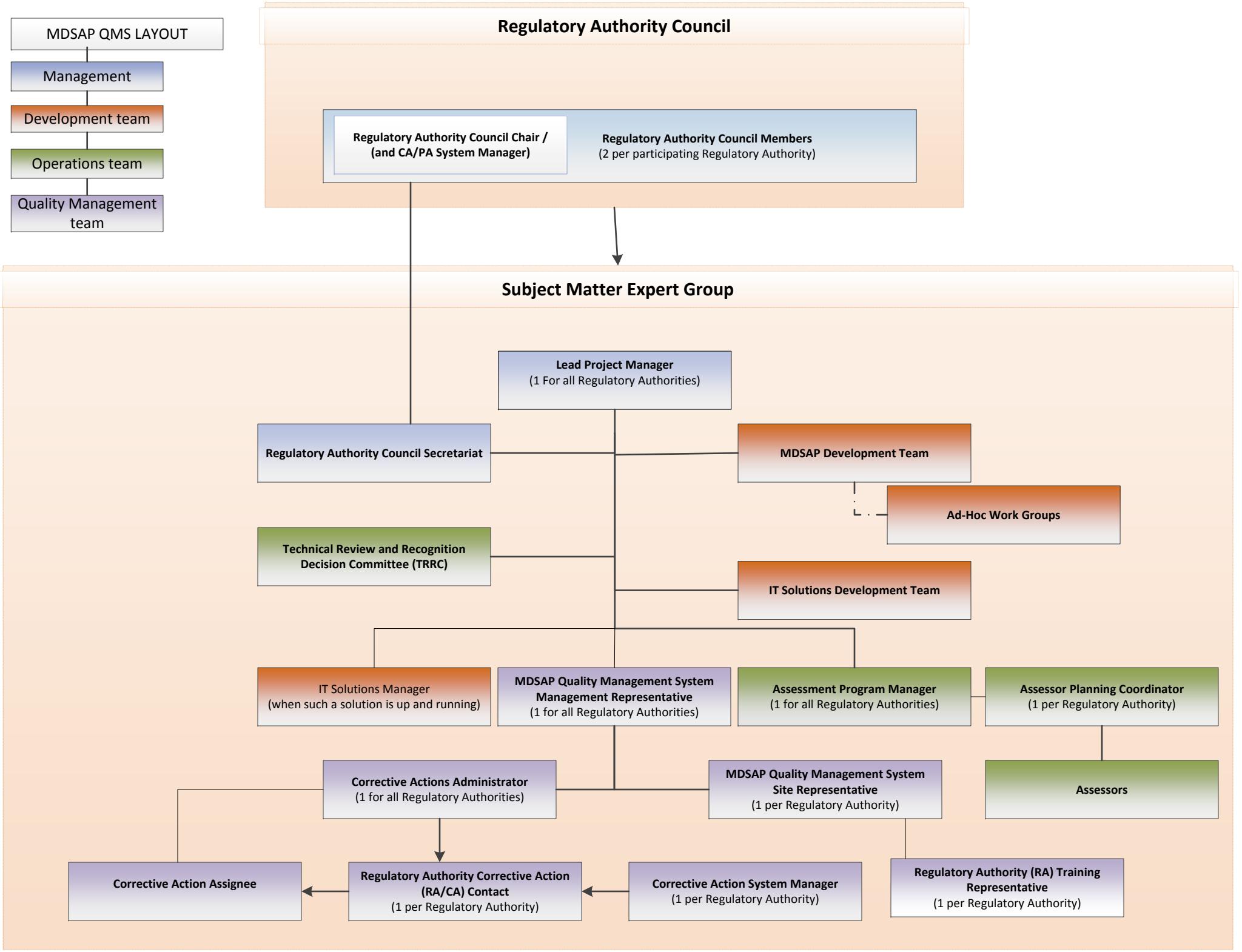
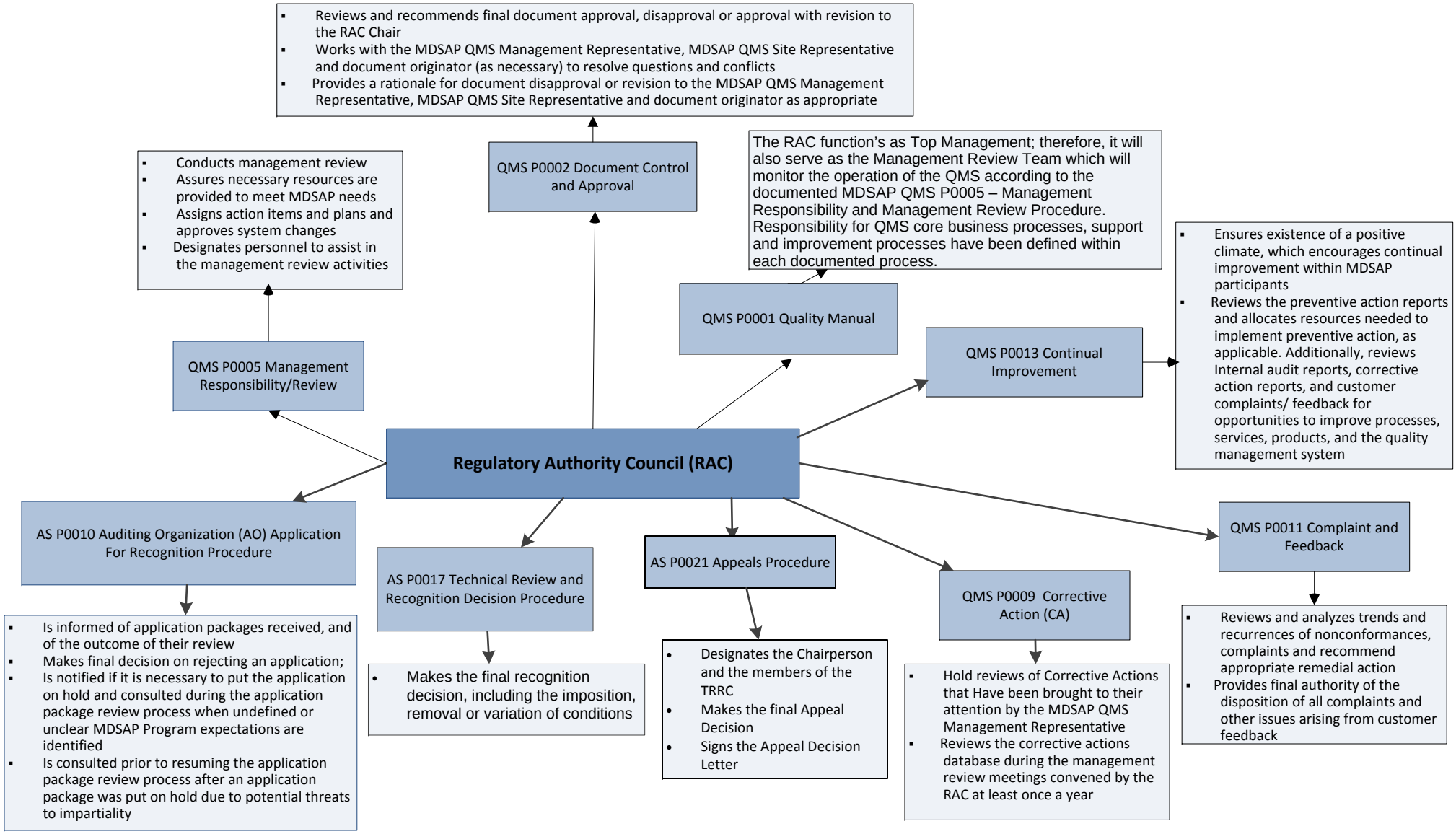
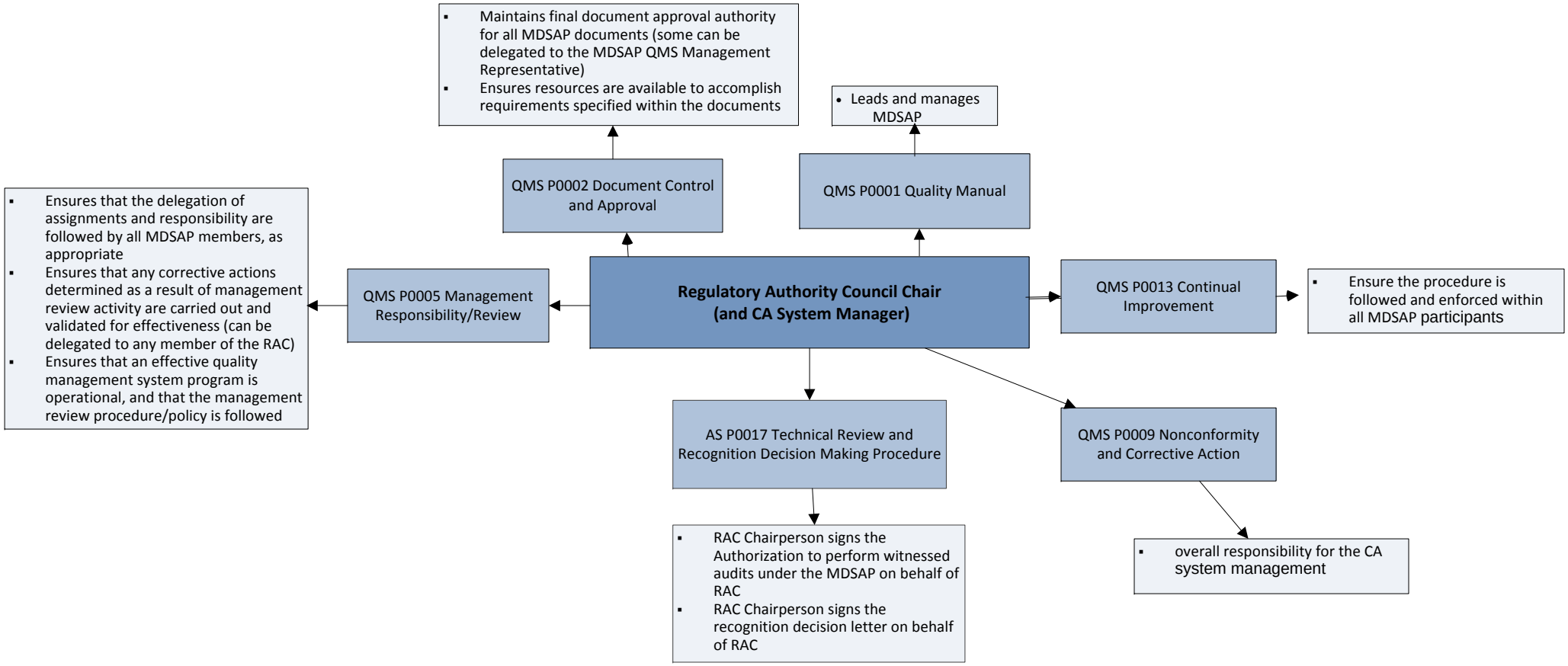
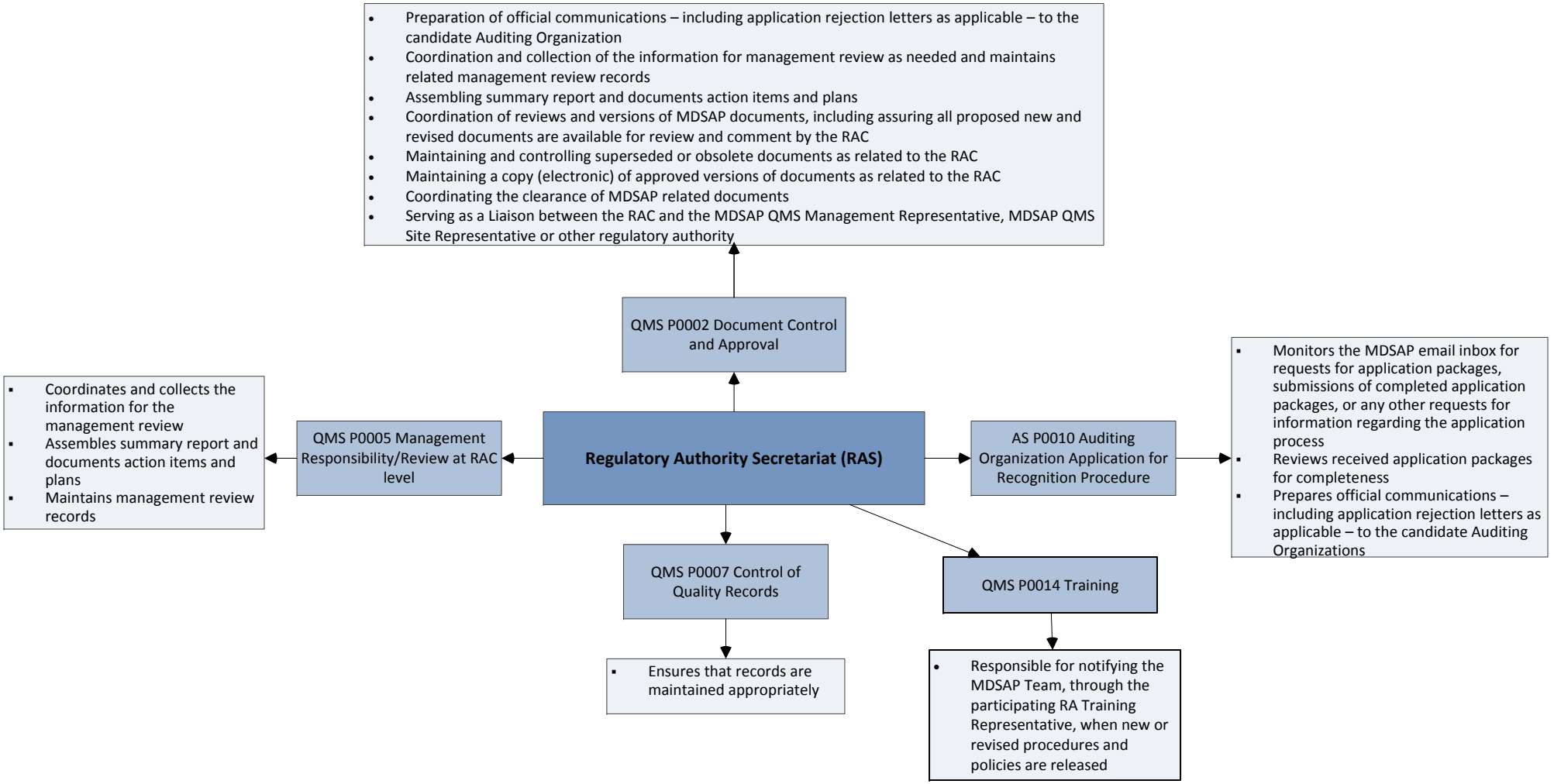
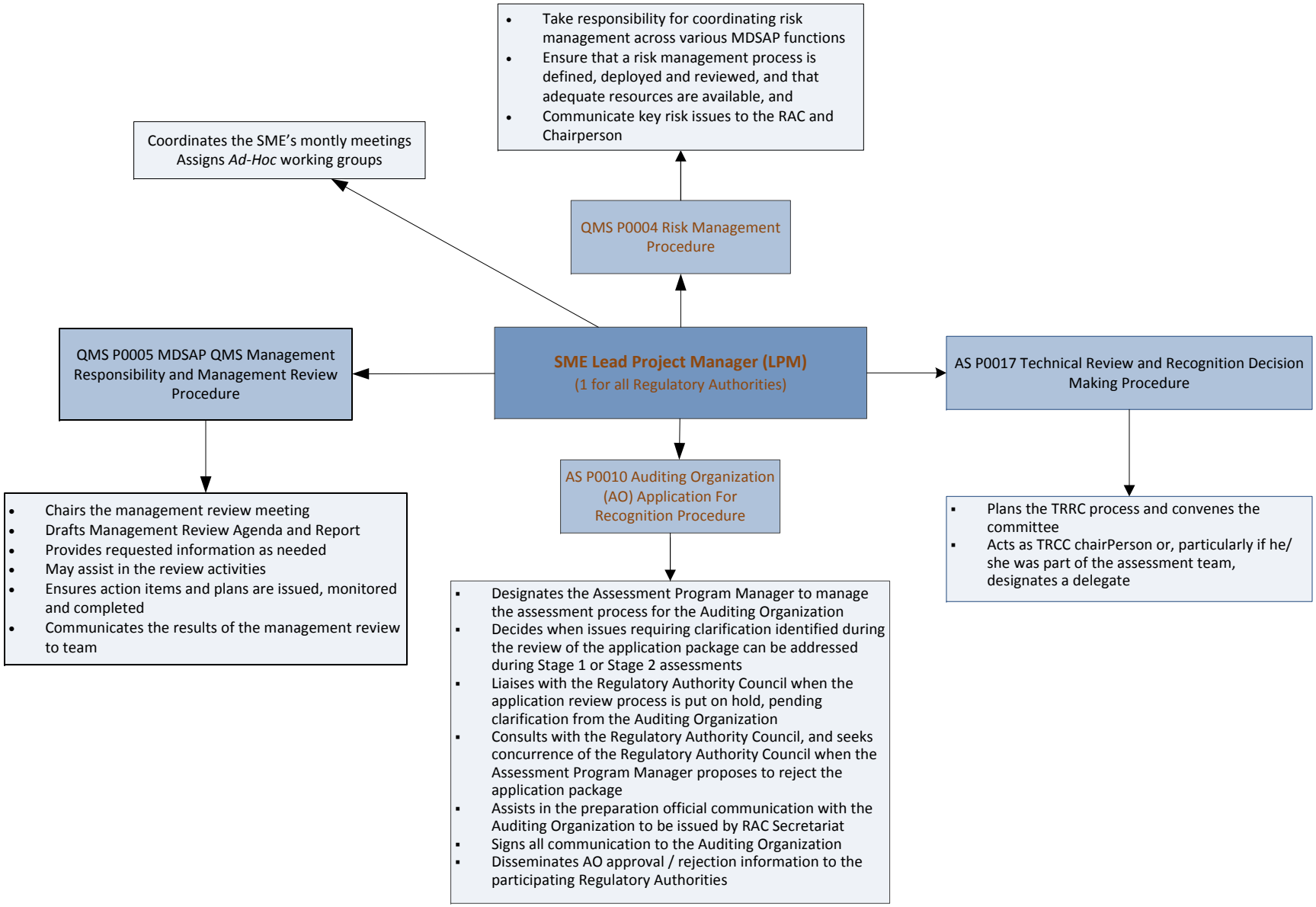
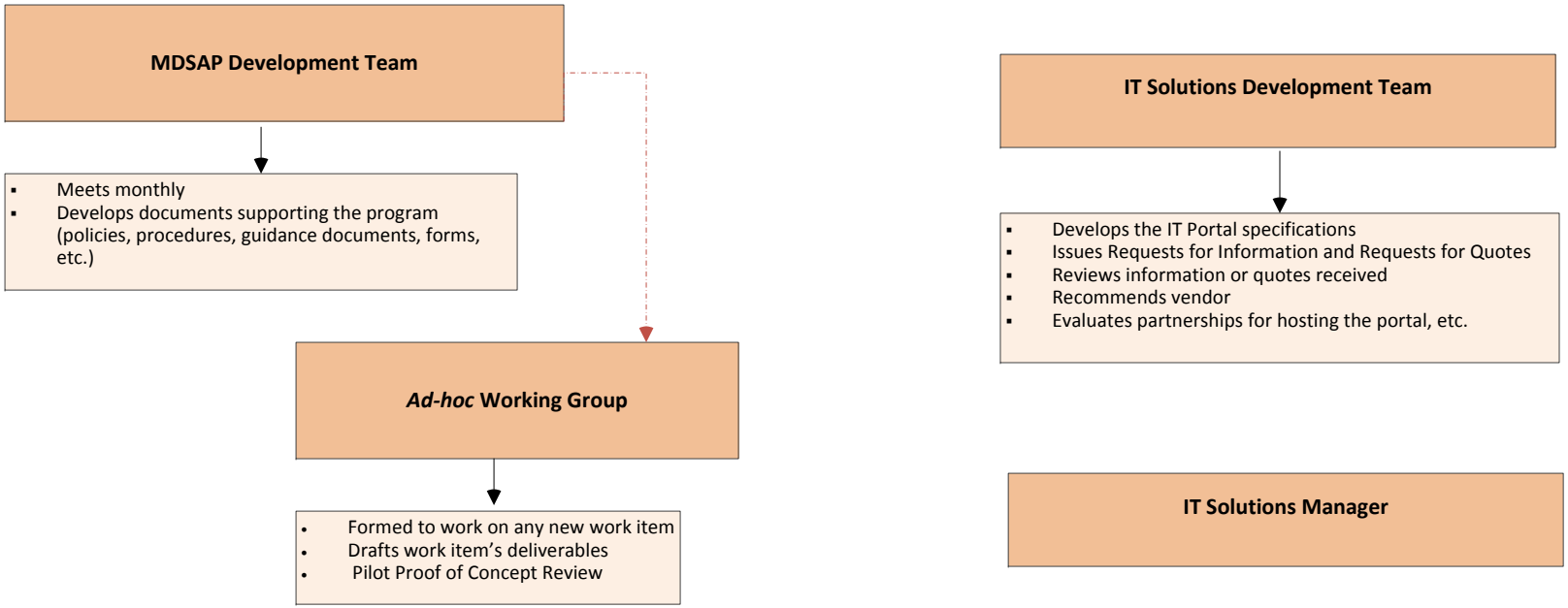

MDSAP QMS LAYOUT
Management
Development team
Operations team
Quality Management team
Regulatory Authority Council
Regulatory Authority Council Chair / (and CA/PA System Manager)
Regulatory Authority Council Members
(2 per participating Regulatory Authority)
Subject Matter Expert Group
Lead Project Manager
(1 For all Regulatory Authorities)
Regulatory Authority Council Secretariat
MDSAP Development Team
Ad-Hoc Work Groups
Technical Review and Recognition Decision Committee (TRRC)
IT Solutions Development Team
IT Solutions Manager
(when such a solution is up and running)
MDSAP Quality Management System Management Representative
(1 for all Regulatory Authorities)
Assessment Program Manager
(1 for all Regulatory Authorities)
Assessor Planning Coordinator
(1 per Regulatory Authority)
Corrective Actions Administrator
(1 for all Regulatory Authorities)
MDSAP Quality Management System Site Representative
(1 per Regulatory Authority)
Assessors
Corrective Action Assignee
Regulatory Authority Corrective Action (RA/CA) Contact
(1 per Regulatory Authority)
Corrective Action System Manager
(1 per Regulatory Authority)
Regulatory Authority (RA) Training Representative
(1 per Regulatory Authority)

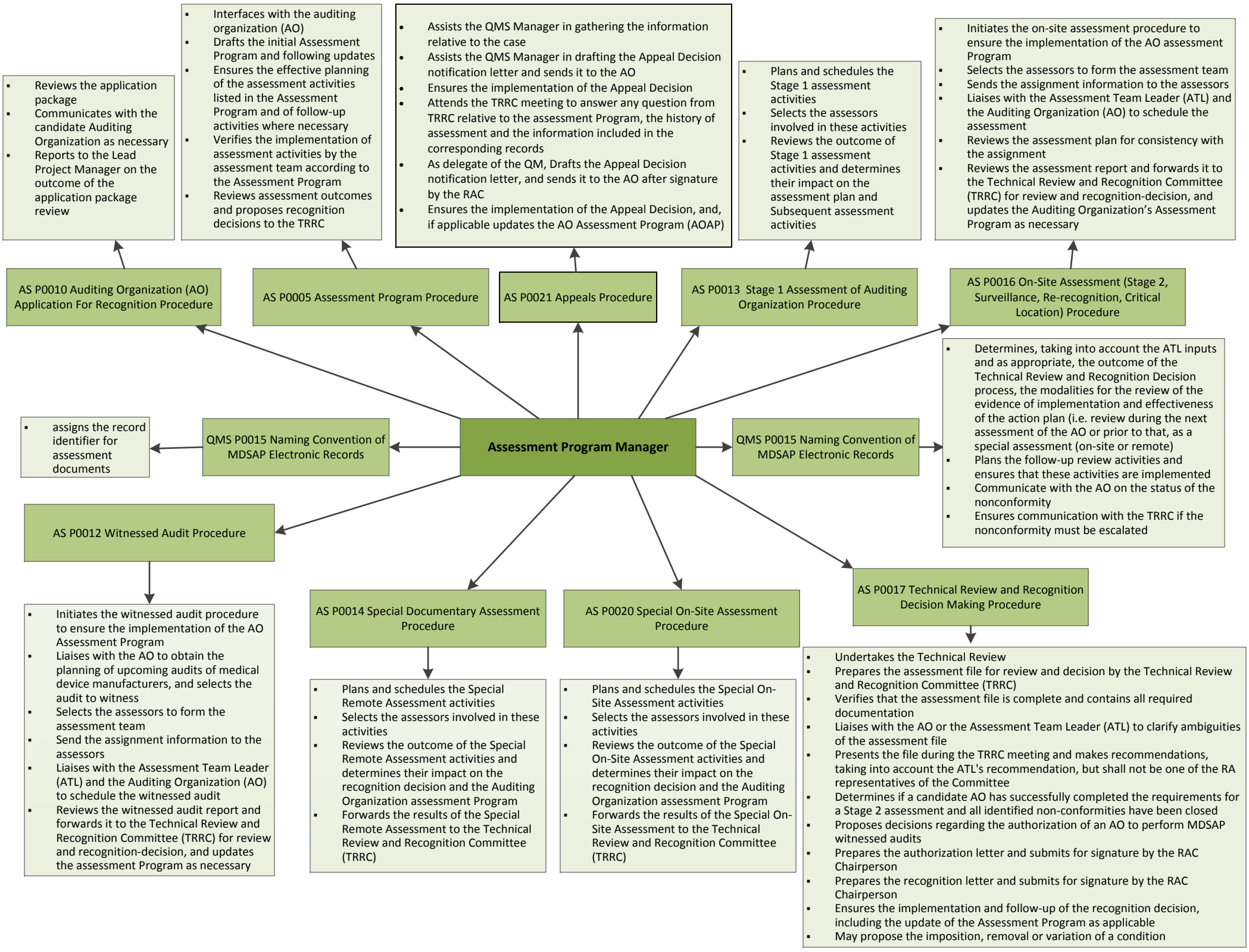

Reviews and recommends final document approval, disapproval or approval with revision to the RAC Chair
Works with the MDSAP QMS Management Representative, MDSAP QMS Site Representative and document originator (as necessary) to resolve questions and conflicts
Provides a rationale for document disapproval or revision to the MDSAP QMS Management Representative, MDSAP QMS Site Representative and document originator as appropriate
QMS P0002 Document Control and Approval
Conducts management review
Assures necessary resources are provided to meet MDSAP needs
Assigns action items and plans and approves system changes
Designates personnel to assist in the management review activities
The RAC function's as Top Management; therefore, it will also serve as the Management Review Team which will monitor the operation of the QMS according to the documented MDSAP QMS P0005 – Management Responsibility and Management Review Procedure. Responsibility for QMS core business processes, support and improvement processes have been defined within each documented process.
QMS P0001 Quality Manual
QMS P0005 Management Responsibility/Review
QMS P0013 Continual Improvement
Ensures existence of a positive climate, which encourages continual improvement within MDSAP participants
Reviews the preventive action reports and allocates resources needed to implement preventive action, as applicable. Additionally, reviews Internal audit reports, corrective action reports, and customer complaints/ feedback for opportunities to improve processes, services, products, and the quality management system
Regulatory Authority Council (RAC)
AS P0010 Auditing Organization (AO) Application For Recognition Procedure
AS P0017 Technical Review and Recognition Decision Procedure
AS P0021 Appeals Procedure
QMS P0009 Corrective Action (CA)
QMS P0011 Complaint and Feedback
Is informed of application packages received, and of the outcome of their review
Makes final decision on rejecting an application;
Is notified if it is necessary to put the application on hold and consulted during the application package review process when undefined or unclear MDSAP Program expectations are identified
Is consulted prior to resuming the application package review process after an application package was put on hold due to potential threats to impartiality
Makes the final recognition decision, including the imposition, removal or variation of conditions
Designates the Chairperson and the members of the TRRC
Makes the final Appeal Decision
Signs the Appeal Decision Letter
Hold reviews of Corrective Actions that Have been brought to their attention by the MDSAP QMS Management Representative
Reviews the corrective actions database during the management review meetings convened by the RAC at least once a year
Reviews and analyzes trends and recurrences of nonconformances, complaints and recommend appropriate remedial action
Provides final authority of the disposition of all complaints and other issues arising from customer feedback

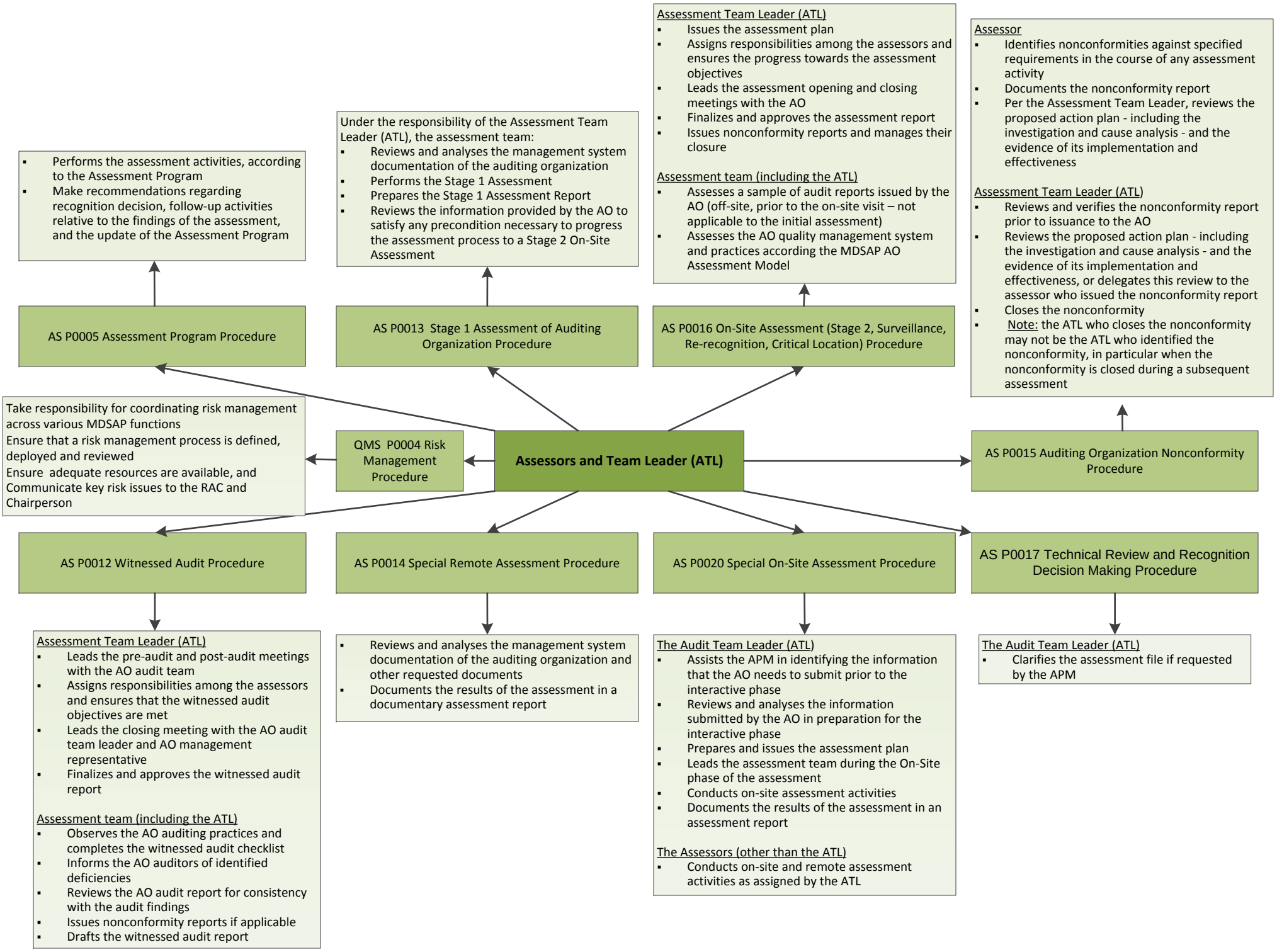

Maintains final document approval authority for all MDSAP documents (some can be delegated to the MDSAP QMS Management Representative)
Ensures resources are available to accomplish requirements specified within the documents
Leads and manages MDSAP
QMS P0002 Document Control and Approval
QMS P0001 Quality Manual
Ensures that the delegation of assignments and responsibility are followed by all MDSAP members, as appropriate
Ensures that any corrective actions determined as a result of management review activity are carried out and validated for effectiveness (can be delegated to any member of the RAC)
Ensures that an effective quality management system program is operational, and that the management review procedure/policy is followed
QMS P0005 Management Responsibility/Review
Regulatory Authority Council Chair (and CA System Manager)
QMS P0013 Continual Improvement
Ensure the procedure is followed and enforced within all MDSAP participants
AS P0017 Technical Review and Recognition Decision Making Procedure
QMS P0009 Nonconformity and Corrective Action
RAC Chairperson signs the Authorization to perform witnessed audits under the MDSAP on behalf of RAC
RAC Chairperson signs the recognition decision letter on behalf of RAC
overall responsibility for the CA system management

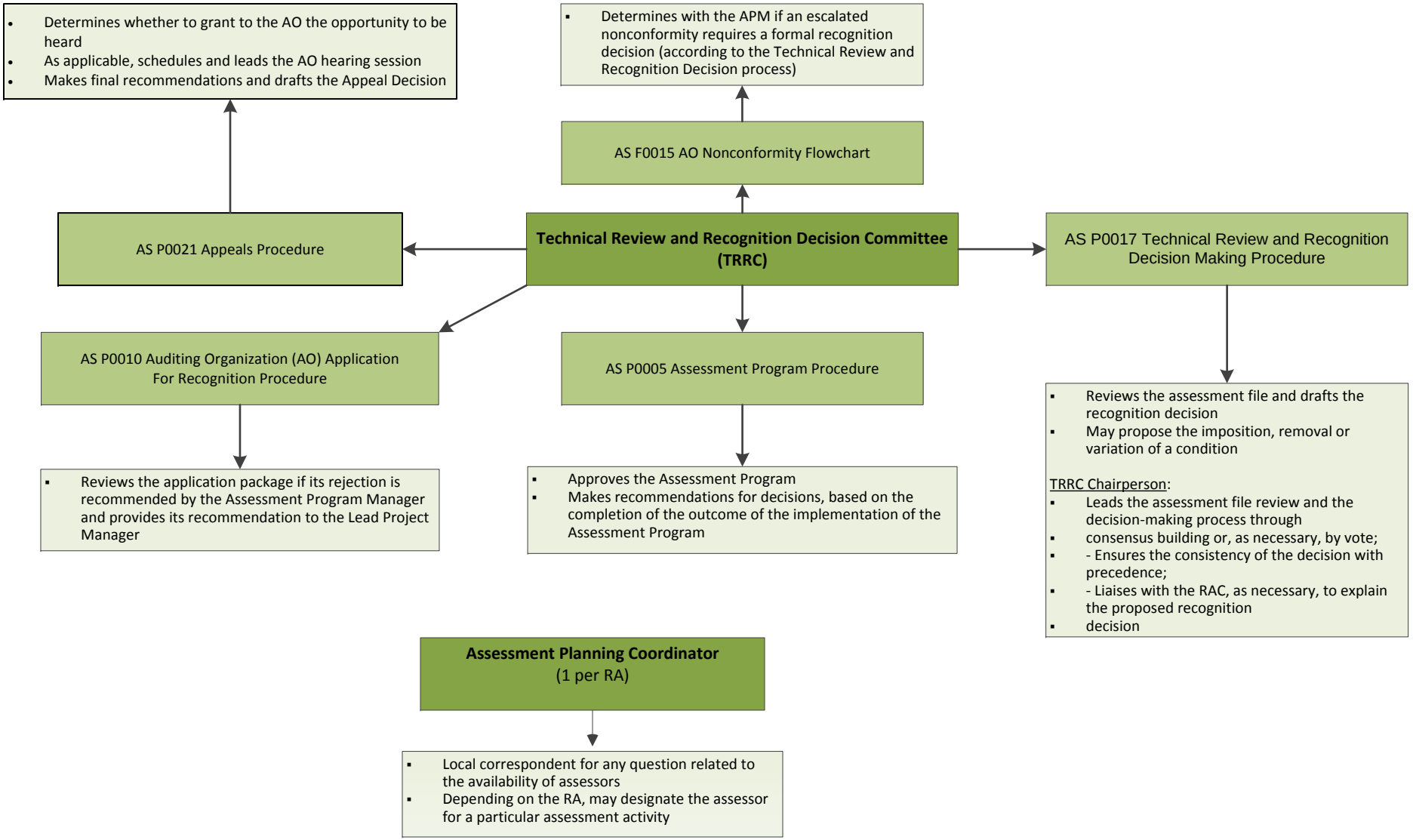

Preparation of official communications – including application rejection letters as applicable – to the candidate Auditing Organization
Coordination and collection of the information for management review as needed and maintains related management review records
Assembling summary report and documents action items and plans
Coordination of reviews and versions of MDSAP documents, including assuring all proposed new and revised documents are available for review and comment by the RAC
Maintaining and controlling superseded or obsolete documents as related to the RAC
Maintaining a copy (electronic) of approved versions of documents as related to the RAC
Coordinating the clearance of MDSAP related documents
Serving as a Liaison between the RAC and the MDSAP QMS Management Representative, MDSAP QMS Site Representative or other regulatory authority
QMS P0002 Document Control and Approval
Coordinates and collects the information for the management review
Assembles summary report and documents action items and plans
Maintains management review records
QMS P0005 Management Responsibility/Review at RAC level
Regulatory Authority Secretariat (RAS)
AS P0010 Auditing Organization Application for Recognition Procedure
Monitors the MDSAP email inbox for requests for application packages, submissions of completed application packages, or any other requests for information regarding the application process
Reviews received application packages for completeness
Prepares official communications – including application rejection letters as applicable – to the candidate Auditing Organizations
QMS P0007 Control of Quality Records
Ensures that records are maintained appropriately
QMS P0014 Training
Responsible for notifying the MDSAP Team, through the participating RA Training Representative, when new or revised procedures and policies are released

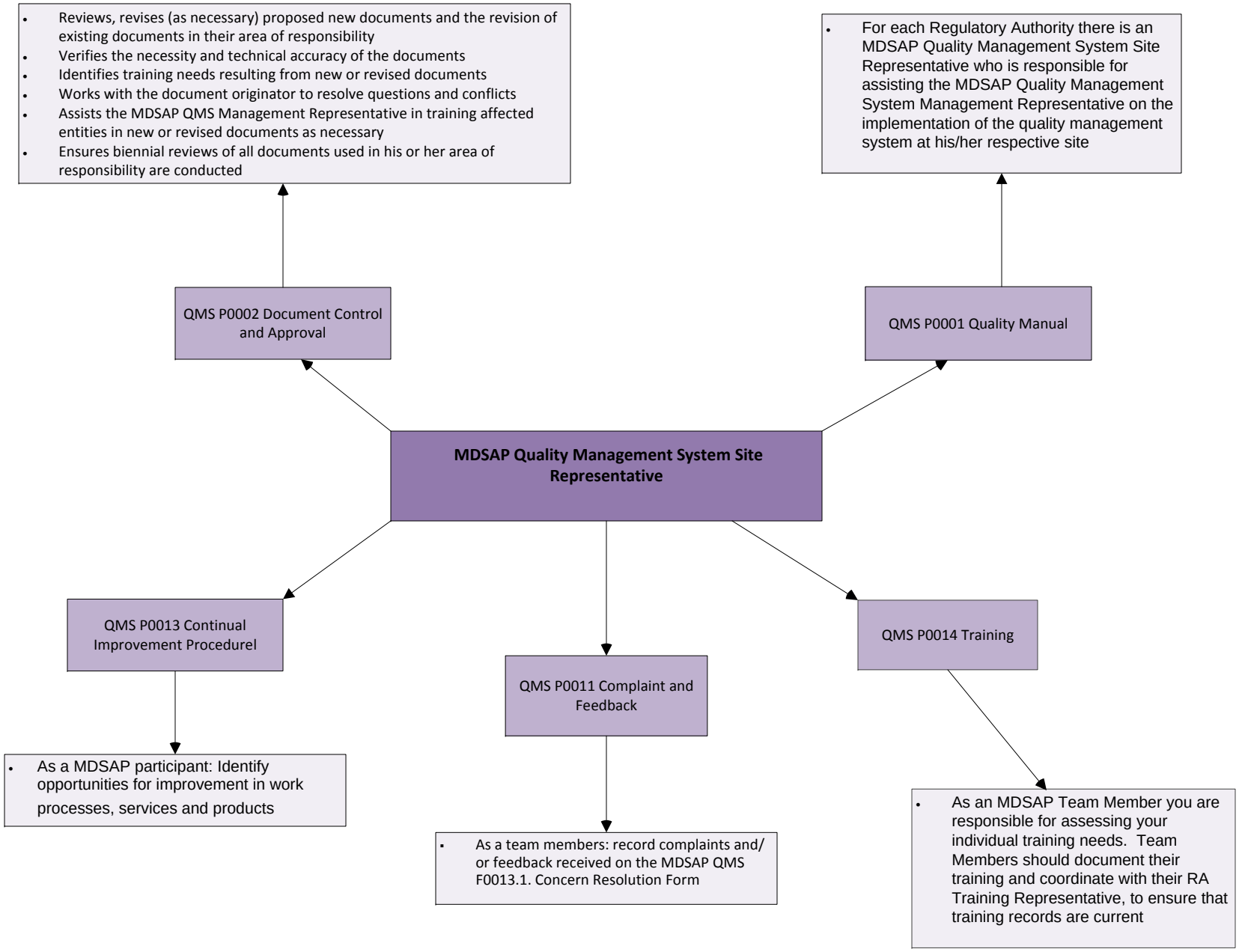

Take responsibility for coordinating risk management across various MDSAP functions
Ensure that a risk management process is defined, deployed and reviewed, and that adequate resources are available, and
Communicate key risk issues to the RAC and Chairperson
Coordinates the SME's montly meetings
Assigns *Ad-Hoc* working groups
QMS P0004 Risk Management Procedure
QMS P0005 MDSAP QMS Management Responsibility and Management Review Procedure
SME Lead Project Manager (LPM)
(1 for all Regulatory Authorities)
AS P0017 Technical Review and Recognition Decision Making Procedure
AS P0010 Auditing Organization (AO) Application For Recognition Procedure
Chairs the management review meeting
Drafts Management Review Agenda and Report
Provides requested information as needed
May assist in the review activities
Ensures action items and plans are issued, monitored and completed
Communicates the results of the management review to team
Designates the Assessment Program Manager to manage the assessment process for the Auditing Organization
Decides when issues requiring clarification identified during the review of the application package can be addressed during Stage 1 or Stage 2 assessments
Liaises with the Regulatory Authority Council when the application review process is put on hold, pending clarification from the Auditing Organization
Consults with the Regulatory Authority Council, and seeks concurrence of the Regulatory Authority Council when the Assessment Program Manager proposes to reject the application package
Assists in the preparation official communication with the Auditing Organization to be issued by RAC Secretariat
Signs all communication to the Auditing Organization
Disseminates AO approval / rejection information to the participating Regulatory Authorities
Plans the TRRC process and convenes the committee
Acts as TRCC chairPerson or, particularly if he/ she was part of the assessment team, designates a delegate

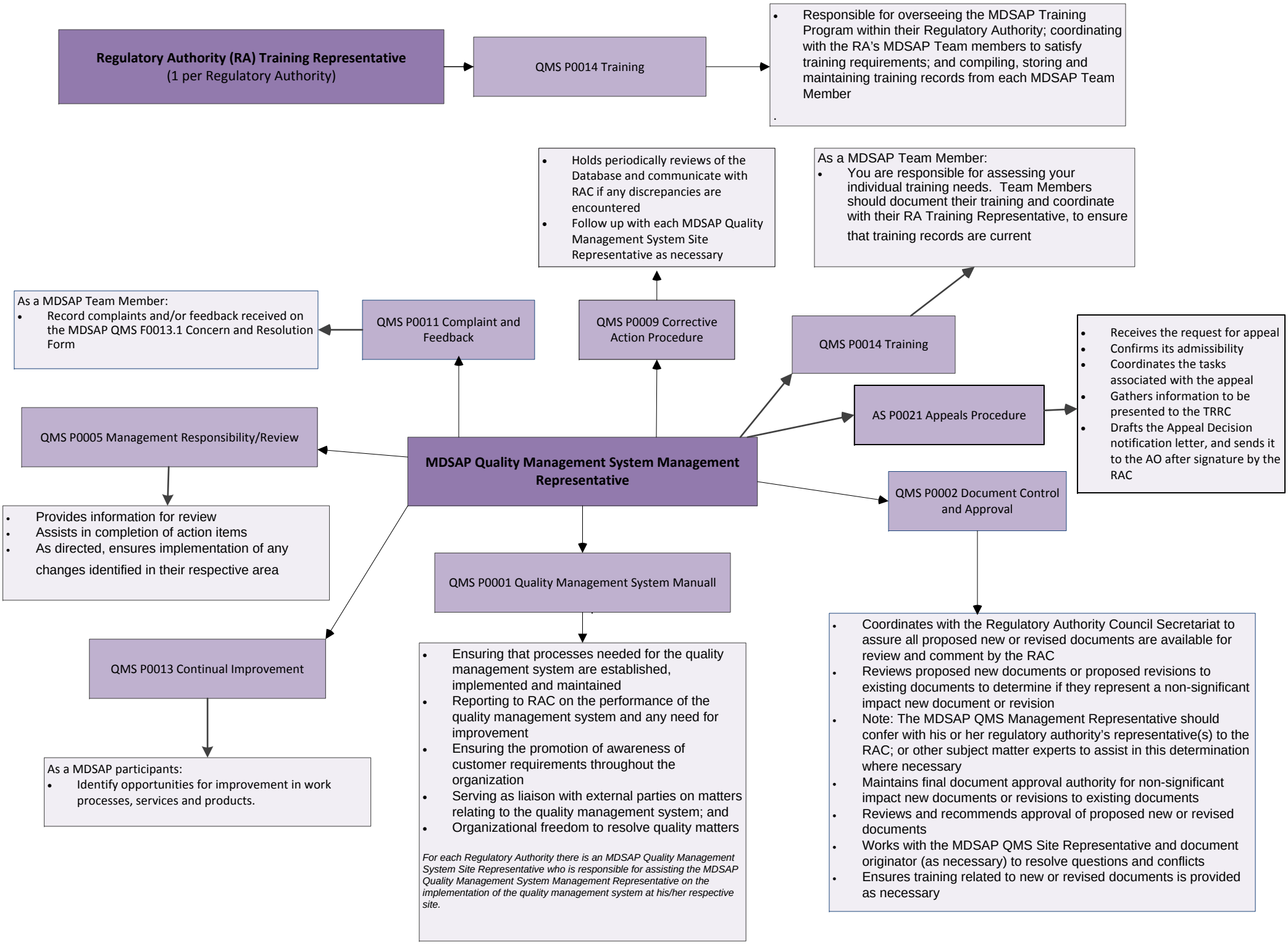

MDSAP Development Team
Meets monthly
Develops documents supporting the program (policies, procedures, guidance documents, forms, etc.)
Ad-hoc Working Group
Formed to work on any new work item
Drafts work item's deliverables
Pilot Proof of Concept Review
IT Solutions Development Team
Develops the IT Portal specifications
Issues Requests for Information and Requests for Quotes
Reviews information or quotes received
Recommends vendor
Evaluates partnerships for hosting the portal, etc.
IT Solutions Manager

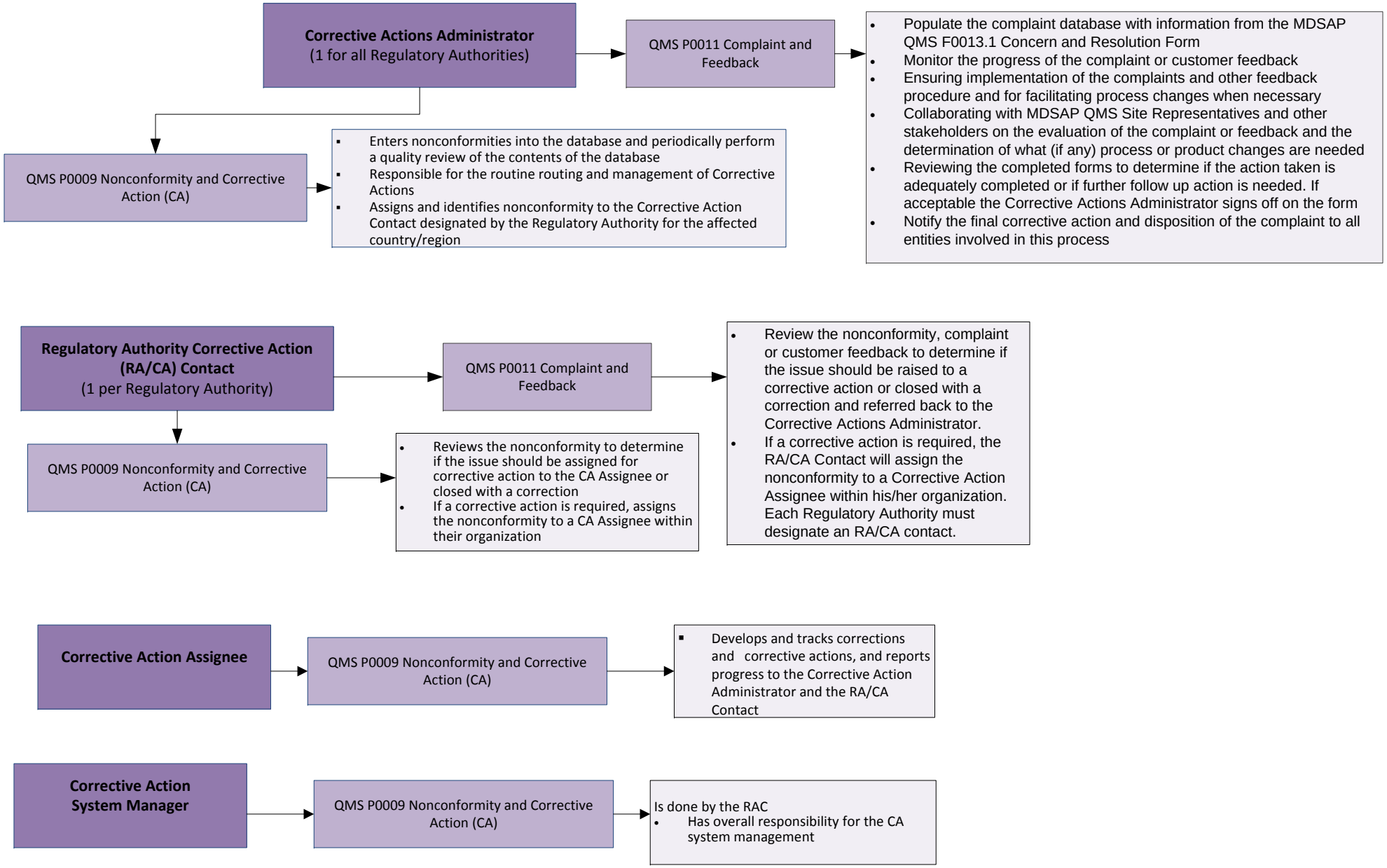

Reviews the application package
Communicates with the candidate Auditing Organization as necessary
Reports to the Lead Project Manager on the outcome of the application package review
Interfaces with the auditing organization (AO)
Drafts the initial Assessment Program and following updates
Ensures the effective planning of the assessment activities listed in the Assessment Program and of follow-up activities where necessary
Verifies the implementation of assessment activities by the assessment team according to the Assessment Program
Reviews assessment outcomes and proposes recognition decisions to the TRRC
Assists the QMS Manager in gathering the information relative to the case
Assists the QMS Manager in drafting the Appeal Decision notification letter and sends it to the AO
Ensures the implementation of the Appeal Decision
Attends the TRRC meeting to answer any question from TRRC relative to the assessment Program, the history of assessment and the information included in the corresponding records
As delegate of the QM, Drafts the Appeal Decision notification letter, and sends it to the AO after signature by the RAC
Ensures the implementation of the Appeal Decision, and, if applicable updates the AO Assessment Program (AOAP)
Plans and schedules the Stage 1 assessment activities
Selects the assessors involved in these activities
Reviews the outcome of Stage 1 assessment activities and determines their impact on the assessment plan and Subsequent assessment activities
Initiates the on-site assessment procedure to ensure the implementation of the AO assessment Program
Selects the assessors to form the assessment team
Sends the assignment information to the assessors
Liaises with the Assessment Team Leader (ATL) and the Auditing Organization (AO) to schedule the assessment
Reviews the assessment plan for consistency with the assignment
Reviews the assessment report and forwards it to the Technical Review and Recognition Committee (TRRC) for review and recognition-decision, and updates the Auditing Organization's Assessment Program as necessary
AS P0010 Auditing Organization (AO) Application For Recognition Procedure
AS P0005 Assessment Program Procedure
AS P0021 Appeals Procedure
AS P0013 Stage 1 Assessment of Auditing Organization Procedure
AS P0016 On-Site Assessment (Stage 2, Surveillance, Re-recognition, Critical Location) Procedure
Determines, taking into account the ATL inputs and as appropriate, the outcome of the Technical Review and Recognition Decision process, the modalities for the review of the evidence of implementation and effectiveness of the action plan (i.e. review during the next assessment of the AO or prior to that, as a special assessment (on-site or remote)
Plans the follow-up review activities and ensures that these activities are implemented
Communicate with the AO on the status of the nonconformity
Ensures communication with the TRRC if the nonconformity must be escalated
assigns the record identifier for assessment documents
QMS P0015 Naming Convention of MDSAP Electronic Records
Assessment Program Manager
QMS P0015 Naming Convention of MDSAP Electronic Records
AS P0012 Witnessed Audit Procedure
Initiates the witnessed audit procedure to ensure the implementation of the AO Assessment Program
Liaises with the AO to obtain the planning of upcoming audits of medical device manufacturers, and selects the audit to witness
Selects the assessors to form the assessment team
Send the assignment information to the assessors
Liaises with the Assessment Team Leader (ATL) and the Auditing Organization (AO) to schedule the witnessed audit
Reviews the witnessed audit report and forwards it to the Technical Review and Recognition Committee (TRRC) for review and recognition-decision, and updates the assessment Program as necessary
AS P0014 Special Documentary Assessment Procedure
Plans and schedules the Special Remote Assessment activities
Selects the assessors involved in these activities
Reviews the outcome of the Special Remote Assessment activities and determines their impact on the recognition decision and the Auditing Organization assessment Program
Forwards the results of the Special Remote Assessment to the Technical Review and Recognition Committee (TRRC)
AS P0020 Special On-Site Assessment Procedure
Plans and schedules the Special On-Site Assessment activities
Selects the assessors involved in these activities
Reviews the outcome of the Special On-Site Assessment activities and determines their impact on the recognition decision and the Auditing Organization assessment Program
Forwards the results of the Special On-Site Assessment to the Technical Review and Recognition Committee (TRRC)
AS P0017 Technical Review and Recognition Decision Making Procedure
Undertakes the Technical Review
Prepares the assessment file for review and decision by the Technical Review and Recognition Committee (TRRC)
Verifies that the assessment file is complete and contains all required documentation
Liaises with the AO or the Assessment Team Leader (ATL) to clarify ambiguities of the assessment file
Presents the file during the TRRC meeting and makes recommendations, taking into account the ATL's recommendation, but shall not be one of the RA representatives of the Committee
Determines if a candidate AO has successfully completed the requirements for a Stage 2 assessment and all identified non-conformities have been closed
Proposes decisions regarding the authorization of an AO to perform MDSAP witnessed audits
Prepares the authorization letter and submits for signature by the RAC Chairperson
Prepares the recognition letter and submits for signature by the RAC Chairperson
Ensures the implementation and follow-up of the recognition decision, including the update of the Assessment Program as applicable
May propose the imposition, removal or variation of a condition


Assessment Team Leader (ATL)
Issues the assessment plan
Assigns responsibilities among the assessors and ensures the progress towards the assessment objectives
Leads the assessment opening and closing meetings with the AO
Finalizes and approves the assessment report
Issues nonconformity reports and manages their closure
Assessment team (including the ATL)
Assesses a sample of audit reports issued by the AO (off-site, prior to the on-site visit – not applicable to the initial assessment)
Assesses the AO quality management system and practices according the MDSAP AO Assessment Model
Assessor
Identifies nonconformities against specified requirements in the course of any assessment activity
Documents the nonconformity report
Per the Assessment Team Leader, reviews the proposed action plan - including the investigation and cause analysis - and the evidence of its implementation and effectiveness
Assessment Team Leader (ATL)
Reviews and verifies the nonconformity report prior to issuance to the AO
Reviews the proposed action plan - including the investigation and cause analysis - and the evidence of its implementation and effectiveness, or delegates this review to the assessor who issued the nonconformity report
Closes the nonconformity
Note: the ATL who closes the nonconformity may not be the ATL who identified the nonconformity, in particular when the nonconformity is closed during a subsequent assessment
Performs the assessment activities, according to the Assessment Program
Make recommendations regarding recognition decision, follow-up activities relative to the findings of the assessment, and the update of the Assessment Program
Under the responsibility of the Assessment Team Leader (ATL), the assessment team:
Reviews and analyses the management system documentation of the auditing organization
Performs the Stage 1 Assessment
Prepares the Stage 1 Assessment Report
Reviews the information provided by the AO to satisfy any precondition necessary to progress the assessment process to a Stage 2 On-Site Assessment
AS P0005 Assessment Program Procedure
AS P0013 Stage 1 Assessment of Auditing Organization Procedure
AS P0016 On-Site Assessment (Stage 2, Surveillance, Re-recognition, Critical Location) Procedure
Take responsibility for coordinating risk management across various MDSAP functions
Ensure that a risk management process is defined, deployed and reviewed
Ensure adequate resources are available, and
Communicate key risk issues to the RAC and Chairperson
QMS P0004 Risk Management Procedure
Assessors and Team Leader (ATL)
AS P0015 Auditing Organization Nonconformity Procedure
AS P0012 Witnessed Audit Procedure
AS P0014 Special Remote Assessment Procedure
AS P0020 Special On-Site Assessment Procedure
AS P0017 Technical Review and Recognition Decision Making Procedure
Assessment Team Leader (ATL)
Leads the pre-audit and post-audit meetings with the AO audit team
Assigns responsibilities among the assessors and ensures that the witnessed audit objectives are met
Leads the closing meeting with the AO audit team leader and AO management representative
Finalizes and approves the witnessed audit report
Assessment team (including the ATL)
Observes the AO auditing practices and completes the witnessed audit checklist
Informs the AO auditors of identified deficiencies
Reviews the AO audit report for consistency with the audit findings
Issues nonconformity reports if applicable
Drafts the witnessed audit report
Reviews and analyses the management system documentation of the auditing organization and other requested documents
Documents the results of the assessment in a documentary assessment report
The Audit Team Leader (ATL)
Assists the APM in identifying the information that the AO needs to submit prior to the interactive phase
Reviews and analyses the information submitted by the AO in preparation for the interactive phase
Prepares and issues the assessment plan
Leads the assessment team during the On-Site phase of the assessment
Conducts on-site assessment activities
Documents the results of the assessment in an assessment report
The Assessors (other than the ATL)
Conducts on-site and remote assessment activities as assigned by the ATL
The Audit Team Leader (ATL)
Clarifies the assessment file if requested by the APM


Determines whether to grant to the AO the opportunity to be heard
As applicable, schedules and leads the AO hearing session
Makes final recommendations and drafts the Appeal Decision
Determines with the APM if an escalated nonconformity requires a formal recognition decision (according to the Technical Review and Recognition Decision process)
AS F0015 AO Nonconformity Flowchart
AS P0021 Appeals Procedure
Technical Review and Recognition Decision Committee (TRRC)
AS P0017 Technical Review and Recognition Decision Making Procedure
AS P0010 Auditing Organization (AO) Application For Recognition Procedure
AS P0005 Assessment Program Procedure
Reviews the assessment file and drafts the recognition decision
May propose the imposition, removal or variation of a condition
TRRC Chairperson:
Leads the assessment file review and the decision-making process through
consensus building or, as necessary, by vote;
- Ensures the consistency of the decision with precedence;
- Liaises with the RAC, as necessary, to explain the proposed recognition
decision
Reviews the application package if its rejection is recommended by the Assessment Program Manager and provides its recommendation to the Lead Project Manager
Approves the Assessment Program
Makes recommendations for decisions, based on the completion of the outcome of the implementation of the Assessment Program
Assessment Planning Coordinator
(1 per RA)
Local correspondent for any question related to the availability of assessors
Depending on the RA, may designate the assessor for a particular assessment activity


Reviews, revises (as necessary) proposed new documents and the revision of existing documents in their area of responsibility
Verifies the necessity and technical accuracy of the documents
Identifies training needs resulting from new or revised documents
Works with the document originator to resolve questions and conflicts
Assists the MDSAP QMS Management Representative in training affected entities in new or revised documents as necessary
Ensures biennial reviews of all documents used in his or her area of responsibility
For each Regulatory Authority there is an MDSAP Quality Management System Site Representative who is responsible for assisting the MDSAP Quality Management System Management Representative on the implementation of the quality management system at his/her respective site
QMS P0002 Document Control and Approval
QMS P0001 Quality Manual
MDSAP Quality Management System Site Representative
QMS P0013 Continual Improvement Procedurel
QMS P0011 Complaint and Feedback
QMS P0014 Training
As a MDSAP participant: Identify opportunities for improvement in work processes, services and products
As a team members: record complaints and/ or feedback received on the MDSAP QMS F0013.1. Concern Resolution Form
As an MDSAP Team Member you are responsible for assessing your individual training needs. Team Members should document their training and coordinate with their RA Training Representative, to ensure that training records are current


Regulatory Authority (RA) Training Representative
(1 per Regulatory Authority)
QMS P0014 Training
Responsible for overseeing the MDSAP Training Program within their Regulatory Authority; coordinating with the RA's MDSAP Team members to satisfy training requirements; and compiling, storing and maintaining training records from each MDSAP Team Member
.
Holds periodically reviews of the Database and communicate with RAC if any discrepancies are encountered
Follow up with each MDSAP Quality Management System Site Representative as necessary
As a MDSAP Team Member:
You are responsible for assessing your individual training needs. Team Members should document their training and coordinate with their RA Training Representative, to ensure that training records are current
As a MDSAP Team Member:
Record complaints and/or feedback received on the MDSAP QMS F0013.1 Concern and Resolution Form
QMS P0011 Complaint and Feedback
QMS P0009 Corrective Action Procedure
QMS P0014 Training
Receives the request for appeal
Confirms its admissibility
Coordinates the tasks associated with the appeal
Gathers information to be presented to the TRRC
Drafts the Appeal Decision notification letter, and sends it to the AO after signature by the RAC
AS P0021 Appeals Procedure
QMS P0005 Management Responsibility/Review
MDSAP Quality Management System Management Representative
QMS P0002 Document Control and Approval
Provides information for review
Assists in completion of action items
As directed, ensures implementation of any changes identified in their respective area
QMS P0001 Quality Management System Manuall
QMS P0013 Continual Improvement
Coordinates with the Regulatory Authority Council Secretariat to assure all proposed new or revised documents are available for review and comment by the RAC
Reviews proposed new documents or proposed revisions to existing documents to determine if they represent a non-significant impact new document or revision
Note: The MDSAP QMS Management Representative should confer with his or her regulatory authority's representative(s) to the RAC; or other subject matter experts to assist in this determination where necessary
Maintains final document approval authority for non-significant impact new documents or revisions to existing documents
Reviews and recommends approval of proposed new or revised documents
Works with the MDSAP QMS Site Representative and document originator (as necessary) to resolve questions and conflicts
Ensures training related to new or revised documents is provided as necessary
Ensuring that processes needed for the quality management system are established, implemented and maintained
Reporting to RAC on the performance of the quality management system and any need for improvement
Ensuring the promotion of awareness of customer requirements throughout the organization
Serving as liaison with external parties on matters relating to the quality management system; and
Organizational freedom to resolve quality matters
For each Regulatory Authority there is an MDSAP Quality Management System Site Representative who is responsible for assisting the MDSAP Quality Management System Management Representative on the implementation of the quality management system at his/her respective site.
As a MDSAP participants:
Identify opportunities for improvement in work processes, services and products.


Corrective Actions Administrator
(1 for all Regulatory Authorities)
QMS P0011 Complaint and Feedback
Populate the complaint database with information from the MDSAP QMS F0013.1 Concern and Resolution Form
Monitor the progress of the complaint or customer feedback
Ensuring implementation of the complaints and other feedback procedure and for facilitating process changes when necessary
Collaborating with MDSAP QMS Site Representatives and other stakeholders on the evaluation of the complaint or feedback and the determination of what (if any) process or product changes are needed
Reviewing the completed forms to determine if the action taken is adequately completed or if further follow up action is needed. If acceptable the Corrective Actions Administrator signs off on the form
Notify the final corrective action and disposition of the complaint to all entities involved in this process
QMS P0009 Nonconformity and Corrective Action (CA)
Enters nonconformities into the database and periodically perform a quality review of the contents of the database
Responsible for the routine routing and management of Corrective Actions
Assigns and identifies nonconformity to the Corrective Action Contact designated by the Regulatory Authority for the affected country/region
Regulatory Authority Corrective Action (RA/CA) Contact
(1 per Regulatory Authority)
QMS P0011 Complaint and Feedback
Review the nonconformity, complaint or customer feedback to determine if the issue should be raised to a corrective action or closed with a correction and referred back to the Corrective Actions Administrator.
If a corrective action is required, the RA/CA Contact will assign the nonconformity to a Corrective Action Assignee within his/her organization. Each Regulatory Authority must designate an RA/CA contact.
QMS P0009 Nonconformity and Corrective Action (CA)
Reviews the nonconformity to determine if the issue should be assigned for corrective action to the CA Assignee or closed with a correction
If a corrective action is required, assigns the nonconformity to a CA Assignee within their organization
Corrective Action Assignee
QMS P0009 Nonconformity and Corrective Action (CA)
Develops and tracks corrections and corrective actions, and reports progress to the Corrective Action Administrator and the RA/CA Contact
Corrective Action System Manager
QMS P0009 Nonconformity and Corrective Action (CA)
Is done by the RAC
Has overall responsibility for the CA system management