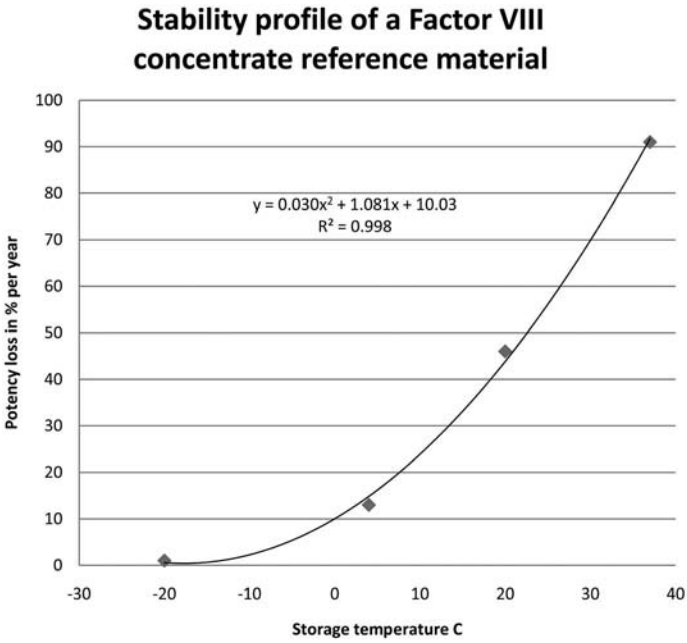

FIGURE 17 Predicted stability at −20°C for factor VIII concentrate reference material based on accelerated elevated temperature degradation studies.

RECENT DEVELOPMENTS

Infectious Filling Capability

NIBSC has a new reference materials production unit, the Center for Biological Reference Materials, which is fully operational. In particular, this facility offers capabilities for processing both infectious liquid and freeze-dried reference materials, in addition to improved facilities for the preparation of noninfectious standards.

The capability to freeze-dry up to 10 L of containment level 3 materials comprises a freeze-drier interfaced with a negatively pressured pharmaceutical-grade isolator containing vial-filling/capping equipment. The freeze-dryer is steam sterilizable and the isolator decontaminated by formaldehyde gassing. This should significantly increase the availability and ease of supply of these key reference materials that currently are available only as liquid preparations. Product can be filled on the automated vial-filling line and then is transferred to the dryer by an operator, working in a half-suit, which is an integral part of the isolator (Fig. 18). Following lyophilization, vials can be removed while maintaining containment through the use of transfer mobiles and reinserted and screw capped prior to the product being decontaminated ready for removal and storage.

Trends in Reference Materials

As predicted in the second edition, there has been over the past few years an increase in the range and variety of reference materials processed by NIBSC. In