

## SOPs – The Memory Banks of an Organisation

Russell Page, Principal Consultant, HFL Consulting, Freeman House, Orbital 24, Oldham Street, Denton, Manchester. M343SU

Russell Page of HFL Consulting presents an alternative approach and methodology for creating SOPs that addresses common shortcomings of those typically used in the process industries, and which will provide a location to capture experience and lessons learnt so providing a structured and controlled corporate memory for an organisation.

Standard Operating Procedures, SOPs, corporate memory, culture, human failure, safety critical tasks, human factors, reducing variation, training, knowledge harvesting, Job Aids, Task Aids, Task Instructions, Visual Aids, standardisation

### Why an interest in SOPs?

For a long time the author has been interested in SOPs – Standard Operating Procedures – and why they have always appeared to be inadequate to their role in the process industries. Since joining picme in 2005, now HFL Consulting, to help companies implement continuous improvement projects and initiatives, usually at some point SOPs will have been looked at and examined, typically to find top tips and methods of working that individuals have developed over the years through their experience which if consistently duplicated by others will result in a significant productivity improvement, an improvement in quality, and/ or an increase in safety. In looking through the SOPs rarely were found procedures that adequately described the methodology without ambiguity, nor contained the top tips actually employed by some personnel to great effect, and so inevitably variation had set in.

As many of HFL Consulting's sites are high hazard sites, often top tier COMAH (Control of Major Accident Hazards Regulations), one began to question the safety of procedures that allowed variation, and failed to explain in specific detail the hazards and risks associated with activities being undertaken.

By way of a typical example of a procedure that poorly defined the task leading to variation, the output from a reactor vessel at a site the author worked at was dropped onto a Nutsche filter where it had to be rinsed with water to remove one of the by-products of the previous reaction. The by-product was dissolvable in water, but to a lesser extent too was the desired product. In reviewing the SOP some operators highlighted the importance of the washing technique in achieving a high yield and low contamination. Key points in the technique included the evenly spreading of the material on the Nutsche filter, ensuring that it was of even density on the filter, how to correctly measure the required volume of water, and how to wash the material evenly. None of this technique was identified in the actual procedure, but the experienced operators explained that failure to evenly spread the material, to ensure that it was of even density, or to wash evenly would result in high levels of contaminants being left behind after the washing and a reduction in yield as some of the product would be washed away, all due to the water either creating rat runs through the material, failing to penetrate the thicker areas of the material, or the water not being sprayed on all the material. During the conversation some operators showed surprise, others sudden understanding as they learnt from listening to their peers, although the person with the largest "a-ha" moment was the QC manager as she began to understand some of the reasons why batches had high levels of contaminants and low yields. What did the procedure actually say? "Drop batch unto Nutche filter. Wash with 10 gallons of water".

A similar, but more concerning, example was a procedure that called for the application of heat to dry a product in a drying vessel. There was no heat available on the drying vessel as it in actual fact dried using ambient temperature, and so the operators were obliged to ignore a step in the procedure.

These are just two examples of many that the author and his colleagues have come across over many years. In companies with poor procedures the precedent is then set that SOPs do not contain the required information, and that SOPs may be ignored as they are incorrect. This can lead to the risk of operators deviating from set procedures when it is unsafe to do so, a serious problem in industries with major accident hazards, or having to invent or develop their techniques potentially leading to the introduction of unsafe, uncontrolled and unknown behaviours.

The formats of procedures often cause behavioural problems too. It is usual to find many pages of safety information and explanation and background information prior to the actual text of the procedure to be followed, which has minimal relevance to the task at hand. This leads to a behavioural trait of skipping over what appears to the user irrelevant information as they search for the detail they require, and they fail to read the safety information provided. This then causes the problem that the inclusion of the safety information was actually trying to address.

And so an interest was born in SOPs.

HFL Consulting have been running some open courses on behalf of the Chemicals Industries Association (the CIA) on SOPs, and as part of the course a simple survey is carried out on the delegates' views of the procedures of their organisations. The question set is based on one given by the HSE on their website (HSE Human Factors Briefing Note No. 4). Delegates are asked to respond to whether they agree, strongly agree, disagree, or strongly disagree with each statement by a show of hands – one hand for agree or disagree, two hands for strongly agree or disagree. The survey is hardly scientific and is not meant to be, being used primarily as an ice-breaker and to get clients to acknowledge that their SOPs have shortcomings, but is informative or at least indicative none-the-less, of the general state of the process industries' procedures. An aggregation of two courses is given in figure 1, representing ten different sites, the majority of which are top tier COMAH sites.

Of immediate concern are the large red bars to the left with a commensurate small blue bar to the right, indicating that SOPs are not up to date, have low levels of accuracy, are not changed quickly in response to issues, and are potentially contradicted by other sources of information. SOPs are almost unanimously viewed as being supported by other job aids, but when considered in conjunction with the view that SOPs are inconsistent with other information the value of the job aids (or the SOP if it is the SOP that is wrong) one has to question to value and reason for the job aids. The view is that all SOPs are in good condition, primarily because they are almost all electronic now and paper copies have been withdrawn from the workplace. They are also identified as being easy to locate when needed, although the cynic would question whether the users would agree (the delegates on the courses have all been exclusively from management), and their view contradicts direct experience where the time and effort required to locate electronic copies of procedures is significant (and indeed for one of the companies on the course some particular procedures looked for when onsite proved to be most difficult to locate, requiring two hours and three different people going up the management tree, and unsurprisingly there was a large gap between what was written in the procedure and what was observed being done), and what is quite often observed when carrying out a Task Analysis as part of a Human Factors Analysis is that either local electronic copies are kept on computer desktops or a set of unofficial paper copies are kept available to reduce the effort required to locate the documents. Paper copies and local electronic copies have always been observed to be out of date and uncontrolled.

While in the main SOPs are viewed as being set out in logical steps, opinion is more divided on whether they are easy to read, as is their use to train people, bringing in to question what it is that some sites use to train their personnel.

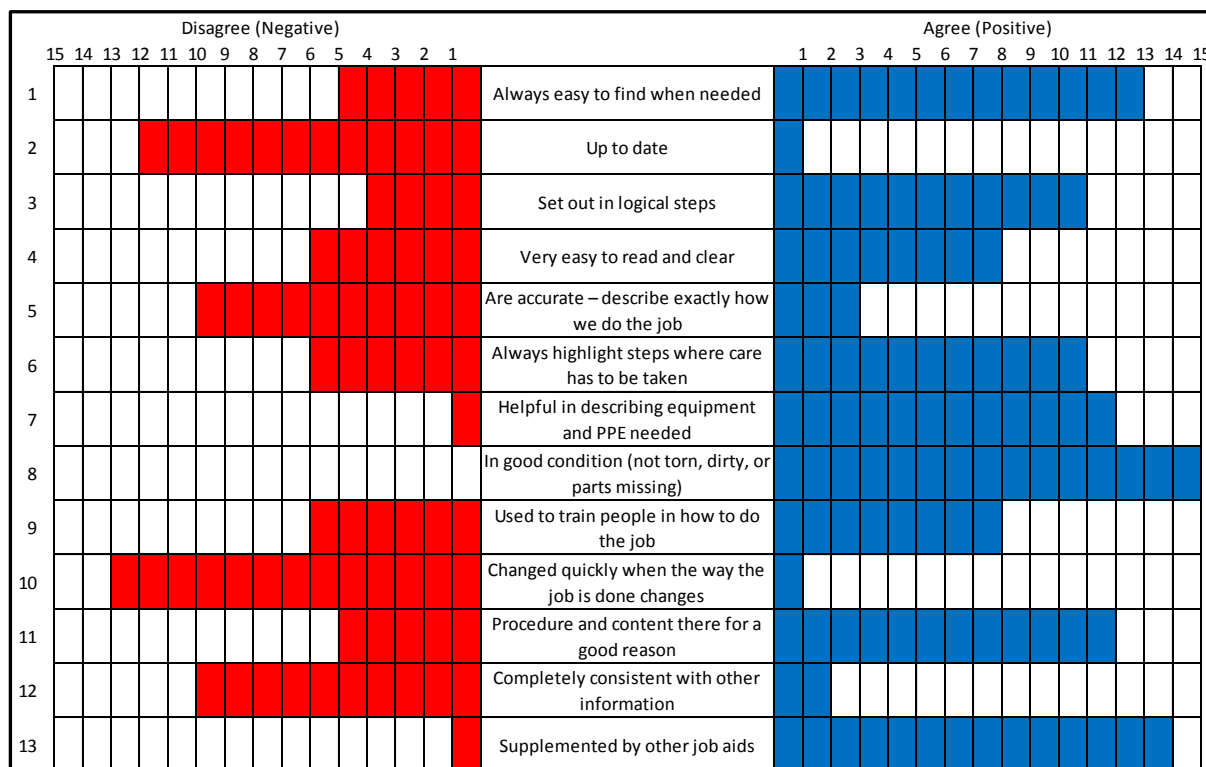
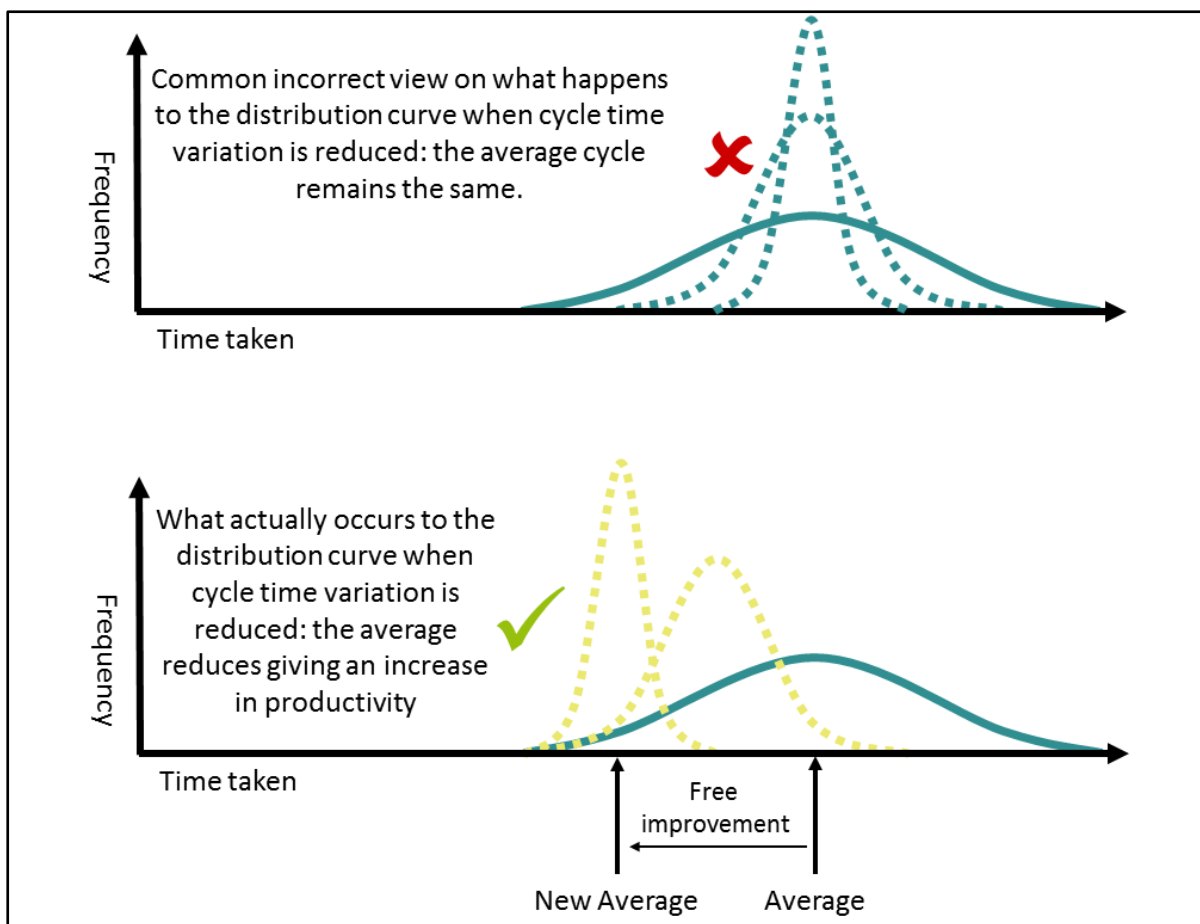


Figure 1: Table showing results of SOP surveys from two CIA open SOP courses

**What are SOPs for?**

Figure 2 shows a variation in the time taken to make a batch of chemicals in a process. If one reduces the variation in the cycle time the intuitive answer often given during courses when asked is that the average remains the same even though the variation reduces. However this is not correct – why would one standardise on the average, when 50% of the time the process has bettered the average? If the variation is due to operator behaviour and operating technique then capturing the knowledge from experienced capable operators that delivers the best batch times (assuming of course it is a safe technique that consistently produces the required quality) and getting all operators to behave the same way will lead to the variation not only reducing, but the average cycle time reducing. As these techniques are already known, at least by some, and are occasionally achieved, this productivity improvement is essentially for free – the knowledge simply needs to be “harvested”, recorded and disseminated.



**Figure 2: Illustration of what happens to average cycle times when their variation is reduced**

So variability is bad for productivity. It is also bad for quality and safety. To have variability in cycle time will give variability in the product characteristics as essentially the recipe is being varied – different times taken to charge, to decant, length of time spent refluxing or at a particular hold temperature, different techniques in opening valves, in tipping materials through manways, can all have and have been observed to have impacts on product quality on various processes. Some of these will inevitably have safety implications, either for personal safety or for process safety. Variation is a problem.

Where knowledge is not collected from the best experienced operators and disseminated to the rest of the workforce the rest of the workforce can only gain the knowledge and experience of the best operators by having to go through the same learning curves and experiences that they had to go through to gain their knowledge – individuals and the business as a whole are forced to repeatedly re-learn again what is or was once known, reducing an organisation’s ability to build upon that knowledge and reach ever new levels of performance, competence and safety – see Figure 3.

Instead, each operator should be able to continue his learning where the previous person left off. Isaac Newton once wrote “If I have seen further it is by standing on the shoulders (sic) of Giants”. So it should be with operators – they can achieve so much more by standing on what their predecessors and colleagues have done and learnt.

Over time knowledge does degrade. One forgets things one once knew, and one develops bad habits that need to be corrected. Looking across different intakes of operators if knowledge is transferred by on the job training and job shadowing, there arises the possibility of incomplete transfer of knowledge from operator A to operator B and operator C, and then a divergence of knowledge as operators B and C in turn train the next round of operators, and so knowledge degrades and diverges as successive operators are trained in their roles. This scenario ignores the effect of incorrect transfer of knowledge, which will compound the problem.

The use of well documented procedures, and training materials, ensures that knowledge transfer is complete and without error, so preventing degradation of knowledge over the long term. Good use of re-validation and checking of adherence to set procedure prevents degradation of knowledge over the shorter term.

Human beings are learning inventive creatures, and so as time passes operators will develop new knowledge and better techniques in response to new problems and issues – SOPs should also capture new knowledge and be used to disseminate it. This will be returned to later in the paper.

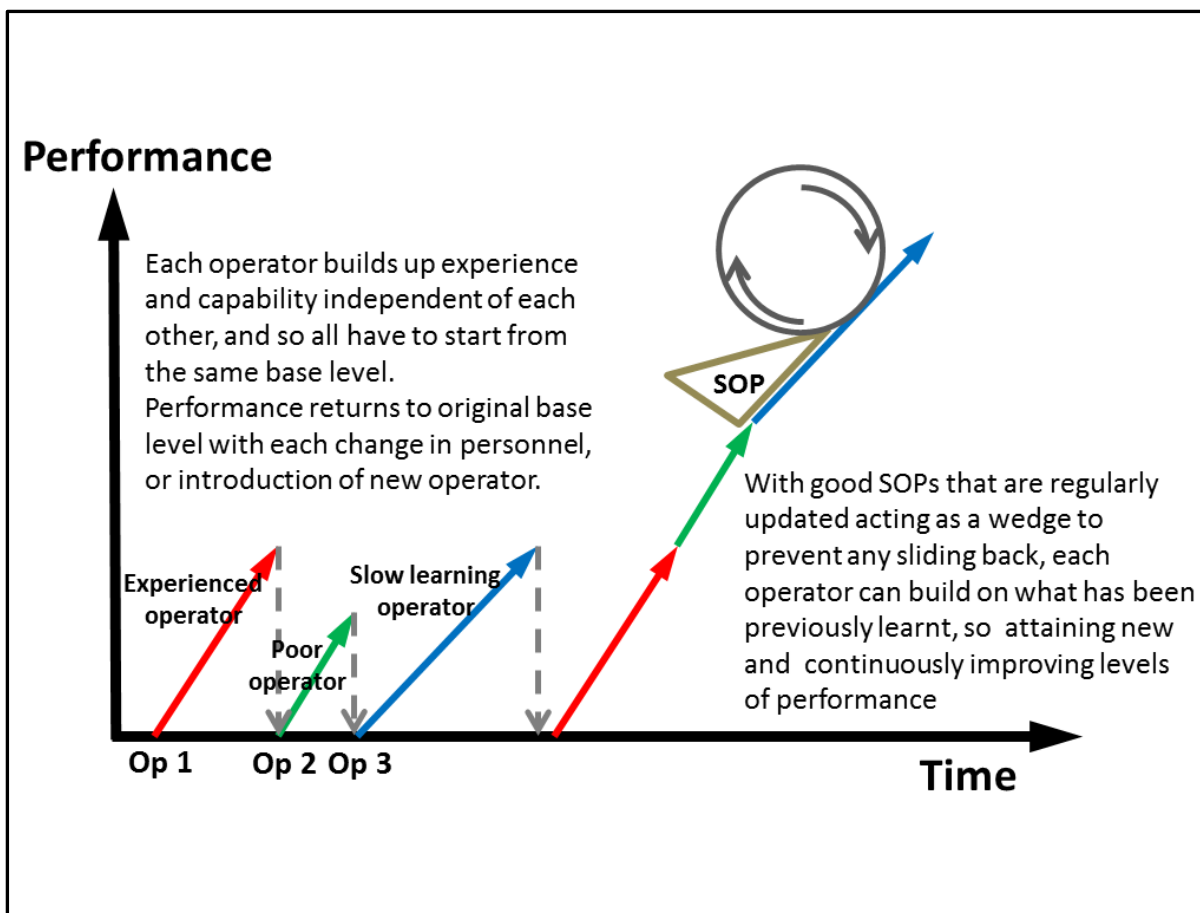


Figure 3: Illustration showing how SOPs can be used to hold the gains and aggregate improvements. Based on the Deming Cycle illustration (Bicheno et al, 2005).

### A Lean SOP Format

HFL Consulting frequently uses Lean techniques, as developed from the Toyota Production System, when working with clients, and so is exposed to the SOP formats commonly used by organisations that have implemented Lean. These SOP formats typically utilise a table format to divide information up, giving a horizontal split in the data. The four main columns are “Major Step”, “Key Point”, “Key Point Reason”, and visual aids.

#### Major Step

The Major Step consists of the actions that need to be done that will typically result in a change. Simply by reading the major steps in sequence vertically down the page one will read the steps required in sequence to complete the task being required, although it will read as a high resolution checklist of steps. Major Steps will typically start with a verb giving an instruction, for example, “Add water”, “Heat reactor vessel”, “Reflux product”, and so on. This sort of information is included in traditional procedures in the process industry, and is not where generic and systemic problems generally lie.

#### Key Point

The Key Points give further detail about the Major Step, typically in a bulleted list, explaining to the user further detail required to complete the Major Step. For example, “Add water” would have Key Points of how much to add, the technique used to add it. “Heat reactor vessel” would have Key Points of the temperature to be reached, how quickly or slowly the vessel should be heated, the detail of how to achieve heating. This sort of information can be found in traditional procedures in the process industry, but it is inconsistently provided, omits much that operators need to know, and in typical SOP formats is contained linearly within the main body of text making it hard to search for, to read, and to extract when required.

The information the Key Points provide is the information that standardises behaviour and adherence to procedures, reducing variation and therefore improving safety, quality and productivity. Without it operators will have to develop their own techniques for achieving the Major Steps.

#### Key Point Reasons

Key Point Reasons give explanation, and contain information and knowledge typically omitted from process industry procedures. It tends to be intuitively assumed that Key Point Reasons refer to the Major Step – why does water have to be added, or why the reactor vessel needs to be heated, but this is rarely useful or informative. Instead the Key Point Reasons primarily refer to the Key Points, giving explanation of why a particular technique should be used to achieve the Major Step.

Key Point Reasons are absolutely critical in reducing variations in following SOPs, and in reducing errors and problems, because they persuade the user to follow them by imparting knowledge of the consequences of failing to follow the Key Points.

### Visual Aids

Visual aids reduce the writing burden in creating SOPs, the reading burden in following them, and the variation in interpretation of the text, by providing images explaining concisely what words can often fail to adequately convey. The inclusion of images has traditionally been problematical due to the software systems utilised by companies. Increasingly procedures are now written as Word documents, or occasionally as Excel documents (which is recommended), and these formats more easily support inclusion of images and the like.

Let us explore the application of the above format to some steps of a typical safety critical procedure of unloading a road tanker. Some typical Major Steps might be:

- Direct tanker driver to unloading location
- Immobilise tanker by removing key from ignition
- Attach earth straps to tanker to prevent explosion
- Barrier off area
- Inform personnel working in the area of off-loading activity
- Ensure that driver is aware of nearest safety shower
- Etc

The above, with some embellishments around COSHH assessments (Control of Substances Hazardous to Health Regulations), safety information around what to do in the event of a spill, etc, would be the typical content of this part of an SOP dealing with unloading of road tankers. It however leaves a great deal open to interpretation, and a large number of opportunities for error – some potentially catastrophic. This is primarily because the SOP has not detailed all that the user needs to know, and a user would only work out the additional details and pitfalls – the unwritten elements of the SOP – by either being told verbally by more experienced operators, or by acquiring experience through discovering the pitfalls directly, hopefully without major incident. A good way of capturing these unwritten but vital bits of knowledge is to simply ask the users what they actually do, and why. What they would tell and demonstrate to a new operator?

Let us develop then a Major Step.

- Direct tanker driver to unloading location

Key Points would revolve around the technique used to direct the tanker to the required location, and the Key Point Reasons would detail why the techniques need to be followed, which are typically based on operators' experiences of it having gone wrong for them and what they now do to avoid repeat scenarios. Not all operators will give the same Key Points as their experience of problems may well be unique to them, as well as unique to specific sites and activities.

Some Key Points for this Major Step might be:

- A site map is used to direct driver
- Route to be drawn on map

These Key Points add flesh to the Major Step, and begin to remove variability in the execution if followed. However the probability of Key Points being applied is reduced if an operator does not appreciate the reasons behind the strictures of the Key Points, and so may rationalise to himself why they are irrelevant or over bearing and give himself excuses as to why he need not observe them. Therefore the Key Point Reasons become critical in reducing variation, giving the reasons for the Key Points. Some Key Point Reasons might be:

- "A site map is used to direct driver"
  - Drivers may not understand English
  - Ensures driver can visualise route
- Route to be drawn on map
  - Avoids error in communication and navigation

It can be seen that previous experiences and problems will inform the writing of both Key Points and Key Point Reasons – an operator has experienced a failure to communicate because the driver did not understand English (a common circumstance these days), the driver getting lost onsite following verbal directions, a driver making errors of navigation round the site, etc.

Figure 4 gives an example of how the layout may look, and gives further examples of Key Points and Key Point Reasons.

SOP Name	<b>How to Offload Road Tankers</b>		Reference	12345678	Author	Safety Officer	Area Manager	Risk & Regulatory Manager
Procedure Name		<b>Job Detail</b>	Issue Date	01/01/2015	A N Other	I B Save	I N Charge	
Product listing			Review Date	01/01/2016				
Notes:								
NO.	MAJOR STEP	KEY POINT	KEY POINT REASON: Safety Quality Ease			VISUAL AIDS		
9	Direct tanker driver to unloading location	A site map is to be given to the tanker driver Site maps are kept in the security hut Route to be drawn on the map	E E E	Drivers may not understand English Ensures driver can visualise the route to be taken Avoids error in communication and navigation				
10	Remove ignition key from vehicle and place in key store	Key store is in Shift supervisor's office Keys to be checked that they are the vehicle ignition keys Driver to be asked if he has a spare set with him	S S	Drivers may hand over car keys and not vehicle keys Possibility driver has a spare set and will use them to turn on ignition and radio				
11	Attach earth straps to tanker	Cable to checked still connected to ground at far end Earth clamp to be attached to earthing point on trailer Earthing point should be free from paint and other insulating materials	S S S	Previous driver may have driven off with clamp still attached and pulled other end off ground fixing Paint and other debris will defeat earthing			Picture of earthing point on a trailer	
PPE Standard		Non Standard	Chemical Hazards			References		
				R12	Extremely flammable	S45	In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)	
				R23	Toxic by inhalation	S53	Avoid exposure - obtain special instructions before use	
				R36/37/38	Irritating to eyes, respiratory system and skin			
		Air-fed or full face with cartridge AX filter to be worn when making or breaking connectors.		R45	May cause cancer			
				R46	May cause heritable genetic damage			
References: PPE Storage Operating Instructions								

**Figure 4: An example of an SOP layout utilising Major Steps, Key Points, Key Point Reasons, and Visual Aids**

A common criticism of the format is that it will significantly increase the size of SOP documents. In practice this has been found false. Indeed, it has been found that procedures written in this format are more concise than previous formats and yet contain significantly more detail and information, and are easier to read and to find specific items of information when quickly referred to for a refresher about a specific step.

A lot of these Key Points have safety implications which are not initially obvious to a technical writer based in an office and remote from the workplace, but operators have highlighted these invaluable lessons to the author during discussions and the drafting of procedures because they have experienced the problems themselves. Not all operators highlight the same things, reflecting their own individual experiences and problems encountered, and their own solutions to the problems. If these lessons are not captured and disseminated to the rest of the workforce, via SOPs, then the site is relying on probability, multiple layers of protection, and luck, that the worst case scenario does not play out, and that each individual operator quickly learns from his experience to prevent a reoccurrence of the scenario.

In this way SOPs may capture the knowledge and experience of individuals within the organisation, acting as a repository for corporate learning, becoming the memory banks of an organisation.

It should be noted that the Key Points and Key Point Reasons are detailed, specific and focused. Statements such as “For Health and Safety” should be avoided, as they fail to educate the user of the procedure, instead using a “do this or else” threatening approach which fails to educate and invest in the user, disengaging them from actively thinking about the task and its hazards, engenders a coercive environment, and potentially leads to gameplaying by personnel (Adler, 1999).

A technique for deciding whether to include certain statements is to decide whether it is vulnerable to the response “No \$£!% Sherlock” by the users of a procedure. If it is, leave it out. For example, an instruction to chock wheels may have the Key Point Reason of “To prevent tanker runaway causing loss of containment?”. This is obvious, and if one’s operators need this explaining one has a very different and fundamental problem. Instead the Key Points should detail the technique of wheel chocking, eg, which wheel to chock (trailer or tractor unit?), how many chocks in to use, which axle to chock, how close to the wheel to set them, etc, and the Key Point Reasons explain the whys of the Key Points. So not why the wheel needs to be chocked, by why it needs to be chocked the specified way. Of course this implies that the wheels need to be chocked too.

**Drafting Procedures**

It can be seen in the above examples that the experiential knowledge resides with the personnel who actually carry out the tasks, and not with management or technical personnel. Therefore users need to be involved in drafting their own procedures, preferably in a manner that captures their actual words, phrases and jargon to ensure that the procedure is understandable by them. This gives a number of additional benefits too:

- Even when it comes to steps or requirements that the users have not provided, eg, requirements identified by technical specialists or management, the procedure should still be written or dictated by the user to ensure that they understand the instruction and the reasons behind it. People will rarely follow procedures that they do not understand or comprehend.
- The user is forced to consider the best way to do a task, and to rationalise different views and opinions from his peer group, resulting in the best way currently known. This is the sum of the best top tips from all personnel.

*“To standardise a method is to choose out of many methods the best one, and use it. What is the best way to do a thing? It is the sum of all the good ways we have discovered up to the present. It therefore becomes the standard. Today’s standardisation is the necessary foundation on which tomorrow’s improvement will be based. If you think of*



*'standardisation as the best we know today, but which is to be improved tomorrow' – you get somewhere. But if you think of standards as confining, then progress stops.*" Henry Ford, *Today and Tomorrow*, 1926

- The responsibility for setting, maintaining and adhering to the procedure becomes the responsibility of the users, increasing their adherence to procedure.

*"In a Western company the standard operation is the property of management or the engineering department. In a Japanese company it is the property of the people doing the job. They prepare it, work to it, and are responsible for improving it. Contrary to Taylor's teaching, the Japanese combine thinking and doing, thus achieve a high level of involvement and commitment."* Peter Wickens, Former HR Director, Nissan UK

- The procedure reflects what actually happens and not what management think should happen (and probably believe is happening), which allows learning to take place when issues that occur are investigated, leading to ongoing improvements to the procedure. It also prevents an organisation from thinking it is protected by certain behaviours when in fact it is not.

It has been found that careful observation of the current practices and structured discussions with the users are useful approaches in gathering knowledge. In particular the use of video to observe a person carrying out a task in question has been found to work well, with a facilitator working with a group of users and appropriate technical experts to go through the procedure by observing the video and using Post-It notes to capture the information and to place them in the correct category on a wall. The video allows the facilitator and the group to pause the activity, to ask questions, and to explore consistency across different operators.

It is not generally possible to involve all users of a procedure in drafting it, and so alternative techniques need to be utilised to capture their inputs. A common method is to circulate a draft and ask for comments back, but this is rarely as successful as it needs to be – personnel do not make time to go through the draft procedure in sufficient detail to identify its shortcomings and to prompt their own recollections that need to be incorporated. To gain good input for a wider group (or indeed any group of people) three things are required. 1) Assimilation of the current knowledge and bringing it to the fore, eg, having the new procedure talked through and explained, perhaps with a walk through talk through. 2) A methodology for analysing and critiquing it, for example, having done a walk through talk through getting personnel to examine the procedure displayed on a large board or wall and adding their thoughts and comments to it via Post-It notes. 3) Time in their head and in their day to do the previous two steps. If any one of these elements is missing personnel will not fully engage and feedback will be reduced leading to issues when the procedure is actually used.

### **Monitoring Adherence and Capturing New Knowledge**

The point has been made that over time knowledge and experience is gained about better ways to run processes, new problems and circumstances are encountered that had not been envisaged and solutions are developed to overcome them. These need to be captured and incorporated into the relevant procedure and the knowledge disseminated to all relevant personnel.

Barriers to doing this must be minimised as much as possible. Procedures cannot be updated in an uncontrolled manner, and so methodologies and controls for updating and approving procedures need to be in place, but these have to be as easy as possible to navigate and the lead time for altering procedures minimised. The alternative is that knowledge is not captured in the updated procedure as personnel either delay making updates until it is worth their while and effort or they indefinitely delay making changes as there are too many hurdles to doing so, so the procedure becomes increasingly out of date, reintroduces variability in the tasks being done, and the organisation again becomes vulnerable to knowledge being lost as it walks out the gates in people's heads at the end of the working day (sometimes never to return as people do retire and change jobs).

Adherence to procedures should also be monitored on a regular basis, and the monitoring exercise used to identify whether new knowledge or techniques have been developed that need to be incorporated into the procedures. So unlike an audit often conducted by an independent person or third party (from another department or an external organisation) where the incentive is usually to receive a good score which drives the behaviour of hiding problems and issues, this monitoring activity must engage users and supervision/ management in a two way dialogue whereby users are able to identify to management issues and problems with the procedures which lead to pressure for them to deviate from what is written down, management is able to identify variability in activity, deviation from the set procedure, and new knowledge that has been gained that needs to be captured, and can reinforce in a positive manner the need to adhere to set procedures as well as altering the procedure to reflect what actually occurs where relevant. This sort of activity in the Lean lexicon is known as Process Confirmation, or sometimes Layered Process Audit, and is conducted by line management and supervision at the place of work, and usually is applied to and by all levels of an organisation.

### **Job/ Task Aids**

In 2014 Dr Atul Gawande gave the Reith Lectures on BBC Radio 4. In his second lecture in the series titled "The Century of the System" he discusses a checklist that was trialled for use prior to surgery, which delivered a 35% reduction in surgery complications, and a 40% reduction in deaths. In Scotland alone it is estimated to have saved 9,000 lives in 4 years. Why does this simple checklist of a style in use for decades by aircraft pilots for pre-flight checks deliver such significant benefits? It reduces errors, the incidences of which are much higher than realised or appreciated. These errors are classified by Gawande as errors of ineptitude – errors made by failing to follow correct procedure or to apply the knowledge held, and because the procedures are long and complex errors become frequent without an aide memoire.

In the context of this paper and SOPs this means Job Aids. A Job Aid is any device, document or artefact that aids the person carrying out a task to remember what needs to be done. This can range from the procedure itself (if used directly during the execution of the task) to checklists to posters and notices on the wall.

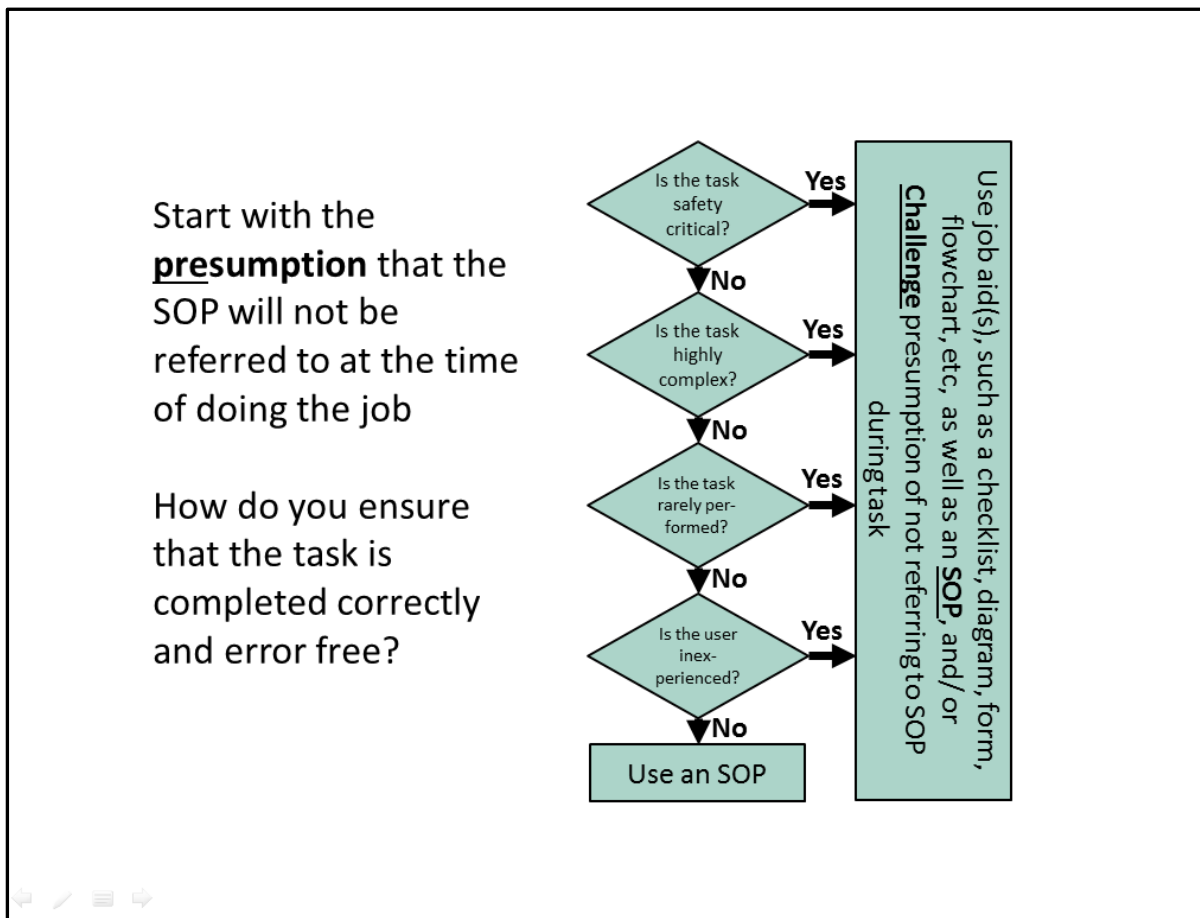


Figure 5: Flowchart for indicating when job aids may be required

However, the author always starts with the strongly held presumption that at the point of task execution the SOP will not be referred to – typically the user will over time have become quite familiar with the task and not feel the need to use the SOP directly as they can remember the task, and the SOP is too bulky and generally too long winded for the purposes of using directly when performing the task. If it is felt that an SOP is too long and complicated, perhaps with specific data that needs to be recalled then a Job Aid may be required as a prompt to remind the user of critical elements to ensure that inadvertent errors do not occur during the task execution.

The HSE have a flowchart as part of their guidance for when an SOP is required (HSE Human Factors Briefing Note No. 4). The flowchart shown in figure 4 is adapted from the HSE's, except the outputs are altered. The version given has as a base requirement the need for an SOP, with any additional complications in the task execution such as the aforementioned complexity and length, but also items such as safety criticality, indicating the need for additional Job Aids to reduce the probability of error in task execution.

In designing a Job Aid it is important to design it carefully, as adding too much detail or making it too onerous to use will result in the Job Aid at best not being used, at worst being filled in (if it is a tick box checklist or some such) after the completion of the task.

It has been mentioned that the author starts with the presumption that an SOP will not be referred to during a task execution, however it is a presumption and as such may be challenged and the use of an SOP insisted upon during task execution perhaps due to the complexity, duration, safety criticality, unfamiliarity with, and infrequency of task execution. However, if this is the case one must address the question how do you ensure and guarantee that this is the case?

**Batch Records**

It is common with batch processes for a batch record and procedure to be combined. It has been found that this places too great a demand on the function of the document, leading to excessive length, resulting in users failing to follow the instructions as intended and frequent errors and omissions made in data recording. Therefore it is advised that the role of SOP and batch record are separated, but that the batch record still acts a Job Aid and as such contains specific but limited prompts and reminders intended to ensure that the operator correctly recalls from the SOP what needs to be done and the order in which to do it.



## Training Documentation and Underpinning Knowledge

Many organisations have confusion of the respective roles SOPs and training documentation. Some sites have training materials that provide further and greater details than the SOP on how to perform a specific task, whereas others will only have SOPs but will adopt a “read and sign” approach to training out procedures. The former situation will result in procedures that do not contain enough information about the task and so reference must be made to the training documents, undermining the role of the SOP while simultaneously the organisation has doubled its workload in keeping documents up to date with the inevitable consequence that training documents, usually being uncontrolled and perceived to be of lesser importance in the eyes of the competent authorities, are left to go out of date, while the latter situation fails to adequately ensure the competence of personnel following procedures and can generate a culture of “the procedures are there to protect management and to trap operators when things go wrong”. The latter scenario often also relies on on-the-job training delivered by other operators, the shortfalls of which have already been discussed.

Underpinning knowledge may be the assumptions of knowledge that are made about an organisation’s personnel. At one end of the scale there may be assumptions about their ability to walk, talk, read and write, and at the other end of the scale (particularly with time served craftsmen) assumptions on their technical competence. All organisations will need to make some assumptions about the level of underpinning knowledge present, and this will vary according to the job role, general education standard of the workforce, the specific industry and even specific companies. However, at some point these assumptions are likely to be challenged and the organisation will need to demonstrate why the assumptions are sound and valid, ie, that they are not in fact assumptions at all.

Underpinning knowledge may also be specific company and process related information important for an operator’s understanding of what is going on in a process that is quite separate from specific knowledge on how to run a process, but nevertheless informs the operator and informs the Key Points and Key Point Reasons in an SOP. A domestic example is a modern kettle. A procedure to boil water in a kettle would go through simple steps of fill kettle, place on stand, turn on, etc, in more or less detail. A Key Point would be that in boiling the kettle the lid must be on. Without an understanding of how a kettle actually works this Key Point would be omitted – the Key Point Reason is that modern kettles have an air temperature sensor in the top of the kettle (usually just under the top near the handle), and if the lid is left off the sensor will not detect that the kettle is boiling water and will fail to turn off automatically.

Job roles where there is a high level of underpinning knowledge, for example maintenance craftsmen, should still have procedures for routine repetitive tasks, and should be provided specific underpinning knowledge pertinent to the environment they are working in. By way of illustration consider a car mechanic. He might be the best car mechanic in the world, but if all he has worked on in his life are classic Minis would one let him change the gearbox on a hybrid Porsche 918? The answer, if it were the author’s Porsche 918, is not without further training and provision of specific procedures in how to remove said gearbox. However, one would not have to train the mechanic in how to use spanners and screwdrivers. Some knowledge is intrinsic to the type of person recruited, some needs to be provided as being required for the specific working environment, and some knowledge is very specific and task focused and needs to be held in SOPs.

In writing SOPs the level and detail of underpinning knowledge needs to be identified and declared, so that SOPs can be pitched at the correct level for their intended audience. If the assumption of underpinning knowledge is too high then the content of the SOP is too low resulting in procedures users are unable to understand, interpret and follow. If the assumption of underpinning knowledge is too low then the content of the SOP will become too high leading to patronisation of the users and them finding the procedure an irrelevance to be left on the shelf.

Training documents, for reasons mentioned above, must not contain any task specific information – this must be held in the SOP. They can contain underpinning knowledge, but most importantly Training documents need to contain instructions in how to provide training, the techniques to be used to transfer knowledge and ensure that the recipient has understood, and also to ensure that the recipient of training has attained the required skill level in addition to knowledge. There is a fundamental difference between knowledge and skill (education and training). For example, as part of a training course a video on how to gown aseptically in a pharmaceutical environment was used by the author as an exercise in writing procedures. This means that the author has seen the video multiple times, and can detail precisely what has to be done in what order, the technique to be used and the reasons why, in order to gown up aseptically. The opportunity arose recently to actually gown aseptically, and the author failed abysmally, because he had not developed the skills and co-ordination necessary despite having the knowledge (by way of illustration of the difference between knowledge and skill, or education and training, the author’s father used to rhetorically ask what the difference between education and training was, and answered by asking whether one would want one’s daughter to undertake sex education or sex training at school).

The training and assessment may range from simple read and sign at one end of the scale, for simple non-critical procedures, to detailed provision of underpinning knowledge provided in a classroom environment followed by extensive practical training followed by on the job training, with tests and sign offs at each stage, and regular re-validation processes. Where the training sits on this continuum will depend on the criticality and the complexity of the task.

## Summary

This paper has covered some of the real world experiences and lessons learnt in writing SOPs and procedures gained by the author and his colleagues. The simple ice-breaker survey, from the beginning of a course given on SOPs, shows that there are issues with SOPs in the process industries, with potentially significant safety implications. One could argue that the surveyed companies and people are biased merely due to their presence on the course, so skewing the results. However, the

author has found the situation to be typical and common across many sites in the UK, and that there is an increasing interest in the subject.

Problems exist with both the format of SOPs commonly used in the process industries – they do not prompt the capture of the right detail nor present it in an easily accessible style – and the level of detail and type of information held. The first issue is addressable by the adopting and adapting of automotive Lean style SOP formats, while the second may be improved by the methodologies of collecting knowledge and experience – harvesting it – to record the already known in an organisation's SOPs instead of leaving it in the heads of the few.

Simply gathering knowledge and placing it in SOPs will not fully address the issues of disseminating the knowledge and updating the SOPs with new lessons learnt so that they reflect the latest current practices and provide a solid base from which to improve an organisation's performance. In addition business processes and systems need to be put in place to adequately train out the knowledge and ensure personnel have the pre-requisite skill levels needed for safe operation, and that management directly observes what is actually occurring to a) reinforce correct behaviour, b) understand the gap between the procedure and what is actually occurring, and c) do something about it, such as updating procedures to correctly reflect safe working practices.

It is time for the process industries to pull their SOPs up.

## References

- Adler, P.S., 1999, Building Better Bureaucracies, *Academy of Management Executive*, 13:4, 36-47
- Bicheno, J., Catherwood, P., 2005, Six Sigma and the Quality Toolbox, *PICSIE Books*, 90
- Ford, H., Crowther, S., 1926, Today and Tomorrow
- Gawande, A., 2014 (6 December), The Future of Medicine, Lecture 2: The Century of the System, Reith Lectures, BBC Radio 4 <http://www.bbc.co.uk/programmes/b04sv1s5>
- Health and Safety Executive (5/11/2007) Human Factors Briefing Note No. 4 Procedures. Accessed 2/3/16 <http://www.hse.gov.uk/humanfactors/topics/04procedures.pdf>
- Newton, I., 1676 (15 February) [dated 5 February 1675 Julian Calendar], Letter to Robert Hooke, 1