**Please complete and include with your application to be recognized as an MDSAP Auditing Organization.**

**Auditing Organization Applicant:**

| **ISO/IEC 17021-1:2015****IMDRF/MDSAP WG/N3 FINAL:2016 (Edition 2)** | **DOCUMENTATION** | **APPLICANT’S REMARKS** | **REGULATORY AUTHORITY REMARKS** |
| --- | --- | --- | --- |
| Criterion | Req. | Manual(document number) | Procedure(document number) | Other(document number) | e.g. Are these activities performed by your organization? If not, by whom? | RA use only |
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| **1. Scope** |  |  |  |  |  |  |
| **2. Normative references** |  |  |  |  |  |  |
| **3. Terms and definitions** |  |  |  |  |  |  |
| **4. Principles**  |  |  |  |  |  |  |
| **5. General requirements** |  |  |  |  |  |  |
| **5.1 Legal and contractual matters** |  |  |  |  |  |  |
| Legal entity that can be held legally responsible for all its certification activities. | 5.1.1 |  |  |  |  |  |
| Legally enforceable arrangement with each client for the provision of certification activities for all sites with the scope of certification. | 5.1.2 |  |  |  |  |  |
| Responsibility and Authority for Certification Decisions | 5.1.3 |  |  |  |  |  |
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| **5.1 Legal and contractual matters** |  |  |  |  |  |  |
| Legal entity ineligible to be AO if found guilty of an offence against national laws or regulations related to medical devices, or relating to any fraudulent or dishonest practices. | 5.1  |  |  |  |  |  |
| Organizational structure, ownership and the legal or natural persons exercising control over the Auditing Organization | 5.1.1 |  |  |  |  |  |
| If part of a larger organization, activities, structure, governance and relationship with AO | 5.1.2 |  |  |  |  |  |
| If AO owns (whole or part) other entities or has multiple offices; define and document activities, roles and responsibilities, and the legal and operational relationship with the AO | 5.1.3 |  |  |  |  |  |
| Legally enforceable arrangements with manufacturers to allow RAs to observe and assess AO audits and to access the manufacturer’s documents and records | 5.1.4 |  |  |  |  |  |
| Legally enforceable arrangements with manufacturers to allow RAs to share information | 5.1.5 |  |  |  |  |  |
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| **5.2 Management of impartiality** |  |  |  |  |  |  |
| Activities shall be performed impartially. Commercial, financial or other pressures shall not compromise the impartiality of activities. | 5.2.1 |  |  |  |  |  |
| Top management commitment to, and a policy for; impartiality, the management of conflict of interest and the objectivity of certification activities.  | 5.2.2 |  |  |  |  |  |
| Process to identify, analyse, evaluate, treat, monitor, and document the risks related to conflict of interests. Risks shall be documented and eliminated, or minimised, to an acceptable level. The risk assessment process shall include consultation with a balanced representation from identified parties on matters affecting impartiality, openness and public perception. Where there are unacceptable threats to impartiality, certification shall not be provided. | 5.2.3 |  |  |  |  |  |
| An AO shall not certify another AO’s quality management system. | 5.2.4 |  |  |  |  |  |
| Not offer or provide management systems consultancy. | 5.2.5 |  |  |  |  |  |
| Not offer or provide internal audits of certified clients. | 5.2.6 |  |  |  |  |  |
| Not certifying a client when the AO has a relationship with a body that provided management systems consultancy. (See N3(ed2): Cl 5.2.5 – 3 year period) | 5.2.7 |  |  |  |  |  |
| Not outsourcing audits to a management system consultancy organization. | 5.2.8 |  |  |  |  |  |
| AO’s activities not to be marketed or linked with the activities of an organization providing management systems consultancy. (See N3(ed2): Cl 5.2.6 – financial or other inducements) | 5.2.9 |  |  |  |  |  |
| Not use personnel for a client who was provided management system consultancy by those personnel. (See N3(ed2): Cl 5.2.5 – 3 year period) | 5.2.10 |  |  |  |  |  |
| Response to any threats to impartiality from other persons, bodies or organizations. | 5.2.11 |  |  |  |  |  |
| Personnel, internal and external, and committees, shall act impartially. | 5.2.12 |  |  |  |  |  |
| Requiring personnel, internal and external, to reveal any potential conflict of interest. Not use personnel when there are known threats to impartiality  | 5.2.13 |  |  |  |  |  |
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| **5.2 Management of Impartiality** |  |  |  |  |  |  |
| Financial and organizational independence from manufacturers or any economic operator or competitor with an interest in the manufacturer’s products | 5.2.1 |  |  |  |  |  |
| Organization structured to promote and safeguard independence, objectivity, and impartiality of its activities. Procedures and records for the investigation and resolution of any conflict of interest. (See N3(ed2): Cl 6.1.4, [MDSAP AU P0028](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM420056.pdf)) | 5.2.2 |  |  |  |  |  |
| Top-level management and responsible personnel, including their spouses or children, responsible for carrying out the audits shall not:* + be the designer, manufacturer, supplier, installer, distributor, importer, purchaser, owner, user, or maintainer/servicer of the medical devices which they assess, nor the authorized representative of any of those parties
	+ be involved in the design, manufacture or construction, the marketing, installation, use or maintenance/servicing of those medical devices, or represent the parties engaged in those activities
	+ offer or provide any service which may undermine the confidence in their independence, impartiality, or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, his authorized representative, a supplier, or a commercial competitor
	+ use the services of any organization or individual that has provided consultancy services to the manufacturer, his authorized representative or a supplier being audited by the Auditing Organization, within a period of three years since the last consultancy services were rendered.
 | 5.2.3 |  |  |  |  |  |
| Documentation of personnel formerly involved in device consulting and monitor and resolve any potential conflicts of interest | 5.2.4 |  |  |  |  |  |
| Three years between consultancy services and assignment of tasks related to previously serviced manufacturers | 5.2.5 |  |  |  |  |  |
| Not advertise, commit to, guarantee or imply the outcome of audits on the basis of financial or other inducements. | 5.2.6 |  |  |  |  |  |
| Action of subsidiaries, subcontractors or any associated body does not affect independence, impartiality, objectivity. | 5.2.7 |  |  |  |  |  |
| Change of audit team assigned to audit a manufacturer over period of time. LA for < 3 consecutive audits.  | 5.2.8 |  |  |  |  |  |
| Formal commitment of personnel to comply with the AO’s confidentiality and independence rules | 5.2.9 |  |  |  |  |  |
| If AO is part of a larger organization, impartiality requirements also apply to the larger organization | 5.2.10 |  |  |  |  |  |
| The individuals involved in the process for managing threats on impartiality shall have access to expert(s) to obtain independent opinions. (See 17021-1:2015 Cl 5.2.2) | 5.2.11 |  |  |  |  |  |
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| **5.3 Liability and financing** |  |  |  |  |  |  |
| Risk analysis and arrangements to cover liabilities arising from activities and geographical areas of operation. | 5.3.1 |  |  |  |  |  |
| Evaluation of finances and sources of income and demonstrate commercial, financial or other pressures do not compromise impartiality initially and on an on-going basis. | 5.3.2 |  |  |  |  |  |
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| **5.3 Liability and Financing** |  |  |  |  |  |  |
| Liability Insurance – Evidence of consideration of the level and geographic scope of activities and the risk profile of devices being produced by the manufacturers being audited  | 5.3.1 |  |  |  |  |  |
| Financial resources | 5.3.2 |  |  |  |  |  |
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| **6. Structural requirements** |  |  |  |  |  |  |
| **6.1 Organizational structure and top management** |  |  |  |  |  |  |
| Document organizational structure, duties, responsibilities, authorities and lines of authority. | 6.1.1 |  |  |  |  |  |
| Activities to be structured and managed to safeguard impartiality | 6.1.2 |  |  |  |  |  |
| Identify top management with overall authority and responsibility for following: | 6.1.3 |  |  |  |  |  |
| * + Operating policy development, process and procedure establishment
 | 6.1.3a |  |  |  |  |  |
| * + Supervision of the implementation of policies, processes and procedures
 | 6.1.3b |  |  |  |  |  |
| * + Ensuring impartiality
 | 6.1.3c |  |  |  |  |  |
| * + Supervision of finances
 | 6.1.3d |  |  |  |  |  |
| * + Development of certification services and schemes
 | 6.1.3e |  |  |  |  |  |
| * + Performance of audits and certification and complaint response
 | 6.1.3f |  |  |  |  |  |
| * + Certification decisions
 | 6.1.3g |  |  |  |  |  |
| * + Delegation of authorities
 | 6.1.3h |  |  |  |  |  |
| * + Contractual arrangements
 | 6.1.3i |  |  |  |  |  |
| * + Provision of adequate resources
 | 6.1.3j |  |  |  |  |  |
| Rules for committees involved in certification activities | 6.1.4 |  |  |  |  |  |
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| **6.1 Organizational structure and top management** |  |  |  |  |  |  |
| Personnel current in practices and knowledge | 6.1.1 |  |  |  |  |  |
| Organizational capacity to include management, administrative support, and infrastructure to undertake all contracted activities | 6.1.2 |  |  |  |  |  |
| Participation in the MDSAP regulatory coordination group | 6.1.3 |  |  |  |  |  |
| Consideration and usage of relevant MDSAP guidance and best practice documents | 6.1.4 |  |  |  |  |  |
| Adopt and adhere to a code of conduct including a mechanism for monitoring and verification (See also N3(ed2): Cl 7.1.6). Violations to be investigated and actions taken | 6.1.5 |  |  |  |  |  |
| Documented roles, responsibilities, and lines of reporting for all personnel, including subcontractors, involved in audits and decision making. | 6.1.6 |  |  |  |  |  |
| Documented processes and procedures for independent review of work | 6.1.7 |  |  |  |  |  |
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| **6.2 Operational Control** |  |  |  |  |  |  |
| Process for effective control of activities by the AO and related entities taking into account risks these entities may pose to competence, consistency and impartiality. | 6.2.1 |  |  |  |  |  |
| Appropriate level and methods for control of activities undertaken and as defined in this clause. | 6.2.2 |  |  |  |  |  |
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| **7. Resource requirements** |  |  |  |  |  |  |
| **7.1 Competence of personnel** |  |  |  |  |  |  |
| **7.1.1 General considerations** |  |  |  |  |  |  |
| Processes for personnel to have appropriate knowledge and skills for quality management systems and geographic areas in which it operates | 7.1.1 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **7.1.2 Determination of competence criteria** |  |  |  |  |  |  |
| Process for determining documented competence criteria (required knowledge and skills), for each standard, technical area (products, processes and services) and function in the certification process to ensure effective auditing and intended results. | 7.1.2 |  |  |  |  |  |
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| **7.1.3 Evaluation processes** |  |  |  |  |  |  |
| Effective and documented evaluation processes, and on-going monitoring, for competence through the application of the documented competence criteria. Personnel with demonstrated competence are to be identified. Methods are to be effective. Competence to be demonstrated before performance. | 7.1.3 |  |  |  |  |  |
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| **7.1.4 Other considerations** |  |  |  |  |  |  |
| Access to the requisite internal or external technical expertise for advice. | 7.1.4 |  |  |  |  |  |
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| **7.1 Competence of personnel** |  |  |  |  |  |  |
| Auditor competence and maintenance of competence to comply with [IMDRF/MDSAP WG/N4 FINAL:2013](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM505243.pdf) (See N3(ed2): Cl 6.1.4, [MDSAP AS F0010.4.001](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM381894.doc))  | 7.1.1 |  |  |  |  |  |
| Access to medical device expertise | 7.1.2 |  |  |  |  |  |
| Management have appropriate knowledge and processes for; |  |  |  |  |  |  |
| * + the selection of auditors
 | 7.1.3 |  |  |  |  |  |
| * + verification of competence
 | 7.1.3 |  |  |  |  |  |
| * + assignment of tasks
 | 7.1.3 |  |  |  |  |  |
| * + initial and on-going training.
 | 7.1.3 |  |  |  |  |  |
| At least one individual within the senior management having overall responsibility for all MDSAP medical device audits | 7.1.4 |  |  |  |  |  |
| Capability to carry out tasks under its responsibility with integrity and technical competence | 7.1.5 |  |  |  |  |  |
| Adherence of auditors and staff to the Code of Conduct defined in this clause | 7.1.6 |  |  |  |  |  |
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| **7.2 Personnel involved in the certification activities** |  |  |  |  |  |  |
| Sufficient and competent personnel for managing and supporting audit programs and other certification work | 7.2.1 |  |  |  |  |  |
| Sufficient number, or access to, lead auditors, auditors, and technical experts for the range and volume of work | 7.2.2 |  |  |  |  |  |
| Clearly informing each person of their duties, responsibilities and authorities | 7.2.3 |  |  |  |  |  |
| Processes for selecting, training, authorizing auditors, and for selecting and familiarizing experts, including an initial evaluation of the ability to apply required knowledge and skills - as observed on-site audit by a competent evaluator. (See N3(ed2): Cl 6.1.4, [MDSAP AU WI0006.1](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM375450.pdf)) | 7.2.4 |  |  |  |  |  |
| Processes for achieving and demonstrating effective auditing, including the use of auditors with generic auditing knowledge and skills as well as knowledge and skills for auditing in specific technical areas  | 7.2.5 |  |  |  |  |  |
| Ensuring auditors and technical experts knowledgeable of processes and requirements, and have access to up-to-date documented procedures, information and instructions | 7.2.6 |  |  |  |  |  |
| Identify training needs and offer or provide access to specific training to ensure personnel are competent for the functions they perform. (See N3(ed2): Cl 6.1.4, [MDSAP AU WI0006.1](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM375450.pdf))  | 7.2.7 |  |  |  |  |  |
| Competence of person(s) making certification decisions | 7.2.8 |  |  |  |  |  |
| Satisfactory performance of personnel involved in audit and certification activities. Documented process for monitoring competence and performance. Review of competence and performance records to identify training needs | 7.2.9 |  |  |  |  |  |
| Procedure to monitor auditors on-site, review audit reports, and client or market feedback | 7.2.10 |  |  |  |  |  |
| Periodically observe performance of each auditor on-site | 7.2.11 |  |  |  |  |  |
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| **IMDRF N3** |  |  |  |  |  |  |
| **7.2 Personnel involved in the auditing activities** |  |  |  |  |  |  |
| Personnel identifying auditor competence requirements and personnel responsible for final review and decision making shall be employees of the AO and have prescribed and proven knowledge and experience defined in this clause | 7.2.1 |  |  |  |  |  |
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| **17021-1:2015** |  |  |  |  |  |  |
| **7.3 Use of individual external auditors and external technical experts** |  |  |  |  |  |  |
| Written agreement with external personnel for a commitment to comply with the AOs policies and processes, and addressing confidentiality, impartiality and an obligation for external personnel to disclose any existing or prior relationship with a client of the AO.  | 7.3 |  |  |  |  |  |
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| **IMDRF N3** |  |  |  |  |  |  |
| **7.3 Use of individual external auditors and external technical experts** |  |  |  |  |  |  |
| External auditors and external experts not responsible for identifying competency requirements for auditors or technical experts or for performing final review and decision making | 7.3.1 |  |  |  |  |  |
| AO requires competence to verify appropriateness and validity of evidence provided by external technical expert | 7.3.2 |  |  |  |  |  |
| Documented arrangements between the AO and the external auditors or technical experts; including allowing RAs to assess or witness activities. | 7.3.3 |  |  |  |  |  |
| AO to ensure that any external auditors and external technical experts are directly assessed by the Auditing Organization to ensure consistency with the [IMDRF/MDSAP WG/N3 FINAL: 2016 (Ed2)](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM505689.pdf) and [IMDRF/MDSAP WG/N4 FINAL:2013](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM505243.pdf) requirements | 7.3.4 |  |  |  |  |  |
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| **7.4 Personnel records** |  |  |  |  |  |  |
| Maintain records for all personnel, including relevant qualifications, training, experience, affiliations, professional status and competence.  | 7.4 |  |  |  |  |  |
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| **IMDRF N3** |  |  |  |  |  |  |
| **7.4 Personnel records** |  |  |  |  |  |  |
| [IMDRF/MDSAP WG/N4 FINAL:2013](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM505243.pdf) records plus up to date records of auditor’s role, qualifications, training, knowledge and experience demonstrating competence for the assigned roles. Documentation of the activities actually performed (audit log) as defined in [IMDRF/MDSAP WG/N3 FINAL: 2016 (Ed2)](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM505689.pdf) shall be maintained at least annually. (See N3(ed2): Cl 6.1.4, [MDSAP AU WI0006.1](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM375450.pdf)) | 7.4.1 |  |  |  |  |  |
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| **7.5 Outsourcing** |  |  |  |  |  |  |
| Process and legally enforceable arrangements for outsourcing including confidentiality and conflict or interest. | 7.5.1 |  |  |  |  |  |
| No outsourcing of certification decisions. | 7.5.2 |  |  |  |  |  |
| AO responsibility for outsourced certification activities. Ensure that the body and personnel that provide outsourced services conform to the requirements of the AO including 17021, competence, impartiality and confidentiality and are not involved with a client in a way that could compromise impartiality  | 7.5.3 |  |  |  |  |  |
| Process for approval and monitoring of bodies providing outsourced services and to ensure that records of competence for personnel involved in certification activities are maintained. | 7.5.4 |  |  |  |  |  |
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| **IMDRF N3** |  |  |  |  |  |  |
| **7.5 Outsourcing** |  |  |  |  |  |  |
| An external organization is one that is not subject to the AO’s QMS. | 7.5 |  |  |  |  |  |
| AO to be responsible for identifying competency requirements for specific activities and performing final review when using an external organization. | 7.5.1 |  |  |  |  |  |
| AO requires competence to verify appropriateness and validity of evidence provided by an external organization | 7.5.2 |  |  |  |  |  |
| Documented arrangements between the AO and the external organization for auditors or technical experts; including allowing RAs to assess or witness activities. | 7.5.3 |  |  |  |  |  |
| AO to ensure that any auditors and external technical experts used by an external organization are directly assessed by the Auditing Organization to ensure consistency with [IMDRF/MDSAP WG/N3 FINAL: 2016 (Ed2)](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM505689.pdf) and [IMDRF/MDSAP WG/N4 FINAL:2013](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM505243.pdf) requirements | 7.5.4 |  |  |  |  |  |
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| **8 Information requirements** |  |  |  |  |  |  |
| **8.1 Public information** |  |  |  |  |  |  |
| Publicly accessible information about schemes, processes, policies, requests for information, complaints and appeals to be available without request as defined in this clause. | 8.1.1 |  |  |  |  |  |
| Information on geographical areas of operation, certificate status and details of a certified client defined in this clause, to be made available on request  | 8.1.2 |  |  |  |  |  |
| Information provided by AO (including advertising) to be accurate and not misleading | 8.1.3 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **8.2 Certification documents**  |  |  |  |  |  |  |
| Means to provide certification documents to certified clients | 8.2.1 |  |  |  |  |  |
| Details of certification document as defined in this clause. (See also N3(ed2): Cl 8.2)  | 8.2.2 |  |  |  |  |  |
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| **IMDRF N3** |  |  |  |  |  |  |
| **8.1 Public information** |  |  |  |  |  |  |
| Where appropriate, the AO must comply with specified RA requirements for the method of making information on the certified manufacturers publically accessible. | 8.1.1 |  |  |  |  |  |
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| **8.2 Certification documents** |  |  |  |  |  |  |
| Audit reports and certificates conform to RA requirements (See N3(ed2): Cl 6.1.4, [MDSAP AU P0019](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM379903.pdf), [MDSAP AU F0019.1](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM387055.pdf), [MDSAP AU F0019.2](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM379900.xls), [MDSAP AU G0019.3](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM399946.pdf), [MDSAP AU G0019.4](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM418825.pdf), [MDSAP AU P0026](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM405993.pdf)) | 8.2.1 |  |  |  |  |  |
| Certificate must reflect the scope of the audit, audit criteria and the scope of the certifications, including regulations covered. Certificate shall not exclude parts of processes, products or services from scope of certification unless permitted by regulation. | 8.2.2 |  |  |  |  |  |
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| **8.3 Reference to certification and use of marks** |  |  |  |  |  |  |
| Rules governing any mark (or accompanying text) an AO authorizes its certified clients to use. Rules are to ensure traceability back to the AO and no ambiguity about what has been certified. Marks are not to denote product conformity.  | 8.3.1 |  |  |  |  |  |
| AO shall not permit its marks to be applied to laboratory test, calibration or inspection reports or certificates. | 8.3.2 |  |  |  |  |  |
| Rules governing the use of statements on products or in accompanying information. Statements are not to imply that the product, process or service is certified by the statement. Statements to include references as defined in this clause. | 8.3.3 |  |  |  |  |  |
| Legally enforceable arrangements with clients in relation to the scope, conditions, or use of certification, or any permissible claims made by clients in relation to certification, and including each requirement defined in this clause. | 8.3.4 |  |  |  |  |  |
| AO ownership of marks and reports, the control of use and references, and actions to deal with incorrect references or misleading use. | 8.3.5 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **8.4 Confidentiality** |  |  |  |  |  |  |
| Through legally enforceable agreements, be responsible to manage all information obtained or created during certification activities. | 8.4.1 |  |  |  |  |  |
| Inform clients in advance of information to be placed in the public domain. All other information to be considered confidential. | 8.4.2 |  |  |  |  |  |
| Written consent for the release information  | 8.4.3 |  |  |  |  |  |
| Written notification to client when confidential information is required by law or contract to be released. | 8.4.4 |  |  |  |  |  |
| Information from sources other than client shall be treated as confidential | 8.4.5 |  |  |  |  |  |
| Personnel to keep all information confidential except as required by law | 8.4.6 |  |  |  |  |  |
| Use processes, equipment and facilities to ensure secure handling of confidential information | 8.4.7 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **IMDRF N3** |  |  |  |  |  |  |
| **8.4 Confidentiality** |  |  |  |  |  |  |
| Documented procedures in place ensuring confidentiality of information | 8.4.1 |  |  |  |  |  |
| Personnel of AO observe professional secrecy and protect manufacturer’s proprietary rights or trade secrets | 8.4.2 |  |  |  |  |  |
|  |  |  |  |  |  |  |
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| **8.5 Information exchange between an AO and its clients** |  |  |  |  |  |  |
| **8.5.1 Information on the certification activity and requirements** |  |  |  |  |  |  |
| Detailed description of all certification activity | 8.5.1a  |  |  |  |  |  |
| Normative requirements for certification | 8.5.1b |  |  |  |  |  |
| Information on the fees for application, initial certification and continuing certification | 8.5.1c |  |  |  |  |  |
| Requirements for prospective clients as defined in this clause | 8.5.1d |  |  |  |  |  |
| Rights and duties of certified clients as defined in this clause | 8.5.1e |  |  |  |  |  |
| Complaint and appeal processes | 8.5.1f |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **8.5.2 Notice of changes by an AO** |  |  |  |  |  |  |
| Give client notice of changes to requirements and verify compliance with the new requirements.  | 8.5.2 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **8.5.3 Notice of changes by a certified client** |  |  |  |  |  |  |
| A legally enforceable arrangement to ensure a client informs the AO of matters that may affect the capability to fulfil requirements including those defined in this clause. AO to take action as appropriate. | 8.5.3 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **IMDRF N3** |  |  |  |  |  |  |
| **8.6 Information exchange between the Auditing Organization (when not a Regulatory Authority) and recognizing Regulatory Authority(s)** |  |  |  |  |  |  |
| Designation of a regulatory correspondent | 8.6.1 |  |  |  |  |  |
| Reporting fraudulent activity or counterfeit products within 5 working days (See N3(ed2): Cl 6.1.4, [MDSAP AU P0027.003](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM406006.pdf)) | 8.6.2 |  |  |  |  |  |
| AO shall provide information to RAs about audits & decisions of conformity  | 8.6.3 |  |  |  |  |  |
| AO shall notify RAs of certificate refusal, suspension, reinstatement, restriction, or withdrawal decisions within 5 working days. Rationale for such action to be provided. (See N3(ed2): Cl 6.1.4, [MDSAP AU P0027.003](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM406006.pdf)) | 8.6.4 |  |  |  |  |  |
| AO shall notify RAs of specific changes within AO | 8.6.5 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **8.7 Information exchange between Auditing Organizations** |  |  |  |  |  |  |
| AO shall make audit reports and a valid certificate available to new AOs for a manufacturer / manufacturing site(s) upon transfer | 8.7.1 |  |  |  |  |  |
|  |  |  |  |  |  |  |
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| **9.0 Process requirements** |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **IMDRF N3** |  |  |  |  |  |  |
| **9.0** **Process requirements** |  |  |  |  |  |  |
| Documented procedures covering at least the following: |  |  |  |  |  |  |
| * + The request for audits by a manufacturer
 | 9.0.1 |  |  |  |  |  |
| * + The processing of such requests
 | 9.0.1 |  |  |  |  |  |
| * + The language of the request
 | 9.0.1 |  |  |  |  |  |
| * + Where appropriate, terms of agreement with manufacturer
 | 9.0.1 |  |  |  |  |  |
| * + Where appropriate, any fees to be charged for audits
 | 9.0.1 |  |  |  |  |  |
| * + The planning, performance, and reporting of initial, surveillance, and re-audit/recertification audits (See N3(ed2): Cl 6.1.4, [MDSAP AU P0002](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM390382.pdf), [MDSAP AU G0002.1](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM390383.pdf), [MDSAP AU P0029](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM425443.pdf), [MDSAP AU F0029.1](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM424496.pdf), [MDSAP AU P0008](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM379901.pdf), [MDSAP AU F0008.1](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM379902.xlsm), [MDSAP AU P0019](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM379903.pdf), [MDSAP AU F0019.1](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM387055.pdf), [MDSAP AU F0019.2](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM379900.xls), [MDSAP AU G0019.3](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM399946.pdf), [MDSAP AU G0019.4](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM418825.pdf), [MDSAP AU P0027](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM406006.pdf))
 | 9.0.1 |  |  |  |  |  |
| * + The process by which the AO determines which sites of manufacturer or their supplier(s) will be audited. (See N3(ed2): Cl 9.6.4)
 | 9.0.1 |  |  |  |  |  |
| * + The assignment of auditors to a specific activity
 | 9.0.1 |  |  |  |  |  |
| * + the decision-making process on the conformity of the QMS, e.g. issue, refusal, suspension, reinstatement, restriction, modification, or withdrawal of certificates as well as possible conditions or limitations to certificate validity
 | 9.0.1 |  |  |  |  |  |
| * + the assessment of specified changes to be submitted for prior approval
 | 9.0.1 |  |  |  |  |  |
| * + the follow-up of corrections and corrective actions for nonconformities identified during audits
 | 9.0.1 |  |  |  |  |  |
| * + the renewal of any certificates
 | 9.0.1 |  |  |  |  |  |
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| **9.1 Pre-certification activities** |  |  |  |  |  |  |
| **9.1.1 Application** |  |  |  |  |  |  |
| Applicant to provide information to establish; scope and details required for certification, the identity of outsourced processes, the applicable standard, who provided consultancy, if any, in relation to the management system.  | 9.1.1 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.1.2 Application Review** |  |  |  |  |  |  |
| Review of application information to ensure; sufficient information to develop an audit programme, resolution of differences in understanding, AO has the required competence, that the certification activity will take into account scope, site, time required and other factors (language, safety, impartiality) | 9.1.2.1 |  |  |  |  |  |
| Accept or decline an application. When declined, provide a statement of reasons. | 9.1.2.2 |  |  |  |  |  |
| Based on the review determine the competence required for audit and the certification decision. | 9.1.2.3 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.1.3 Audit Programme** |  |  |  |  |  |  |
| Development of an audit programme for the full certification cycle and for the complete management system requirements | 9.1.3.1 |  |  |  |  |  |
| Audit programme for a two-stage initial audit, surveillance in 1st and 2nd years and recertification in the 3rd year prior to expiration of certification. Certification cycle begins with the certification decision. Subsequent cycles to begin with the recertification decision. Adjustments to the audit program when circumstances change as defined in this clause. | 9.1.3.2 |  |  |  |  |  |
| Annual surveillance audits, except in recertification years. First surveillance <= decision date + 12 months. | 9.1.3.3 |  |  |  |  |  |
| When taking account of certification already granted, or audits, must obtain and retain evidence including reports and documentation on corrective actions. Justify and record adjustments to existing programme and follow up implementation of corrective actions. | 9.1.3.4 |  |  |  |  |  |
| Take into account shifts when developing audit programmes and audit plans | 9.1.3.5 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.1.4 Determining Audit Time**  |  |  |  |  |  |  |
| Documented procedures for determining time needed for planning and an effective audit of each client’s management system | 9.1.4.1 |  |  |  |  |  |
| Audit time calculations shall consider the requirements defined in this clause. (See N3(ed2): Cl 6.1.4,[MDSAP AU P0008](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM379901.pdf), [MDSAP AU F0008.1](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM379902.xlsm))  | 9.1.4.2 |  |  |  |  |  |
| The duration of audit and its justification shall be recorded | 9.1.4.3 |  |  |  |  |  |
| Duration calculations not to include time to be spent by a non-auditor in the team | 9.1.4.4 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.1.5 Multi-site sampling** |  |  |  |  |  |  |
| Sampling plans, with a documented rationale, for multiple sites performing the same activities. (See N3(ed2): Cl 9.3.2) | 9.1.5 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.1.6 Multiple management systems standards** |  |  |  |  |  |  |
| Planning for an audit to cover multiple standards shall provide confidence in certification. | 9.1.6 |  |  |  |  |  |
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| **IMDRF N3** |  |  |  |  |  |  |
| **9.1 Pre-certification requirements** |  |  |  |  |  |  |
| Information relating to the name and location of the manufacturer’s critical suppliers of products and services | 9.1.1 |  |  |  |  |  |
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| **9.2 Planning Audits** |  |  |  |  |  |  |
| **9.2.1 Determining audit objectives, scope and criteria** |  |  |  |  |  |  |
| Audit objectives shall be determined by the AO. Scope and criteria, including changes, established by the AO after discussion with the client | 9.2.1.1 |  |  |  |  |  |
| Audit objective shall include determination of; conformity to audit criteria, ability to meet statutory, regulatory and contractual requirements, and effectiveness. Opportunities for improvement are not to be identified by the AO in an audit report (See N3(ed2): Cl 9.4.1) | 9.2.1.2 |  |  |  |  |  |
| Audit scope shall describe extent and boundaries of the audit as defined in this clause.  | 9.2.1.3 |  |  |  |  |  |
| Audit criteria include ISO13485 and the processes and documentation of the client’s management system  | 9.2.1.4 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.2.2 Audit team selection and assignments** |  |  |  |  |  |  |
| **9.2.2.1 General** |  |  |  |  |  |  |
| Process to select and appoint audit team accounting for competence to achieve objectives and impartiality | 9.2.2.1.1 |  |  |  |  |  |
| Size and composition of audit team taking into account the considerations defined in this clause | 9.2.2.1.2 |  |  |  |  |  |
| Technical experts, translators and interpreters operate under direction of an auditor | 9.2.2.1.3 |  |  |  |  |  |
| An auditor appointed as an evaluator is to be responsible for auditors in training | 9.2.2.1.4 |  |  |  |  |  |
| Audit team leader shall assign tasks and responsibility, as required, and taking into account the need for competence and the effective and efficient use of an audit team. | 9.2.2.1.5 |  |  |  |  |  |
| **9.2.2.2 Observers, technical experts and guides** |  |  |  |  |  |  |
| **9.2.2.2.1 Observers** |  |  |  |  |  |  |
| Observers not to unduly influence or interfere | 9.2.2.2.1 |  |  |  |  |  |
| **9.2.2.2.2 Technical experts** |  |  |  |  |  |  |
| Technical experts not to act as an auditor. Must be accompanied by an auditor | 9.2.2.2.2 |  |  |  |  |  |
| **9.2.2.2.3 Guides** |  |  |  |  |  |  |
| Each auditor to be accompanied by a guide. Guides not to influence or interfere in audit process or outcome. | 9.2.2.2.3 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.2.3 Audit Plan** |  |  |  |  |  |  |
| **9.2.3.1 General** |  |  |  |  |  |  |
| Audit plan established before each audit | 9.2.3.1 |  |  |  |  |  |
| **9.2.3.2 Preparing the audit plan** |  |  |  |  |  |  |
| Audit plan to include; objectives, criteria, scope, dates and sites, duration, roles and responsibilities as defined in this clause | 9.2.3.2 |  |  |  |  |  |
| **9.2.3.3 Communication of audit team tasks** |  |  |  |  |  |  |
| Examine and verify the structure, policies, processes, procedures, records and related documents | 9.2.3.3a |  |  |  |  |  |
| Determine that 9.2.3.3 a) meets the requirements for the intended scope of certification | 9.2.3.3b |  |  |  |  |  |
| Determine that processes and procedures are established, implemented and maintained effectively | 9.2.3.3c |  |  |  |  |  |
| Communicate to the client any inconsistencies between the client’s policy, objectives and targets | 9.2.3.3d |  |  |  |  |  |
| **9.2.3.4 Communication of audit plan** |  |  |  |  |  |  |
| Communication of audit plan and agreed dates to client in advance of the audit. | 9.2.3.4 |  |  |  |  |  |
| **9.2.3.5 Communication concerning audit team members**  |  |  |  |  |  |  |
| Provide information about audit team members to the client prior to the audit. Manufacturers may appeal the composition of the audit team (See N3(ed2): Cl 9.2) | 9.2.3.5 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **IMDRF N3** |  |  |  |  |  |  |
| **9.2 Planning Audits** |  |  |  |  |  |  |
| Manufacturers may not object to audit team composition. May utilize the AOs appeals process. | 9.2 |  |  |  |  |  |
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| **9.3 Initial Certification** |  |  |  |  |  |  |
| **9.3.1 Initial certification audit** |  |  |  |  |  |  |
| **9.3.1.1 General** |  |  |  |  |  |  |
| Initial Certification shall be in two stages | 9.3.1.1 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.3.1.2 Stage 1** |  |  |  |  |  |  |
| Planning shall ensure Stage 1 objectives can be met. Client is to be informed of any “on-site” activities | 9.3.1.2.1 |  |  |  |  |  |
| Stage 1 objectives: | 9.3.1.2.2 |  |  |  |  |  |
| * + Review the client’s management system documentation
 | 9.3.1.2.2a |  |  |  |  |  |
| * + Evaluate site-specific conditions and undertake discussions with the client’s personnel to determine preparedness for Stage 2
 | 9.3.1.2.2b |  |  |  |  |  |
| * + Review the client’s status and understanding regarding requirements of the standard
 | 9.3.1.2.2c |  |  |  |  |  |
| * + Obtain necessary information regarding the scope of the management system; site, processes and equipment used, established levels of control, and the applicable statutory and regulatory requirements
 | 9.3.1.2.2d |  |  |  |  |  |
| * + Review the allocation of resources for stage 2 and agree the details with client
 | 9.3.1.2.2e |  |  |  |  |  |
| * + Provide a focus for planning stage 2 through an understanding of the QMS and site operations
 | 9.3.1.2.2f |  |  |  |  |  |
| * + Evaluate if the internal audits and management review are being planned and performed and level of implementation substantiates proceeding to stage 2
 | 9.3.1.2.2g |  |  |  |  |  |
| Document conclusions, readiness for Stage 2 and identification of potential nonconformity shall be communicated to the client. | 9.3.1.2.3 |  |  |  |  |  |
| Consideration of stage 2 audit arrangements taking into account stage 1 findings and the time for the client to resolve. If significant changes to the QMS are required the AO shall consider repeating some or all of Stage 1 and postponing / cancelling Stage 2.  | 9.3.1.2.4 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.3.1.3 Stage 2** |  |  |  |  |  |  |
| Evaluate implementation and effectiveness at the client’s QMS. Stage 2 audit shall take place at the clients site and include: | 9.3.1.3 |  |  |  |  |  |
| * + Information and evidence about conformity to all requirements of ISO13485 or other normative documents
 | 9.3.1.3a |  |  |  |  |  |
| * + Performance monitoring, measuring, reporting and reviewing against key performance objectives and targets
 | 9.3.1.3b |  |  |  |  |  |
| * + The client’s management system and performance as regards legal compliance
 | 9.3.1.3c |  |  |  |  |  |
| * + Operational control of the client’s processes
 | 9.3.1.3d |  |  |  |  |  |
| * + Internal auditing and management review
 | 9.3.1.3e |  |  |  |  |  |
| * + Management responsibility for the client’s policies
 | 9.3.1.3f |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.3.1.4 Initial certification audit conclusions** |  |  |  |  |  |  |
| Analyse information and evidence from Stage 1 & 2 to review findings and agree conclusions | 9.3.1.4 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **IMDRF N3** |  |  |  |  |  |  |
| **9.3 Initial Certification** |  |  |  |  |  |  |
| Elements of Stage 1 and Stage 2 may be combined to allow for a single on-site audit | 9.3.1 |  |  |  |  |  |
| All sites covered by the certificate must be audited | 9.3.2 |  |  |  |  |  |
| Stage 2 audit objectives to include evaluation of; effectiveness of QMS incorporating regulatory requirements, product/ process related technologies, adequate product technical documentation in relation to relevant regulatory requirements, ability to comply with these requirements.  | 9.3.3 |  |  |  |  |  |
|  |  |  |  |  |  |  |
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| **9.4 Conducting Audits** |  |  |  |  |  |  |
| **9.4.1 General** |  |  |  |  |  |  |
| Process for conducting on-site audits including and opening and closing meeting. Virtual audits are to be conducted by personnel with appropriate competence. | 9.4.1 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.4.2 Conducting the opening meeting** |  |  |  |  |  |  |
| Opening meeting with management and those responsible for functions or process and include agenda items defined in this clause. | 9.4.2 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.4.3 Communication during the audit** |  |  |  |  |  |  |
| During the audit, assess and redistribute work to team members. Communicate any concerns to the client | 9.4.3.1 |  |  |  |  |  |
| Unattainable audit objectives or the presence of significant risks, shall be reported to the client and the AO and may alter the audit plan. Outcomes to be reported to the AO | 9.4.3.2 |  |  |  |  |  |
| Changes to scope to be discussed with the client and reported to the AO | 9.4.3.3 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.4.4 Obtaining and verifying information** |  |  |  |  |  |  |
| Information obtained from interviews, observation and sampling, is to be verified to become audit evidence | 9.4.4.1 |  |  |  |  |  |
| Methods to obtain information shall include interviews, observation of processes and activities and the review of documentation and records | 9.4.4.2 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.4.5 Identifying and recording audit findings** |  |  |  |  |  |  |
| Audit findings to be identified, classified and recorded.  | 9.4.5.1 |  |  |  |  |  |
| Nonconformities not to be recorded as opportunities for improvement. (See N3(ed2): Cl 9.4.1) | 9.4.5.2 |  |  |  |  |  |
| Findings of nonconformity to be recorded against a specific requirement, contain a statement of NC, and identify objective evidence. AOs are to ensure nonconformities are understood and are to refrain from suggesting the cause of nonconformity or a solution.  | 9.4.5.3 |  |  |  |  |  |
| Unresolved diverging opinions to be recorded. | 9.4.5.4 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.4.6 Preparing audit conclusions** |  |  |  |  |  |  |
| Review findings, classify nonconformities, agree upon audit conclusions, agree upon follow-up actions, and confirm the appropriateness of, or identify modifications for, the audit programme. |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.4.7 Conducting the closing meeting** |  |  |  |  |  |  |
| Closing meeting with management, and those responsible for functions or process, to present audit conclusions, ensure nonconformities are understood, and the timeframe for response is agreed. Attendance recorded.  | 9.4.7.1 |  |  |  |  |  |
| Agenda to include items defined in this clause. | 9.4.7.2 |  |  |  |  |  |
| Opportunity for questions given. Unresolved diverging opinions to be recorded and referred to the AO. | 9.4.7.3 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.4.8 Audit report** |  |  |  |  |  |  |
| Written report for each audit. AO not to record opportunities for improvement (See N3(ed2): Cl 9.4.1) | 9.4.8.1 |  |  |  |  |  |
| Report to provide an accurate, concise and clear record that allows an informed certification decision and includes the items defined in this clause. (See also N3(ed2): Cl 8.2) | 9.4.8.2 |  |  |  |  |  |
| Report to include the statements and conclusions defined in this clause (See also N3(ed2): Cl 8.2) | 9.4.8.3 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.4.9 Cause analysis of nonconformities** |  |  |  |  |  |  |
| Clients to analyse cause and describe corrections and corrective actions to eliminate nonconformity within a defined timeframe  | 9.4.9 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.4.10 Effectiveness of corrections and corrective actions** |  |  |  |  |  |  |
| Review corrections, causes and corrective actions to determine if acceptable. Verify the effectiveness of actions taken and record evidence obtained to support the resolution. Inform client of the result and any further actions. | 9.4.10 |  |  |  |  |  |
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| **IMDRF N3** |  |  |  |  |  |  |
| **9.4 Conducting on-site audits** |  |  |  |  |  |  |
| Audit reports shall not contain “opportunities for improvement”. May contain observations where insufficient audit evidence is available | 9.4.1 |  |  |  |  |  |
| Use of [GHTF/SG3/N19:2013](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM468937.pdf), nonconformity grading system | 9.4.2 |  |  |  |  |  |
| Findings from any prior audit shall be used when grading NCs identified at a subsequent regulatory audit. | 9.4.3 |  |  |  |  |  |
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| **9.5 Certification Decision** |  |  |  |  |  |  |
| **9.5.1. General** |  |  |  |  |  |  |
| Certifiers to be different from those that carried out the audits and have appropriate competence | 9.5.1.1 |  |  |  |  |  |
| Certifiers to be employed by the AO, or under a legally enforceable arrangement with the AO. (See also N3(ed2): Cl 9.5)  | 9.5.1.2 |  |  |  |  |  |
| Not applicable (See also N3(ed2): Cl 9.5) | 9.5.1.3 |  |  |  |  |  |
| The AO shall record each certification decision including any additional information or clarification sought from the audit team or other sources. | 9.5.1.4 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.5.2 Actions taken prior to making a decision** |  |  |  |  |  |  |
| Process to conduct an effective review prior to a certification decision including sufficient audit information, verification of corrections and corrective actions or a plan for corrections and corrective actions as defined in this clause. | 9.5.2 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.5.3 Information for granting initial certification** |  |  |  |  |  |  |
| Minimum information to be provided by audit team for the initial certification decision as defined in this clause | 9.5.3.1 |  |  |  |  |  |
| AO to verify corrections and corrective actions within 6 months of Stage 2 else conduct another Stage 2 prior to certification as defined in this clause. (See N3(ed2): Cl 6.1.4, [GHTF/SG3/N19:2013](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM468937.pdf), [MDSAP AU P0027.003](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM406006.pdf)) | 9.5.3.2 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.5.4 Information for granting recertification** |  |  |  |  |  |  |
| Decisions on renewing certification based on the results of the recertification audit, the results of the review of the system over the period of certification and complaints received from users of certification. | 9.5.4 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **IMDRF N3** |  |  |  |  |  |  |
| **9.5 Certification decision** |  |  |  |  |  |  |
| The AO’s certifier shall be employed or shall be under a legally enforceable arrangement with the AO. (See N3(ed2): Cl 6.1.4, [IMDRF/MDSAP WG/N29 FINAL:2015](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM470363.pdf)) | 9.5 |  |  |  |  |  |
| AO cannot conclude that a manufacturer complies with regulatory requirements if the AO, using GHTF N19; has graded one or more nonconformity (ies) as a “5”; or, has graded more than two nonconformities as a “4.” | 9.5.1 |  |  |  |  |  |
| An AO shall have sufficient and reliable evidence to support a decision of compliance or non-compliance with regulatory requirements | 9.5.2 |  |  |  |  |  |
| An AO shall not conclude that a manufacturer complies with regulatory requirements, if the AO is aware of information that indicates a public health threat. Such information shall be reported to the recognizing Regulatory Authority in writing within 5 working days. (See 8.6.4) (See N3(ed2): Cl 6.1.4, [MDSAP AU P0027.003](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM406006.pdf)) | 9.5.3 |  |  |  |  |  |
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| **17021-1:2015** |  |  |  |  |  |  |
| **9.6 Maintaining certification** |  |  |  |  |  |  |
| **9.6.1 General** |  |  |  |  |  |  |
| AO may maintain certification on a conclusion of the Audit Team Leader that the manufacturer continues to satisfy requirements  | 9.6.1 |  |  |  |  |  |
| Independent review and decision is required when there is a nonconformity or situation that may lead to the suspension or withdrawal of a certificate. The lead auditor is to report to the AO the need to initiate an independent review by competent personnel.  | 9.6.1a |  |  |  |  |  |
| Competent personnel are to monitor surveillance activities, and the reporting by auditors, for effective operation of certification activities. | 9.6.1b |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.6.2 Surveillance activities** |  |  |  |  |  |  |
| **9.6.2.1 General** |  |  |  |  |  |  |
| Surveillance activities on representative areas and functions are regularly monitored and take into account changes | 9.6.2.1.1 |  |  |  |  |  |
| Surveillance audits to include on-site audits using ISO13485 and may include enquiries raised by the AO, the review of certified client’s public statements with respect to its operations, requests for information and other monitoring the client’s performance. | 9.6.2.1.2 |  |  |  |  |  |
| **9.6.2.2 Surveillance audit** |  |  |  |  |  |  |
| Surveillance audits are planned on-site audits for maintaining confidence and are to include the items defined in this clause. (See N3(ed2): Cl 6.1.4, [MDSAP G0026.1.001](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM406225.pdf)) | 9.6.2.2 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.6.3 Recertification** |  |  |  |  |  |  |
| **9.6.3.1 Recertification audit planning** |  |  |  |  |  |  |
| Planned and conducted to evaluate continued fulfilment of the requirements of ISO13485, the continued relevance of the QMS for the scope of certification, and to allow timely renewal of certificate before its expiry date. | 9.6.3.1.1 |  |  |  |  |  |
| Includes a review of previous surveillance audit reports and the performance of the QMS over the most recent certification cycle.  | 9.6.3.1.2 |  |  |  |  |  |
| Stage 1 required where there have been significant changes or changes to the context of the certification system | 9.6.3.1.3 |  |  |  |  |  |
| **9.6.3.2 Recertification audit** |  |  |  |  |  |  |
| Recertification includes an on-site audit that addresses effectiveness, continued relevance and applicability, commitment to maintain effectiveness and improvement, and the contribution of the QMS to the achievement of the client’s policies and objectives. | 9.6.3.2.1 |  |  |  |  |  |
| Time limits for corrections and corrective actions for nonconformities to be implemented and verified prior to certificate expiration. (See N3(ed2): Cl 6.1.4, [MDSAP AU P0027.003](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM406006.pdf)) | 9.6.3.2.2 |  |  |  |  |  |
| Expiry date of new certification – activities conducted before existing certification expiry date as defined in this clause | 9.6.3.2.3 |  |  |  |  |  |
| Certificate date not to be extended when activities are not completed before existing certification expiry date as defined in this clause (See N3(ed2): Cl 9.6) | 9.6.3.2.4 |  |  |  |  |  |
| Certification may be restored with 6 months of expiry of previous certification if activities completed, or a stage 2 conducted. Effective date after recertification decision. Expiry date based on previous certification cycle as defined in this clause.  | 9.6.3.2.5 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.6.4 Special audits** |  |  |  |  |  |  |
| **9.6.4.1 Expanding scope** |  |  |  |  |  |  |
| Determine whether audit activities are necessary when a request to expand scope has been made. These activities may be conducted in conjunction with the next surveillance audit.  | 9.6.4.1 |  |  |  |  |  |
| **9.6.4.2 Short-notice audits** |  |  |  |  |  |  |
| AO to make known the process for short notice or unannounced audits in response to complaints, changes or suspension. (See N3(ed2): Cl 9.2) | 9.6.4.2 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.6.5 Suspending, withdrawing or reducing the scope of certification** |  |  |  |  |  |  |
| AO policy and procedure for suspension, withdrawal or reduction of scope of certification  | 9.6.5.1 |  |  |  |  |  |
| Reasons for suspending a certificate; persistent failure to meet requirements, including effectiveness, client does not allow audits at required frequencies, request for voluntary suspension | 9.6.5.2 |  |  |  |  |  |
| When suspended, certification is temporarily invalid | 9.6.5.3 |  |  |  |  |  |
| Certificate restored if the issue resolved. Withdrawal or reduction of scope, if issue not resolved in the allocated timeframe. (<6 mo) | 9.6.5.4 |  |  |  |  |  |
| Reduce scope to exclude parts of QMS that do not meet requirements | 9.6.5.5 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **IMDRF N3** |  |  |  |  |  |  |
| **9.6 Maintaining Certification** |  |  |  |  |  |  |
| AO shall schedule recertification audits with sufficient time to complete the recertification process prior to the end of the certificate period.  | 9.6 |  |  |  |  |  |
| Surveillance audits shall include a review of issues related to medical device safety and effectiveness since the last audit such as complaints, problem reports, vigilance reports, and recalls/field corrections/advisory notices. | 9.6.1 |  |  |  |  |  |
| Surveillance audit objectives shall specifically include evaluation of;* + effectiveness of the manufacturer’s QMS incorporating the applicable regulatory requirements,
	+ the manufacturer’s ability to comply with these requirements,
	+ new or changed product/process related technologies, and,
	+ new or amended product technical documentation in relation to relevant regulatory requirements.
 | 9.6.2 |  |  |  |  |  |
| Decision to maintain a certificate by the lead auditor requires independent review if audit team leader is an external resource  | 9.6.3 |  |  |  |  |  |
| During a recertification audit, the Auditing Organization shall audit all sites that are recorded on the certificate. | 9.6.4 |  |  |  |  |  |
| Recertification audit objectives shall specifically include evaluation of:* + the effectiveness of the manufacturer’s QMS incorporating the applicable regulatory requirements;
	+ product/process related technologies;
	+ adequate product technical documentation in relation to relevant regulatory requirements; and,
	+ the manufacturer’s ability to comply with these requirements.
 | 9.6.5 |  |  |  |  |  |
| Special audits requested by RA (See N3(ed2): Cl 9.6.6, 9.6.8) | 9.6.6 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.6.7 Criteria for unannounced regulatory audits** |  |  |  |  |  |  |
| Triggering criteria: previous audit findings indicate serious / frequent nonconformity. Frequent and serious if; one or more Grade 5, or more than two Grade 4 nonconformities, when using GHTF/SG3/N19:2012. The timing, allowance for the implementation of corrective actions, focus and resource requirements of the unannounced audit are to meet the requirements defined in this clause | 9.6.7.1 |  |  |  |  |  |
| Triggering criteria: specific information provides a reason to suspect serious nonconformities of devices, or their manufacturer, or if requested by an RA. Focus is on the specific information or the substance of the request from the RA.  | 9.6.7.2 |  |  |  |  |  |
| Contractual arrangements with the manufacturer for unannounced audits | 9.6.7.3 |  |  |  |  |  |
| An AO that performs a special audit at the request of the RA(s) or an unannounced audit shall submit the audit report to the RA(s) within 15 days from the last day of the audit. | 9.6.8 |  |  |  |  |  |
| If the AO suspends, withdraws, cancels, or reduces the scope of a certificate, AO shall inform the RAs. | 9.6.9 |  |  |  |  |  |
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| **17021-1:2015** |  |  |  |  |  |  |
| **9.7. Appeals** |  |  |  |  |  |  |
| Documented process on appeals | 9.7.1 |  |  |  |  |  |
| AO responsible for all appeal decisions and to ensure persons engaged in appeal handling are different from those who carried out audit or made the certification decisions. | 9.7.2 |  |  |  |  |  |
| No discriminatory actions against appellant | 9.7.3 |  |  |  |  |  |
| Appeals process to include the elements defined in this clause (receiving, validating, investigating, deciding actions, tracking and recording, ensuring appropriate corrections and corrective actions) | 9.7.4 |  |  |  |  |  |
| AO is responsible for gathering and verifying all information to validate the appeal. | 9.7.5 |  |  |  |  |  |
| Acknowledge receipt of appeals and provide progress reports | 9.7.6 |  |  |  |  |  |
| The appeal decision made by, or reviewed and approved by, an independent party | 9.7.7 |  |  |  |  |  |
| AO shall give formal notice at end of process | 9.7.8 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **9.8 Complaints** |  |  |  |  |  |  |
| AO responsible for all decisions from complaint handling | 9.8.1 |  |  |  |  |  |
| No discriminatory actions against the complainant | 9.8.2 |  |  |  |  |  |
| AO shall deal with any complaint related to its certification activities. AO shall examine the effectiveness of a client’s QMS if a complaint is raised against them. | 9.8.3 |  |  |  |  |  |
| Complaints about a client, sent to the client | 9.8.4 |  |  |  |  |  |
| Documented process to deal with complaints (receive, evaluate, decide) with appropriate considerations for confidentiality. | 9.8.5 |  |  |  |  |  |
| Complaints process to include the elements defined in this clause (receiving, validating, investigating, deciding actions, tracking and recording, ensuring appropriate corrections and corrective actions) | 9.8.6 |  |  |  |  |  |
| AO responsible for gathering and verifying all necessary information to validate the complaint | 9.8.7 |  |  |  |  |  |
| Whenever, possible, AO shall acknowledge receipt of complaint and provide progress reports and the outcome | 9.8.8 |  |  |  |  |  |
| Final decision made by, or reviewed and approved by an independent party | 9.8.9 |  |  |  |  |  |
| Whenever, possible, AO shall give formal notice at end of process | 9.8.10 |  |  |  |  |  |
| Determining whether to, and to what extent, announce a complaint and its resolution publicly | 9.8.11 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **IMDRF N3** |  |  |  |  |  |  |
| **9.8 Complaints** |  |  |  |  |  |  |
| AO sends RA copy of any safety and effectiveness, or public health risk complaint related to a medical device manufacturer | 9.8.1 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **17021-1:2015** |  |  |  |  |  |  |
| **9.9 Client Records** |  |  |  |  |  |  |
| AO to maintain all records of application, audit and certification activities (certified, suspended, withdrawn) for all clients | 9.9.1 |  |  |  |  |  |
| Records on certified clients to include the following: | 9.9.2 |  |  |  |  |  |
| * + Application information and initial, surveillance and recertification audit reports (See N3(ed2): Cl 6.1.4, [MDSAP AU P0019](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM379903.pdf), [MDSAP AU F0019.1](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM387055.pdf), [MDSAP AU F0019.2](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM379900.xls), [MDSAP AU G0019.3](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM399946.pdf), [MDSAP AU G0019.4](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM418825.pdf), [MDSAP AU P0026](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM405993.pdf))
 | 9.9.2a |  |  |  |  |  |
| * + Certification agreement
 | 9.9.2b |  |  |  |  |  |
| * + Justification on the methodology used for sampling of sites (See N3(ed2): Cl 9.3.2)
 | 9.9.2c |  |  |  |  |  |
| * + Justification for audit time determination (See N3(ed2): Cl 6.1.4,[MDSAP AU P0008](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM379901.pdf), [MDSAP AU F0008.1](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM379902.xlsm))
 | 9.9.2d |  |  |  |  |  |
| * + Verification of correction and corrective actions
 | 9.9.2e |  |  |  |  |  |
| * + Records of complaints and appeals, and any subsequent correction or corrective actions
 | 9.9.2f |  |  |  |  |  |
| * + Committee deliberations and decisions
 | 9.9.2g |  |  |  |  |  |
| * + Documentation of certification decisions
 | 9.9.2h |  |  |  |  |  |
| * + Certification documents (See N3(ed2): Cl 9.1.4, [MDSAP AU P0026](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM405993.pdf))
 | 9.9.2i |  |  |  |  |  |
| * + Related records necessary to establish credibility of the certification including the competence of auditors and technical experts
 | 9.9.2j |  |  |  |  |  |
| The storage and transmittal of records shall ensure confidentiality | 9.9.3 |  |  |  |  |  |
| Documented policy and procedure on record retention. Records to be retained for a period equivalent to the current cycle plus one full certification (See N3(ed2): Cl 10.1.2) | 9.9.4 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **10. Management system requirements for certification bodies** |  |  |  |  |  |  |
| **10.1 Options** |  |  |  |  |  |  |
| AO shall establish, document, implement and maintain a QMS that is capable of supporting and demonstrating the consistent achievement of the requirements of Clauses 5 to 9 of ISO/IEC 17021-1:2015 and either Clause 10.2 or 10.3 (ISO9001) | 10.1 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **IMDRF N3** |  |  |  |  |  |  |
| **10.0 Management system requirements for Auditing Organizations** |  |  |  |  |  |  |
| **10.1 Options** |  |  |  |  |  |  |
| AO’s management system capable of consistent achievement of applicable medical device legislation or regulatory policies or programs | 10.1.1 |  |  |  |  |  |
| AO shall retain records of conformity to this document for a period of time not less than 15 years. | 10.1.2 |  |  |  |  |  |
| AO shall measure, monitor and analyse their audit program to identify trends | 10.1.3 |  |  |  |  |  |
| Internal audits must cover all locations involved in medical device regulatory auditing. | 10.1.4 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **17021-1:2015** |  |  |  |  |  |  |
| **10.2 Option A: General management system requirements** |  |  |  |  |  |  |
| **10.2.1. General** |  |  |  |  |  |  |
| Establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of Clause 10.2 of 17021-1:2015 | 10.2.1 |  |  |  |  |  |
| Top Management shall; establish and document policies and objectives, provide evidence of commitment to development and implementation of the QMS, ensure understanding, implementation and maintenance at all levels of the AO and assign responsibility and authority for the establishment, implementation and maintenance of processes and procedures and for reporting to top management on performance and any need for improvement. | 10.2.1 |  |  |  |  |  |
| **10.2.2 Management system manual** |  |  |  |  |  |  |
| Applicable requirements addressed in a manual or associated documents. Documentation to be accessible to personnel | 10.2.2 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **10.2.3 Control of Documents** |  |  |  |  |  |  |
| Define procedures for the control of documents (internal and external) defined in this clause (a-g) | 10.2.3 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **10.2.4 Control of Records**  |  |  |  |  |  |  |
| Define procedures for the control of records defined in this clause, the retention of records to meet contractual and legal obligations and to ensure access is consistent with confidentiality arrangements. (N3(ed2): Cl 10.1.2 – >15 years) | 10.2.4 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **10.2.5 Management Review** |  |  |  |  |  |  |
| Management shall establish procedures to review its management system at planned intervals (at least annually) to ensure its continuing suitability, adequacy and effectiveness. | 10.2.5.1 |  |  |  |  |  |
| Elements of review inputs as defined in this clause | 10.2.5.2 |  |  |  |  |  |
| Elements of review outputs as defined in this clause | 10.2.5.3 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **10.2.6 Internal audits** |  |  |  |  |  |  |
| AO shall establish procedures for internal audits | 10.2.6.1 |  |  |  |  |  |
| An audit programme shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits | 10.2.6.2 |  |  |  |  |  |
| Internal audits shall be performed at least once every 12 months. Less frequent if AO can demonstrate effective implementation of the QMS by other means | 10.2.6.3 |  |  |  |  |  |
| AO shall ensure audits conducted by competent personnel, auditors do not audit their own work, personnel informed of outcome, actions resulting from internal audits are taken in a timely and appropriate manner and any opportunities for improvement are identified. | 10.2.6.4 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **10.2.7 Corrective actions** |  |  |  |  |  |  |
| AO shall establish procedures for identification and management of nonconformities and take actions, appropriate to the impact of the nonconformities, to eliminate the causes of nonconformities to prevent recurrence. Procedures shall address the requirements defined in this clause (a-g). | 10.2.7 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **10.3 Option B: Management system requirements in accordance with ISO 9001** |  |  |  |  |  |  |
| **10.3.1 General** |  |  |  |  |  |  |
| AO to establish and maintain a management system, in accordance with the requirements of ISO 9001, which is capable of supporting and demonstrating the consistent achievementof requirements of this part of ISO/IEC 17021, amplified by 10.3.2 to 10.3.4. | 10.3.1 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **10.3.2 Scope** |  |  |  |  |  |  |
| Scope of management system includes design and development of certification services | 10.3.2 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **10.3.3 Customer Focus** |  |  |  |  |  |  |
| AO to consider its credibility of certification and address needs of all parties that rely upon its audit and certification services, not just its clients (See N3(ed2): Cl 6.1.4) | 10.3.3 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **10.3.4 Management Review** |  |  |  |  |  |  |
| AO to include in management review information on relevant appeals and complaints and a review of impartiality | 10.3.4 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **IMDRF N3** |  |  |  |  |  |  |
| **11.0 Revoking Recognition of an Auditing Organization** |  |  |  |  |  |  |
| The recognition of an Auditing Organization shall be revoked if an Auditing Organization does not meet the requirements of [IMDRF/MDSAP WG/N3 FINAL:2013](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM450646.pdf) with due process. For further information on revoking recognition, see [IMDRF/MDSAP WG/N11 FINAL:2014](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM450652.pdf) | 11.0 |  |  |  |  |  |
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| --- | --- | --- |
|  | **ADDITIONAL INFORMATION REQUIRED** | **Cross Reference** |
|  | Please complete and provide [MDSAP AS F0010.4: Supplemental AO Application Matrix - IMDRF N4](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM381894.doc) |  |
|  | Please complete and provide [MDSAP AS F0010.7: AO Critical Location Information Form](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM380004.pdf) and [MDSAP AS F0013.3: Key Activities Matrix](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM426534.docx)If applicable, please provide a copy of the working agreement between the Head Office and the Branch, Regional and/or National offices, and any related bodies, to operate under the MDSAP.Note: Sub-contracting will be addressed under question 8. |  |
|  | Provide a statement agreeing to conduct medical device regulatory audits in conformance with the requirements of applicable MDSAP participating Regulatory Authorities. The statement should be provided on the Manufacturer’s letterhead and signed by a senior manager. |  |
|  | Provide a list identifying the AO personnel or committee members who make certification decisions under MDSAP. For each person on the list, please include:a) Title; b) Qualifications (both academic and professional); c) Membership on committees involved in certification decisions, as applicable. |  |
|  | Using the form [MDSAP AS F0010.8: Auditor and Technical Expert Competency Summary](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM380005.doc), provide a list of all auditors, both AO employees and external resources, used by the AO who will perform regulatory audits under MDSAP.  |  |
|  | Using the form [MDSAP AS F0010.8: Auditor and Technical Expert Competency Summary](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM380005.doc), provide a list of all technical experts, both AO employees and external resources, used by the AO to assess processes or medical device technologies.  |
|  | Provide a copy of a contract template that the AO and its client will use. The template should include clauses addressing requirements of the IMDRF MDSAP WG document N3 on contractual agreements between the Auditing Organization and the audited manufacturer.  |  |
|  | Provide a template for certification documents to be issued by the AO under the MDSAP. (See N3(ed2): Cl 6.1.4, [MDSAP AU P0026: Certificate Document Requirements](http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM405993.pdf)  |  |
|  | Provide copies of the Auditing Organization’s contractual agreements, and other documents related to sub-contracting arrangements for activities conducted under MDSAP (as applicable) |  |