TPSoP®

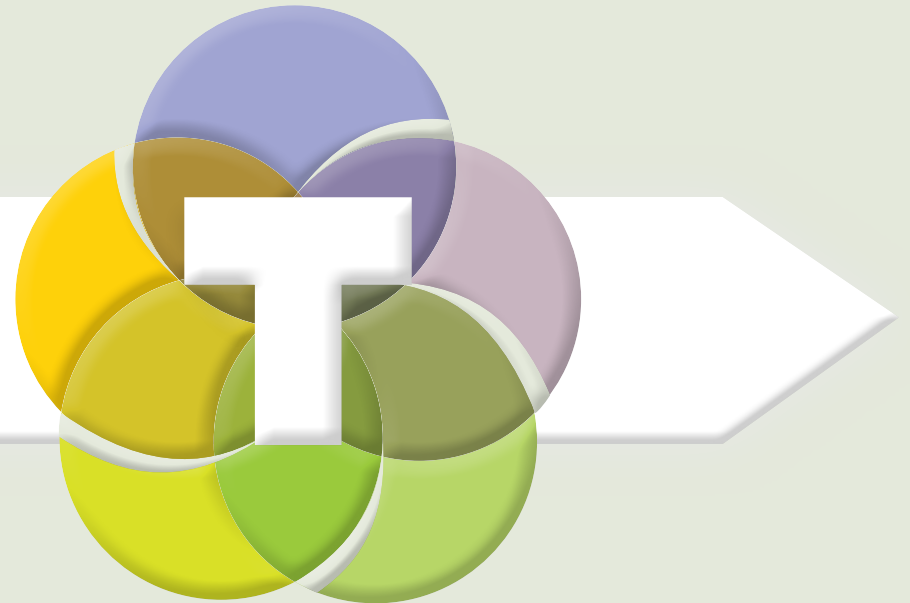## EXECUTIVE SUMMARY

THE RIGHT PERSON DOING THE RIGHT THING RIGHT EVERY TIME

WHY DO WE NEED SOPS/WIS?

Compliance – itself driven by regulation is the single biggest driver of SOP and WI development. The reasons for regulation are simple: consumers and the public in general are more risk aware, more knowledgeable and more demanding of high standards from business.

Meanwhile, government and regulators want a greater degree of visibility and control of business, hoping that more control will prevent a repeat of the ethical, product and financial scandals that have dogged economies over the last decade.

In combination, these drivers have created a larger and more complex compliance agenda. The result is a compliance burden carried by all businesses with regulation becoming more diverse and wide-ranging. Certain sectors, such as Life Sciences and Aerospace, are subject to more regulation than others. For those charged with the management of business, this has resulted in a growing and complex web of compliance activities spanning all operational areas:

Figure 1. The multi-faceted compliance agenda

The compliance agenda is complex and growing

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On top of the compliance agenda, many organisations opt to overlay a quality agenda to demonstrate accreditation to an external quality standard e.g. ISO, OHSAS, CE standards etc. resulting in overlapping quality and compliance agendas.

To meet each of these individual compliance and quality agendas, documented policies and procedures need to be developed, implemented and maintained, together with evidence that "proves" or "attests" compliance (for examination by inspectors, external partners, auditors and regulators).

The cost of this "proof "or "attestation" places a considerable burden and cost on management systems and business operations and it takes quite an effort to create and govern this body of documentation:

- Governance committees and independent quality/assurance audit functions are required to provide internal oversight

- ICT infrastructure and systems are needed to provide secure content management and control of documentation

- All areas of operation are required to develop and implement their procedures.

As a result, organisations have sunk vast sums of money developing, documenting, implementing and managing Standard Operating Procedures (SOPs).

We contend that there is a great opportunity to reduce costs, improve compliance posture and SOP effectiveness by taking a process-centric approach to SOPS/WIs. Furthermore, a process-centric approach can help organisations to adapt faster to changes, giving them a competitive advantage.

This is the backdrop to our examination of current SOP/WI practices and the development of an alternative process-centric approach.

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THE PROBLEMS WITH SOPs/WIs

There is a an expectation that, using SOPs/WIs, Workers have clear instructions on how to perform tasks, making them more productive and making tasks repeatable with consistent outcomes. The reality is that there is a major performance gap between this expectation and the results from most SOPs/WIs.

Mention of the words "SOP" or "SOPs" generally invokes a litany of woe; they don't work, they don't reflect reality, they are wrong, they can't be found, they are hard to understand, they take too long to develop, they take too long to approve, it is a pain to change them, it takes too long to train on them, they are a good example of rampant bureaucracy.
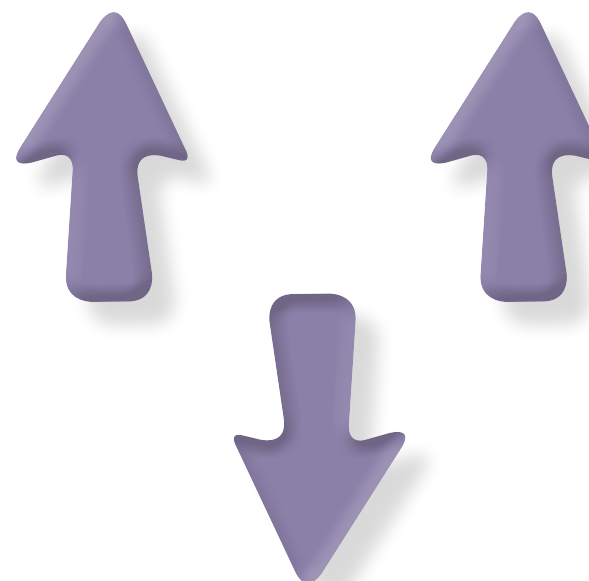
Sound familiar?

Figure 2. Problems with text-based SOP performance

PROBLEMS WITH TEXT BASED PROCEDURES

1. Duplication
2. Defects
3. Time to Effectivenes
4. Information Availability
5. Compliance Infrastructure
6. Enterprise Governance and Flexibility

High Risk   High Cost

Low Effectiveness: 31% Defective

We've analysed SOP/WI problems and find that they fit into specific categories:

- *Duplication* is rampant between Enterprise, Functions, Business Units, Departments and between SOPs themselves. This is expensive and confusing for SOP Users.

- Text-based SOPs are *defective*, resulting in 2 sigma performance in environments where 5 sigma performance is required. Moreover, many of the defects are avoidable. And, because everyone gets trained on SOPs, defects are embedded in the organisation - ouch!

- Workers spend an inordinate amount of time (up to 9.5 hours per week) *searching* for the information they need to carry out their tasks. This is information that should and can be on-hand and immediately available (seconds, not hours or days).

- Time to *Effectiveness* with SOPs *takes too long* for new hires and role changers and it is difficult to establish knowledge retention rates. Information overload from SOP reading calls into question "I have read and understood" signoffs.

- Compliance Infrastructure (Organisation and Systems) for SOPs is *not fit for purpose*. It is disparate, expensive, fragmented and non-collaborative with the result that it does not encourage and enable continual improvement and innovation; something all organisations claim to want.

- *Change Management* systems and methodologies are cumbersome and protracted. Meanwhile, change cycles are becoming faster and regulation is increasing and becoming more complex. The result is that most organisations are permanently in react mode and it is normal to have a backlog of changes awaiting introduction.

It is also important to acknowledge that most organisations classify non-conformances/deficiencies with non-adherence to documented SOPs/WIs as "human error"[1]. Many studies and regulatory inspection reports indicate that "human error" runs at approximately 30%, and it remains stubbornly high. Our research and analysis shows that often times these non-conformances and deviations are not, in fact due to "human errors" but the result of defective SOPs/WIs.

We recommend, therefore, that organisations should implement a more granular classification of deviations/non-conformances to expose SOP/WI problems and then use this data to create the business case for change.

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1. Human error is a separate topic and outside of the scope of this paper.

FIVE KEY REQUIREMENTS

At Torque Management, we spent a lot of time and effort examining and analysing the problems with "traditional" text-based SOPs.

Our research identified that traditional methods for developing, implementing, training, changing and managing text-based SOPs has created a complicated, confused and defective situation that exposes organisations and results into a huge loss of productivity and limits flexibility.

The research also identified that even the most competent and diligent analysts can't create great text-based procedures using traditional content management systems and methodologies. This is due to a number of factors including technical problems that are inherent in text-based SOPS - Fig. 5 (table on page 11) provides a summary.

We identified five key requirements for efficient and effective SOPs/WIs.

1. The SOP/WI system ensures that *the right person performs the right task right, every time*

2. The SOP/WI system provides *End-to-end visibility of processes*

3. It is possible to *drill-up / drill-down* from Regulation, Policy or Standard to the lowest level WI

4. *Performance measures* can be attached to SOPs/WIs

5. *Collaboration* and knowledge capture is easy and shareable across the Enterprise

We concluded that traditional systems and methods can't address our five key questions so we began to experiment with other solutions and methodologies. Ultimately, this experimentation led us to design, build and test a solution we named Torque Management Process-Centric Standard Operating Procedures (TPSoP®).

Importantly, TPSoP® *satisfies* our five key requirements whilst retaining the original (good) attributes of a text-based SOP.

Furthermore, it can deliver to a broader, more strategic agenda through the development of a full blown Integrated Management System - a single location for enterprise Quality, Compliance and Performance Management, SOP and WI artefacts, and associated process and role based training.

TPSOP® A SOLUTION FOR INTEGRATED COMPLIANCE, QUALITY AND PERFORMANCE

TPSoP® replaces text-based SOPs with on-line process centric SOPs/WIs. It lowers risk, lowers cost and improves compliance effectiveness, making it a "win" for both businesses and regulators. Simply put, TPSoP® creates great procedures!

TPSOP® THREE MAIN COMPONENTS

1. Process: The TPSoP® methodology

Developed by Lean/Six Sigma/BPM experts, TPSoP® is a highly-structured, repeatable, scalable, documented methodology that creates great procedures.

Whether the purpose of an improvement initative is to transform specific groups of processes e.g. Quality Management System, Environmental Health and Safety Management System or just the SOPs associated with a specific activity e.g. Clinical Trials, TPSoP® methodology is equally effective.

Working collaboratively, the methodically leads the team through four phases (see figure 3 below), each specifically designed to deliver results efficiently and effectively:

Figure 3. TPSoP® phases

Discover

Measure & Analyse
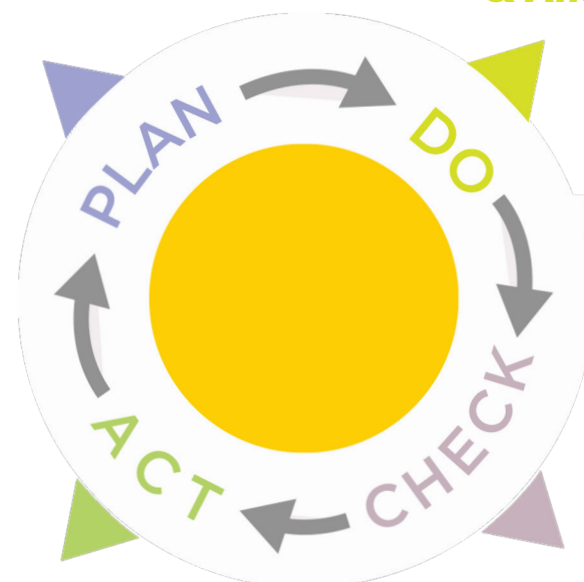
Improve & Control

Report & Improve

Discover Phase

In the Discover phase, we identify the requirements for:

- The management framework (applicable regulation, policies, sector framework(s), standards).

- The scope of procedures required to be developed and/or transformed, template, and presentation design.

- Project governance to manage the initiative.

Measure & Analyse

- Process Architect(s) develop the Management Framework and translate them into Management Processes.

- Business Process specialists develop or convert your procedures into on-line processes and procedures, linking them to all artefacts required for their execution, efficiently and effectively.

- The Management Framework and the processes are integrated, creating an Integrated Management System.

Improve & Control

- Improved online processes and procedures are published to personalised "landing pages" using automated workflow, access control and audit trails.

- Role based storyboards are developed, ensuring that Users are correctly trained, training records are created and processes can be accessed easily for on-demand consumption.

- Control is about proving the benefits and this is achieved by creating scorecards and measures to processes, activities and roles.

Report & Improve

The Report & Improve phase is about maintaining the gains, managing and improving.

- Day-to-day management, reporting, process scorecards, ad-hoc and solicited user feedback, formal and informal reviews provide incomparable input to keeping the processes "live", relevant and accurate, contributing to the governance, risk and compliance agenda, fast-tracking changes e.g. regulatory and continual improvement.

TPSoP® IS MORE THAN A SOP/WI DEVELOPMENT TOOL...

Ultimately, with TPSoP®, it is possible to create an enterprise-wide Integrated Management System. An Integrated Management System comprises a repository that contains and integrates regulations, policies, and standards, SOPs and Work Instructions, roles, performance metrics and training materials. An IMS also improves accountability and makes relationships traceable and auditable.

Figure 4. Integrated Management System
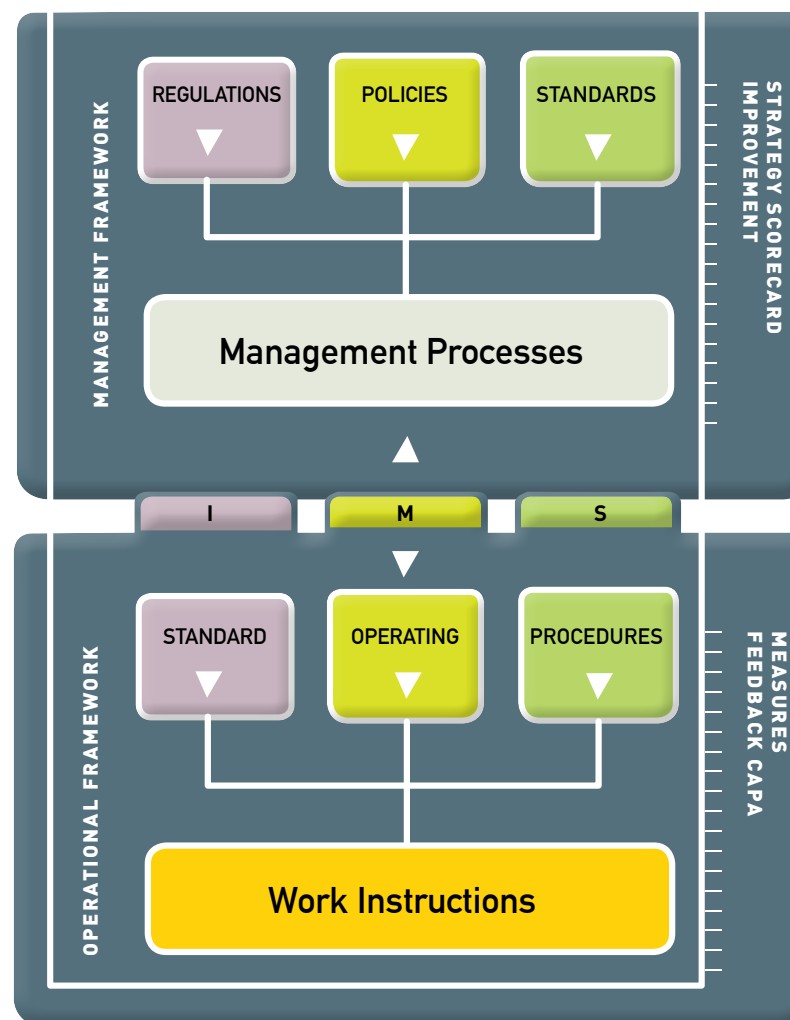
2. PEOPLE: TORQUE MANAGEMENT BUSINESS PROCESS EXPERTS

– Torque Management staff are uniquely qualified and trained to support TPSoP® implementation projects and programmes. They are process professionals uniquely equipped with the skills necessary to transform processes for maximum operability. They understand what works and what doesn't for Users of procedures/processes and for Managers who need to monitor and control performance. Working collaboratively with client teams, procedures are transformed quickly and efficiently into processes while role-based Storyboards are developed for training and implementation.

Our expert resources are available for short and tactical projects or longer term support and guidance necessary for strategic change programmes such as the development of an Integrated Management System.

3. ICT: A BUSINESS PROCESS MANAGEMENT SYSTEM

– TPSoP® is designed to exploit features of Tibco's Nimbus BPMS e.g. a simple, common language for process modelling. As you would expect, collaboration and feedback is a strong feature of Nimbus and we recognise the ability of the system to report on process map usage, feedback, change requests and actions. Armed with this newly accessible information, quality professionals, managers and staff can identify and analyse problems and variation and conduct root cause analysis in a much more focussed manner e.g. analysis of possible causal relationships between processes, operational performance and compliance deviations.

In combination, the three components of TPSoP® provide organisations with the resources and skills essential for a successful SOP/WI improvement initiative.

WHAT SPECIFIC SOP/WI IMPROVEMENTS ARE AVAILABLE FROM TPSOP® VERSUS TRADITIONAL TEXT-BASED PROCEDURES?

There are substantial improvements, and therefore benefits available to those with the vision and determination to transform text-based SOPs/WIs. Note that some of the improvements cannot be achieved using traditional technologies.

Figure 5. SOP/WI Improvements available from a process - centric approach.

IMPROVEMENT	*TRADITIONAL Text-based procedures	TPSoP
Create dynamic links between regulations, policies and standards to Roles, Management Processes, SOPs and Work Instructions	Can't do	Can do
Create standard Roles (& therefore responsibilities and training requirements)	Extremely difficult	Can do
View local process variants in one system location	Can't do	Can do
Provide ability to add and route actions to individual tasks, sub-processes, processes, compliance requirements	Can't do	Can do
View processes: end-to-end , top to bottom, bottom to top	Can't do	Can do
Remove duplication across the SOP/Work Instruction estate	Extremely difficult, might be impossible	Can do
Remove defects from SOPs and Work Instructions	Extremely difficult, might be impossible	Can do
Create visual, step-by-step process	Can't do	Can do
Provide the ability to display multiple languages, if required	Can't do	Can do
Provide fast and easy access to all necessary materials e.g. business Apps, forms, documents, external resources	Can't do	Can do
Add Scorecards, KPIs and measures to processes	Can't do	Can do
Provide a feedback loop for suggestions, corrections, change requests	Manual - doesn't work	Can do
Provide role-based training and process-based training	Can't do	Can do
Reinforce training / re-use of procedure documentation	Can't do	Can do
Provide collaboration and workflow capability for development and innovation of procedures and work instructions	Can't do	Can do
Provide automated workflow for change management	Can't do	Can do
Provide permanent records of feedback, changes requests and action requests	Can't do	Can do

*Traditional = Text-based documents stored in a content management system e.g. SharePoint, Documentum.

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THE BUSINESS CASE FOR CHANGE

The most tangible benefits associated with a process-centric approach are:

- Waste associated with duplication can be removed in a range of 30% to 40%

- Time to develop SOPs/WIs is up to 50% faster

- Training is up to 87% more effective

- Defects can be removed in a range of two to five sigma difference

- Information required by workers can be provided "just in time"

- Change management is faster

Benefits that are less tangible but equally important and valuable:

- End-to-end visibility of SOPs/WIs and regulation eliminates gaps, overlaps and underlaps

- Accountability is improved

- Collaboration and knowledge sharing is easy

- Objective, fact-based performance measures can be associated with SOPS/WIs

- A closed loop QMS/IMS can improve management and compliance outcomes

- Benchmarking is possible and easy

Organisations with the vision and determination to improve can reduce costs, improve compliance posture, SOP effectiveness and gain a competitive advantage by implementing TpsoP®.

TPSoP®: The right person, doing the right thing right, every time.
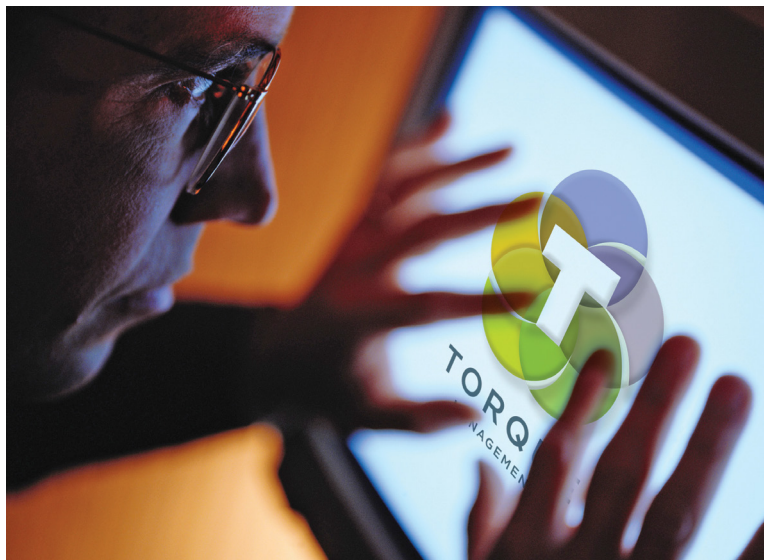
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LEARN MORE/FIRST STEPS

While transitioning from text-based to process-centric procedures is a delicate process and takes time, the starting point is to understand the capabilities of TPSoP® and the potential benefits to your organisation. Torque Management has created many supporting materials that can assist with this understanding:

1. Book a demonstration - seeing is believing!

In the first instance, we recommend that you request a demonstration of TPSoP®

The demonstration covers topics such as:

– General orientation through a process-centric presentation of SOPs/WIs

– Navigation of a published SOP

– Navigation of a published WI that is visually enhanced for improved operability, including a performance scorecard

– Audit Trail from Regulation/Standard to SOP/WI

– An overview of an Integrated, closed loop Management System

– Overview of how Regulations, Policies and Standards are managed

– Overview of "actions"

– Overview of how process variants are documented

A TPSoP® demonstration requires a commitment of approximately 2 hours.

2. **Conduct a TPSoP® opportunity/benefits analysis workshop**

a) The TPSoP® opportunity/benefits analysis workshop starts with a demonstration and general discussion about opportunities and the current status of your organisation's SOPs/WIs and QMS/IMS. This develops a joint understanding of the scope and type of opportunity available.

b) Working collaboratively and using our benefits analysis tool, we will then drill down to assess the specific benefits and risk reduction opportunities that might arise from the implementation of TPSoP®. The output from this exercise is a clear definition of the specific opportunities and benefits that are available in your organisation.

c) In the final part of the workshop, we develop an understanding of the data that needs to be gathered in order to develop a tangible benefits statement and a compelling case for change.

A TPSoP® Opportunity/Benefits analysis workshop is a 2-day, on-site event.

ABOUT TPSOP®

TPSoP® (Torque Management Process-centric Standard Operating Procedures) is a licensed product.

Owned by Torque Management Ltd.
TPSoP® provides the tools and platform required to:

- Develop and manage process-centric Standard Operating Procedures/Work Instructions

- Develop and manage a closed-loop Quality Management System/Integrated Management System.

The TPSoP® solution includes:

- Management and Operational Frameworks

- The TPSoP® process: the methodology for the development of Frameworks, SOPs and Work Instructions.

- Specialist services to support TPSoP® implementations

- TPSoP® certified training and quality assurance programmes

- A BPMS Platform (Tibco/Nimbus)

ABOUT TORQUE MANAGEMENT

Established in 2002, Torque Management provides a specialist global consultancy in Business Process Management (BPM) and optimisation and IT in all business sectors. We are experts in multiple disciplines including Lean, Six Sigma and ISO and are the creators of two successful, process-led methodologies; Rapid System™ and TPSoP®.

Rapid System™ accelerates and improves delivery of IT and ERP projects and TPSoP® was created to develop and improve online procedures and a means to optimise and deliver instructions in a consistent, repeatable manner.

Torque Management's mission is to improve and implement BPM best practice, innovation and performance through education, support, research and benchmarking. We work with blue-chip, global, public and private organisations and industries in all sectors including life sciences and finance where we have specialist expertise.

To engineer successful change and transformation within an organisation, our senior analysts and consultants provide a comprehensive, specialist range of services in all areas of performance, including BPM, Performance Management and Quality Management Systems (QMS).

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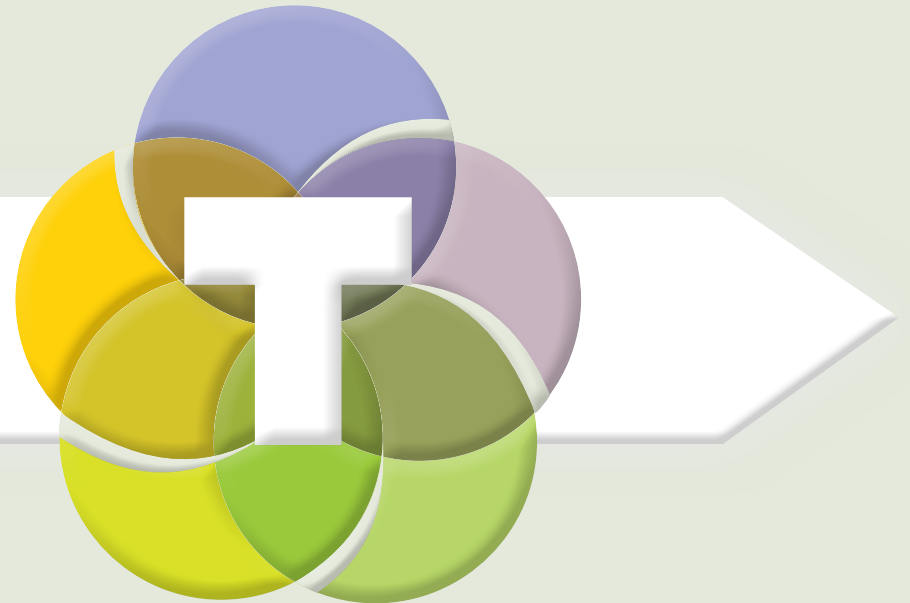
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