



TRANSITIONING TECHNOLOGY FROM THE LABORATORY TO THE FIELD

Process and Considerations for the Forensic Sciences

2019

ANZPAA
Australia New Zealand
Policing Advisory Agency



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PURPOSE

This document describes a process for transitioning forensic science technology from the laboratory to the field, including crime scenes. The key considerations for a successful transition are provided for each step of the process. Individuals or teams leading the change to in-field analysis of evidence can use this document as a resource to help ensure that the new in-field technology meets end user requirements. The document may assist in the development of a business case for change or for the design of a robust implementation project plan.

INTRODUCTION

This document is the culmination of learnings and experiences from forensic science service providers across Australia and New Zealand and has been developed in response to the growing demand for rapid analysis in the field, at the point of response.

Conventional forensic analysis has been restricted to the laboratory due to the size, sensitivity and cost of available instrumentation. However, recent technological innovation has led to the development of portable, compact, robust, low cost, smart and network ready devices ideal for use in the field. The potential benefits of using this technology in the field include:

- ▶ Provision of rapid analytical results to expedite decision by forensic examiners and law enforcement personal at the point of response.
- ▶ Evidence can be analysed in situ in its most original state, reducing the risk that evidence is analysed following damage, deteriorating or contamination possibly due to handling, transportation and storage.
- ▶ Automated analysis and machine learning embedded devices enable operation by non-scientific personal.

It is recognised that in order to reach the point at which the processes described within this document can be utilised, organisational business models must be conducive to implementing service innovation in the field. Jurisdictional policies and business strategies are outside of the scope of this document.

The transition process outlined in this document focuses on assessing if a change in service delivery through the transition of laboratory processes to the field is beneficial, and provides considerations for piloting, implementing and evaluating the in-field process to maximise benefit realisation. It is important that this is considered in the context of entire end-to-end (E2E) process.

A process for defining end user requirements is out of scope of this document. These requirements should be defined prior to initiating the process for transitioning technology to the field.

PROCESS OVERVIEW

The diagram at *Figure 1* depicts the four phases of the process for transitioning laboratory-based technology to the field at the point of response. Each phase of the process is explained in subsequent sections of this document.

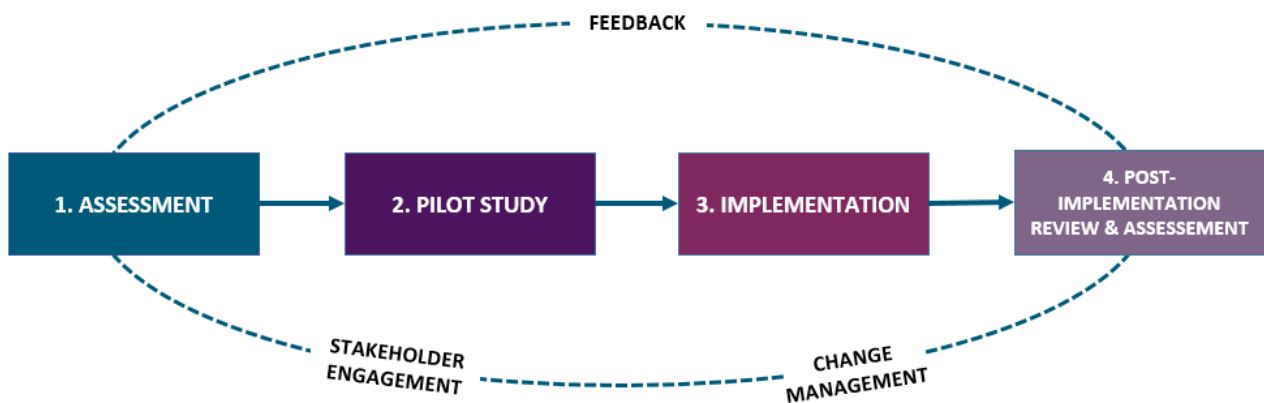


Figure 1. Process for Transitioning Laboratory-Based Technology to the Field

Stakeholder engagement and change management are critical to the success of any process modification and should be continually considered and reviewed across all phases of the transition process as detailed below.

STAKEHOLDER ENGAGEMENT

Identification of key stakeholders should commence at the assessment phase and be reviewed throughout the transition process. Consultation should be continual and frequent to ensure that the transition is smooth, the technology is implemented appropriately for the intended purpose and all opportunities for improvement are identified and documented.

The stakeholder engagement strategy will vary depending on the scale of transition, degree of change and end user requirements. At a minimum, the following stakeholders should be engaged:

▶ *End Users*

An end user is defined as any person who uses or intends to use the information derived from the implemented technology. In the forensic environment this will most commonly be police officers and the justice system in the relevant jurisdiction. This could also include health agencies, coronial staff, forensic personnel from different disciplines or data analysts (business improvement/intelligence).

▶ *Operational Staff*

Operational staff may include subject matter experts (including those who currently perform the laboratory-based analysis) or personnel who will be using or training other personnel to use the technology. This may require cross-jurisdictional or cross-agency collaboration if traditional laboratory-based technology is being transitioned to the point of response and responsibility for operating the device is being transferred from scientific to policing personnel.

A mechanism for feedback should be established during the planning stages and carried through implementation to review and assessment. The feedback mechanism may provide avenues for continuous feedback or request feedback from stakeholders at defined intervals over the four phases. A process for analysing and acting upon feedback should be considered.

CHANGE MANAGEMENT

Technology implementation may occur through the development and delivery of a formalised project plan or by an informal process that draws upon project management principles. Regardless of the strategy, the implementation will result in a change in how business is conducted.

Managing the human element of this change is critical to its success. Engagement with key stakeholders is one component to change management. In addition to this, creating an organisational culture where feedback, both positive and negative, are actively encouraged will create a sense of organisational ownership and drive improvement in a forward direction.

1. ASSESSMENT

The Assessment Phase is the first step in the transition process. Once a clear problem or opportunity has been identified, the current state should be mapped to enable identification of the components that would need to be retained, modified or removed if the process was transitioned from the laboratory to the field. Mapping should focus on establishing how evidence currently flows and how it would flow through the laboratory and field systems in order to identify barriers to implementing a service at the point of response. The mapping will also assist in identifying any gaps in capability that might result in the service not meeting end user requirements. The assessment should consider the end-to-end process. Key considerations for the mapping process are outlined in *Figure 2* and detailed below.

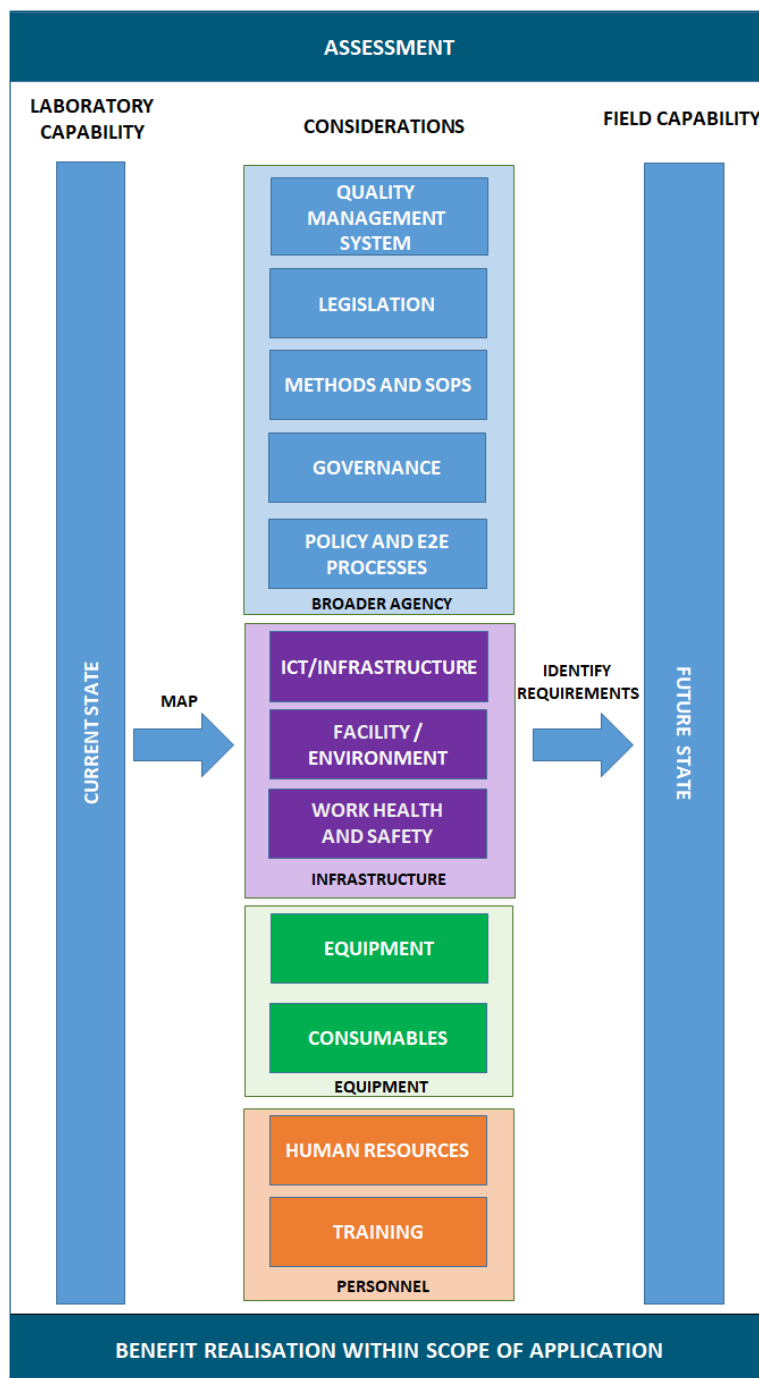


Figure 2. Assessment Phase

BROADER AGENCY

Forensic science service delivery operates within the confines of legislation, accreditation and certification. To ensure systems operate within these confines, policies and processes are developed and adhered to. Changes to systems may therefore have broader implications that should be considered during the Assessment Phase. A collaborative approach with all agencies involved in the end-to-end process or that are likely to be affected by the proposed transition, will reduce the potential for unforeseen flow-on effects.

Considerations include:

- ▶ *Will the transition result in a transfer of risk and/or responsibility? If yes, how will this be managed?*
- ▶ *Who has ownership of and responsibility for the device and the data generated by the device?*
- ▶ *Does current legislation, including Privacy and Ethics Acts, permit the transition and access to the information required to fully utilise the device?*
- ▶ *Is the quality management system in use in the laboratory applicable to the field?*
- ▶ *How can the quality management system best cover the field environment?*
- ▶ *What Methods and Standard Operating Procedures (SOPs) require updating or development to document the change in process?*
- ▶ *How does the new technology and environment of operation fit within the end-to-end process? Are there any changes required to utilise the technology within the end-to-end process?*
- ▶ *What is the intended use of the field-generated results and how will any level of confidence in the result be communicated?*
- ▶ *Will the in-field device consume all of the evidence or can some be preserved for further laboratory-based testing, if required?*
- ▶ *Will in-field analysis reduce the demand for laboratory services? What impact or opportunities for future laboratory capabilities may be created as a result of the transition?*

INFRASTRUCTURE

The laboratory is a controlled environment backed by infrastructure and Information Communication Technology (ICT) systems. Consideration should be given to both the impact on the current environment and infrastructure and ICT requirements at the point of response during the Assessment Phase.

Considerations include:

- ▶ *What are the environmental/facility requirements for operating the device?*
- ▶ *Will environmental factors impact on the ability of the device to achieve end user requirements? Would the establishment of new in-field facilities (e.g. a mobile laboratory) be fit for purpose?*
- ▶ *Does the device generate auditable data required for forensic case management? How will the data generated by the device be integrated into existing systems, including ICT (e.g. connectivity and compatible file formats)?*
- ▶ *What are the requirements for storage of the in-field device? Does current infrastructure fulfil these requirements?*
- ▶ *Are there any requirements for reach back to database or interpretation expertise? How will these best be implemented?*
- ▶ *What are the requirements for data storage of results? How will this be implemented?*
- ▶ *What are the requirements for data security? How will this be implemented and audited?*

- ▶ *What modifications to current ICT systems and infrastructure are required to aid in a smooth transition to in-field analysis?*
- ▶ *What are the Work Health and Safety considerations for operating the equipment? Are there additional considerations for using the equipment in the field which were not considerations for laboratory use?*

EQUIPMENT

Different techniques, and even different devices utilising the same foundational technology, will provide various opportunities for forensic science service delivery. If a specific field-deployable device has been identified, performing a comparison of the mapped current state to the proposed future state will establish the requirements for transition. If several field-deployable devices are being investigated, an environmental scan as part of the Assessment Phase may assist in identifying which technology/device is fit for purpose, prior to this comparison. The following questions have been developed to aid in this comparison:

- ▶ *Is the equipment used in the laboratory able to be transitioned to the field? If not, is similar technology available in a portable/transportable device and is the device able to produce results that fulfil end user requirements? Is a new type of technology available that could enable a useful result to be generated in the field?*
- ▶ *What is the cost of the field device, including ongoing operation, maintenance and replacement costs, and how does this differ to the laboratory? Can this be accommodated within the budget constraints?*
- ▶ *What are the performance parameters for the current laboratory-based system? Are these same parameters appropriate for in-field analysis?*
- ▶ *Has another forensic science service provider, or another industry, answered the problem or question opportunity? Should a national or collaborative approach to this transition be considered?*
- ▶ *Are the consumables utilised in the laboratory appropriate for use in the field? If different consumables are required, what is the price differential?*
- ▶ *What new analysis opportunities might be enabled by the field technology?*
- ▶ *How does the device integrate within the end-to-end process? Are any changes required?*

PERSONNEL

Operational requirements for both the laboratory and proposed field capabilities should be analysed and compared. This may include resources and training for personnel who will operate the device, analyse the data generated through the analysis, report the results, and manage processes and staff.

Considerations include:

- ▶ *What human resources are currently required in the laboratory and what resources will be required for the new process in the field?*
- ▶ *What resourcing change management is required to affect the implementation of the technology? How will this be managed?*
- ▶ *Do current training programs cover the knowledge and skills required, including Work Health and Safety requirements, for the new process or will new modules need to be created?*
- ▶ *What other training/information awareness regarding the new processes will be required (considering current staff within the laboratory, staff conducting the new processes, end users of the service, investigators, the justice system etc.)?*

BENEFIT REALISATION WITHIN SCOPE OF APPLICATION

In addition to system mapping, the Assessment Phase should include an analysis of the current (laboratory) and potential future (field) Scope of Application (see *Figure 3*). The benefits, limitations, cost, output and turn-around times (TAT) for the current process should be compared to the proposed transition. A fit for purpose overlay should be applied, as the laboratory and field services may have different functions (e.g. evidentiary versus investigative).

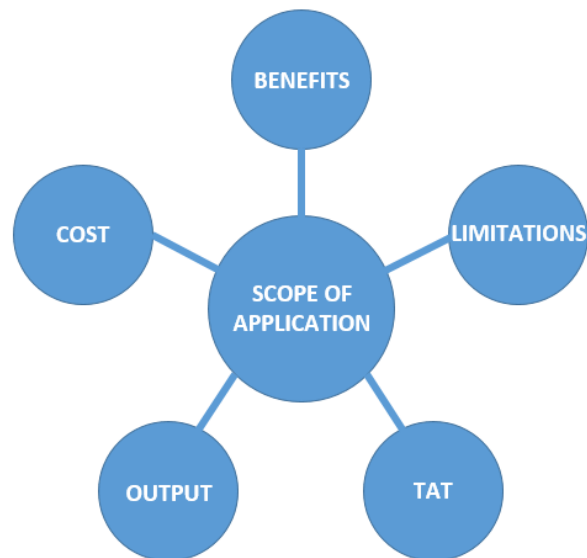


Figure 3. Scope of Application Assessment

The comparison of the current and future states through mapping and assessing the Scope of Application will give insight into the potential benefits of the transition. If the expected benefits are not clear as a result of the mapping process, the proposed plan for the transition can be:

- ▶ modified and the Assessment Phase repeated until benefits are identified
- ▶ placed on hold until blockers inhibiting the benefits from being realised can be removed
- ▶ abandoned if the blockers to transition significantly outweigh the benefits expected to be realised through in-field analysis.

2. PILOT STUDY

Following the identification of intended benefits during the Assessment Phase, a pilot study should be developed and commenced. The purpose of a pilot study is to evaluate the feasibility of the proposed system against end user requirements, as determined prior to the transition process. The pilot phase also enables unknown factors in success and unintended consequences to be identified and evaluated. It should therefore test the end-to-end processes of the systems. The extent of the trial should be driven by the size and scope of the technology implementation; however, a well-executed pilot study should consider the steps described in *Figure 4* below.

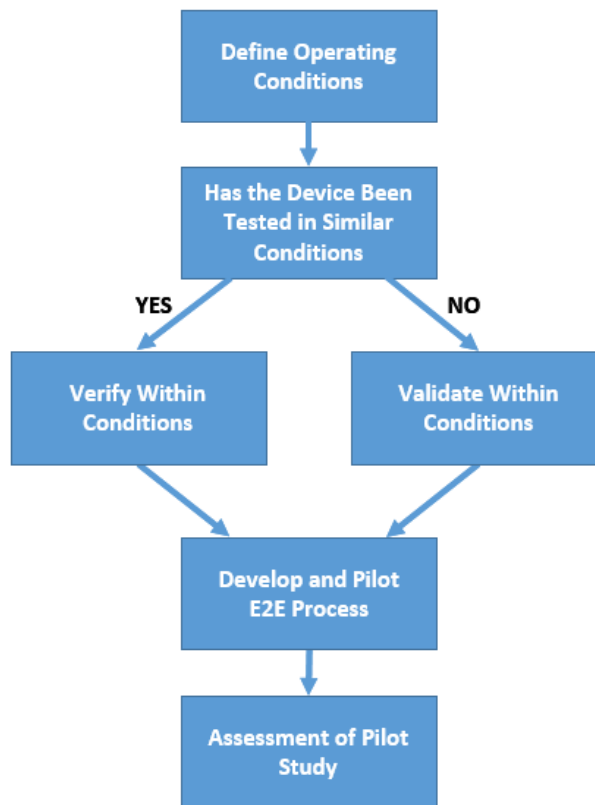


Figure 4. Pilot Study Flow Diagram

DEFINE OPERATING CONDITIONS

The scope of testing in the field should be defined and documented. The scope should consider the following:

- ▶ technical specifications of the device
- ▶ conditions of operation, including environment, if applicable
- ▶ types of evidence suitable for in-field analysis
- ▶ range in quantity of the sample type(s) to be examined
- ▶ how results will be used (e.g. evidentiary or investigative, presumptive or confirmatory)
- ▶ performance parameters
- ▶ when should samples be analysed at the point of response (in-field criteria) versus diverted to the laboratory (laboratory criteria).

VALIDATION AND VERIFICATION

Evaluation of the field-deployable device should be guided by the scope of forensic testing. The device should be validated/verified under the intended operational conditions; however, initial assessment of the device may be performed in a controlled environment to ensure it is able to meet manufacturer specifications without environmental influences. Limitations or restrictions to the use of the technology should be identified through this process and should be considered during process development.

A risk based approach to validation/verification should be utilised. The validation/verification should be fit for purpose and robust enough to ensure results meet the determined end user requirements without being unnecessarily onerous. If the device has been validated within the defined operating conditions, consideration should be given to obtaining the validation data and performing a more targeted verification process. Validation would be required if the device has not previously been validated within the defined conditions. For both validation and verification, the experimental design should be constructed to ensure that the results will be fit for purpose and robust enough to withstand scientific review. Specific considerations relevant to forensic science are outlined in the ANZPAA NIFS *Empirical Study Design in Forensic Science – A Guideline to Forensic Fundamentals* (2019).

In addition to providing objective evidence that a method meets particular requirements, validation/verification is an essential requirement of accreditation to ISO/IEC 17025 *General Requirements for the Competence of Testing and Calibration Laboratories*¹. Further guidance on verification is available in the referenced resources.

DEVELOP AND PILOT E2E PROCESS

An E2E process should be developed, documented and piloted. The considerations detailed in the Assessment Phase (Broader Agency, Infrastructure, Equipment and Personnel) should be incorporated in the development of the pilot study. Thought should also be given to how human factors could impact the delivery and procedures implemented to reduce or mitigate the risk. The process should strike a balance between effectiveness and practicality.

A pilot study should be commenced following the development and documentation of the end-to-end process. The pilot study can be undertaken in stages prior to completing an end-to-end. A staged pilot approach provides the opportunity to specifically targeting various hypotheses to test. Success at each stage provides valuable insights and confirmation that the proposed solution can achieve the desired outcome. It also provides the potential to generate new information about any additional benefits or any unintended consequences that may not have been anticipated during the initial design and planning phase. Once staged testing is completed an end-to-end pilot should be conducted that covers the entire process and should be conducted within the defined operating conditions. Success or failure of the pilot study, including a mechanism for determination, should be defined to ensure appropriate data is capture during the trial. Success or failure is best determined through an evaluation of the pilot against end user requirements and the analysis of stakeholder feedback.

ASSESSMENT OF THE PILOT STUDY

The pilot study should be assessed against the developed process and the ability of the technology to meet the defined operating requirements. Opportunities for improvement should be identified and a method to ensure they are addressed and incorporated back into the process established.

¹ NATA, ISO/IEC 17025 *General Requirements for the Competence of Testing and Calibration Laboratories* (2017), <https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html>

3. IMPLEMENTATION

Following a successful pilot study, and the ratification of any opportunities for improvement identified as part of the study, an implementation strategy should be developed and initiated in consultation with key stakeholders. The stakeholder engagement strategy should complement the implementation strategy. Consideration should be given to a staged implementation. The following checklist has been developed to provide a broad overview to the requirements of an implementation strategy for transitioning laboratory based technology to the field:

Implementation Strategy	Y	N	N/A
Broader Agency			
Quality Management System <ul style="list-style-type: none"> > <i>Have requirements for accreditation been fulfilled, if required? Will the process be covered under an agency accreditation program? If so, how will this be implemented?</i> > <i>Has a process for device maintenance and periodic performance checks been developed and documented?</i> > <i>Have the auditing requirements been defined and a process developed with clear responsibilities?</i> > <i>Has an appropriate proficiency testing program been identified? Who will have oversight of this?</i> 			
Legislation <ul style="list-style-type: none"> > <i>Have any required legislative changes been implemented?</i> > <i>Have any legislative constraints been defined and are they understood by the users?</i> 			
Methods and SOPS <ul style="list-style-type: none"> > <i>Have methods and standard operating procedures been developed and documented for the device?</i> > <i>Has a process for method review been documented?</i> > <i>Has a process for ongoing calibration and service of the device been developed and documented?</i> 			
Governance <ul style="list-style-type: none"> > <i>Has an equipment and assets management process, including an ongoing funding model covering the lifespan of the device, been developed?</i> > <i>Has ownership of the device, including generated data, been established and documented?</i> > <i>Has a communication strategy been developed and initiated?</i> 			
Policy and E2E Processes <ul style="list-style-type: none"> > <i>Have key performance indicators for processes been defined and a process for reporting established?</i> > <i>Have any required changes to organisational policies been completed?</i> 			

Implementation Strategy	Y	N	N/A
Equipment			
Equipment <ul style="list-style-type: none"> > <i>Have the appropriate number of devices been purchased?</i> > <i>Are all the devices validated/verified and operational?</i> 			
Consumables <ul style="list-style-type: none"> > <i>Have the required consumables been purchased ready for implementation?</i> > <i>Has a consumable supplier been identified and a process for purchasing and storing consumables been developed?</i> 			
Infrastructure			
ICT/Infrastructure <ul style="list-style-type: none"> > <i>Have required infrastructure modifications been completed?</i> > <i>Are ICT facilities ready for implementation?</i> > <i>Has the data transfer and storage system been developed?</i> 			
Facility/Environment <ul style="list-style-type: none"> > <i>Has the operating environment been defined, and appropriate consideration of any limitations been conducted?</i> > <i>Have any facilities required for operation been created or modified?</i> 			
Work Health and Safety <ul style="list-style-type: none"> > <i>Has a Work Health and Safety risk assessment been completed for the operation of the device within the environment(s) it is to be used?</i> 			
Personnel			
Human Resources <ul style="list-style-type: none"> > <i>Have sufficient human resources been identified and are they operational?</i> > <i>Has a change management strategy been implemented?</i> 			
Training <ul style="list-style-type: none"> > <i>Has an appropriate training package for operational staff been developed and implemented?</i> > <i>Has an appropriate training program for end users been developed and implemented?</i> 			

4. POST-IMPLEMENTATION REVIEW AND ASSESSMENT

A post-implementation review and assessment is the final phase in the transition process. The time elapsed since implementation will be dependent on the scale and scope of the implementation and whether a staged implementation strategy was engaged. A successful implementation is characterised by positive stakeholder feedback and establishing that the new service delivery model is meeting end user requirements and expected benefits identified during the Assessment Phase (see *Benefits Realisation within Scope of Application*). While an implementation may be successful, the post-implementation review and assessment phase is still critical as opportunities may be identified that can improve the in-field process.

The post-implementation review and assessment phase should consider:

BROADER AGENCY

- ▶ *What is the cost benefit ratio of in-field? How does this compare to laboratory analysis, if applicable?*
- ▶ *Is the current in-field analysis capability optimal and sustainable? Is there a desire to upscale?*
- ▶ *Is the quality management system, including policy and procedure documents, fit for purpose and do they reflect the process in operation?*
- ▶ *Have any unintended consequences or benefits of the transition been identified? How and when should these be acted upon?*
- ▶ *Should a process for periodic review of the process be implemented?*
- ▶ *Were any lessons learnt from this implementation and could others benefit from them being shared?*

INFRASTRUCTURE

- ▶ *Are ICT integrating effectively with the in-field analysis process? Are there modifications to the ICT system that could improve the process?*
- ▶ *Is the current infrastructure appropriate or could modifications or additions be made to improve the operating environment?*
- ▶ *Have there been any incidents related to the use of the device in the field?*

EQUIPMENT

- ▶ *Have any issues been identified with the field-deployable device or consumables?*
- ▶ *Is the technology being used as expected? If not, why? Can the technology or process be altered to achieve the intended goal?*
- ▶ *What is the lifespan of the technology and what is the replacement protocol?*
- ▶ *Who will be responsible for and what is the mechanism for investigating next generation devices?*

PERSONNEL

- ▶ *Is the resourcing allocated to processes surrounding the use of the technology adequate?*
- ▶ *Is the current training program appropriate? Is it producing operational personnel that are competent to perform the required duties? Are end users able to use the information generated by the device?*

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RESOURCES

EXPERIMENTAL DESIGN

- ▶ ANZPAA NIFS, *Empirical Study Design in Forensic Science – A Guideline to Forensic Fundamentals* (2019), <http://www.anzpaa.org.au/forensic-science/our-work/products/publications>

VALIDATION AND VERIFICATION

- ▶ ANZPAA NIFS, *Empirical Study Design in Forensic Science – A Guideline to Forensic Fundamentals* (2019), <http://www.anzpaa.org.au/forensic-science/our-work/products/publications>
- ▶ ANZPAA NIFS, *A Guideline to Forensic Fundamentals – Identifying the Underpinning Science of Human Based Forensic Science Discipline* (2016), <http://www.anzpaa.org.au/forensic-science/our-work/products/publications>
- ▶ NATA, *General Accreditation Guidance – Validation and Verification of Quantitative and Qualitative Test Methods* (2018), www.nata.com.au
- ▶ NATA, *ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories* (2017), <https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html>

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