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Inspections, Compliance, Enforcement, and Criminal Investigations

Steam Pressure for Retorts and Autoclaves

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DEPT. OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION *ORA/ORO/DEIO/IB* Date: 6/29/73 Number: 11 Related Program Areas: Sterile drugs & devices, low acid canned foods, biologics

ITG SUBJECT: STEAM PRESSURE CONTROL FOR RETORTS AND AUTOCLAVES

Regulation of the temperature (measured with a metal-stem mercury thermometer) of the steam-filled space within a retort (autoclave) to that specified by the process is achieved by varying the steam pressure. The temperature of saturated steam of high quality with no superheat (we will explain these terms later), bears a fixed relationship to its absolute pressure (psia). In most instances, however, steam pressure is measured as gauge pressure (psig), which has its zero point at an absolute pressure of 14.7 psi (equivalent to atmospheric pressure at sea level). Tables showing the relationship of steam temperature to pressure are readily available, e.g., see page 65, NCA Bulletin 26-L, Processes for Low Acid Foods in Metal Containers.

A high quality steam (100% quality) is one containing no entrained liquid water spray. Most boilers, when operated properly, will produce acceptable, high quality steam. Steam demand greater than the normal capacity of the boilers will result in entrainment of water spray in the steam. Such low quality steam has significantly lower heat content. Superheated steam is steam at a higher temperature than its equivalent pressure, created either by further heating of the steam in a separate superheater section of the boiler, or by dropping the pressure abruptly and expanding the steam to a lower pressure before the extra heat can dissipate. Moderate pressure boilers customarily found in canneries, and in small and medium size drug plants are not likely to be found with superheater sections. Superheat may, however, be observed within a retort (autoclave) during the venting and the come-up periods. For this reason, a thermometer installed in the supply line between the pressure regulator and the retort will often indicate a higher temperature during venting than the actual temperature in the retort, and this method of installation is undesirable. After come-up, the quantity of steam entering the retort with some superheat and mixing with the saturated steam will be so small as to make its effect negligible.

Use of steam pressure control valves is required by 21 CFR 128(b) for retort operation. Many different type of control valves are found in many configurations, and actuated by many different means. With the exception of electrically modulated valves, operated with small servo-motors, all types of control valves except two types (discussed below) are actuated by means of a flexible diaphram, enclosed in a superstructure above the valves. The diaphram will be moved by air pressure, steam pressure, or hydraulic pressure from some controlling source, supplied through small diameter tubing. Use of this type of valve is desirable. A typical example is shown in Figure 1⁴. Air-operated control valves, for which the pressure of the air supply is controlled by a recorder-controller are the most desirable, accurate, and dependable devices for use. To prevent serious accidents, all such control valves must be operated in the reverse acting, fail-safe, mode (air-to-open).

Two types of control valves which are less desirable are often found. On one, the valve is actuated in one direction by a lever arm with adjustable weights, operating against an opposing fixed spring. In the other, the valve is set to open a fixed amount by adjusting the compression of a moveable spring, operating against an opposing fixed spring. If the steam header pressure does not fluctuate appreciably, these will perform satisfactorily. If the header pressure does vary, the retort pressure will vary also; for these valves are essentially steam pressure ratio valves.

For example: Assume that header pressure is 105 psig when a valve of this type is adjusted to hold 15 psig

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in the retort. If the header pressure drops to 90 psig at any time, the retort pressure will drop to 12.5 psig. 105-15 6 90-15 6

-----; x = 12.5 psig 15 1 x 1

For this reason, in installations where these types of pressure ratio regulating valves are found, together with a boiler room where on - off or high - low burner control operation of one of the boilers is utilized, observation of the steam header pressure through several cycle of on - off boiler operation, and observation of the retort (autoclave) cycle through several cycles, is strongly indicated. For further information, call (301) 443-3340.

Figure2:⁵ Typical Installation diagram of Type 655-A reducing valve. Increased pressure on diaphragm, caused by rise in down-stream pressure, will stem downward to close inner valve.

A Sectional View

Figure 1⁶



(image size 38KB)⁸

Typical Installation Diagram

Figure 2⁹



(image size 18KB)¹¹

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