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**Table 3. Summary of Part 11 Warning Letters by sections and filenames.**

Title 21 CFR Part 11 Section	File names on FDA web site <sup>1,2</sup>
<b><u>Subpart B - Electronic Records</u></b>	g1393d, g1989d, g1784d, g1822d, g2098d, g3419d, m2811n, m3799n
11.10 Controls for closed system	d1830d, [g1244d], g2098d, g3420d, g3735d, m699n, m2567n, m2677n, m3450n, m5146n
11.10(a) Validation	d1074b, d1242b, d1498b, d1588b, d1605b, [d1718b], [d1902b], g1113d, g1121d, g1148d, g1244d, g1370d, g1393d, g1473d, g1483d, g1485d, g1514d, [g1542d], [g1559d], g1581d, g1590d, g1615d, [g1641d], g1727d, [g1737d], g1750d, g1773d, g1784d, g1822dg1832d, g1860d, g1877d, g1906d, g1989d, g2073d, g3036d, [g3160d], g3211d, g3446d, g3476d, g3626d, [g3654d], g3667d, g3880d, g3890d, g3896d, g3917d, g3956d, g4001d, g4022d, m430n, m999n, m2387n, m2485n, m2579n, m2633n, m2638n, m2811n, m2848n, m2875n, m3150n, m3401n, m3450n, m3471n, m3588n, m3668n, m3799n, m3844n, m3851n, m3911n, m4287n, m4314n, m4956n, m5056n, m5057n, m5067n, m5071n, m5094n, m5162n
11.10(b) Generate accurate & complete copies	g1244d, g1784d, g1822d, m2811n
11.10(c) Protection of records	d1074b, d1588b, g3419d, m699n, m2633n, m2819n, m3488n, m3847n, m4182n, m5146n
11.10(d) Limiting access [Physical]	g1148d, m2567n, m2811n
11.10(e) Time stamp, audit trail	d1588b, g1860d, g3419d, m699n, m2811n, m3091n, m3844n, m3851n, m4116n, m4892n, [m5146n]
11.10(f) Operational Checks	No files identified by authors
11.10(g) Authority checks [Logical]	d1588b, d1902b, g1485d, g1784d, g1822d, g3419d, m699n, m2811n, m3450n, m3488n, m3844n, m3955n, m5093n
11.10(h) Device Checks	d1316b, g1750d
11.10(i) Education, training, experience	d1718b, g1473d, m2638n, m3844n
11.10(j) Written policies for accountability	m2811n
11.10(k) System documentation controls	d1588b, d1605b, d1830d, g1121d, g1393d, g1615d, g1822d, g1860d, g3213d, g3957d, m2567n, m3799n, m5056n, m5057n
11.30 Controls for open system	d1902b, g1393d, [m3450n]
11.50 Signature manifestations	No files identified by authors
11.70 Signature/record linking	No files identified by authors
<b><u>Subpart C - Electronic Signatures</u></b>	
11.100 E-signatures	g1989d
11.200 Components and controls	m3851n
11.300 ID/password controls	d1588b, d1605b, m2567n, m2633n, m2677n, m2886n, m3799n, m5093n

<sup>1</sup> URL to access FDA Warning Letter files: [http://www.fda.gov/foi/warning\\_letters/filename.pdf](http://www.fda.gov/foi/warning_letters/filename.pdf)

<sup>2</sup> [ ] denotes an implied Part 11 element assigned by authors, but not explicitly identified by keywords.

**Table 4. Summary of Part 11 Warning Letters by topics and filenames.**

Title 21 CFR Part 11 Topics	File names on FDA web site <sup>1,2</sup>
Active Pharmaceutical Ingredient	d1074b, g1559d, g1581d, m3488n, m4182n, m4314n, m4892n, m4956n
Blood (software, banks, products)	d1718b, g1244d, g1473d, g1542d, g1615d, g1832d, m2638n, m2886n, m3668n, m5162n
Clinical Investigator	d1498b, d1902b, g3160d
Cites 21 CFR Part 11	g1148d, g1393d, g1784d, g1822d, g3419d, m2811n, m4105n
Devices	Numerous
Global action plan	[g1113d], m2811n, m4105n
Good Manufacturing Practice	Numerous
Laboratory - Analytical, QC, Technical Services	d1588b, g1485d, g1590d, g3419d, m430n , m999n, m2633n, m2819n, m3488n, m3844n, m4182n, m4105n, m4314n, m5146n
Access, Database, Excel, Spreadsheet	d1316b, d1902, m699n, m2677n, m2579n, m2848n, m3851n, m4116n, m5162n, g1393d, g1483d, g1485d, g1542d, g3160d, g3667d
Network, LIMS	m3450n, m5056n, m5057n, m5093n
Paper versus electronic files	g3420d, m2811n, m3851n
Quality System Regulation	Numerous
SOPs	d1588d, d1605b, m2886n, g1485d, g2073d
Sponsor Obligations	m2875n, m4116n

<sup>1</sup> URL to access FDA Warning Letter files: [http://www.fda.gov/foi/warning\\_letters/filename.pdf](http://www.fda.gov/foi/warning_letters/filename.pdf)

<sup>2</sup> [ ] denotes an implied Part 11 element assigned by authors, but not explicitly identified by keywords.