Hour (40 X 20 X 10)

2. Firms that Manufacture Non-Sterile Drugs

A. Determine the direction of airflow in dusty areas such as mixing and weighing rooms, tableting and encapsulation cubicles, and milling.

3. Food and Cosmetic Plants

A. Determine the direction of airflow from "dirty" areas of the plant to assure that airflow is not into "clean" areas such as preparation and filling rooms, and drying rooms of Non Fat Dry Milk plants.

Field Sciences Branch has advised that most District Laboratories have an air velocity meter of one type or another.

It is suggested that Investigations Branch in each District assess its needs for this equipment and purchase whatever is deemed necessary.

A listing of suppliers of air velocity meters may be found in the "Chemical Engineering Equipment Buyers Guide", 1975-76, page 323.

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