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STERILIZATION BY FILTRATION

Although the use of filtration for sterilization is well established, some reluctance has been shown by potential users because of the difficulty of being certain of the integrity of the filter. This is especially so when the material to be sterilized, such as a short-lived isotope, is to be used before the sterility of the product can be checked. We have been in the practice of visually examining the filter after use, but this is somewhat unsatisfactory since small defects might easily be missed. If the user was doubtful about any particular filter, a second and third opinion was often sought with the usual result that to "be on the safe side" the material was filtered again, probably unnecessarily in many cases.

Following a suggestion by Millipore (U.K.) Ltd.,* a simple apparatus to test the "bubble point" of filters has been constructed. This test depends on the fact that filters saturated with liquid will not permit the passage of a gas until a limiting pressure, which depends on the pore size, is reached. The pressure also depends on whether the solution is aqueous or not, but for a 0.22-micron filter and an aqueous solution the pressure is 55 lb/in.^{2} and for a 0.45-micron filter 32 lb/in.^{2} However, we have found that after autoclaving the necessary pressure is somewhat less—about 50 lb/in.^{2} for the smaller pore size.

* Millipore (U.K.) Ltd., Heron House, 109, Wembley Hill Road, Wembley, Middlesex, U.K.

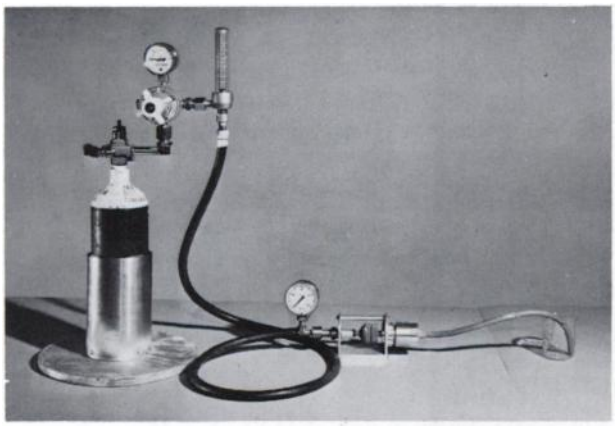

FIG. 1. Simple apparatus to test integrity of filters used for sterilization.

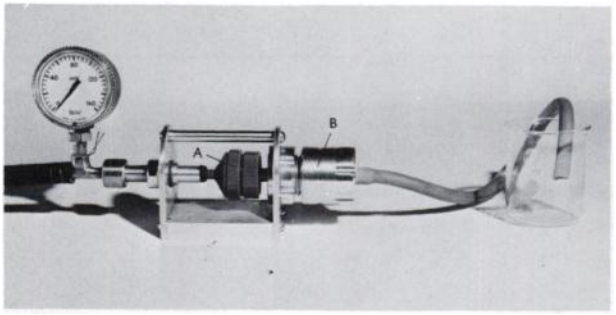

FIG. 2. In apparatus shown in Fig. 1 filter holder (A) containing filter is placed in position and ring B turned until gas-tight seal results. Cylinder tap is then slowly turned on until bubbles are observed in beaker. If premature bubbling occurs before given pressure is reached, there is defect in filter.

A general view of the apparatus is shown in Fig. 1. An oxygen cylinder is used in our case because this was easily available, but nitrogen is probably preferable for safety reasons.

It has been suggested that the filter should be tested after autoclaving and before use but this is not considered worthwhile in our case since very few filters are in fact rejected. Hence after sterilization is complete and while the filter is still wet, the filter holder (A) is placed in the device and the holder tightened by turning the ring B until a gas-tight seal is obtained (Fig. 2). Then the gas cylinder tap is slowly turned on until bubbles are observed in the beaker which should not occur until the given pressure is reached (hence the term bubble point). If premature bubbling is observed, the material must of course be refiltered. We have checked the method with a filter pricked with the tip of a fine needle when the defect was immediately obvious. One must take

precautions to ensure that radioactivity is not sprayed around, but otherwise the method presents no difficulties except that the filter must of course remain wet until the test is performed. The apparatus has been in daily use for about 3 months and has proved invaluable. We are pleased to acknowledge the expert technical help of William Williams who constructed the device.

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EFFECT OF RADIONUCLIDE CONTAMINATION ON THE CALIBRATION OF ^{99}Mo

The U.S. Atomic Energy Commission requires the users of ^{99m}Tc eluted from ^{99}Mo generators to demonstrate that the ^{99m}Tc to be injected into a patient contains not more than 1 μCi of ^{99}Mo/mCi of ^{99m}Tc or 5 μCi of ^{99}Mo/dose of ^{99m}Tc administered. There are a variety of physical methods for testing ^{99}Mo breakthrough:

1. In laboratories equipped with multichannel analyzers the ^{99}Mo contamination can easily be measured spectroscopically. Small laboratories, however, may be unable to use this method because of the high cost of such an instrument.
2. The method recommended by a commercial supplier of ^{99}Mo generators (Squibb) involves successive measurements of the total ^{99m}Tc eluate and a ^{137}Cs standard in a 6-mm lead container with subsequent calculation of the ^{99}Mo activity per milliliter of eluate (*1*).
3. Richards and O'Brien have recently suggested a simpler method (*2*). They used a 4-mm lead container and found by measurements with a pressurized well ionization detector (Mediac Dose Calibrator, Nuclear Chicago) a reduction of the ^{99m}Tc reading to 0.002% of the unshielded reading while the ^{99}Mo reading was reduced by only approximately 50%.

We have fabricated a container using the same concept; however, instead of 4 mm lead a slightly greater wall thickness of 4.8 mm lead and 1.3 mm stainless steel was used to make any contribution caused by the ^{99m}Tc radiation negligible. Under these conditions using a nonpressurized well ionization detector (Mark IV, RADX Corp.) no measurable reading was obtained with 270 mCi of ^{99m}Tc and the ^{99}Mo reading was reduced by about 40%. The HVL of the ^{99m}Tc measured under relatively broad beam conditions was found to be 0.33 mm lead.

The test methods described above are based on the assumption that besides ^{99m}Tc only ^{99}Mo may be present in the elution and all other contamination is small enough to be neglected. To calibrate for ^{99}Mo we used the alumina column of a several-week-old ^{99m}Tc generator and found a considerable difference between calculated and measured ^{99}Mo activity. For this reason we took a portion of the alumina column from a newly arrived ^{99m}Tc generator and measured the spectrum with a multichannel analyser and a 4 $\times$ 4-in. NaI(Tl) crystal at intervals of several days over a period of 5 weeks. Figure 1 shows the change of the spectrum with time. The counting rate of the ^{99}Mo peak at 740 keV has been used as ref-

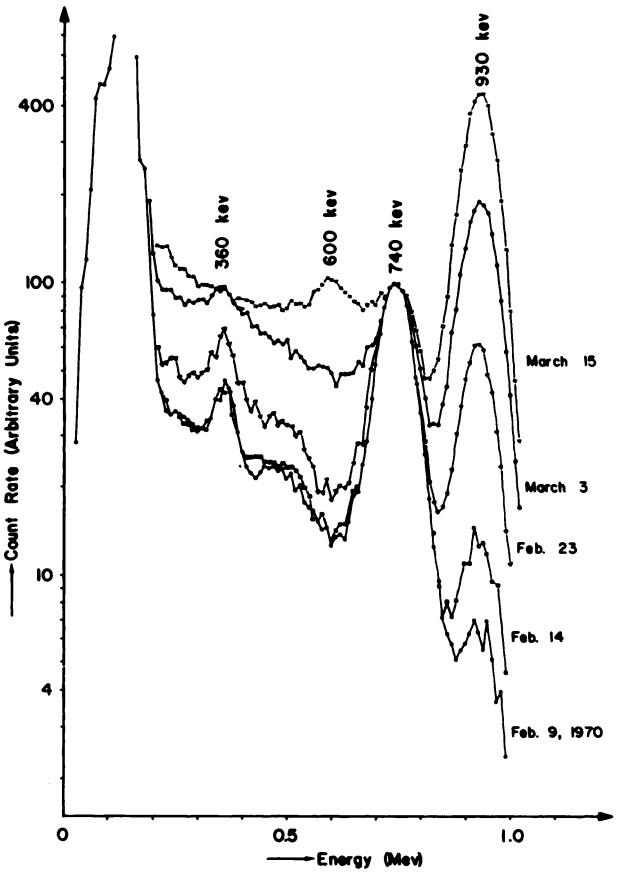

FIG. 1. Spectrum of ^{99}Mo obtained from alumina column (Squibb) at various time intervals.