

Table 1--DISTRIBUTION OF AFFECTED ESTABLISHMENTS BY EMPLOYMENT SIZE

Type of Establishment	Total <sup>1</sup>	Employment Size <sup>2</sup>			
		Small (1-19)	Medium (20-99)	Large (100-249)	Very Large (≥ 250)
Manufacturer	5,415	3,323	1,414	415	265
Contract Manufacturer	419	257	109	32	20
Specification Developer	541	352	162	27	0
Repacker/ Relabeler	828	538	248	41	0
Contract Sterilizer	34	22	10	2	0
<b>Total</b>	<b>7,237</b>	<b>4,492</b>	<b>1,943</b>	<b>517</b>	<b>285</b>

<sup>1</sup>Based on data from FDA's Registration and Listing Branch, 1992, adjusted to reflect 13 percent not required to register and 6 percent exempt from CGMP requirements.

<sup>2</sup>ERG, Section 3.

Table 2--DISTRIBUTION OF ESTABLISHMENTS BY HIGHEST  
CLASS OF MEDICAL DEVICE MANUFACTURED

Type of Establishment	Total <sup>1</sup>	Class <sup>2</sup>				
		I	II	III	Noncritical	Critical
Manufacturer	5,415	1,137	3,844	433	4,873	541
Contract Manufacturer	419	88	297	33	377	42
Specification Developer	541	114	384	43	487	54
Total	6,375	1,339	4,525	510	5,737	637

<sup>1</sup>Includes manufacturing and product development establishments only.

<sup>2</sup>The Evolving Medical Device Industry 1976 through 1984. OPE, FDA (OPE study 74).

Note: Totals may not add due to rounding

class III and critical devices are subject to more stringent and costly premarket review and CGMP requirements but are also more likely to be in greater compliance with the proposed changes to the CGMP regulation. Also, larger establishments tend to have more formal procedures and more layers of management than smaller ones, increasing the cost and complexity of writing and implementing new procedures. However, because of their more formal structure, larger firms have already implemented many of the proposed changes to the CGMP regulations.

The rate of new product introductions has a major effect on the incremental costs of the proposed CGMP regulation. Based on a limited sample of 510(k) and PMA applications, ERG estimated that the average affected medical device establishment submits 1.1 new product applications per year (Table 3). The submittal rate by size of establishment varied from 0.6 applications per year from small and medium-sized establishments to 6.9 applications per year from very large establishments. Because a substantial number of establishments are small, they remain an important source of new product introductions.

The great diversity of this industry makes it extremely difficult to characterize. Medical devices are classified under one of six Standard Industrial Classification (SIC) codes-- Surgical and Medical Instruments (3841); Surgical Appliances and Supplies (3842); Dental Equipment and Supplies (3843); X-ray

Table 3--ANNUAL NUMBER OF 510(K) AND PMA  
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	Total	Employment Size			
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Average Number of Product Submissions	6,317 <sup>1</sup>	2,264	885	1,342	1,826
Number of Affected Establishments	5,956 <sup>2</sup>	3,675	1,576	442	265
Average Number of 510(k) and PMA Submissions per Establishment	1.1	0.6	0.6	3.0	6.9

<sup>1</sup>Number includes 50 percent of PMA supplements.

<sup>2</sup>The number of manufacturers and the number of specification developers that would incur design costs associated with new product introduction.

Source: ERG, Section 3.

Apparatus and Tubes (3844); Electromedical Equipment (3845); and Ophthalmic Goods (3851). However, many medical devices are produced by establishments whose primary classification is for another SIC, such as in vitro diagnostics (SIC 2835). An earlier FDA study<sup>6</sup> found primary classifications in over 150 different SIC codes for a significant number of manufacturing establishments registered with the agency.

### C. Industry Costs

ERG estimated the total annual incremental cost of the proposed changes to the CGMP regulation at \$84.5 million. This includes \$6.3 million in one-time costs that were annualized over 5 years at a 10 percent discount rate. Table 4 lists the most costly of the new requirements.

Costs were based on the incremental tasks each manufacturer must perform to achieve compliance. To develop these estimates, ERG assembled a team of economists, industrial engineers, and other industry consultants, who addressed each compliance activity in turn, first assessing the state of current practice and next the level and cost of the needed additional tasks. These estimates take into account the added labor and capital resources that would be needed to move from existing compliance

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<sup>6</sup>Food and Drug Administration, "Baseline Data on Medical Device Industries in the Census of Manufacturers," (OPE Study 53), 1980.

Table 4--TOTAL COMPLIANCE COSTS BY MOST COSTLY  
INCREMENTAL TASKS (\$ millions)

Incremental Tasks	One-time Annualized <sup>1</sup>	Annual		Total Annualized
		Labor	Nonlabor	
PREPRODUCTION DESIGN				
Design Verification	NA	19.7	29.5	49.2
Design Review	NA	6.4	NA	6.4
Design Changes	0.1	3.9	NA	4.0
Design and Development	0.9	1.6	NA	2.5
Planning				
OTHER				
Quality Audit	0.5	4.7	NA	5.2
Purchasing Controls	0.6	4.7	2.6	7.9
Management Review	NA	2.2	NA	2.2
Corrective Action	0.9	0.3	NA	1.2
ALL REMAINING	3.3	2.0	0.5	5.9
TOTAL OF PROPOSED REGULATION	6.3	45.5	32.6	84.5

<sup>1</sup>One-time costs annualized over 5 years at discount rate of 10 percent.

Notes: NA = Not Applicable; Totals may not add due to rounding; Source: ERG, Section 4.

levels to new, more stringent levels required under the proposal. For the most part, ERG determined that most very large and large establishments are already in compliance with many of the new requirements and thus would not experience large increases in costs.

The great majority of the costs for all size establishments will be to establish preproduction design controls for new products. Therefore, the more innovative establishments will experience greater compliance costs than the less innovative establishments. The estimated annual preproduction design control costs total \$62.1 million, which represents 74 percent of the total annual incremental cost of compliance. The most costly task within the preproduction design category is design verification (\$49.2 million), which includes verifying design output. Other costly tasks are design review (\$6.4 million), which encompasses conducting and documenting design review meetings; design changes (\$4.0 million), which includes drawing, documenting, and maintaining design change procedures; and design and development planning (\$2.5 million), which includes drafting and maintaining standardized plans for device design and development. The requirement for extending the quality system audit to new areas of production such as design and servicing (\$5.2 million) and establishing greater purchasing controls (\$7.9 million) are also relatively high cost items.

The projected average cost per establishment (Table 5) varies substantially across establishment size categories and by

product type, design complexity, and innovation rate. For most sectors of the medical device industry (excluding dental and ophthalmics) the average annual incremental cost per establishment is estimated to be: \$19,300 for small, \$15,800 for medium, \$27,800 for large, and \$11,600 for very large establishments. The dental and ophthalmic industries have a lower rate of new product development than other device industries and, therefore, a lower average cost of compliance (\$8,800 per establishment versus \$18,700).

Because average current compliance rates vary directly with establishment size and the majority of establishments are small, the largest share of the costs are incurred by small establishments, \$50.2 million (59 percent), while the smallest share is incurred by very large establishments, \$3.1 million (3.7 percent) (Table 6).

D. Benefits From Proposed Changes to the CGMP

The proposed changes to the CGMP regulation will provide public health benefits to medical device users and economic benefits to the medical device industry. Based on its review of medical device recalls over the past 4 years, FDA has estimated that 30 percent of all medical device product recalls are due to inadequate preproduction design controls. It is extremely

Table 5--TOTAL ANNUALIZED<sup>1</sup> AVERAGE COSTS PER  
ESTABLISHMENT BY EMPLOYMENT SIZE

Establishment Employment Size	Medical and Surgical Instruments, X-Ray, and Electromedical Device Industries (SIC 3841, 3842, 3844, and 3845) (dollars)	Dental and Ophthalmic Industries (SIC 3843 and 3851) (dollars)
Small (1-19)	19,300	7,700
Medium (20-99)	15,800	8,700
Large (100-249)	27,800	16,300
Very Large ( $\geq$ 250)	11,600	11,600
All Establishments	18,700	8,800

<sup>1</sup>One-time costs annualized over 5 years at discount rate of 10 percent.

Source: ERG, Section 6.

Table 6--TOTAL ANNUALIZED COSTS  
BY SIZE CATEGORY (\$ millions)

Establishment Size	One-time Annualized <sup>1</sup>	Annual		Total Annualized
		Labor	Nonlabor	
Small (1-19)	3.2	26.0	21.0	50.2
Medium (20-99)	2.0	11.3	7.7	21.0
Large (100-249)	0.7	5.8	3.8	10.2
Very Large (≥ 250)	0.5	2.5	0.1	3.1
All Establish- ments	6.3	45.6	32.6	84.5

<sup>1</sup>One-time costs annualized over 5 years at discount rate of 10 percent.

Notes: Totals may not add due to rounding; Source: ERG, Section 4.

difficult to judge how many of these recalls could have been avoided, ERG judged that a majority would have been prevented if manufacturers had fully implemented the proposed CGMP design controls.

#### 1. Public Health Benefits

FDA requires manufacturers to submit an MDR when their device is associated with a patient or user death, serious injury, serious illness, or device malfunction. ERG used the MDR database to estimate the public health benefits of the proposed changes to the CGMP regulation. There were over 47,000 MDR's submitted to FDA in 1991. FDA reviews each report for cause and assigns it a code. An MDR is considered closed when the review is completed. At the time of this report, 22,674 of the 1991 MDR's were closed. Of these closed cases, FDA determined that 19 percent of the fatalities and 23 percent of the serious injuries were device-related. The bulk of the remaining incidents were due to user problems, but also include procedural problems and cases where cause could not be clearly established.

To estimate the total number of deaths and serious injuries for 1991 by cause, the MDR's that were still open were distributed across cause codes based on the 1988 through 1991 averages. To estimate the number of deaths and serious injuries due to design-related causes, ERG assumed that the percent of the device-related MDR's that were design-related MDR's was the same as that for recalls (30 percent). Because MDR's are

substantially underreported<sup>7</sup>, ERG made an upward adjustment in the number of MDR's of 20 percent for fatalities and 40 percent for serious injuries. Based on these assumptions, medical devices contributed to an estimated 72 fatalities and 1,576 serious injuries in 1991 due to design-related problems in class II and class III devices (Table 7).

To develop an approximate idea of the preventability of these incidents, ERG convened a panel of industrial engineers and regulatory specialists with extensive experience in the design of medical devices. Each panel member evaluated a random sample of 100 design-related recalls. ERG found that the expected value of their judgments implied that proper design controls would have prevented about 73 percent of these recalls. Based on this preventability ratio, ERG calculated that the proposal would prevent about 53 deaths and 1,150 serious injuries per year.

To verify the reasonableness of these estimates, FDA examined an alternative method of estimating the number of fatalities caused by design-related device failures. For this calculation, 3 years of design-related recalls were assumed to be linked to MDR fatalities that occurred for these devices 1 year before or 3 months after the date of the recall. This approach, which provides a lower-bound estimate, because not all relevant

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<sup>7</sup>General Accounting Office, "Medical Devices: Early Warning is Hampered by Severe Underreporting," GAO/PMED-87-1, Washington, DC, 1986.

Table 7--NUMBER OF DESIGN-RELATED REPORTS AND ESTIMATED AVOIDED DEATHS AND SERIOUS INJURIES

	Fatalities			Serious Injuries		
	Class II	Class III	Total	Class II	Class III	Total
Number in 1991	551	482	1,033	4,269	12,175	16,444
Device-related	124	76	200	538	3,214	3,752
Design-related <sup>1</sup>	37	23	60	161	964	1,126
Adjusted total number of design-related MDR's <sup>2</sup>	45	27	72	226	1,350	1,576
Number Avoided	33	20	53	165	984	1,149

<sup>1</sup>Assumes 30 percent of device-related MDR's are design-related, based on FDA recall data.

<sup>2</sup>Total number of fatalities and injuries increased by 20 and 40 percent, respectively, to adjust for underreporting.

Source: ERG, Section 5.

fatalities and subsequent MDR's would occur during this limited time period, found that about 60 deaths per year were due to design-related device failures. If 73 percent of such incidents could be avoided through compliance with the proposed CGMP regulation, 44 deaths per year would be prevented.

These estimates of the public health benefits from fewer design-related deaths and serious injuries represent FDA's best projections, given the limitations and uncertainties of the data and assumptions. It should be noted that the failure of just one widely used device can cause an exceptionally large number of deaths and injuries. For example over 500 fractures of the Bjork-Shiley convexo-concave heart valve, with over 300 deaths, have been reported since 1980. Worldwide, there are over 56,000 surviving recipients of this device and fractures still occur at a rate of 30 to 40 per year.

Moreover, the above numbers do not capture the quality of life losses to patients who experience less severe injuries than those reported in MDR's, who experience anxiety as a result of diagnosis or treatment with an unreliable medical device, or who experience inconvenience and additional medical costs because of device failure.

Medical device malfunctions are substantially more numerous than deaths or injuries from device failures and also represent a cost to society. Malfunctions represent a loss of product and an inconvenience to users and/or patients. Additionally, medical device malfunctions burden medical personnel with additional

tasks, such as repeating treatments, replacing devices, returning and seeking reimbursement for failed devices, and providing reports on the circumstances of medical device failures. No attempt was made to quantify these additional costs.

## 2. Industry Benefits

The medical device industry would gain substantial economic benefits from the proposed changes to the CGMP regulations in three ways: cost savings from fewer recalls, productivity gains from improved designs, and efficiency gains for export-oriented manufacturers, who would now need to comply with only one set of quality standards.

An average of 359 medical device recall events per year were reported to FDA over the period 1988 to 1991. As stated above, FDA estimates that design-related deficiencies contributed to 30 percent of those recall events annually. Applying the 73 percent recall preventability factor, ERG projects that there would be 67 fewer recalls of class II and class III devices each year under the proposed CGMP regulation (Table 8). Although substantial medical device recall cost data were not available, ERG estimated that if the cost and distribution of medical device recalls were similar to those reported in previous drug and device recall studies, the industry would avoid roughly \$45 million worth of recall expenses per year by adopting the new CGMP regulation.

Table 8--NUMBER OF AVOIDED DESIGN-RELATED RECALL EVENTS  
BY CLASS OF DEVICE

Device Class	Average Number of Design-Related Recall Events <sup>1</sup>	Number of Avoided Design-Related Recall Events <sup>2</sup>
I	16	NA
II	79	58
III	<u>12</u>	<u>9</u>
All devices	107	67

<sup>1</sup>Office of Compliance and Surveillance, CDRH.

<sup>2</sup>ERG estimates based on random sample of recent design-related recalls.

ERG also found that the design control requirements in the proposed CGMP regulation would require manufacturers to integrate their design and production operations and that most industry experts believe that this change would lead to better quality products, more efficient engineering, lower manufacturing costs, and reduced product development time. These savings, however, could not be quantified.

Still another benefit of the revised regulation relates to the harmonization of the proposed CGMP rule with the ISO 9001 international standard. This change would especially benefit export-oriented establishments, because they would need to meet only one set of quality standards. The EC in particular is important because it is second only to the United States in market size and purchases \$3.4 billion (43 percent) of U.S. medical device exports<sup>8</sup>. ERG could not derive quantitative measures of this benefit, however, due to the lack of data regarding implementation of the standard in the EC.

E. Costs and Benefits if all Device Classes Were Subject to Preproduction Design Requirements

If all device classes were subject to the proposed design control requirements the total annualized compliance cost would increase from \$84.5 million to \$91.3 million (Table 9), solely due to a \$6.8 million increase in annualized compliance costs for class I devices. In contrast, ERG estimates that subjecting class I devices to the design control requirements would have no

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<sup>8</sup>Health Industry Manufacturers Association, "The Global Medical Device Report: Markets for Health Care Technology Products," vol. I, Washington, DC, 1992.

expected impact on the number of fatalities avoided. There would, however, be 108 fewer design-related serious injuries (Table 10) and 11 fewer design-related recalls (Table 11).

F. Economic and Small Business Impact

The ability of medical device establishments to pass on the added cost of the proposed changes will determine their economic impact on the industry. Under the current medical care system, the demand for medical devices tends to be price inelastic because they are often prescribed by physicians and frequently paid for by third parties. Thus, small price increases have not typically prompted significant declines in industry sales. Nonetheless, competitive pressures would rise under new health care cost-containment measures. Therefore, to examine the potential effect of the costs of compliance on the industry's competitive structure, ERG calculated the maximum impact on industry average prices and profits, using extreme scenarios.

Based on the assumption that all costs of compliance are passed through to the end user, with no loss in sales and no offset for avoided recalls or other industry productivity gains, ERG found that the average increase in the price of medical devices would be less than 0.2 percent. Estimated price increases ranged from 0.06 percent for X-ray Apparatus and Tubes (SIC 3844) and Electromedical Equipment (SIC 3845) to 0.24 percent for Dental Equipment and Supplies (SIC 3843) (Table 12).

Table 9--TOTAL ANNUALIZED<sup>1</sup> COST BY DEVICE CLASS FOR PROPOSAL AND ALTERNATIVE(\$ millions)

Device Class	Proposal		Alternative	
	Annualized Costs	Percent of Total	Annualized Costs	Percent of Total
Class I	5.2	6	11.9	13
Class II	71.4	85	71.4	78
Class III	7.9	9	7.9	9
Total	84.5	100	91.3	100

<sup>1</sup>One-time costs annualized over 5 years at discount rate of 10 percent

Source: ERG, Section 4.

Table 10--NUMBER OF DESIGN-RELATED REPORTS AND ESTIMATED AVOIDED DEATHS AND SERIOUS INJURIES WHEN ALL DEVICES ARE SUBJECT TO DESIGN CONTROLS

	Fatalities				Serious Injuries			
	Class I	Class II	Class III	Total	Class I	Class II	Class III	Total
Number in 1991	38	551	482	1,071	1,092	4,269	12,175	17,536
Device-related	1	124	76	201	355	538	3,214	4,107
Design-related <sup>1</sup>	<1	37	23	60	106	161	964	1,232
Adjusted total number of design-related MDR's <sup>2</sup>	<1	45	27	72	148	226	1,350	1,725
Number Avoided	<1	33	20	53	108	165	984	1,257

TABLE 11--NUMBER OF AVOIDED DESIGN-RELATED RECALL EVENTS BY CLASS OF DEVICE WHEN ALL DEVICES ARE SUBJECT TO DESIGN CONTROLS

Device Class	Average Number of Design-Related Recall Events <sup>3</sup>	Number of Avoided Design-Related Recall Events <sup>4</sup>
I	16	11
II	79	58
III	<u>12</u>	<u>9</u>
All Devices	91	78

<sup>1</sup>Assumes 30 percent of device-related MDR's are design-related, based on FDA recall data.

<sup>2</sup>Total number of fatalities and injuries increased by 20 and 40 percent, respectively, to adjust for underreporting.

<sup>3</sup>Office of Compliance and Surveillance, CDRH.

<sup>4</sup>ERG estimates based on random sample of recent design-related recalls.  
Source: ERG, Section 5.

(The maximum price increase was calculated using aggregate compliance costs as a percentage of the value of shipments.) The price increases calculated by size of establishment suggest that small establishments will be under greater pressure to increase prices. The cost of compliance represented an average of 1.8 percent of the value of shipments for small establishments and only 0.01 percent for very large establishments.

To estimate the potential impact of compliance costs on medical device industry profits, ERG calculated after-tax compliance costs as a percentage of after-tax income for each medical device SIC (Table 12). Again, no adjustments were made for avoided recalls or expected productivity gains. If manufacturers have no ability to increase prices to offset the increase in compliance costs, this estimate represents an upper-bound of the potential effect on entity income. Under these circumstances, the medical device sectors would incur reductions in net income ranging from about 1 percent (SIC 3844 and 3845, X-ray Apparatus and Tubes and Electromedical Equipment) to about 3 percent (SIC 3843 and 3851, Dental Equipment and Ophthalmic Goods). ERG concluded that such impacts may affect some

Table 12--MAXIMUM POTENTIAL IMPACT ON PRICE OR PROFITS  
BY INDUSTRY AND EMPLOYMENT SIZE

Industry	Total Annualized Compliance Costs as a Percentage of Shipments	After-tax Compliance Costs as a Percentage of After-tax Income
3841 Surgical and Medical Instruments	0.15	2.41
3842 Surgical Appliances and Supplies	0.18	2.29
3843 Dental Equipment and Supplies	0.24	3.02
3844 X-ray Apparatus and Tubes	0.06	1.10
3845 Electromedical Equipment	0.06	0.88
3851 Ophthalmic Goods	0.20	3.00
ALL	0.15	2.11
ESTABLISHMENT SIZE		
Small (1-19)	1.78	NA
Medium (20-99)	0.23	NA
Large (100-249)	0.11	NA
Very Large ( $\geq$ 250)	0.01	NA
ALL	0.15	NA

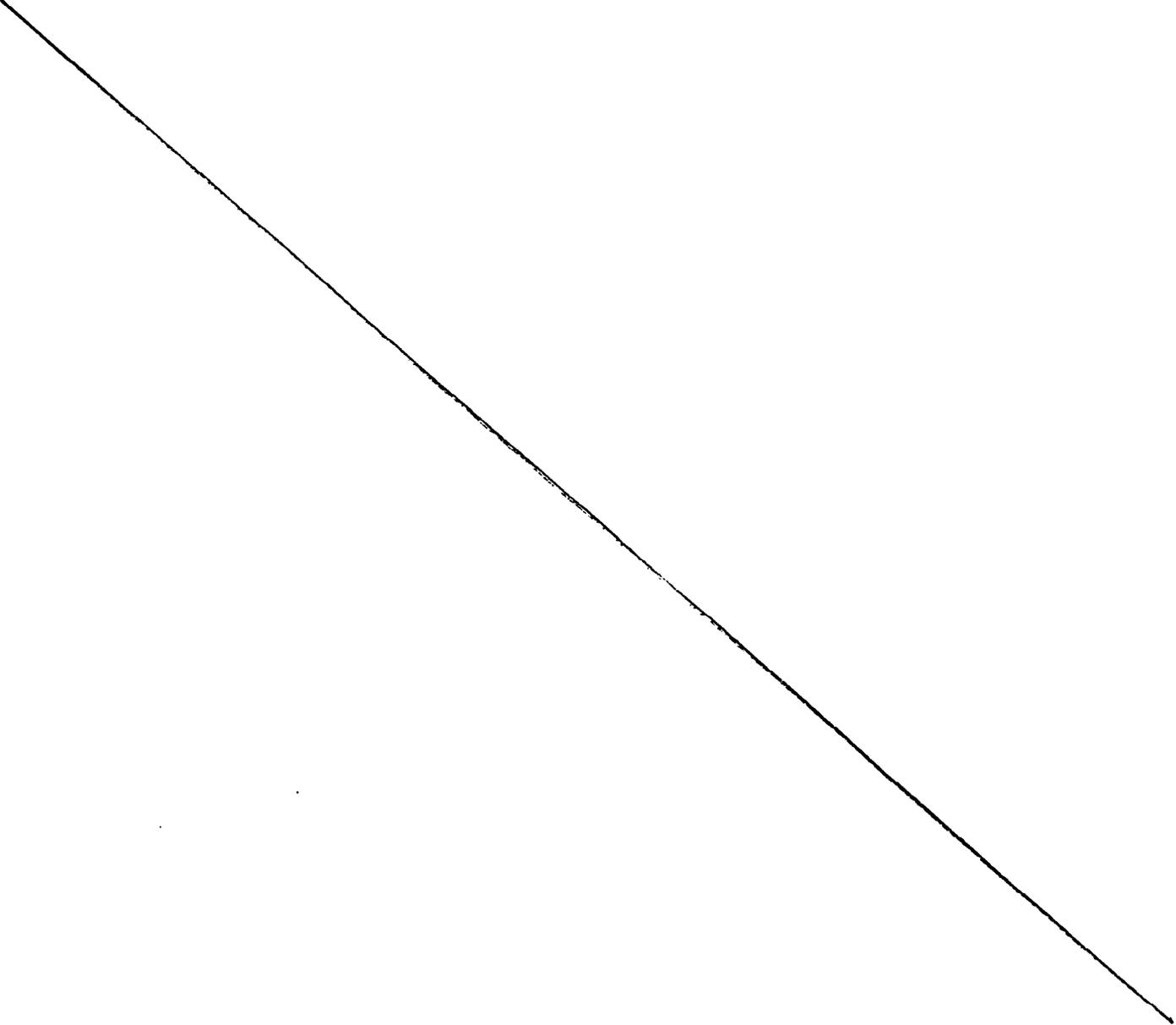
Notes: NA = not available; Source: ERG, Section 5.

establishments' decisions to develop new products where expected profits are marginal or highly uncertain, but judged that the level of incremental costs imposed by this regulation would not substantially lower the innovation rate of products with significant medical benefits.

In accordance with the Regulatory Flexibility Act, FDA has considered the effect of this action on small businesses and has determined that there will be a significant impact on a substantial number of small businesses. The increase in costs is greatest for small establishments due to the large number of small establishments in the industry (62 percent are small) and the lower rate of current compliance by small establishments. The actual added cost per establishment will vary by the establishment's current level of compliance, complexity of product design, product type, and rate of product innovation. Small establishments producing differentiated products or marketing to niche markets may not be at a disadvantage because of their ability to pass on the added cost of compliance. However, small establishments that compete with larger establishments based on price alone would suffer a drop in profits if they currently operate at a lower level of compliance than their competitors. For small start-up establishments that have not yet developed significant sales volume, regulatory costs would amount to a substantial fraction of company revenues.

FDA, through its Division of Small Manufacturers Assistance has a number of programs designed to assist small businesses. The Division of Small Manufacturers Assistance provides guidance materials, regional seminars and technical assistance that can

help small businesses with their compliance activities. In addition, FDA's decision to exempt the majority of class I device manufacturers from preproduction design requirements decreases the cost of compliance by \$6.8 million and minimized the potential burden on small establishments that manufacture class I devices. About 60 percent of that \$6.8 million would have been bourn by small establishments.



In summary, FDA concludes that the \$84.5 million annual incremental cost to comply with the proposed changes to the CGMP regulation would be substantially offset by significant savings from avoided recalls and more importantly, the avoidance of deaths and serious injuries due to design-related device failures or malfunctions. FDA's estimate of public health benefits includes the prevention of about 53 deaths and 1,150 serious injuries annually. In addition, establishing preproduction design controls would result in better designed and higher quality devices and fewer device malfunctions or failures would reduce the inconvenience and expense of repetitive treatments or diagnoses. These public health benefits exceed industry's cost of compliance.

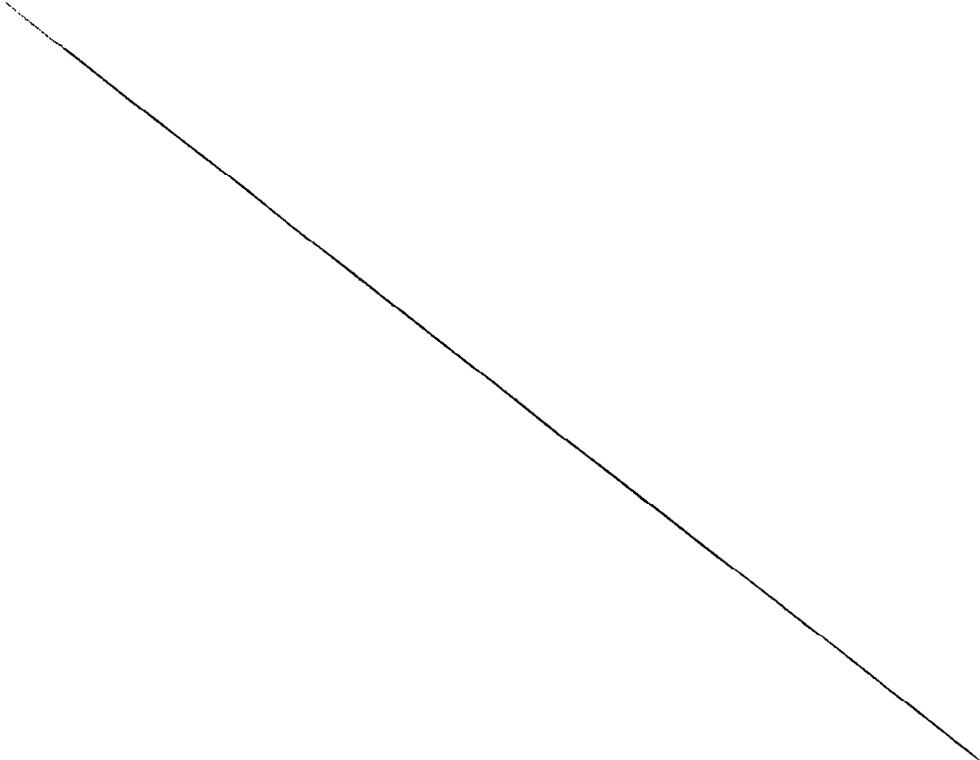


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Management Review	NA	2.2	NA	2.2
Corrective Action	0.9	0.3	NA	1.2
ALL REMAINING	3.3	2.0	0.5	5.9
TOTAL OF PROPOSED REGULATION	6.3	45.5	32.6	84.5

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Very Large ( $\geq$ 250)	11,600	11,600
All Establishments	18,700	8,800

<sup>1</sup>One-time costs annualized over 5 years at discount rate of 10 percent.

Source: ERG, Section 6.

Table 6--TOTAL ANNUALIZED COSTS  
BY SIZE CATEGORY (\$ millions)

Establishment Size	One-time Annualized <sup>1</sup>	Annual		Total Annualized
		Labor	Nonlabor	
Small (1-19)	3.2	26.0	21.0	50.2
Medium (20-99)	2.0	11.3	7.7	21.0
Large (100-249)	0.7	5.8	3.8	10.2
Very Large (≥ 250)	0.5	2.5	0.1	3.1
All Establish- ments	6.3	45.6	32.6	84.5

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	Fatalities			Serious Injuries		
	Class II	Class III	Total	Class II	Class III	Total
Number in 1991	551	482	1,033	4,269	12,175	16,444
Device-related	124	76	200	538	3,214	3,752
Design-related <sup>1</sup>	37	23	60	161	964	1,126
Adjusted total number of design-related MDR's <sup>2</sup>	45	27	72	226	1,350	1,576
Number Avoided	33	20	53	165	984	1,149

<sup>1</sup>Assumes 30 percent of device-related MDR's are design-related, based on FDA recall data.

<sup>2</sup>Total number of fatalities and injuries increased by 20 and 40 percent, respectively, to adjust for underreporting.

Source: ERG, Section 5.

Table 8--NUMBER OF AVOIDED DESIGN-RELATED RECALL EVENTS  
BY CLASS OF DEVICE

Device Class	Average Number of Design-Related Recall Events <sup>1</sup>	Number of Avoided Design-Related Recall Events <sup>2</sup>
I	16	NA
II	79	58
III	<u>12</u>	<u>9</u>
All devices	107	67

<sup>1</sup>Office of Compliance and Surveillance, CDRH.

<sup>2</sup>ERG estimates based on random sample of recent design-related recalls.

Table 9--TOTAL ANNUALIZED<sup>1</sup> COST BY DEVICE CLASS FOR PROPOSAL AND ALTERNATIVE(\$ millions)

Device Class	Proposal		Alternative	
	Annualized Costs	Percent of Total	Annualized Costs	Percent of Total
Class I	5.2	6	11.9	13
Class II	71.4	85	71.4	78
Class III	7.9	9	7.9	9
Total	84.5	100	91.3	100

<sup>1</sup>One-time costs annualized over 5 years at discount rate of 10 percent

Source: ERG, Section 4.

Table 10--NUMBER OF DESIGN-RELATED REPORTS AND ESTIMATED AVOIDED DEATHS AND SERIOUS INJURIES WHEN ALL DEVICES ARE SUBJECT TO DESIGN CONTROLS

	Fatalities				Serious Injuries			
	Class I	Class II	Class III	Total	Class I	Class II	Class III	Total
Number in 1991	38	551	482	1,071	1,092	4,269	12,175	17,536
Device-related	1	124	76	201	355	538	3,214	4,107
Design-related <sup>1</sup>	<1	37	23	60	106	161	964	1,232
Adjusted total number of design-related MDR's <sup>2</sup>	<1	45	27	72	148	226	1,350	1,725
Number Avoided	<1	33	20	53	108	165	984	1,257

<sup>1</sup>Assumes 30 percent of device-related MDR's are design-related, based on FDA recall data.

<sup>2</sup>Total number of fatalities and injuries increased by 20 and 40 percent, respectively, to adjust for underreporting.

TABLE 11--NUMBER OF AVOIDED DESIGN-RELATED RECALL EVENTS BY CLASS OF DEVICE WHEN ALL DEVICES ARE SUBJECT TO DESIGN CONTROLS

Device Class	Average Number of Design-Related Recall Events <sup>1</sup>	Number of Avoided Design-Related Recall Events <sup>2</sup>
I	16	11
II	79	58
III	<u>12</u>	<u>9</u>
All Devices	91	78

<sup>1</sup>Office of Compliance and Surveillance, CDRH.

<sup>2</sup>ERG estimates based on random sample of recent design-related recalls.

Source: ERG, Section 5.

Table 12--MAXIMUM POTENTIAL IMPACT ON PRICE OR PROFITS  
BY INDUSTRY AND EMPLOYMENT SIZE

Industry	Total Annualized Compliance Costs as a Percentage of Shipments	After-tax Compliance Costs as a Percentage of After-tax Income
3841 Surgical and Medical Instruments	0.15	2.41
3842 Surgical Appliances and Supplies	0.18	2.29
3843 Dental Equipment and Supplies	0.24	3.02
3844 X-ray Apparatus and Tubes	0.06	1.10
3845 Electromedical Equipment	0.06	0.88
3851 Ophthalmic Goods	0.20	3.00
ALL	0.15	2.11
ESTABLISHMENT SIZE		
Small (1-19)	1.78	NA
Medium (20-99)	0.23	NA
Large (100-249)	0.11	NA
Very Large ( $\geq 250$ )	0.01	NA
ALL	0.15	NA

Notes: NA = not available; Source: ERG, Section 5.

## VIII. PAPERWORK REDUCTION ACT OF 1980

This proposed rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35). The title, description, and respondents of the information collection are shown below with an estimate of the annual recordkeeping burden.

Title: Medical Devices, Current Good Manufacturing Practice Regulations, Proposed Revisions, Request for Comments.

Description: FDA is proposing to revise the CGMP regulations for medical devices in part 820. Changes proposed include revisions that would: Replace quality assurance program requirements with quality system requirements, including design, procurement and servicing controls; eliminate critical component and critical operation terminology; expand procedures for device failure and complaint investigations; clarify requirements to qualify, verify, and validate processes and changes; and, clarify requirements to evaluate quality data and correct quality problems. Through reorganization and modification of terms, the revised CGMP requirements for medical devices are compatible with specifications for quality systems contained in international quality standards, ISO 9001/EN 29001, "Quality Systems Part 1. Specification for design/development, production, installation and servicing."

Description of Respondents: Businesses or other for-profit and small businesses or organizations.

ESTIMATED ANNUAL BURDEN FOR RECORDKEEPING			
Part	Annual no. of recordkeepers	Annual hours per recordkeeper	Total recordkeeping hours
820	7,237	55.880842	404,410

Under OMB information collection No. 0910-0073, an estimated 375,266 burden hours have already been approved for 21 CFR part 820. The information requirements contained in this proposed rule will add 463,128 hours to the burden estimate.

As required by section 3504(h) of the Paperwork Reduction Act, FDA is submitting to OMB a request that it approve these information collection requirements. Organizations and individuals desiring to submit comments for consideration by OMB on these information collection requirements, should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, Office of Management and Budget, rm. 3001, New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503, Attn: Desk Officer for FDA.

#### IX. REFERENCES

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. ISO 9001/EN 29001 "Quality Systems Part 1. Specification for Design/Development, Production, Installation, and Servicing," International Organization for Standardization, 1987.

2. "Suggested Changes to the Medical Device Good Manufacturing Practices Regulation Information Document November 1990," FDA, Center for Devices and Radiological Health, Rockville, MD 20857, Docket No. 90N-0172.

3. "Device Recalls: A Study of Quality Problems," FDA, Center for Devices and Radiological Health, Rockville, MD 20857, HHS Publication FDA 90-4235, January 1990.

4. "Preproduction Quality Assurance Planning; Recommendations for Medical Device Manufacturers," FDA, Center for Devices and Radiological Health, Rockville, MD 20857, HHS Publication FDA 90-4236, September 1989.

5. "Software Related Recalls for Fiscal Years FY 83--FY 91," FDA, Center for Devices and Radiological Health, Rockville, MD 20857, May 1992.

6. "FDA Medical Device Regulation From Premarket Review to Recall," Office of

Inspector General, Washington, DC, HHS  
Publication OEI 09-90-00040, February 1991.

7. Letter from American Cyanamid  
Company to Dockets Management Branch (HFA-  
305), in response to Docket No. 90N-0172,  
February 28, 1991.

8. Letter from XRE Corporation to  
Dockets Management Branch (HFA-305) in  
response to Docket No. 90N-0172, August 16,  
1990.

9. "Guideline on General Principles of  
Process Validation," FDA, Center for Drugs  
and Biologics, and Center for Devices and  
Radiological Health, Rockville, MD 20857,  
May 1987.

10. EN46001 "Quality Systems-- Medical  
Devices--Particular Requirements for the  
Application of EN29001."

11. EN46002 "Quality Systems--Medical  
Devices--Particular Requirements for the  
Application of EN29002."

12. ISO 8402 "Quality Vocabulary,"  
International Organization for  
Standardization, 1986.

13. "Management Practices; U.S.  
Companies Improve Performance Through Quality  
Efforts," General Accounting Office,

Washington, DC 20548, May 1991,  
GAO/NSLAD-91-190.

14. "Economic Analysis of Proposed Revisions to the Good Manufacturing Practices Regulation for Medical Devices," FDA Contract No. 223-91-8100, Eastern Research Group, Inc., Lexington, MA 02173.

#### X. REQUEST FOR COMMENTS

Interested persons may, on or before (insert date 120 days after date of publication in the FEDERAL REGISTER), submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

FDA is establishing a 120-day comment period, rather than its usual 60 days, in anticipation that the agency will be requested to extend the comment period. The agency will not entertain requests to extend the comment period further.

#### List of Subjects in 21 CFR Part 820

Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 820 be revised to read as follows:

PART 820--GOOD MANUFACTURING PRACTICE FOR MEDICAL DEVICES

Subpart A--General Provisions

Sec.

820.1 Scope.

820.3 Definitions.

820.5 Quality system.

Subpart B--Quality System Requirements

820.20 Management responsibility.

820.22 Quality audit.

820.25 Personnel.

Subpart C--Design Controls

820.30 Design controls.

Subpart D--Document and Record Controls

820.40 Document controls.

Subpart E--Purchasing Controls

820.50 Purchasing controls.

Subpart F--Identification and Traceability

820.60 Identification and traceability.

820.65 Critical devices, traceability.

Subpart G--Production and Process Controls

820.70 Production and process controls.

820.75 Special processes.

Subpart H--Inspection and Testing

820.80 Inspection and testing.

820.84 Inspection, measuring, and test equipment.

820.86 Inspection and test status.

Subpart I--Nonconforming Components and Devices

820.90 Nonconforming components and devices.

Subpart J--Corrective Action

820.100 Corrective action.

Subpart K--Handling, Storage, Distribution, and Installation

820.120 Handling.

820.122 Storage.

820.124 Distribution.

820.126 Installation.

Subpart L--Packaging and Labeling Control

820.160 Device packaging.

820.162 Device labeling.

820.165 Critical devices, labeling.

Subpart M--Records

820.180 General requirements.

820.181 Device master record (DMR).

820.184 Device history record.

820.198 Complaint files.

#### Subpart N--Servicing

820.200 Servicing.

#### Subpart O--Statistical Techniques

820.250 Statistical techniques.

AUTHORITY: Secs. 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360<sup>l</sup>, 371, 374, 381, 383).

#### Subpart A--General Provisions

§ 820.1 Scope.

(a) Applicability. (1) The regulations set forth in this part describe current good manufacturing practices (CGMP's) for methods used in, and the facilities and controls used for, the design, purchasing, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The regulations in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (the act). This part establishes minimum requirements applicable to manufacturers of finished devices, including additional requirements for critical devices. With respect to class I devices, design controls apply only to those devices listed in

§ 820.30(a)(2). The regulations in this part do not apply to manufacturers of components or parts of finished devices when such components or parts are not intended specifically for use as part of a medical device, but such manufacturers are encouraged to use appropriate provisions of this regulation as guidelines. Manufacturers of human blood and blood components are not subject to this part, but are subject to part 606 of this chapter.

(2) The provisions of this part shall be applicable to any finished device, as defined in this part, intended for human use, that is manufactured, imported, or offered for import in any State or Territory of the United States.

(b) Limitations. The CGMP regulation in this part supplements regulations in other parts of this chapter except where explicitly stated otherwise. In the event it is impossible to comply with all applicable regulations, both in this part and in other parts of this chapter, the regulations specifically applicable to the device in question shall supersede any other regulations.

(c) Consequences of failure to comply with the regulations.

(1) The failure to comply with any applicable provision in this part in the design, purchasing, manufacture, packaging, labeling, storage, installation, or servicing of a device renders the device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action under sections 301, 302, 303, 304, and 801 of the act.

(2) If a manufacturer who imports devices into the United States refuses to schedule an FDA inspection of a foreign

facility for compliance with this part or refuses to permit FDA to conduct or complete a scheduled inspection at a foreign facility, it shall appear, for purposes of 801(a) of the act, that the methods used in, and the facilities and controls used for, the design, purchasing, manufacture, packaging, labeling, storage, installation, or servicing of any devices produced at such facility that are offered for import into the United States do not conform to the requirements of section 520(f) of the act and this part and that the devices manufactured at that facility are adulterated under section 501(h) of the act. Foreign CGMP inspections will be scheduled in advance by FDA in writing.

(d) Exemptions or variances. Any person who wishes to petition for an exemption or variance from any device good manufacturing practice requirement is subject to the requirements of section 520(f)(2) of the act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in § 10.30 of this chapter, the Food and Drug Administration's administrative procedures. Guidance is available from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance, Regulatory Assistance Branch (HFZ-220), 1901 Chapman Ave., Rockville, MD 20857, telephone 1-800-638-2041. Maryland and foreign residents, 1-301-443-6597, FAX 301-443-8818.

§ 820.3 Definitions.

(a) Act means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-903, 52 Stat. 1040 et seq., as amended (21

U.S.C. 321-394)). All definitions in section 201 of the act shall apply to these regulations.

(b) Complaint means any written, electronic, or oral communication that relates to or concerns the unacceptability of the identity, quality, durability, reliability, safety, effectiveness, or performance of a device.

(c) Component means any raw material, substance, piece, part, software, firmware, packaging, labeling, or assembly used during device manufacture which is intended to be included as part of the finished, packaged, and labeled device.

(d) Control number means any distinctive combination of letters or numbers, or both, from which the complete history of the purchasing, manufacturing, packaging, labeling, and distribution of a lot or batch of finished devices can be determined.

(e) Critical device means a device that is intended to be surgically implanted into the body or to support or sustain life the failure of which to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a serious injury to the user. Examples of critical devices are identified by the Commissioner of Food and Drugs after consultation with the Device Good Manufacturing Practice Advisory Committee authorized under section 520(f) of the act, and an illustrative list of critical devices is available from the Center for Devices and Radiological Health, Food and Drug Administration, at the addresses given in § 820.1(d).

(f) Design history record means a compilation of records containing the complete design history of a finished device.

(g) Design input means the physical and performance requirements of a device that are used as a basis for device design.

(h) Design output means the results of a design effort at each design phase and at the end of the total design effort. The total finished design output consists of the device, its packaging and labeling, and the associated specifications and drawings and the production and quality system specifications and procedures which are included in the device master record (DMR).

(i) Design review means a comprehensive, systematic examination of a design to evaluate the adequacy of the device requirements, to evaluate the capability of the design to meet these requirements, and to identify problems with the design and design requirements and to propose solutions to all such problems.

(j) Device history record means a compilation of records containing the complete production history of a finished device.

(k) Device master record (DMR) means a compilation of records containing a device's complete design, formulation, and specifications, the purchasing and manufacturing procedures and specifications, the quality system requirements and procedures, and the packaging, labeling, servicing, maintenance, and installation procedures of a finished device.

(l) <sup>all</sup> Establish means define, document, and implement.

(m) Executive management means those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy, quality system requirements, or to a device's design specifications or its production, distribution, servicing, maintenance, or installation procedures.

(n) Finished device means any device or accessory to any device that is suitable for use, whether or not it is packaged or labeled for commercial distribution. A finished device includes a device that is intended to be sterile that is not yet sterilized.

(o) Lot or batch means a unit of components or finished devices that consists of a single type, model, class, size, composition, and software version that are manufactured under essentially the same conditions and that are intended to have uniform character and quality within specified limits.

(p) Manufacturer means any person who designs, manufactures, fabricates, assembles, or processes a finished device, including contract sterilizers, specification developers, repackers, relabelers, and initial distributors of imported devices.

(q) Manufacturing material means any material or substance used in, or to facilitate, a manufacturing process that is not intended by the manufacturer to be included in the finished device, including cleaning agents, mold-release agents, lubricating oils, ethylene oxide or other sterilant residues, or other byproducts of the manufacturing process.

(r) Nonconforming means the failure of a component, manufacturing material, or finished device to meet its specifications, either before or after distribution of the finished device.

(s) Production means all activities subsequent to design transfer and to the point of distribution.

(t) Quality means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.

(u) Quality audit means an established systematic, independent, examination of a manufacturer's entire quality system that is performed at defined intervals and at sufficient frequency to ensure that both quality system activities and the results of such activities comply with specified quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives. "Quality audit" is different from, and in addition to, the other quality system activities required by or under this part.

(v) Quality policy means the overall quality intentions and direction of an organization with respect to quality, as formally expressed by executive management.

(w) Quality system means the organizational structure, responsibilities, procedures, specifications, processes, and resources for implementing quality management.

(x) Record means any written or automated document, including specifications, procedures, protocols, standards,

methods, instructions, plans, files, forms, notes, reviews, analyses, and reports.

(y) Reprocessing means all or part of a manufacturing operation which is intended to correct nonconformance in a component or finished device.

(z) Servicing means maintenance or repair of a finished device for purposes of returning a device to its specifications.

(aa) Special process means any process the results of which cannot be completely verified by subsequent inspection and testing.

(bb) Specifications means the documents that prescribe the requirements with which a device, component, production or servicing activity, or quality system must conform.

(cc) Validation means, with respect to a device, establishing and documenting evidence that the device is fit for its intended use. With respect to a process, "validation" means establishing and documenting evidence that the process will consistently produce a result or product meeting its predetermined specifications and quality attributes.

(dd) Verification means confirming and documenting, with valid, objective evidence, that specified requirements have been met. Verification includes the process of examining the results of an activity to determine conformity with the stated specifications for that activity and ensuring that the device is adequate for its intended use.

#### § 820.5 Quality system.

Each manufacturer shall establish and maintain a quality system that ensures that the requirements of this part are met,

and that devices produced are safe, effective, and otherwise fit for their intended uses. As part of its quality system activities, each manufacturer shall:

(a) Establish effective quality system instructions and procedures in accordance with the requirements of this part; and

(b) Maintain the established quality system instructions and procedures effectively.

#### Subpart B--Quality System Requirements

##### § 820.20 Management responsibility.

(a) Quality policy. Each manufacturer's executive management shall establish its policy and objectives for, and commitment to, quality. Executive management shall maintain the policy at all levels in the organization. Executive management shall ensure that this policy is understood by all employees who may affect or influence the quality of a device.

(b) Organization. Each manufacturer shall establish and maintain an adequate organizational structure with sufficient personnel to ensure that devices are produced in accordance with the requirements of this part.

(1) Responsibility and authority. With respect to each section in this part, each manufacturer shall establish the responsibility, authority, and interrelation of all personnel who manage, perform, and verify work affecting quality, particularly for personnel who need the organizational freedom and authority to:

(i) Initiate or implement action to prevent the occurrence or use of nonconforming components, manufacturing materials, or finished devices;

(ii) Identify or document quality problems with devices, production, or the quality system;

(iii) Initiate, recommend, provide, or implement solutions or corrective actions to quality problems;

(iv) Verify the adequacy or implementation of solutions or corrective actions to quality problems; and

(v) Direct or control further processing, distribution, or installation of nonconforming components, manufacturing materials, or finished devices.

(2) Verification resources and personnel. Each manufacturer shall establish verification functions and shall provide adequate resources and assign adequately trained personnel to perform verification activities.

(3) Management representative. Each manufacturer's executive management shall appoint an individual in executive management, who irrespective of other responsibilities, shall have established authority over and responsibility for:

(i) Ensuring that quality system requirements are established and maintained in accordance with this part; and

(ii) Reporting on the performance of the quality system to executive management for review and to provide information for improvement of the quality system; and the appointment shall be documented.

(c) Management review. Each manufacturer's executive management shall review the suitability and effectiveness of the quality system at defined intervals and at sufficient frequency to ensure that the quality system satisfies the requirements of this part and the manufacturer's established quality policy objectives. The management review shall be conducted in accordance with established review procedures, and the results of each quality system review shall be documented.

§ 820.22 Quality audit.

(a) Each manufacturer shall conduct quality audits to verify that the quality system is in compliance with the established quality system requirements. Quality audits shall be conducted in accordance with established audit procedures by appropriately trained individuals who do not have direct responsibilities for the matters being audited. A report of the results of each quality audit shall be made and the audit reports shall be reviewed by management having responsibility for the matters audited. Followup corrective action, including reaudit of deficient matters, shall be taken when necessary and shall be documented in the audit report.

(b) Section 820.180 does not apply to quality audit reports required under this section, except reports written to satisfy § 820.50(a), but does apply to established quality audit procedures. Audit reports written as part of the assessment of suppliers or contractors (§ 820.50(a)) are subject to review and copying by FDA. Upon request of a designated employee of the Food and Drug Administration, an employee in executive management shall certify in writing that the audits of the quality system

required under this section have been performed and documented and that any required corrective action has been taken.

§ 820.25 Personnel.

(a) General. Each manufacturer shall employ sufficient personnel with the necessary education, background, training, and experience to ensure that all activities required by this part are correctly performed.

(b) Training. Each manufacturer shall ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be conducted in accordance with established procedures by qualified individuals to ensure that employees have a thorough understanding of their current job functions and with the CGMP requirements applicable to their job functions. As part of their training, all employees shall be made aware of device defects which may occur from the improper performance of their specific jobs. Personnel who perform verification activities shall be made aware of defects and errors that may be encountered as part of their verification functions. Employee training shall be documented.

(c) Consultants. (1) Each manufacturer shall ensure that any consultant advising on the methods used in, or facilities or controls used for, the design, purchasing, manufacture, packaging, labeling, storage, installation, or servicing of devices has sufficient qualifications (education, training, and experience) to advise on the subjects about which the consultant will advise.

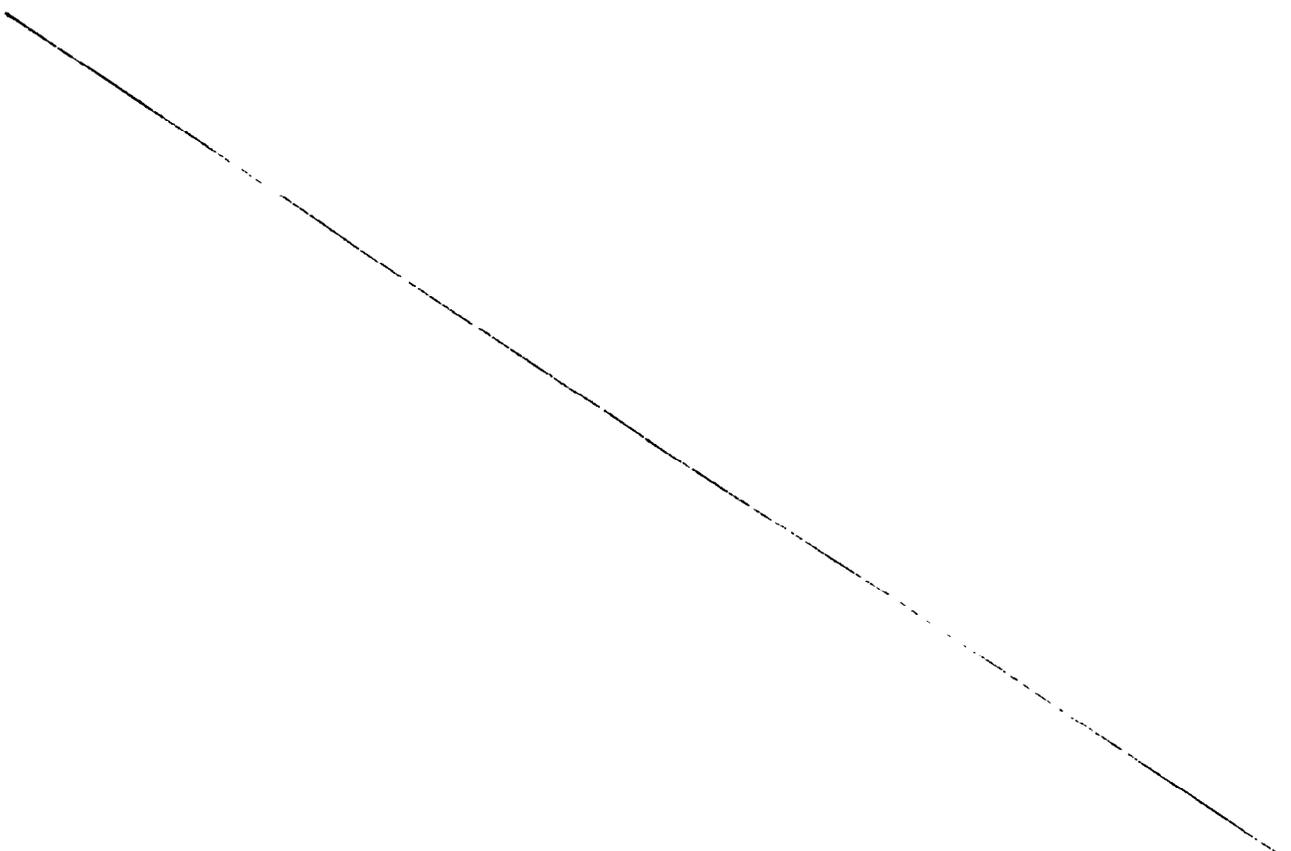
(2) Each manufacturer shall maintain records pertaining to each consultant. Such records shall include the consultant's name and address, the consultant's qualifications, including a copy of the curriculum vitae and a list of previous jobs, and a specific description of the subjects on which the consultant advised.

Subpart C--Design Controls

§ 820.30 Design controls.

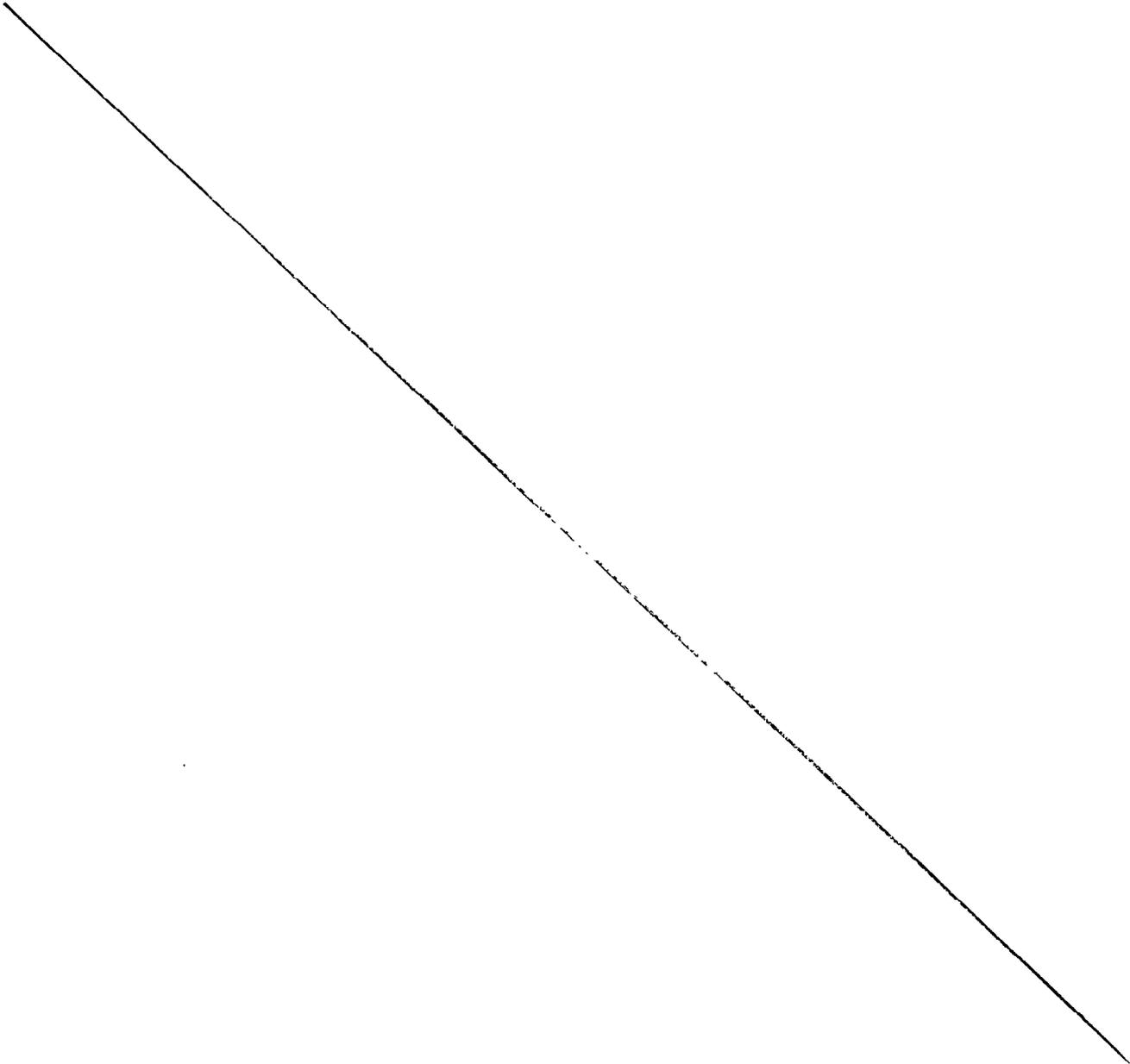
(a) General. (1) Each manufacturer of any class III, or class II device, and the class I devices listed in paragraph (a)(2) of this section shall establish and maintain procedures to control and verify the design of the device in order to ensure that specified design requirements are met.

(2) The following class I devices are subject to design controls:



Section	Device
862.2050 through 862.2920	Instruments, Clinical Laboratory
868.6810	Catheter, Tracheobronchial Suction
878.4460	Glove, Surgeon's
880.4680	Apparatus, Single Patient, Portable Suction
880.6760	Restraint, Protection
892.1100	Camera, Scintillation (gamma)
892.1110	Camera, Positron
892.1130	Counter, Whole Body, Nuclear
892.1300	Scanner, Rectilinear, Nuclear
892.1320	Probe, Uptake, Nuclear
892.1330	Scanner, Rectilinear, Nuclear
892.1410	Synchronizer, Electrocardiograph, Nuclear
892.1970	Synchronizer, Radiographic, ECG/Respirator
892.5650	System, Applicator, Radionuclide, Manual
892.5740	Source, Radionuclide, Teletherapy

(b) Design and development planning. Each manufacturer shall establish and maintain plans that identify each design and development activity and the persons responsible for each activity. The plans shall describe or reference the description of these design and development activities, including any interaction between or among different organizational and technical groups. The plans shall be updated as design and development evolves.



(c) Design input. Each manufacturer shall establish design input requirements relating to a device. The design input requirements shall completely address the intended use of the device, including the needs of the user and patient, and shall be reviewed and approved by a designated qualified individual. The approval of design input requirements, including the date and the person(s) approving the requirements, shall be documented.

(d) Design verification. Each manufacturer shall establish and maintain procedures for verification of the device design and assign such functions to competent personnel. Design verification shall be performed in a timely manner and shall confirm that design output meets the design input requirements and that the design is adequate for its intended use. The results of the design verification, including identification of the design verified, verification method(s), the date, and the person(s) performing the verification shall be documented in the design history record. Where applicable, design verification shall include software validation and hazard analysis.

(e) Design review. Each manufacturer shall conduct a formal design review of the design output according to established procedures. Each manufacturer shall assign design review responsibility to qualified individuals who do not have direct responsibility for the design development. The assignments shall be documented. The results of a design review shall be documented in the design history record.

(f) Design output. Each manufacturer shall define and document design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output shall

meet the design input requirements and shall include those design characteristics that are essential for the intended use of the device.

(g) Design transfer. Each manufacturer shall establish and maintain procedures to ensure that the design basis for a device and its components are correctly translated into production specifications. The production specifications shall be approved by an individual designated by the manufacturer. The approval, including identification of the design, the date, and the person(s) approving the specifications, shall be documented. Each manufacturer shall select a representative sample of a device from the first three production lots or batches and test such sample under actual or simulated use conditions. Each manufacturer shall conduct such testing according to established procedures and shall maintain records of all results of the testing. Each manufacturer shall also conduct such testing when changes are made in the device or manufacturing process.

(h) Design release. Each manufacturer shall ensure that a design is not released for production until the design is approved by individuals designated by the manufacturer. The designated individuals shall review all records required for the design history record to ensure that the design history file is complete and that the final design is consistent with the approved design plan before releasing the design. The release, including the date and signature of the individual(s) approving release, shall be documented.

(i) Design changes. Each manufacturer shall establish and maintain procedures for the identification, documentation, validation, review, and approval of design changes.

(j) Design history record. Each manufacturer shall establish and maintain a design history record for each device. Each design history record shall contain or reference all records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.

#### Subpart D--Document and Record Controls

##### § 820.40 Document controls.

Each manufacturer shall establish and maintain document control procedures to ensure that all documents that must be established and maintained under this part meet the requirements of this part and are accurate and adequate for their intended use.

(a) Document approval and issue. Each manufacturer shall designate individuals to review and approve all documents established under this part for adequacy prior to issuance. The approval, including the date and signature of the individual(s) approving the document, shall be documented.

(b) Document distribution. Each manufacturer shall ensure that all documents are current and available at all locations for which they are designed, and that all unneeded or obsolete documents are removed from all points of use in a timely manner.

(c) Documentation changes. Changes to specifications, methods, or procedures for components, finished devices,

manufacturing materials, production, installation, servicing, or the quality system shall be documented, reviewed, and approved by individuals in the same functions/organizations that performed the original review and approval unless specifically designated otherwise. In addition, any change to a specification, method, or procedure that may affect quality shall be validated as adequate for their intended use before approval and issuance. Validation results shall be recorded. Approved changes shall be communicated to the appropriate personnel in a timely manner. When changes are made to a specification, method, or procedure, each manufacturer shall evaluate the change in accordance with an established procedure to determine if the submission of a premarket notification (510(k)) under § 807.81(a)(3) of this chapter, or the submission of a supplement to a premarket approval application (PMA) under § 814.39(a) of this chapter is required, as applicable. Records of this evaluation and its results shall be maintained.

(d) Documentation change records. Each manufacturer shall maintain records of changes to documents. Documentation change records shall include a description of the change, identification of the affected documents, the signature of the approving individuals, the approval date, and the date the change becomes effective. A list, index, or equivalent document control procedure shall be established and maintained to identify the current revision of documents in order to ensure that only current, approved documents are in use.

## Subpart E--Purchasing Controls

§ 820.50 Purchasing controls.

Each manufacturer shall establish and maintain procedures to ensure that all components, manufacturing materials, and finished devices that are manufactured, processed, labeled, or packaged by other persons or held by other persons under contract conform to specifications. Each manufacturer shall also ensure that services provided by other persons conform to specifications.

(a) Assessment of suppliers and contractors. Each manufacturer shall establish and maintain assessment criteria for suppliers and contractors that specify the requirements, including quality requirements that suppliers and contractors must meet. Each manufacturer shall assess and select potential suppliers and contractors on the basis of their ability to meet requirements, including quality requirements and shall establish and maintain a list of suppliers and contractors that meet the manufacturer's documented assessment criteria. Records of the assessment, and assessment results shall be maintained.

(b) Purchasing forms. Each manufacturer shall establish and maintain purchasing forms that clearly describe or reference the specifications, including quality requirements, for the components, manufacturing materials, finished devices, or services ordered or contracted for. Purchasing forms shall include an agreement that the suppliers agree to notify the manufacturer of any changes in the product or service so that manufacturers may determine whether the change may affect the quality of a finished device. Each manufacturer shall review and

approve purchasing documents prior to release. The approval, including the date and signature of the individual(s) approving the form, shall be documented.

Subpart F--Identification and Traceability

§ 820.60 Identification and traceability.

Each manufacturer shall establish and maintain procedures for identifying components, manufacturing materials, and finished devices during all stages of production, distribution, and installation to prevent mixups and to ensure orderly handlings. For certain devices, additional traceability requirements apply under section 519(e) of the act and part §§ 820.65 and 820.165 of this chapter.

§ 820.65 Critical devices, traceability.

Each manufacturer shall identify each unit, batch, or lot of critical devices with a control number. Such identification shall be recorded in the device history record.

Subpart G--Production and Process Controls

§ 820.70 Production and process controls.

(a) General. Each manufacturer shall design, conduct, and control all production processes to ensure that a device conforms to its specifications. Where any deviation from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe all process controls necessary to ensure conformance to specifications. Process controls shall include:

(1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production, installation, and servicing;

(2) Monitoring and control of process parameters and component and device characteristics during production, installation, and servicing;

(3) Compliance with applied reference standards or codes and process control procedures;

(4) The approval of processes and process equipment; and

(5) Criteria for workmanship which shall be expressed in documented standards or by means of representative samples.

(b) Environmental control. Each manufacturer shall establish and maintain a control system to prevent contamination or other adverse effects on the device and to provide proper conditions for all operations. Conditions to be considered for control include: Lighting, ventilation, space, temperature, humidity, air pressure, filtration, airborne contamination, static electricity, and other environmental conditions. Each manufacturer shall periodically inspect its facilities and review its control system to verify that the system is adequate and functioning properly. Records of the results of such inspections shall be made and reviewed.

(c) Cleaning and sanitation. Each manufacturer shall establish and maintain adequate cleaning procedures and schedules to meet manufacturing process specifications. Each manufacturer

shall ensure that the appropriate personnel understand such procedures.

(d) Personnel health and cleanliness. Each manufacturer shall ensure that personnel in contact with a device or its environment are clean, healthy, and suitably attired where lack of cleanliness, good health, or suitable attire could adversely affect the device. Any person who appears to be unclean or inappropriately attired shall be excluded from operations until he or she is clean and suitably attired. Any person who, by medical examination or supervisory observation, appears to have a condition which could adversely affect the device shall be excluded from operations until the condition is corrected. Each manufacturer shall instruct personnel to report such conditions to their supervisors.

(1) Clothing. When special clothing requirements are necessary to ensure that a device is fit for its intended use, each manufacturer shall provide clean dressing for personnel.

(2) Hygiene. Each manufacturer shall provide clean and adequate washing and toilet facilities.

(3) Personnel practices. When eating, drinking, smoking, and other activities by personnel may have an adverse effect on a device, each manufacturer shall limit such practices to designated areas. Each manufacturer shall ensure that its personnel understand any such limits. Each manufacturer shall designate selected areas to avoid any adverse effects on a device.

(e) Contamination control. Each manufacturer shall establish and maintain procedures to prevent contamination of equipment, components, manufacturing materials, and in-process and finished devices by rodenticides, insecticides, fungicides, fumigants, cleaning and sanitizing substances, and hazardous substances, including hazardous substances or contaminants generated by the manufacturing process.

(f) Sewage and refuse disposal. Each manufacturer shall dispose of sewage, trash, byproducts, chemical effluents, and other refuse in a safe, timely, and sanitary manner.

(g) Equipment. Each manufacturer shall ensure that all equipment used in the manufacturing process is adequate for its intended use and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.

(1) Maintenance schedule. Each manufacturer shall establish and maintain schedules for the maintenance, adjustment, and, where applicable, cleaning of equipment to ensure that manufacturing specifications are met. The maintenance schedule shall be visibly posted on or near each piece of equipment or shall be readily available to personnel performing maintenance activities. A written record shall be maintained documenting the date when scheduled maintenance activities were performed and the individual(s) performing the maintenance activity.

(2) Inspection. Each manufacturer shall conduct periodic inspections in accordance with established procedures to ensure

adherence to applicable equipment maintenance schedules. The inspections, including the date and individual conducting the inspections, shall be documented

(3) Adjustment. Each manufacturer shall ensure that any inherent limitations or allowable tolerances are visibly posted on or near equipment requiring periodic adjustments or are readily available to personnel performing these adjustments.

(4) Manufacturing material. Each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material to ensure that such material is removed from the device or limited to a specified amount that does not adversely affect the device's quality. The removal of such manufacturing material shall be documented.

(h) Automated processes. When computers are used as part of production, the quality system, or automated data processing systems, individuals designated by the manufacturer shall validate the computer software according to an established protocol. The results shall be documented. All software changes shall be made by a designated individual(s) through an established validation and approval procedure in accordance with § 820.40(c) document changes.

§ 820.75 Special processes.

(a) Each manufacturer shall ensure that special processes are:

(1) Validated according to an established protocol and records shall be made of the results of validation, including the date of and individual responsible for the validation;

(2) Conducted according to established procedures that describe all processing controls necessary to ensure conformance to specifications;

(3) Monitored according to establish procedures to ensure process parameters are met; and

(4) Performed by qualified, designated individuals.

(b) The individual(s) responsible for the performance of a special process shall record the completion of the process in the device history record. The record shall include identification of the process, the date performed, each individual that performed the special process, and the equipment used.

#### Subpart H--Inspection and Testing

##### § 820.80 Inspection and testing.

(a) General. Each manufacturer shall establish and maintain the inspection and testing activities necessary to ensure that specified requirements are met. The results of all inspection and testing shall be documented.

(b) Receiving inspection and testing. Each manufacturer shall establish and maintain procedures for acceptance of incoming components, manufacturing materials, and finished devices. Incoming components, manufacturing materials, and finished devices shall not be used or processed until they have been verified as conforming to specified requirements.

Individual(s) designated by the manufacturer shall accept or reject incoming components, finished devices, and manufacturing materials. Acceptance and rejection shall be documented.

(c) In-process inspection and testing. Each manufacturer shall establish and maintain procedures for inspecting and testing in-process components, finished devices, and manufacturing materials. Each manufacturer shall establish and maintain procedures for holding in-process components, finished devices, and manufacturing materials until the required inspection and tests have been completed or necessary reports have been received and verified.

(d) Final inspection and testing. Each manufacturer shall establish and maintain procedures for finished device inspection to ensure each lot or batch meets device specifications. Finished devices shall be held in quarantine or otherwise adequately controlled until released by an individual designated by the manufacturer. Finished devices shall not be released until all the required activities specified in the DMR have been completed and the associated data and documentation are reviewed to ensure all acceptance criteria have been met. Release, including the date and signature of the designated individual(s) responsible for release, shall be documented.

(e) Inspection and test records. Each manufacturer shall maintain records of the results of all inspections and tests required by this part. These records shall include the acceptance criteria, inspection checks performed; results;

equipment used; and the date and signature of the individual(s) conducting the inspection and testing. These records shall be part of the device history record.

§ 820.84 Inspection, measuring, and test equipment.

Each manufacturer shall ensure that all measurement and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, and checked. Records documenting these activities shall be maintained.

(a) Calibration. Each manufacturer shall establish and maintain calibration procedures that include specific directions and limits for accuracy and precision and provisions for remedial action when accuracy and precision limits are not met. Calibration shall be performed by personnel who have the necessary education, training, background, and experience.

(b) Calibration standards. Each manufacturer shall establish and maintain calibration standards for measurement equipment that are traceable to the national standards of the National Institute for Standards and Technology, Department of Commerce. If national standards are not practical or available, the manufacturer shall use an independent reproducible standard. If no applicable standard exists, the manufacturer shall establish and maintain an in-house standard.

(c) Calibration records. Each manufacturer shall ensure that records of calibration dates, the individual performing each calibration, and the next calibration date are maintained. These records shall be maintained by individuals designated by the manufacturer and displayed on or near each piece of equipment or shall be readily available to the personnel using such equipment and the individuals responsible for calibrating the equipment.

(d) Maintenance. Each manufacturer shall establish and maintain procedures to ensure that the handling, preservation, and storage of inspection, measuring, and test equipment is such that their accuracy and fitness-for-use are maintained.

(e) Facilities. Each manufacturer shall protect inspection, measuring, and test facilities and equipment, including both test hardware and test software, from adjustments that would invalidate the calibration.

§ 820.86 Inspection and test status.

(a) Each manufacturer shall identify the inspection and test status of all components, manufacturing materials, and finished devices. The identification shall be visible, shall indicate the conformance or nonconformance of these items with respect to acceptance criteria, and shall be maintained, as necessary, throughout component acceptance, manufacturing, packaging, labeling, installation, and servicing of the device to ensure that only components, finished devices, and manufacturing materials which have passed the required inspections and tests are distributed, used, or installed.

(b) Each manufacturer shall ensure that records shall identify the individual(s) responsible for the release of components, of manufacturing materials, and of finished devices.

Subpart I--Nonconforming Components and Devices

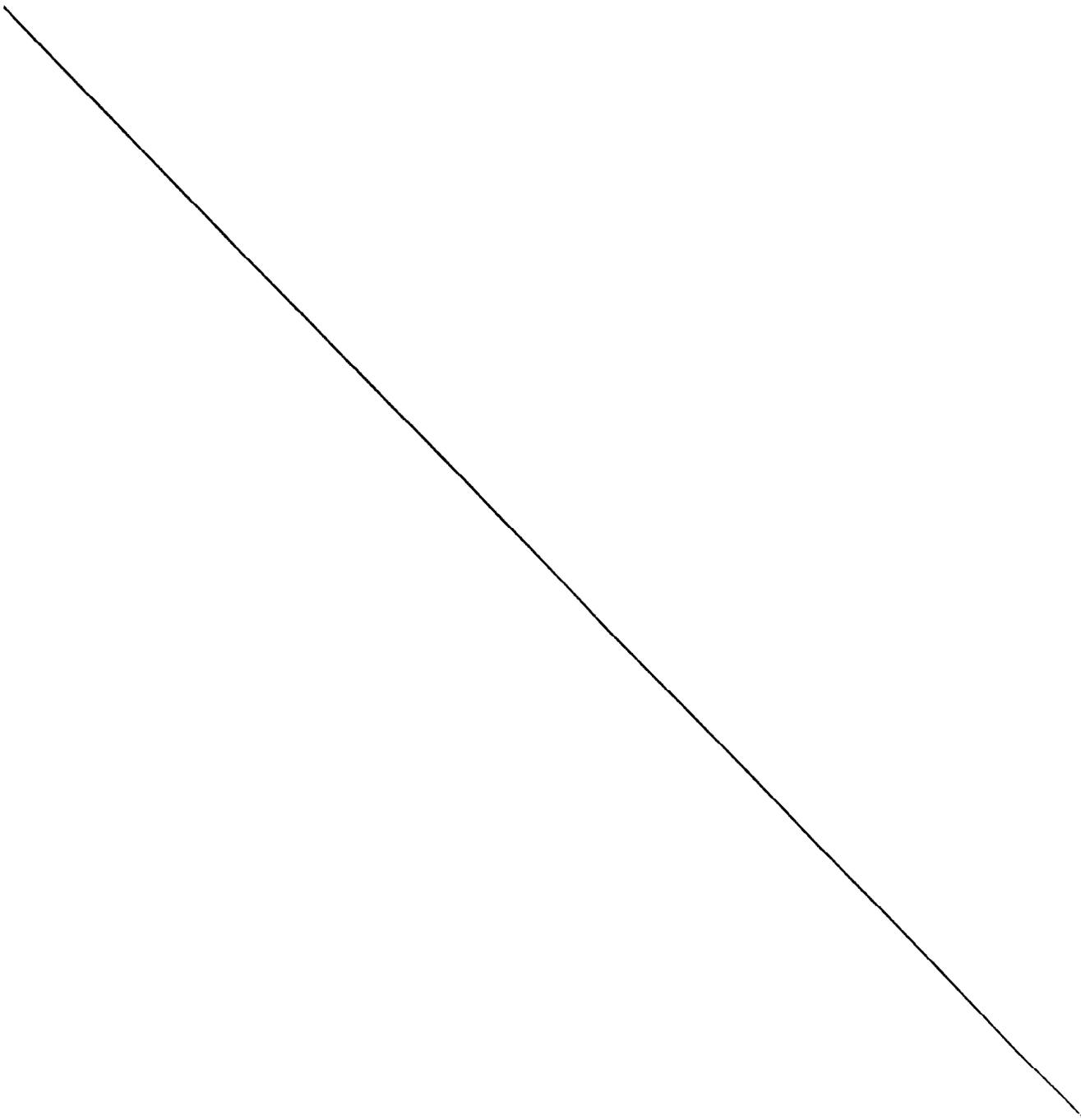
§ 820.90 Nonconforming components and devices.

(a) Control of nonconforming components and devices. Each manufacturer shall establish and maintain procedures to ensure that components, manufacturing materials, finished devices, and returned devices that do not conform to specified requirements are not inadvertently used or installed. The procedures shall provide for the identification, documentation, investigation, segregation, and disposition of nonconforming components, manufacturing materials, finished devices, and returned devices, and for notification of the persons or organizations responsible for the nonconformance.

(b) Nonconformity review and disposition. (1) The responsibility for review and the authority for the disposition of nonconforming components, manufacturing materials, finished devices, and returned devices shall be defined.

(2) Each manufacturer shall establish and maintain procedures for the reprocessing, retesting, and reinspection of nonconforming components and finished devices, to ensure that they meet their original, or subsequently modified and approved, specifications. The procedures shall be contained or referenced in the device master record. Reprocessed devices or components shall be clearly identified as reprocessed, and the reprocessing

and reinspection results shall be recorded in the device history record. Reprocessed devices or components shall be subject to another complete reinspection for any characteristic of the device which may be adversely affected by such reprocessing. When there is repeated reprocessing of a device or component, a determination of the effect of the reprocessing upon the device or component shall be made and documented.



Subpart J--Corrective Action

§ 820.100 Corrective action.

(a) Each manufacturer shall establish and maintain procedures for:

(1) Analyzing all processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming components, finished devices, or other quality problems (analysis shall include trend analysis to detect recurring quality problems);

(2) Investigating the failure of any distributed device to meet specifications;

(3) Identifying action needed to correct the cause and prevent recurrence of nonconforming components or finished devices and other quality problems;

(4) Verifying or validating the adequacy of the corrective action to ensure that the corrective action does not adversely affect the finished device and that the corrective action is effective;

(5) Implementing and recording changes in methods and procedures needed as a result of the identification of quality problems and corrective action; and

(6) Ensuring that quality problem information is disseminated to those directly responsible for ensuring quality and is reviewed by management.

(b) All activities required under this section, and their results, shall be documented.

Subpart K--Handling, Storage, Distribution, and Installation  
§ 820.120 Handling.

Each manufacturer shall establish and maintain procedures to ensure that mixups, damage, deterioration, or other adverse effects to components, finished devices, and manufacturing materials do not occur during any stage of handling.

§ 820.122 Storage.

(a) Each manufacturer shall establish and maintain procedures for the control of storage areas or stock rooms for components, manufacturing materials, and finished devices to prevent mixups, damage, deterioration, or other adverse effects pending use or distribution.

(b) Each manufacturer shall establish and maintain procedures for authorizing receipt from and dispatch to such designated areas. Any control number or other identification used shall be legible and clearly visible. When the quality of components or finished devices deteriorates over time, such devices shall be stored in a manner to facilitate proper stock rotation and their condition shall be assessed at appropriate intervals. Each manufacturer shall establish and maintain procedures to ensure that all obsolete, rejected, or deteriorated manufacturing materials, components, and devices located in storage are not inadvertently used or distributed.

§ 820.124 Distribution.

(a) Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed. Where a device's fitness-for-use or quality deteriorates over time, the procedures shall ensure that the oldest approved devices are distributed first and that expired devices are not distributed.

(b) Each manufacturer shall maintain distribution records which include or make reference to the location of:

- (1) The name and address of the consignee;
- (2) The identification and quantity of devices shipped, the date shipped; and
- (3) Any control number used for traceability.

§ 820.126 Installation.

Each manufacturer shall establish and maintain adequate instructions and procedures for proper device installation. Instructions and procedures shall include directions for verifying proper performance of the installation. When a manufacturer or its authorized representative installs a device, the manufacturer or representative shall verify that the device(s) will perform as intended after installation. The results of verification shall be recorded. When a person other than the manufacturer or its authorized representative installs a device, the manufacturer shall ensure that the installation

instructions and procedures are distributed with the device or otherwise available to the person installing the device.

Subpart L--Packaging and Labeling Control

§ 820.160 Device packaging.

Each manufacturer shall design and construct device packaging and shipping containers to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.

§ 820.162 Device labeling.

Each manufacturer shall establish and maintain procedures to maintain labeling integrity and to prevent labeling mixups.

(a) Labeling integrity. Each manufacturer shall ensure that labels are designed, printed, and, where applicable, applied so as to remain legible and affixed to the device during the customary conditions of processing, storage, handling, distribution, and use.

(b) Labeling inspection. Labels shall not be released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct expiration date, control number, storage instructions, handling instructions, and additional processing instructions. The release, including the date, name and signature of the individuals performing the examination, shall be documented in the device history record.

(c) Labeling storage. Each manufacturer shall store and maintain labeling in a manner that provides proper identification and is designed to prevent mixups.

(d) Labeling control. Each manufacturer shall control labeling and packaging operations to prevent labeling mixups.

§ 820.165 Critical devices, labeling.

Labeling for critical devices shall contain a control number.

Subpart M--Records

§ 820.180 General requirements.

All records shall be legible and shall be stored to minimize deterioration, prevent loss, and allow rapid retrieval. All records stored in automated data processing systems shall be backed up. All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of the Food and Drug Administration designated to perform inspections. Such records shall be available for review and copying by such employee. Except as specifically provided elsewhere, the following general provisions shall apply to all records required by this part.

(a) Confidentiality. Those records deemed confidential by the manufacturer may be marked to aid the Food and Drug Administration in determining whether information may be

disclosed under the public information regulation in part 20 of this chapter.

(b) Record retention period. All required records pertaining to a device shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer. Photostatic or other reproductions of records required by this part may be used. Where reduction techniques such as microfilming are used, suitable reading and photocopying equipment shall be available for use with the records.

§ 820.181 Device master record (DMR).

Each manufacturer shall maintain device master records (DMR's). Each manufacturer shall ensure that each DMR is prepared, dated, and signed by qualified individual(s) designated by the manufacturer. Any changes in a DMR shall meet the applicable requirements of § 820.40. The DMR for each type of device shall include, or refer to the location of, the following information:

(a) Device specifications including appropriate drawings, composition, formulation, component specifications, software design specifications, and software source code;

(b) Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;

(c) Quality system documents, including verification checks used, the verification apparatus used, and validation protocols and results;

(d) Packaging and labeling specifications, including methods and processes used; and

(e) Installation, maintenance, and servicing procedures and methods.

§ 820.184 Device history record.

Each manufacturer shall maintain device history records. Each manufacturer shall establish and maintain procedures to ensure that device history records are maintained for each batch lot, or unit to demonstrate that the device(s) was manufactured in accordance with the device master record and the requirements of this part. Device history records shall be readily accessible and maintained by a designated individual(s). The device history record shall include, or refer to the location of, the following information:

- (a) The dates of manufacture;
- (b) The quantity manufactured;
- (c) The quantity released for distribution;
- (d) The labeling; and
- (e) Any control number(s) used.

§ 820.198 Complaint files.

(a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for

receiving, reviewing, evaluating, and maintaining complaints. Such procedures shall ensure that:

- (1) Complaints are received, reviewed, evaluated, investigated, and maintained by a formally designated unit;
- (2) Oral complaints are documented upon receipt; and
- (3) The complaint is reviewed to determine whether an investigation is necessary. When no investigation is made, the unit shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

(b) Each manufacturer shall review, evaluate, and investigate all complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications. Any complaint pertaining to death, injury, or any hazard to safety shall be immediately reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files. Investigations shall include a determination of whether there was an actual device failure to perform pursuant to specifications; whether the device was being used to treat or diagnose a patient; whether a death, injury, or serious illness was involved; and the relationship, if any, of the device to the reported incident or adverse event.

(c) When an investigation is made, a written record of each investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:

- (1) The name of the device;
- (2) The date the complaint was received;
- (3) Any control number used;
- (4) The name, address, and phone number of the complainant;

- (5) The nature of the complaint; and
- (6) The results of the investigation.

(d) The investigation results shall include:

- (1) The corrective action taken;
- (2) The dates of the investigation;
- (3) The details of the complaint; and
- (4) The reply to the complainant.

(e) When no reply is made to the complainant, the reason shall be recorded.

(f) Records of investigations of events that are determined to be reportable under medical device reporting (MDR) requirements of part 803 of this chapter shall include the information required by part 803 of this chapter. When such information cannot be obtained, a record of the reason shall be made and retained in the record of investigation.

(g) When the formally designated complaint unit is located at a site separate from the actual manufacturing establishment and a complaint involves the manufacturing site, a duplicate copy of the complaint and the record of investigation of the complaint shall be transmitted to and maintained at the actual

manufacturing establishment in a file designated for device complaints.

(h) If a manufacturer's formally designated complaint unit is located outside of the United States, a copy of all of each records required under this section shall be maintained in the United States. If a manufacturer has a location in the United States where records are regularly kept, the copies required under this paragraph may be maintained at such location. Otherwise, the copies required under this paragraph shall be provided to and kept by the agent designated under § 803.26(g)(3) of this chapter.

(i) Each manufacturer shall establish and maintain procedures for processing complaints to ensure that all complaints are processed in a uniform and timely manner. Such procedures shall include provisions for determining whether the complaint represents an event which is required to be reported to the Food and Drug Administration under part 803 of this chapter.

(j) Any written or oral complaint that is also a reportable event under part 803 of this chapter shall be identified in the complaint file as such.

#### Subpart N--Servicing

##### § 820.200 Servicing.

Each manufacturer shall establish and maintain procedures to ensure that finished devices that are serviced by the a manufacturer or it representatives meet specifications. Procedures for servicing shall include provisions for determining

if service requests represent an event which must be reported to the Food and Drug Administration under the requirements of part 803 of this chapter.

(a) Service records. Each manufacturer shall establish and maintain procedures to ensure that service records are maintained that identify the device serviced, including any control number used, the date of service, the service performed, and individual(s) servicing the device.

(b) Service record evaluation. Each manufacturer shall analyze servicing records in accordance with § 820.100; except that when a service report involves a death, serious injury, or safety hazard, the report shall be considered a complaint and shall be investigated in accordance with the requirements of § 820.198.

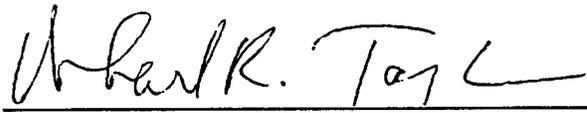
#### Subpart O--Statistical Techniques

§ 820.250 Statistical techniques.

(a) Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for verifying the acceptability of process capability and product characteristics.

(b) Sampling plans shall be written and based on an valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and are regularly reviewed, especially for events such as nonconforming devices, adverse quality audit reports, or complaints.

Dated: October 15, 1993.



Michael R. Taylor  
Deputy Commissioner for Policy

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