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| Standard Operation Procedures | SOP_052_Transform EFSA |
| Effective Date: 22/12/2022 | Public |

Transform EFSA

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| Special Requirements | This procedure is a controlled document maintained by Quality Management. It may not be deleted without comparable controls. Please note that this document becomes uncontrolled once printed. Make sure by always referring only to the Repository that you have the right version in use. Deviations from the provision of this document need to be recorded in the Exception Request Workflow. The procedure should be updated when there are changes in EFSA with respect to what is stated in the document (e.g. Relevant Standards, legislation, and documents, change in procedure, etc.). The person responsible for maintaining this procedure up to date is the Lead author with the support of the QM. |
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| Process Responsibility | Process owners are accountable this procedure being adhered to within their respective or unit. All relevant staff is responsible for the correct implementation of the procedure. Responsibilities for performing specific steps are outlined in the document. |
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SCOPE AND OBJECTIVES

The SOP 052 Transform requires a holistic and integrated approach as Business Transformation could imply new business processes design and implementation, reorganization, reassignment of staff, new IT applications and capabilities. This SOP takes into consideration the following aspects related to the Business Transformation process:

- Business process design and implementation
- Organizational changes
- Communication with business users and stakeholders
- Risk management and mitigation actions
- Architecture and Solution Design
- IT implementation and transition to operations (BAU)
- Training, documentation & support
- Benefits and business values evaluation (Value Chain)
- Project management

The process also identifies the toll-gates necessary to respect the quality, data protection and security standards set forth by the EU regulations and the EFSA quality standards.

EFSA Process Architecture

In the framework of the EPA 3 process Architecture, this SOP is part of these processes: 13.1 "Enterprise Architecture" and 13.2 "Transformation Implementation".



RELEVANT STANDARDS, LEGISLATION AND DOCUMENTS

The following international standards apply to this process:

- BABOK – Business Analyst Body of Knowledge
- EU legislation
- ISO 27001 and ISO 22301
- ITIL 4 – Information Technology Infrastructure Library
- PM2 Project Management (v3.0.1)
- TOGAF 9.2 Enterprise Architecture
- BRM Body of Knowledge

ABBREVIATIONS AND DEFINITION

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|--------|---|
| A&S | Architecture & Solutions Team (TS) |
| AGB | Appropriate Governance Body |
| BIG | Business Implementation Group |
| BM | Business Manager |
| BRM | Business Relationship Management team (TS) |
| CORSER | Corporate Services Unit |
| DPO | Data Protection Officer |
| HUCAP | Human Capital Services Unit |
| ISO | Information Security Officer |
| PCT | Project Core Team (include all the professional expertise A&S/TP/Development team/DW necessary) |
| PgM | Programme Manager |
| PM | Project Manager |
| PO | Project Owner |
| PSC | Project Steering Committee |
| SP | Solution Provider |
| TP | Transformation Partners Team (TS) |
| TS | Transformation Services Unit |

PROCEDURE

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| | Previous SOPs in the process: |
| Step 1 | 1.0 Business Transformation Initiative |



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| <ul style="list-style-type: none"> - TS TP - GPS - Process Owner - CORSER - IDATA | <p>1.1 Identify digital transformation opportunities</p> <p>In this phase, Business Relationship Management (BRM) team ensure needs, problems, performance improvements, processes optimisation, strategic gaps to be filled, new opportunities, potential projects are identified and explored in collaboration with the business leaders.</p> <p>Digital Transformation Experts (DTE) provide strategic vision and recommendations for the achievement of EFSA's strategic ambitions defined in their role theme e.g. Methods, Models, Ecosystem, Chemical Strategy.</p> <p>These parallel streams of engagement activity are carried out under BRM-BOK methodology. They are aligned and they feed into the development of business-led ideas for projects and initiatives that take advantage of available digital technology and move EFSA towards our agreed strategic ambitions.</p> <p>1.2 Develop a new Business Transformation Initiative</p> <p>For the classification PII/DEV refer to WIN/SOP051/01 Portfolio Management of change requests, to SOP_051 Corporate Planning and Monitoring, to SOP Continuous Improvement.</p> <p>In this phase, new initiatives are developed and elaborated by Process Owner in collaboration with GPS and TS-Transformation Partners.</p> <p>The resulting analysis and recommendation is handed over to the SMU Planner as input for the classification PII/DEV¹.</p> <p>It's important that every new business transformation initiative is analysed by the Process Owner considering the four dimensions of POTI model (Process, Organization, Technology and Information) and that GPS and TS support in this analysis, ensuring PM2 methodology is followed, and digital transformation opportunities are included for consideration.</p> <p>In particular, the following points must be covered by the Process Owner to finalise this initiative:</p> <ul style="list-style-type: none"> • Describe in alignment with GPS the context in which this new initiative can be placed and the alignment to the EFSA Strategy • Figure out and document in alignment with GPS the potential benefits and strategic or operational gaps that this new initiative can cover • Describe at a high level the POTI implications of this new initiative (ref. SOP_051 Corporate Planning and Monitoring, ref.SOP 047 Advise - request Advice from TP) • Describe at a high-level the potential legal implications (LA) • Describe at a high-level the potential consequences of this new initiative at the technology, data, and application level (ref. SOP 047 – request Advice from A&S/CORSER/IDATA) • Calculate the cost/benefit of these changes and a potential Return on Investment for the EFSA organisation (if applicable) • Evaluate the potential Risks of this new initiative and a possible mitigations scenario • Prepare a "Business Transformation Initiative" document that contains all these aspects as mentioned above |
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¹ See step 1.2 of the WIN/SOP051/01



| | <p>1.3 Business Sponsor review</p> <p>The Business Sponsor reviews the document with the support of GPS, HUCAP, IDATA, and TS. If the assessment is positive, a decision must be taken based on the complexity of this new initiative in terms of IT implementation. This can lead to implement a new project (ref. SOP 052 Transform) or Enhance Products and Services (ref. SOP 050 Enhance Product and services) or new Process Improvement Initiative (ref. SOP Continuous Improvement).</p> <table border="1" data-bbox="528 562 1461 1032"> <thead> <tr> <th data-bbox="528 562 842 600">Input</th> <th data-bbox="842 562 1193 600">RACI</th> <th data-bbox="1193 562 1461 600">Output</th> </tr> </thead> <tbody> <tr> <td data-bbox="528 600 842 1032">A Draft Project Idea including high level description of the business requirement to enhance a specified EPA3 process prepared by the Initiator with the support of TP, A&S, CORSER, GPS, and IDATA</td> <td data-bbox="842 600 1193 1032">Process Owner = A Initiator = R TP = R A&S = R CORSER = R GPS = R IDATA = R</td> <td data-bbox="1193 600 1461 1032">Recommendation: 1) Project (SOP 052) 2) Enhance Products and Services (SOP 050)</td> </tr> </tbody> </table> | Input | RACI | Output | A Draft Project Idea including high level description of the business requirement to enhance a specified EPA3 process prepared by the Initiator with the support of TP, A&S, CORSER, GPS, and IDATA | Process Owner = A Initiator = R TP = R A&S = R CORSER = R GPS = R IDATA = R | Recommendation: 1) Project (SOP 052) 2) Enhance Products and Services (SOP 050) |
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| <p>Step 2</p> | <p>2.0_Project Initiation Request (PIR)</p> | | | | | | |
| <ul style="list-style-type: none"> - Project Owner (PO) - Business Manager (BM) - Programme Manager (PgM) | <p>The PIR is a project’s starting point and formalises its initiation. By creating a PIR, the project initiator ensures that the current context/situation (i.e., problem, need or opportunity) and the project’s desired outcomes are formally captured and can be used as a basis for further exploration and elaboration.</p> <p>The following tasks must be executed during the Project Initiating phase:</p> <ol style="list-style-type: none"> a) The BM or PgM prepares the PIR. To help with this, the BM can ask for the advice of TS (as specified in SOP 047 Advise). b) The BM or PgM submits the PIR to the PO for approval. c) The PO assesses the PIR. If the assessment is positive, the process continues. <table border="1" data-bbox="528 1608 1461 1803"> <thead> <tr> <th data-bbox="528 1608 863 1646">Input</th> <th data-bbox="863 1608 1114 1646">RACI</th> <th data-bbox="1114 1608 1461 1646">Output</th> </tr> </thead> <tbody> <tr> <td data-bbox="528 1646 863 1803">A problem, a need or an opportunity expressed by the initiator</td> <td data-bbox="863 1646 1114 1803">PO = A BM/PgM = R</td> <td data-bbox="1114 1646 1461 1803"><u>Project Initiation Request</u></td> </tr> </tbody> </table> | Input | RACI | Output | A problem, a need or an opportunity expressed by the initiator | PO = A BM/PgM = R | <u>Project Initiation Request</u> |
| Input | RACI | Output | | | | | |
| A problem, a need or an opportunity expressed by the initiator | PO = A BM/PgM = R | <u>Project Initiation Request</u> | | | | | |
| <p>Step 3</p> | <p>3.0 PM 2 Initiating phase</p> | | | | | | |
| <ul style="list-style-type: none"> - TS TP - TS A&S - Business Manager (BM) | <p>3.1 Business case</p> <p>The purpose of the Business Case describes the project’s alignment with the organisation’s strategic objectives, provide a justification for</p> | | | | | | |



| <ul style="list-style-type: none"> - Project Owner (PO) - Project Steering Committee (PSC) | <p>the investment in time and effort, and set out the budgetary needs. Business Case may also include an assessment of impact and risks along with a more detailed cost- benefit analysis.</p> <p>It's important to highlight the Business Case (As-Is), Business Case (To-Be), and the recommend solution to cover the gap. At the same time, the analysis of portfolio proposals must be taken into consideration and this aspect will be covered by GPS.</p> <p>The following tasks must be executed for producing the Business Case document²:</p> <ul style="list-style-type: none"> a) The BM prepares a Business case and asks for the support of TS (TP and A&S) (as specified in SOP 047 Advise), GPS for Application Portfolio Management and well as Strategic and benefit alignment, and POTI owners (GPS, HUCAP, TS, IDATA) for a POTI review. Also, if it's necessary other departments can be involved: Finance, CORSER, HUCAP, and Legal Affair (LA). b) The PO assesses the Business Case. If the assessment is positive, a PM is assigned, the PSC will be formalised, and the process continues. <table border="1" data-bbox="528 891 1465 1077"> <thead> <tr> <th data-bbox="528 891 858 927">Input</th> <th data-bbox="858 891 1114 927">RACI</th> <th data-bbox="1114 891 1465 927">Output</th> </tr> </thead> <tbody> <tr> <td data-bbox="528 927 858 1077"><u>Project Initiation Request</u></td> <td data-bbox="858 927 1114 1077">PO = A BM = R</td> <td data-bbox="1114 927 1465 1077"><u>Business case</u></td> </tr> </tbody> </table> | Input | RACI | Output | <u>Project Initiation Request</u> | PO = A BM = R | <u>Business case</u> |
|--|--|----------------------|------|--------|-----------------------------------|------------------|----------------------|
| Input | RACI | Output | | | | | |
| <u>Project Initiation Request</u> | PO = A BM = R | <u>Business case</u> | | | | | |
| <ul style="list-style-type: none"> - Project Manager (PM) - Programme Steering Committee (PrgSC) | <p>3.2 Project Charter</p> <p>The Project Charter defines the project's objectives (i.e., scope, time, cost, quality), high-level requirements, risks, and constraints, as well as the project milestones and deliverable(s). Information Security is also a fundamental part of the Project charter deliverable and is strictly related to the information availability, integrity, and confidentiality. If the application is defined as critical in terms of business impact analysis, the Business Continuity and Disaster Recovery plan must be considered in this deliverable in terms of resources and technology infrastructure.</p> <p>The following tasks must be executed in this phase³:</p> <ul style="list-style-type: none"> a) The PM prepares the Project Charter and asks for the advice of TS (A&S, TP) (as specified in SOP 047 Advise) and GPS, POTI owners and Finance (and other actors as necessary) the following tasks must be executed in this step: <ul style="list-style-type: none"> 1) Assign the Project Core team 2) Assess change impact in term of resources, competency, organization, IT & IM requirements, and business continuity 3) Prepare implementation plan 4) Schedule the project and integrate into Application Portfolio Planning | | | | | | |

² Further, during the preparation of the Business Case the tasks indicated in the Portfolio WIN whall be performed.

³ Further, during the preparation of the Business Case the tasks indicated in the Portfolio WIN whall be performed.



| | <p>5) Prepare cost analysis, resources need, benefit evaluation, and plan 6) Prepare WBS statement work</p> <p>b) The PrgSC (= AGB) assesses the Project Charter. If the assessment is positive, and the process continues with the launch of the project.</p> <table border="1" data-bbox="528 434 1463 629"> <thead> <tr> <th data-bbox="528 434 863 472">Input</th> <th data-bbox="863 434 1114 472">RACI</th> <th data-bbox="1114 434 1463 472">Output</th> </tr> </thead> <tbody> <tr> <td data-bbox="528 472 863 629"> <ul style="list-style-type: none"> Project Initiation Request Business case </td> <td data-bbox="863 472 1114 629"> PrgSC = A PM = R </td> <td data-bbox="1114 472 1463 629"> <ul style="list-style-type: none"> Project Charter </td> </tr> </tbody> </table> <p>Ready for Planning (RfP)</p> <p>This is the first phase gate.</p> <p>The PM assesses whether the Planning Phase of the project is ready to start. When it is ready to start, the PM formalises the new status of the project.</p> | Input | RACI | Output | <ul style="list-style-type: none"> Project Initiation Request Business case | PrgSC = A PM = R | <ul style="list-style-type: none"> Project Charter |
|---|--|--|------|--------|---|---------------------|--|
| Input | RACI | Output | | | | | |
| <ul style="list-style-type: none"> Project Initiation Request Business case | PrgSC = A PM = R | <ul style="list-style-type: none"> Project Charter | | | | | |
| <p>Step 4</p> | <p>4.0 PM2 Planning phase</p> | | | | | | |
| <ul style="list-style-type: none"> Project Manager (PM) Business Manager (BM) Project Owner (PO) | <p>4.1 Project handbook</p> <p>The Project Handbook summarises the project objectives and documents the selected approach for achieving the project goals. It documents the Critical Success Factors (CSFs), defines the key controlling processes, the conflict resolution and escalation procedure, policies and rules, and the project mindsets. The Project Handbook also documents the project governance roles and their responsibilities and defines the plans necessary for managing the project as well as any methodology-tailoring decisions.</p> <p>The following tasks must be executed in this phase:</p> <ol style="list-style-type: none"> The PM prepares the Project Handbook that must include the Business implementation plan, Communication plan, Organizational changes, and Risk Management Plan The Project Manager asks for the support of Business relationship Manager for preparing the Communication plan, and Digital Transformation Experts for preparing the Risk Management Plan The PM must also involve the BM in defining the document's key elements The PO assess the Project Handbook. If the assessment is positive, the process continues. <table border="1" data-bbox="528 1794 1463 1939"> <thead> <tr> <th data-bbox="528 1794 863 1832">Input</th> <th data-bbox="863 1794 1114 1832">RACI</th> <th data-bbox="1114 1794 1463 1832">Output</th> </tr> </thead> <tbody> <tr> <td data-bbox="528 1832 863 1939"> <ul style="list-style-type: none"> Business case and Project Charter </td> <td data-bbox="863 1832 1114 1939"> PO = A PM = R </td> <td data-bbox="1114 1832 1463 1939"> <ul style="list-style-type: none"> Project Handbook </td> </tr> </tbody> </table> | Input | RACI | Output | <ul style="list-style-type: none"> Business case and Project Charter | PO = A PM = R | <ul style="list-style-type: none"> Project Handbook |
| Input | RACI | Output | | | | | |
| <ul style="list-style-type: none"> Business case and Project Charter | PO = A PM = R | <ul style="list-style-type: none"> Project Handbook | | | | | |



| | <ul style="list-style-type: none"> • Planning Kick-off Minutes of Meeting (MoM) | | | | | | | | |
|---|---|--|--|-------|------|--------|--|-------------------|--|
| <ul style="list-style-type: none"> - TS A&S - TS TP - TS PMO - Project Manager (PM) - Project Steering Committee (PSC) | <p>4.2 Project Work Plan</p> <p>The Project Work Plan establishes a basis on which to estimate the project's duration, calculate the required resources, and schedule the work. The Project Work Plan should be baselined but also kept up-to-date during the life of the project and capture all project related work as identified during planning phase or emerged during the executing phase (e.g. risks, issues, corrective actions etc.)</p> <p>The following tasks are executed:</p> <ol style="list-style-type: none"> a) The PM, based on high level requirements contained in the Business Case and Project Charter, prepares and coordinates all the activities in the development of the Project Work Plan. b) PSC assesses the Project Work Plan. If the assessment is positive, the process continues. <p>In this phase is not foreseen to perform any detail business analysis and low level system design.</p> <table border="1" data-bbox="528 931 1461 1084"> <thead> <tr> <th>Input</th> <th>RACI</th> <th>Output</th> </tr> </thead> <tbody> <tr> <td> <ul style="list-style-type: none"> • <u>Business case</u> • <u>Project Charter</u> </td> <td> PSC = A PM = R </td> <td> <ul style="list-style-type: none"> • <u>Project Work Plan</u> </td> </tr> </tbody> </table> <p>Ready for Executing (RfE)</p> <p>This is the second phase gate.</p> <p>The PM assesses whether the project is ready to commence the Executing Phase. If the project is ready to move on to Executing phase, PM formalizes the new status of the project.</p> | | | Input | RACI | Output | <ul style="list-style-type: none"> • <u>Business case</u> • <u>Project Charter</u> | PSC = A PM = R | <ul style="list-style-type: none"> • <u>Project Work Plan</u> |
| Input | RACI | Output | | | | | | | |
| <ul style="list-style-type: none"> • <u>Business case</u> • <u>Project Charter</u> | PSC = A PM = R | <ul style="list-style-type: none"> • <u>Project Work Plan</u> | | | | | | | |
| <p>Step 5</p> | <p>5.0 PM2 Executing phase</p> | | | | | | | | |
| <ul style="list-style-type: none"> - Project Owner (PO) - Project Manager (PM) - Business Relationship Management (BRM) | <p>The Next steps must be executed according to the Project Plan. The Project Manager has the responsibility of monitoring the design and implementation of all the steps described in the executing phase of the project and to escalate issues/problems in case of deviations. Business process, Organisational changes, Communication, Risk Management, Training, and IT application implementation are parts of a Business Transformation process, and they must be performed all together.</p> <p>5.1 Business Processes design and implementation</p> <p>Processes are what the organisation does and transforming organisations requires changing the organisation's processes.</p> <p>This aspect of business processes design and implementation is strictly correlated with the IT transformation, which includes design, implementation, roll-out and deployment of new applications.</p> | | | | | | | | |



| | <p>This step focuses on design and implementation of the new business process that must be supported by the new application.</p> <p>The following tasks must be executed in this phase:</p> <ol style="list-style-type: none"> The PM coordinates all the activities related to the design and implementation of (an) improved Business process as per the Project Handbook with the support of PCT and with the involvement of the PO and GPS in their role as Process Experts. The PM informs the PO on the progress, on any problems encountered and prepares mitigation actions. <p>The Business Analyst Body of Knowledge (BABOK) must be adopted as a reference framework to prepare the Business requirements, Use Case specifications, and the Business Process design.</p> <table border="1" data-bbox="528 846 1465 1106"> <thead> <tr> <th>Input</th> <th>RACI</th> <th>Output</th> </tr> </thead> <tbody> <tr> <td>Business implementation plan (ref. Project Handbook)</td> <td>PO = A PM = R BRM = R</td> <td>Design of the proposed Business process according to the BABOK framework methodology</td> </tr> </tbody> </table> | Input | RACI | Output | Business implementation plan (ref. Project Handbook) | PO = A PM = R BRM = R | Design of the proposed Business process according to the BABOK framework methodology |
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| Input | RACI | Output | | | | | |
| Business implementation plan (ref. Project Handbook) | PO = A PM = R BRM = R | Design of the proposed Business process according to the BABOK framework methodology | | | | | |
| <ul style="list-style-type: none"> - Project Owner (PO) - HuCap - Project Manager (PM) | <p>5.2 Organizational change implementation</p> <p>The following tasks must be executed in this phase:</p> <ol style="list-style-type: none"> The PM monitors all the activities related to the implementation of the proposed organisational changes with the support of HUCAP and PO The PM informs the PO of the progress, of any problems encountered and prepares proposed mitigation actions <p>The PROSCI Project Change Triangle Analysis must be adopted as a framework to prepare and implement the organisational change plan to support the Business Transformation Initiative.</p> <table border="1" data-bbox="528 1592 1465 1852"> <thead> <tr> <th>Input</th> <th>RASCI</th> <th>Output</th> </tr> </thead> <tbody> <tr> <td>Organisational changes plan (Ref. Project Handbook)</td> <td>PO = A PM = R HuCAP= R</td> <td>Implementation of the new design. New roles and responsibilities to support the proposed new design will be created.</td> </tr> </tbody> </table> | Input | RASCI | Output | Organisational changes plan (Ref. Project Handbook) | PO = A PM = R HuCAP= R | Implementation of the new design. New roles and responsibilities to support the proposed new design will be created. |
| Input | RASCI | Output | | | | | |
| Organisational changes plan (Ref. Project Handbook) | PO = A PM = R HuCAP= R | Implementation of the new design. New roles and responsibilities to support the proposed new design will be created. | | | | | |
| <ul style="list-style-type: none"> - Project Manager (PM) - Project Owner (PO) | <p>5.3 Communication implementation</p> <p>Ineffective communication and lack of stakeholder involvement are often cited as factors that contribute to transformational failure.</p> | | | | | | |



| | <p>The following tasks must be executed in:</p> <ul style="list-style-type: none"> a) The PM coordinates all the activities related to the implementation of the Communication Plan with the support of HUCAP and if needed also TS (TP and A&S). b) The PM informs the PO of the progress, of any problems encountered and prepares proposed mitigation actions <table border="1" data-bbox="528 477 1465 629"> <thead> <tr> <th>Input</th> <th>RACI</th> <th>Output</th> </tr> </thead> <tbody> <tr> <td>Communication plan (Ref. Project handbook)</td> <td>PO = A PM = R</td> <td>Design and implementation of the <u>Communication plan</u></td> </tr> </tbody> </table> | Input | RACI | Output | Communication plan (Ref. Project handbook) | PO = A PM = R | Design and implementation of the <u>Communication plan</u> |
|---|--|--|------|--------|--|------------------|--|
| Input | RACI | Output | | | | | |
| Communication plan (Ref. Project handbook) | PO = A PM = R | Design and implementation of the <u>Communication plan</u> | | | | | |
| <ul style="list-style-type: none"> - Project Manager (PM) - Project Owner (PO) | <p>5.4 Risk management implementation</p> <p>During the PM² executing phase, it's necessary to take into consideration:</p> <ul style="list-style-type: none"> • Poor skills of the project team • High complexity of integration • Lack of stakeholder's commitment • Insufficient scope and motivation management • Organizational changes partially or not implemented • Technology risks • Competence shortcomings • Conflicts • Inadequate change readiness <p>The following tasks must be executed in this phase:</p> <ul style="list-style-type: none"> a) The PM coordinates all the activities related to the definition and implementation of the Risk management Plan as per Project handbook with the support of the BM b) The PM informs the PO of the level of risks and prepares mitigation actions <table border="1" data-bbox="528 1346 1465 1570"> <thead> <tr> <th>Input</th> <th>RACI</th> <th>Output</th> </tr> </thead> <tbody> <tr> <td>Risk Management plan (Ref. Project Handbook)</td> <td>PO = A PM = R</td> <td>• Definition and Implementation of the <u>Risk Management plan</u></td> </tr> </tbody> </table> | Input | RACI | Output | Risk Management plan (Ref. Project Handbook) | PO = A PM = R | • Definition and Implementation of the <u>Risk Management plan</u> |
| Input | RACI | Output | | | | | |
| Risk Management plan (Ref. Project Handbook) | PO = A PM = R | • Definition and Implementation of the <u>Risk Management plan</u> | | | | | |
| | <p>5.5 Project Implementation (V-Model)</p> <p>No matter the type of the project (BESPOKE, Semi-Agile or COTS), the following steps must be performed:</p> <ul style="list-style-type: none"> • Architecture and Information Security design • Application Implementation • Technical integration testing (Verification) • User Acceptance Testing (Validation) | | | | | | |
| <ul style="list-style-type: none"> - Project Manager (PM) - Project Core Team (PCT) | <p>5.5.1 Architecture and Information security design</p> <p>Based on the Requirements Analysis as defined the planning phase of PM², the system is designed at the functional and non-functional level. This must also include:</p> | | | | | | |



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| <ul style="list-style-type: none"> - Business Analyst (BA) - Architecture & Solution (A&S) - Information Security Officer (ISO) - Data Protection Officer (DPO) - Business Continuity Officer (BCO) | <ul style="list-style-type: none"> • The definition of functions, user interface elements, including dialogs and menus, workflows, and data structures • The standards and the models for data collection, storage, and data management • Logical and physical data assets • Technology infrastructure • The Business Continuity and Disaster Recovery architecture design • The Software Configuration Lifecycle management • The Release Software and Deployment application management in the prod environment • The User Access Management policies definition • The Security Measures as per Security Plan in place. <p>The next step is about the low-level design of the specific components. Each component is described in detail, including the internal logic to be implemented, a detailed interface specification with the API description, and database tables, if any. Component tests must be prepared.</p> <p>Information Security Design and implementation Security and Data Protection by design is an approach to cybersecurity that enables an organization to automate its data security controls and formalize the design of its infrastructure so it can build security into its IT management processes.</p> <p>The Information Security Design is a document which objective is to provide an overview of the information security requirements for an IT system and to describe the information security risks relevant to the system and the security control in place or planned for meeting those requirements.</p> <p>Information Security is strictly related to the information availability, integrity, and confidentiality. If the application is defined as critical in terms of Business Impact Analysis (BIA), the Business Continuity and Disaster Recovery design and implementation plan must be considered in this deliverable in terms of resources and technology infrastructure.</p> <p>The Application security architecture by design must include:</p> <ul style="list-style-type: none"> • Data Protection Impact Analysis (DPIA) • Risks Assessment • Verify compliance • Access management control • Authentication policy • Architecture security by design <p>The following tasks must be executed:</p> |
|--|--|



| | <ul style="list-style-type: none"> • The PM coordinates all the activities related to the Architecture and Security design with the technical support of the PCT • The PM submits the Architecture Design to the A&S team for the quality review • The A&S team with the support of ISO and DPO assess the Architecture and Security design. If the design passes the assessment, the process continues. <p>The TOGAF 9 (The Open Group Architecture Framework) must be adopted as a reference framework to prepare the Architecture design (Data, Application, and Technology Architecture).</p> <p>The ITIL (Information Technology Infrastructure Library) 4 must be adopted as a reference framework for Business Continuity Disaster Recovery (BCDR) process, Service Catalogue Management, and other processes correlated to this phase.</p> <table border="1" data-bbox="528 768 1465 1216"> <thead> <tr> <th>Input</th> <th>RACI</th> <th>Output</th> <th>Quality review</th> </tr> </thead> <tbody> <tr> <td> <ul style="list-style-type: none"> •Business Requirements specifications •Validation criteria •Acceptance test cases </td> <td> PM = A PCT = R </td> <td> <ul style="list-style-type: none"> •Architecture and Information Security Design •Verification criteria •Integration test cases </td> <td> A&S = A/R ISO = R DPO = R BCO = R </td> </tr> </tbody> </table> | Input | RACI | Output | Quality review | <ul style="list-style-type: none"> •Business Requirements specifications •Validation criteria •Acceptance test cases | PM = A PCT = R | <ul style="list-style-type: none"> •Architecture and Information Security Design •Verification criteria •Integration test cases | A&S = A/R ISO = R DPO = R BCO = R |
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| <ul style="list-style-type: none"> - Project Manager (PM) - Project Core Team (PCT) - CORSER | <p>5.5.2 Application development and implementation</p> <p>During the application development and implementation step, these aspects shall be completed:</p> <ol style="list-style-type: none"> Develop the Application package, or a Cloud solution or a Semi-Agile solution Perform release software management Perform master data cleansing and conversion Test solution with a real-world pilot Confirm pilot validates business case Evaluate Enhancements required prior to implementation Prepare for implementation Incident Management Tool adapted, and incident types identified with problem management and escalation procedures (optional) Service Catalogues amended Standard changes defined | | | | | | | | |



| | <p>The PM coordinates all the activities related to the implementation and keeps the project plan and registry updated and informs the PSC on the project status.</p> <p>The V-Model must be adopted as the reference framework for the Application development and implementation phase.</p> <table border="1" data-bbox="523 479 1469 779"> <thead> <tr> <th data-bbox="523 479 855 517">Input</th> <th data-bbox="855 479 1163 517">RACI</th> <th data-bbox="1163 479 1469 517">Output</th> </tr> </thead> <tbody> <tr> <td data-bbox="523 517 855 779"> <ul style="list-style-type: none"> • Architecture and Information Security Design • Verification criteria • Integration test cases </td> <td data-bbox="855 517 1163 779"> PM = A PCT = R </td> <td data-bbox="1163 517 1469 779"> <ul style="list-style-type: none"> • Application package • Cloud Solution • Semi-Agile solution </td> </tr> </tbody> </table> | Input | RACI | Output | <ul style="list-style-type: none"> • Architecture and Information Security Design • Verification criteria • Integration test cases | PM = A PCT = R | <ul style="list-style-type: none"> • Application package • Cloud Solution • Semi-Agile solution | | |
|---|--|--|----------------|--------|---|--|--|--|-----------|
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| <ul style="list-style-type: none"> - Project Manager (PM) - Project Core Team (PCT) - Architecture & Solutions (A&S) | <p>5.5.3 Technical Integration testing (verification phase)</p> <p>The technical integration test is expected to have very extensive coverage checking also the entire functionality and the communication of the application under development with external applications. Most of the compatibility issues can be uncovered during the Technical Integration testing. Depending on the project complexity additional specific security test could be necessary e.g.:</p> <ul style="list-style-type: none"> • Penetration test • Multilevel authentication test • Business logic test • Remediation plan <p>The following tasks must be executed:</p> <ol style="list-style-type: none"> a) The PM coordinates all the activities related to the execution of the Technical Integration testing with the technical support of the PCT. b) The A&S team with the support of ISO and DPO assess the results of the Technical Integration Testing. If the assessment is positive, the process continues. <p>The V-Model is the reference framework to adopt for the Technical Integration Testing phase.</p> <table border="1" data-bbox="523 1648 1469 1982"> <thead> <tr> <th data-bbox="523 1648 778 1727">Input</th> <th data-bbox="778 1648 983 1727">RACI</th> <th data-bbox="983 1648 1233 1727">Output</th> <th data-bbox="1233 1648 1469 1727">Quality review</th> </tr> </thead> <tbody> <tr> <td data-bbox="523 1727 778 1982"> <ul style="list-style-type: none"> • Application Package • Verification criteria • Integration test cases </td> <td data-bbox="778 1727 983 1982"> PM = A PCT = R </td> <td data-bbox="983 1727 1233 1982"> Technical Integration testing report that includes the lists of all planned test cases and last execution result </td> <td data-bbox="1233 1727 1469 1982"> A&S = A/R </td> </tr> </tbody> </table> | Input | RACI | Output | Quality review | <ul style="list-style-type: none"> • Application Package • Verification criteria • Integration test cases | PM = A PCT = R | Technical Integration testing report that includes the lists of all planned test cases and last execution result | A&S = A/R |
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| <ul style="list-style-type: none"> - Project Manager (PM) - Project Core Team (PCT) - Project Owner (PO) - Business Implementation Group (BIG) - Architecture & Solutions (A&S) | <p>5.5.4 User Acceptance Test (validation phase)</p> <p>User Acceptance Testing (UAT) is a type of testing performed by the end user to verify/accept the application before moving to the production environment. UAT is performed in the final phase of testing after functional, and technical integration test is done.</p> <p>The following tasks must be executed:</p> <ol style="list-style-type: none"> a) The PM coordinates all the activities related to the execution of the User Acceptance Test with the technical support of the PCT. b) The PO with the support of BIG assesses the results of the User Acceptance Testing. If the result of the assessment is positive, the process continues. <p>The V-Model is the reference framework to adopt for the User Acceptance Test phase. The Business Analyst Body of Knowledge (BABOK) must be also adopted as a reference framework because it manages the lifecycle of a requirements until its final validation in test.</p> <table border="1" data-bbox="523 891 1469 1227"> <thead> <tr> <th>Input</th> <th>RACI</th> <th>Output</th> <th>Quality review</th> </tr> </thead> <tbody> <tr> <td> <ul style="list-style-type: none"> •Application package •Validation criteria •Acceptance test cases </td> <td> PM = A PCT = R </td> <td> <ul style="list-style-type: none"> •UAT validation •validation criteria •test cases execution report </td> <td> PO = A BIG = R </td> </tr> </tbody> </table> | Input | RACI | Output | Quality review | <ul style="list-style-type: none"> •Application package •Validation criteria •Acceptance test cases | PM = A PCT = R | <ul style="list-style-type: none"> •UAT validation •validation criteria •test cases execution report | PO = A BIG = R |
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| <ul style="list-style-type: none"> - Project Manager (PM) - Project Owner (PO) - Business Implementation Group (BIG) | <p>5.6 Training implementation</p> <p>Competence and skills are basic elements to be successful in business transformation. Once competence gaps and training requirements have been identified, a training plan it's necessary.</p> <p>The following tasks must be executed :</p> <ol style="list-style-type: none"> a) The PM coordinates all the activities related to the execution of the training plan with the technical support of the PCT. b) The PO with the support of the BIG assesses the results of the training. If the assessment result is positive, the process continues otherwise additional training sessions must be organised to fill the knowledge gap(s). <table border="1" data-bbox="523 1697 1469 1850"> <thead> <tr> <th>Input</th> <th>RACI</th> <th>Output</th> <th>Quality review</th> </tr> </thead> <tbody> <tr> <td> <ul style="list-style-type: none"> •Training plan </td> <td> PO = A PM = R </td> <td> <ul style="list-style-type: none"> •Training execution </td> <td> BIG = R </td> </tr> </tbody> </table> | Input | RACI | Output | Quality review | <ul style="list-style-type: none"> •Training plan | PO = A PM = R | <ul style="list-style-type: none"> •Training execution | BIG = R |
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| <p>Exit criteria</p> | <p>Rollout plan</p> <ul style="list-style-type: none"> • Go/No-Go checklist for rollout readiness: DPO and ISO confirm | | | | | | | | |



| | <p>Data Protection and Information Security risks under control</p> <ul style="list-style-type: none"> • Configuration Review successful • Functional Test Successful (UAT) <p>Rollout Communication Plan agreed with PCT and BO.</p> | | | |
|--|--|--------|------|--------|
| | <p>Go-live checklist</p> <ul style="list-style-type: none"> • Go/No-Go checklist fulfilled • User Access Management Procedure completed • Data Reconciliation Confirmed by PM and BO • Trainings and Change management completed successfully • Policies completed • Communication plan fulfilled <p>Hypercare planned and resources available</p> | | | |
| | <p>Digital Workplace confirms the following checklist:</p> <ul style="list-style-type: none"> • Solution can be operated and supported • Business Continuity Disaster Recovery (BCDR) including configuration changes alignment to DR site • Software Configuration Management procedures defined • Possible additional effort during rollout planned • No subsidizing between Run-IT and the project • Number of defects identified are below the acceptable criteria threshold • User Access Management Procedure defined <p>Security Measures as per Security Plan in place</p> | | | |
| | <p>End-user training performed</p> | | | |
| | <p>Business process and organization changes implemented</p> | | | |
| | <p>Communication plan performed</p> | | | |
| | <p>Risk mitigations and monitoring performed</p> | | | |
| | <p>Project benefits review and evaluated</p> | | | |
| <ul style="list-style-type: none"> - Project Steering Committee (PSC) - Project Owner (PO) | <p>PSC decision for Go/no-Go live</p> <p>All previous aspects must be considered during the decision phase before taking the application into production.</p> <table border="1" data-bbox="523 1951 1209 1986"> <thead> <tr> <th data-bbox="523 1951 767 1986">Input</th> <th data-bbox="767 1951 948 1986">RACI</th> <th data-bbox="948 1951 1209 1986">Output</th> </tr> </thead> </table> | Input | RACI | Output |
| Input | RACI | Output | | |



| | | | | |
|--|---|---------|----------------------------|--|
| | <ul style="list-style-type: none"> • UAT • Issue log • Security Plan • Roll-out Run book • Roll-back Run book • Backup and DR ready • Other documents requested by PSC. | PSC = A | PSC approves Go/No-go live | |
| - Service Manager (SM) | <p>5.7 Transition to Operation</p> <p>Operational checklist confirmed by EFSA Service Manager:</p> <ul style="list-style-type: none"> • CAB approved the project go-live • Incident Management Tool adapted (if needed) • Incident types identified with problem management and escalation procedures • Service Catalogues amended • Standard changes defined • Monitoring system ready • Release management procedures agreed <p>Before planning the transition to operations it's necessary that all the tasks highlighted in the previous steps must be verified and implemented.</p> <p>In case of go-live decision, the process to be followed is described in the in SOP 049 Deliver Services.</p> | | | |
| - | <p>Ready for Closing (RfC)</p> <p>The PM assesses whether the goals of the Executing phase have been achieved, verifies that all planned activities are carried out, that all requirements have been met, and that the project's output have been fully delivered. The PM is also responsible for ensuring that the PO accepts the deliverables. If the project is ready to move on to Closing phase, PM formalizes the new status of the project.</p> | | | |
| Step 6 | 6.0 PM2 Closing phase | | | |
| - Project Manager (PM) - Project Owner (PO) | <p>6.1 Project closing</p> <p>During the Closing Phase, the project's activities are completed, the project's final state is documented, and the finished deliverables are officially transferred to the PO.</p> <p>The following tasks must be executed for closing the project:</p> <p>a) The PM organizes the meeting with PCT, BM, and PO and setup the agenda with points to be discussed related to the project's closing.</p> <p>b) The PM prepares the Project-End report that also must contain all these aspects:</p> <ul style="list-style-type: none"> • Lesson learned • Complete handover (BAU) | | | |



| | |
|--|---|
| | <ul style="list-style-type: none">• Publish and communicate the benefit achieved and promised in the Business Transformation Initiative step• Verify compliance and performance after implementation• Plan additional benefit realization• Other aspects as described in the PM2 closing phase methodology <p>c) The PM ensures that all project deliverables have been accepted by the relevant stakeholders and that the PO has approved the project</p> <p>d) At this stage, the project is officially closed and that brings project on the next step: "Transition to Operation"</p> |
| | Following SOPs in the process:n/a |



ANNEXES

SOP Processes overview

The EPA macroprocesses of Enterprise Architecture (ref. EPA 13.1), Transform EFSA (ref. EPA 13.2) and Continuous improvement (ref. EPA 13.3) have been considered while defining the Standard Operating Procedures (SOPs). To better identify the interrelations with the EPA 3.0. processes and the other Units processes, the TS+Corser SOPs can be grouped and interrelated in 3 macro scenarios:

- Technological Advice (ref. EPA 13.1 Enterprise Architecture)
- Project Implementation (ref. EPA 13.2 Innovation Implementation)
- Compliance and Performance Improvement (ref. EPA 13.3 Continuous improvement)
- Digital Services (ref. EPA 5.6)

The figure below provides an overview of the SOPs and their interrelationships

