Quality System Record

The Context
Device manufacturers, as part of the QMS implementation, create documents based on the requirements for management responsibility in §820.20. The documents created reside in the Quality System Record described in §820.186, which is under document control as described in §820.40.

In general, the Quality System Record contains the documentation of activities that are not specific to a particular type of device. Management responsibility, called out specifically, is an example of activities that are more general than a device type.

The Warning Letter
FDA sent this September 23, 2011 Warning Letter to X-Ray Support, Inc., a manufacturer of Dental X-Ray Automatic Film Processors located in Spokane Valley, Washington. The Warning Letter was the result of an FDA inspection.

The Issue Cited
The Warning Letter cited a failure to maintain a quality system record (QSR), as required by 21 CFR §820.186. The citation says, "[Y]our firm has not established a quality system record. Upon request by the investigator for the above referenced procedures, you indicated the requested procedures were located in your head."

The Requirement
The Quality System Regulation requires, in §820.186, "Each manufacturer shall maintain a quality system record (QSR). The QSR shall include, or refer to the location of, procedures and the documentation of activities required by this part that are not specific to a particular type of device(s), including, but not limited to, the records required by §820.20. Each manufacturer shall ensure that the QSR is prepared and approved in accordance with §820.40."

Neither ISO 13485:2003 nor ISO 13485:2016 has a similar requirement.

Recommendations
Develop a Quality System Record (QSR) as a formal document under document control. The control is analogous to the Device Master Record (DMR).

Include the minimum contents. In a report to the Office of Management and Budget (OMB) FDA listed:

> §820.20(a) – Executive management shall establish (*i.e.*, define, document, implement) the quality policy and maintain it at all organizational levels.
>
> §820.20(b) – Manufacturers shall establish and maintain organizational structure adequate to design and produce devices, and establish responsibilities and resources appropriate to manage, perform, and assess activities affecting quality.

§820.20(c) – Quality systems shall be reviewed for suitability and effectiveness at defined intervals; and dates and results, documented.

§820.20(d) – A quality plan defining quality practices, resources, and activities, shall be established and maintained.

§820.20(e) – Manufacturers shall establish and maintain quality system procedures, instructions; and outline appropriate documentation.

Determine other contents for the QSR. For example, the DMR includes production environment specifications. However, if they are for a cleanroom used to manufacture many device types, the QSR could contain the specifications instead of putting them into the individual DMRs. This could help simplify change control.

Include QSR creation and maintenance in the internal quality program. This can help identify any problems and prevent a 483 or Warning Letter.