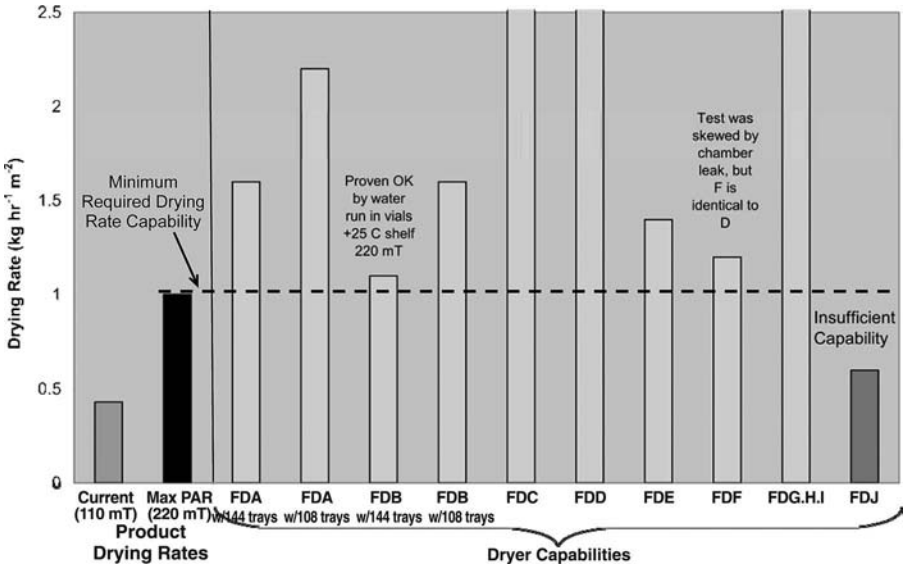

FIGURE 5 Drying rate capabilities (*bold black and dashed black bars*) compared to the required drying rate for the new process (*black bar*) and the current process (*gray bar*).

temperatures early in primary drying, and the single ice slab study result confirmed that it is indeed very close to being unable to hold pressure. Two other dryers, E and F, showed a similar sign of stress at their higher-pressure tests, so dotted lines were also extended to the right of those points. Three identical dryers that were still in start-up mode, dryers G, H, and I, gave identical results. They were able to run at a set point of 200 mTorr, with fresh ice slabs and shelf fluid inlet temperature of +70°C, so they have no data points shown for that pressure.

Overall, Figure 4 reveals that if primary drying were to remain at 110-mTorr pressure, there would be no room for an increased drying rate because the current process is close to the limit measured and/or interpolated for a number of the dryers. However, at the higher pressure of 200 mTorr, we can achieve a significantly higher drying rate of product while having sufficient additional drying rate capability in all of the machines except unit J.

Figure 5 shows the results in a different format. All dryers except J are projected to be able to support the higher drying rate of the new cycle with a full load at 200 mTorr. Dryer F's test had been successful except a small leak into the dryer, so its results were not as close as the bar height would indicate. In addition, dryer B was projected to be close to failure but able to handle the new cycle fully loaded, so a water run was conducted to verify the projection. It was known that a load of vials filled with only water would initially dry faster than product. To make the test even more conservative the test was run at slightly higher shelf fluid inlet and chamber pressure set points than those for the new cycle. The water run was successful with pressure set point holding and no other signs of stress to that dryer was also approved for the new cycle.

Other aspects of freeze-dryer capability were assessed by calculation. The surface area of condenser coils/plates was compared to the shelf surface area of