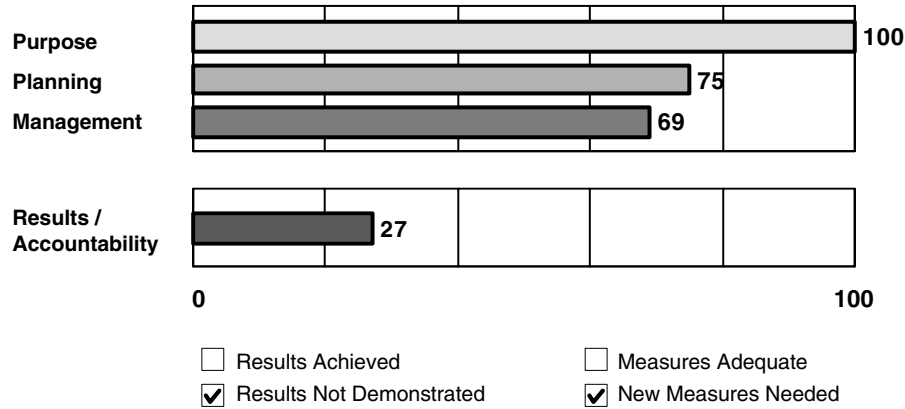


Program: Center for Devices and Radiologic Health

Agency: Department of Health and Human Services

Bureau: Food and Drug Administration



Key Performance Measures

Year Target Actual

Measure	Year	Target	Actual
Long-term Measure: Measures under development			
Annual Measure: Percent of premarket approval application "first actions" for new devices completed within 180 days of receipt	1999	65%	74%
	2000	85%	96%
	2001	90%	96%
	2004	90%	
Annual Measure: Percent of domestic medical device manufacturers inspected (Statutory performance target is 50%.)	1999	26%	30%
	2000	22%	13%
	2001	17%	20%
	2004	20%	

Rating: Results Not Demonstrated

Program Type: Regulatory

Program Summary:

The Center for Devices and Radiological Health (CDRH) reviews new medical devices, ranging from pacemakers to hearing aids, for safety and effectiveness. CDRH also ensures that medical devices available to the public remain safe and effective.

Findings from the PART assessment include the following:

1. CDRH achieved a high score for their Planning efforts. CDRH's list of annual performance goals allows for measurement of performance results.
2. CDRH does have "strategic goals" (such as "Protect the public health by keeping marketed products safe") that aim to produce long term improvements. However, there is no way to measure progress on those strategic goals. Thus the program cannot currently prove long-term results.
3. Financial management is sound, and managers take meaningful steps to address management problems.
4. In recent years, CDRH has shown some improvement in the review of new medical devices, but further performance improvements are needed.
5. Inspection coverage for medical device manufacturers is poor, and falls far below the statutory expectation each year. CDRH focuses inspection coverage on highest priority establishments.
6. CDRH uses performance data to recommend program improvements.

In response to these findings, the Administration will:

1. Establish new, measurable long term performance goals for CDRH.
2. Improve current annual performance goals for the review of new products. CDRH is developing new annual goals that measure time to completion of CDRH review, an important review process milestone. Past goals measured an intermediate step in the review process.
3. Increase funding for medical device reviews through recently-authorized medical device review user fees.

Program Funding Level (in millions of dollars)

<u>2002 Actual</u>	<u>2003 Estimate</u>	<u>2004 Estimate</u>
196	221	218