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|-----------|---|
| QOP-73-02 | Design Risk Management<br>EF-380-1: Risk Project<br>EF-380-2: Risk Case<br>EF-380-3: Risk Reduction Action  |
| QOP-73-03 | Control of Design Changes<br>EF-390-1 Change Request  |
| QOP-74-01 | Supplier Evaluation and Monitoring<br>EF-180-1: Supplier<br>EF-180-2: Nonconforming Delivery<br>EF-180-3: Corrective Action Request                         |
| QOP-74-02 | Purchasing  |
| QOP-74-03 | Verification of Purchased Product   |
| QOP-75-01 | Production Work Order and History Record<br>QOP-75-01-F1: Production Work Order   |
| QOP-75-02 | Cleanliness and Contamination of Product  |
| QOP-75-03 | Validation of Processes   |
| QOP-75-04 | Control of Process Changes<br>EF-390-1 Change Request   |
| QOP-75-05 | Installation and Servicing<br>QOP-75-05-F1 Service Report   |
| QOP-75-06 | Product Identification and Traceability   |
| QOP-75-07 | Labeling and Packaging  |
| QOP-75-08 | Storage and Distribution  |
| QOP-76-01 | Measuring and Monitoring Equipment<br>EF-200-1: Measuring Equipment   |
| QOP-82-01 | Feedback and Customer Satisfaction  |
| QOP-82-02 | Internal Quality Audits<br>QOP-82-02-F1: Internal Audit Checklist<br>EF-140-1: Quality System Audit<br>EF-140-2: Audit Plan Item<br>EF-140-3: Audit Finding |
| QOP-82-03 | In-process Inspections  |
| QOP-82-04 | Final Inspection and Product Release  |
| QOP-83-01 | Control of Nonconforming Product<br>EF-170-1: Nonconforming Product   |
| QOP-84-01 | Analysis of Data  |
| QOP-85-01 | Device Recall and Advisory Notices  |
| QOP-85-02 | Complaints<br>EF-190-1: Complaint   |
| QOP-85-03 | Corrective and Preventive Action<br>EF-130-1: Corrective Action   |

<h2>ACCESS CONTROL</h2>	<h2>TOPIC: ACCESS CONTROL</h2> <p>The security mechanism should reduce potential damage after a penetration point. It is generally recommended that there is at least one access control mechanism.</p>
<h3>TOPIC: ACCESS CONTROL</h3> <p>A general rule of thumb: the more difficult access control mechanisms are, the more damage can be inflicted by penetration.</p>	<h3>TOPIC: ACCESS CONTROL</h3> <p>Penetration should always be kept as far away as possible from the main access mechanism.</p>
<h3>TOPIC: ACCESS CONTROL</h3> <p>Although access control systems are not necessarily the best way to prevent damage, they are usually the most effective way to do so.</p>	<h3>TOPIC: ACCESS CONTROL</h3> <p>The access control mechanism will reduce consequences for short periods. It is generally recommended that there is at least one access control mechanism.</p>
<h3>TOPIC: ACCESS CONTROL</h3> <p>It is recommended that access to the penetration point be controlled by a combination of two or more different types of access controls.</p>	<h3>TOPIC: ACCESS CONTROL</h3> <p>When penetration can occur, the user should be automatically forced to re-authenticate.</p>
<h3>TOPIC: ACCESS CONTROL</h3> <p>Generally, it is recommended that the location of penetration point access attempts is limited to the first few bytes.</p>	<h3>TOPIC: ACCESS CONTROL</h3> <p>The security mechanism should implement this approach if it is possible. If not, penetration is kept within the indicated range.</p>

9. PHYSICAL & ENVIRONMENTAL SECURITY MANAGEMENT AUDIT		RESPONSES		NOTES AND COMMENTS	
<b>9.1 USE SECURITY AREAS TO PROTECT FACILITIES</b>					
1	<b>GOAL</b> Do you use physical methods to prevent unauthorized access to your organization's information and premises?	100%	100%	100%	
2	<b>GOAL</b> Do you use physical methods to prevent people from damaging your information and premises?	100%	100%	100%	
3	<b>GOAL</b> Do you use physical methods to prevent people from interfering with your information and premises?	100%	100%	100%	
4	<b>GOAL</b> Do you keep your organization's critical or sensitive information processing facilities in secure areas?	100%	100%	100%	
5	<b>GOAL</b> Do you use defined security perimeters to protect your critical or sensitive information processing facilities?	100%	100%	100%	
6	<b>GOAL</b> Do you use appropriate security barriers to protect your critical or sensitive information processing facilities?	100%	100%	100%	
7	<b>GOAL</b> Do you use entry controls to protect your critical or sensitive information processing facilities?	100%	100%	100%	
8	<b>GOAL</b> Are your physical protection methods commensurate with identified security risks?	100%	100%	100%	
<b>9.1.1 USE PHYSICAL SECURITY PERIMETERS TO PROTECT AREAS</b>					
9	<b>CTRL</b> Do you use physical security perimeters and barriers to protect areas that contain information?	100%	100%	100%	
10	<b>CTRL</b> Do you use physical security perimeters and barriers to protect areas that contain information processing facilities?	100%	100%	100%	
11	<b>CTRL</b> Do you use walls to protect areas that contain your information and information processing facilities?	100%	100%	100%	
12	<b>CTRL</b> Do you use manned reception desks to protect areas that contain information and information processing facilities?	100%	100%	100%	
13	<b>CTRL</b> Do you use card controlled entry gates to protect areas that contain information and information processing facilities?	100%	100%	100%	
14	<b>GUIDE</b> Are your security perimeters clearly defined?	100%	100%	100%	
ORGANIZATION:		YOUR LOCATION:			
COMPLETED BY:		DATE COMPLETED:			
REVIEWED BY:		DATE REVIEWED:			
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- International cleanroom standard
- Part 1 in 1999
- 12 part standard
  - Electronics, healthcare, biotechnology, pharmaceuticals
- Replaced FS 209E in 2001
- Accepted by EU GMP in 2003 for classification but not monitoring
- FDA aseptic filling guide in 2004.

<b>IS 7799 Audit Checklist</b>	
6/08/2003	
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Security of Electronic email.....	12
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