Appendix E.—Method Used for OTA's Analysis of Applications to the National Institutes of Health for Small Business Innovation Research Grants

The data in table 31 (see ch. 4) are the result of an OTA analysis of the Small Business Innovation Research (SBIR) grant applications submitted to the National Institutes of Health (NIH) for funding in October 1983. OTA obtained copies of all applications submitted to NIH. A 50-percent-interval sample of applications (one of every two) was selected for analysis. (The total sample of *297* was selected from the 593 applications submitted.)

Using the Food and Drug Administration's definition of a medical device, OTA divided the NIH SBIR grant applications into three categories:

- biotechnology applications (includes medical device and other applications involving biotechnology),
- medical device applications (includes medical device applications not using biotechnology), and
- all other applications.

An application was categorized as a biotechnology application if the proposed research and development involved the use of recombinant DNA or other recently developed genetic, cell fusion, or bioprocessing techniques. An application was classified as a medical device application if, first, it did not use biotechnology and, second, it involved either research leading to the actual development of a medical device or research into techniques or products that would subsequently be used in the development of a medical device (i.e., the development of new materials for use in a medical device).

Because judgment was involved in categorizing the applications, inter-rater reliability was tested by having an independent rater analyze 36 randomly selected applications from the sample (approximately 10 percent of the sample). The two independent raters agreed on *26* out of the 36 applications *(72* percent). This is significantly higher than the level that would be expected by chance, but nevertheless allows a substantial level of variation.