OMBU
ENTERPRISES, LLC

Docket Number FDA-2010-N-0273
Comments on Recordkeeping Requirements for Medical Devices under QSR

Preliminary Information
The FDA "collects" data required by 21 CFR Part 820, the Quality System Regulation (QSR) for medical device manufacturers; Part 820 is the CGMP for medical device manufacturers. The part serves the role of a Quality Management System (QMS) for medical device manufacturers.

The notice intends to collect information in the following areas:

(1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.

(2) The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected.

(4) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The comments below address each of the proposed areas of information collection.

Role of cGMP
The Federal Register notice describes the purpose and implementing authority of the QSR contained in 21 CFR Part 820.

The notice states, "Requirements are compatible with specifications in the international standards ''ISO 9001: Quality Systems Model for Quality Assurance in Design/Development, Production, Installation, and Servicing.''

While true, the comment is misleading. This is a reference to ISO 9001:1994, the standard in place at the time the FDA adopted QSR. This standard, while serving as a basis for the current QSR, is the second edition of ISO 9001. The fourth edition, ISO 9001:2008 Quality management systems – Requirements, is the current version.

Moreover, at the time FDA issued QSR, it also considered ISO/DIS 13485:1996. The current version is ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes.

In *The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices,* Kimberly A. Trautman describes these basic documents.

Is the information necessary for FDA's function?
In this case, collection of the data is a potentially misleading phrase. The firm retains the information and uses it on a regular basis as part of the management of the Quality Management System (QMS). The FDA does not "collect" the data in the sense that a firm submits it to FDA. The firm retains the information unless the agency conducts an inspection of the firm subject to QSR. QSR does not require a firm to file any reports with FDA.

The primary role of the information, from a collection point of view, is the demonstration, by provision of objective evidence, that the firm has all the necessary procedures, forms, and records. In this sense, the information collection is necessary.

FDA's Estimate of the Burden
The Federal Register notice provides a brief description of how FDA estimated the recordkeeping burden. One of the factors is a report prepared by Eastern Research Group, Inc. (ERG). It appears that this report is not publically available. Searches of the FDA website did not reveal a copy of the report. In addition, inquires to various FDA officials did not yield results.

The Federal Register notice says, "Except for manufacturers, not every type of firm is subject to every CGMP/QS requirement." It goes on to explain that only manufactures and specification developers are subject to Subpart C, Design Controls. Apparently, the ERG study identifies the type of firm subject to each requirement.

Without the ERG study it is not possible to determine the classification of firms or the appropriateness of the applicability of each section. For example, manufacturers of most Class I devices are not subject to Subpart C, Design controls.

OMBU ENTERPRISES, LLC RECOMMENDS THAT FDA MAKE THIS DOCUMENT AVAILABLE AS PART OF THE DOCKET

In the Federal Register, FDA assumes that the burden for each firm is the same, *i.e.*, each of the 8,924 firms has exactly the same burden.

This implicit assumption is not borne out by the QSR Preamble, [Federal Register Volume 61, Number 195, Pages 52601-52662]. FDA, in discussing the low frequency of petitions (for relief from cGMP requirements) states, "FDA has attempted to write the current regulation with at least the same degree of flexibility, if not more, to allow manufacturers to design a quality system that is appropriate for their devices and operations and that is not overly burdensome."

The flexibility of the system suggests that the "one size fits all" approach in the Federal Register is not appropriate.

Lastly, in our experience, the estimate of the actual burden is extraordinary low. For example, 21 CFR §820.22, quality audits, requires that, "A report of the results of each quality audit, and re-audit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited." The estimate is 33 "hours per record" with a frequency of 1 record per year. This means the total record keeping for all audits in a firm in a one year period is 33 hours. If a firm were to audit at the subpart level the firm would conduct 15 audits or 2.2 hours of recordkeeping per audit. Most firms would find the estimate per audit as low and would not consider a strategy of subsection only audits as effective. The Preamble, in discussing internal quality audits, says, "The frequency of internal quality audits should be commensurate with, among other things, the importance of the activity, the difficulty of the activity to perform, and the problems found." In another section, the Preamble states, "The requirements under Sec. 820.22 Quality audit are for an internal audit and review of the quality system to verify compliance with the quality system regulation. The review and evaluations under Sec. 820.22 are very focused. During the internal quality audit, the manufacturer should review all procedures to ensure adequacy and compliance with the regulation, and determine whether the procedures are being effectively implemented at all times." Ombu questions if a firm could satisfy the intent of QSR in only 33 hours per year.

As another example, consider Management Review as required by 21 CFR §820.20(c). If a firm conducted one management review each year the burden of developing the inputs and documenting the output and decisions would take considerably more than the 6 hours estimated. Quoting from the preamble, "The management review may include a review of the following:

> (1) The organizational structure, including the adequacy of staffing and resources;
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> (2) the quality of the finished device in relation to the quality objectives;
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> (3) combined information based on purchaser feedback, internal feedback (such as results of internal audits), process performance, product (including servicing) performance, among other things; and
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> (4) internal audit results and corrective and preventive actions taken.

Management reviews should include considerations for updating the quality system in relation to changes brought about by new technologies, quality concepts, market strategies, and other social or environmental conditions. Management should also review periodically the appropriateness of the review frequency, based on the findings of previous reviews."

Performing one Management Review per year, and creating the records that demonstrate conformance, will require considerably more than the estimated 6 hours. Most firms conduct Management Review 2 or 4 times per year.

Similar issues abound, demonstrating the low estimates of the record keeping burden.

Enhancing the quality, utility, and clarity of the collected information
FDA bases this record keeping information on the 1996 Eastern Research Group study. As stated above, Ombu believes this study probably contains flaws based on the improbable low recording keeping estimates. In addition it may not consider the variety of firms and applicability of the requirements to the various types.

FDA now has many years of experience with QSR, but the estimate of hours per record has not changed since the 1996. FDA exercised enforcement discretion in the first year of Design Control, including a potential mid course correction. FDA has not incorporated this experience or learning into the estimates.

Since FDA does not require firms to submit the information directly to the agency the measure of *quality* must come from the EIR, 483s, and Warning Letters.

The measure of *utility* must come from the value of each record in the overarching goal of producing safe and effective devices.

The measure of *clarity* must come the understanding that device manufacturers have of the requirements. One measure is, potentially, the number of seminars, conferences, *etc*. that help explain QSR. Since FDA attends and presents at many of these conferences, FDA is in a good position to determine anecdotal information.

OMBU ENTERPRISES, LLC RECOMMENDS THAT FDA PERFORM A NEW ANALYSIS SIMILAR TO THE 1996 ERG STUDY. SINCE FDA WILL START TO ACCEPT INFORMATION ON ISO 13485 SURVEILLANCE AUDITS[1], THIS NEW ANALYSIS SHOULD INCLUDE A COMPARATIVE ANALYSIS OF THE QSR AND ISO 13485 RECORDKEEPING BURDENS.

Minimizing the collection burden
The collection burden for device manufacturers means the firms maintains quality procedures, work instructions, and records. During the inspection, the manufacturer produces the documents.

The Federal Register notice asked about the use of automated collection techniques, when appropriate, and other forms of information technology.

The greatest inhibition comes from 21 CFR Part 11. Most firms avoid using systems that include automated collection techniques and information technology because they do not wish to incur the burdens of Part 11 compliance. Many firms, especially small firms, decide to print out and maintain any documents created electronically to demonstrate that the firm has not implemented Part 11.

[1] See Docket Number FDA-2010-D-0226 Draft Guidance for Industry, Third Parties and Food and Drug Administration Staff; Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program; Availability

Summary

The basis for collection burden seems to have originated with an Eastern Research Group, Inc. study conducted in 1996.

The estimates from this study seem inappropriately low, but, since the study is not publically available, one cannot evaluate the study methodology or its conclusions.

Since FDA published QSR, the structure, type, and roles of device manufacturers has changed. Rather than depending on the 1996 study, FDA should reevaluate the record keeping burden. In addition, FDA should conduct a comparative study of the ISO 13485 record keeping burden at the same time.

FDA should reevaluate the intent and role of Part 11, since it is often a *de facto* impediment to the use of automated collection techniques and other forms of information technology.