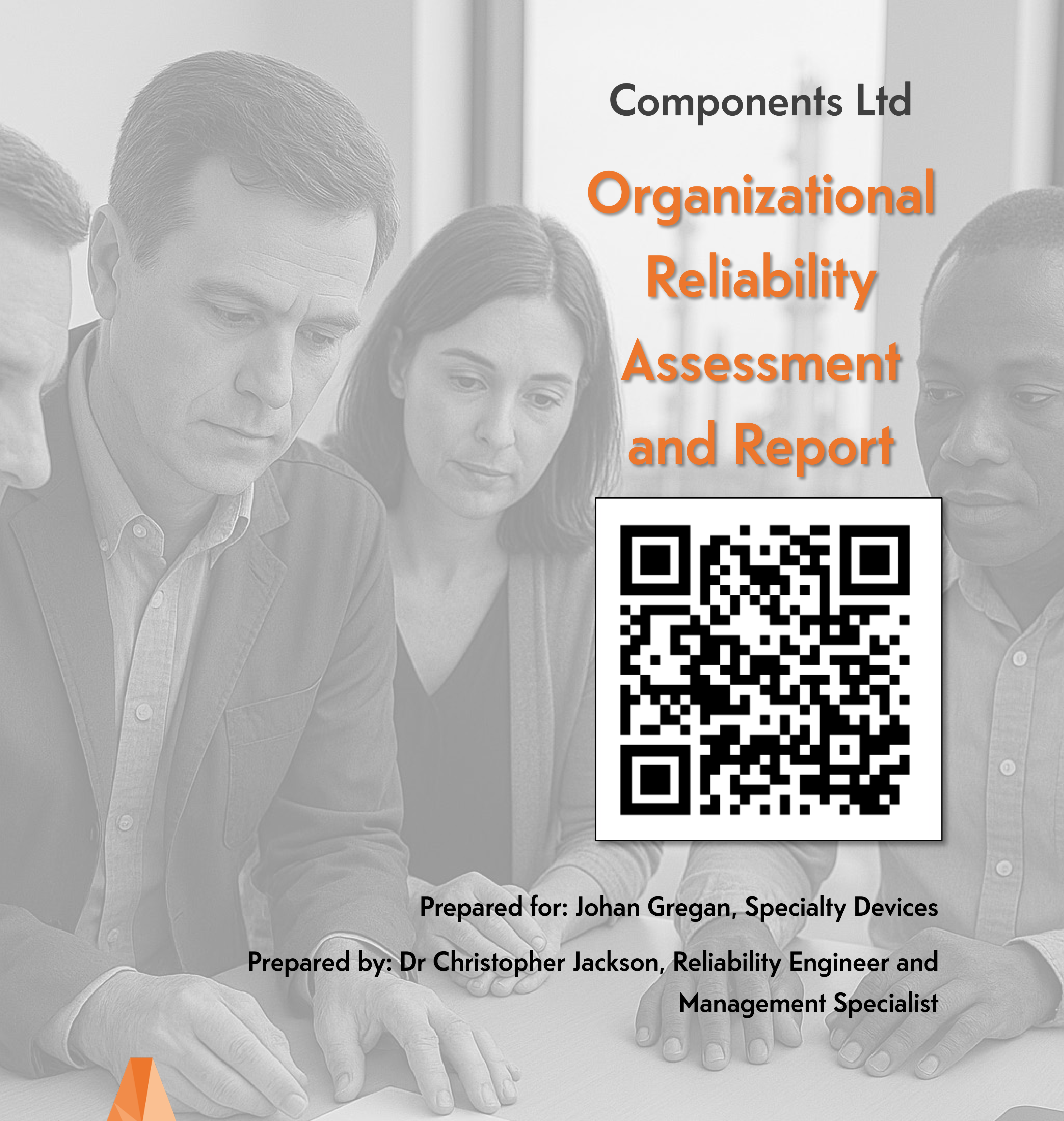

Components Ltd

Organizational Reliability Assessment and Report

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acuitas reliability

A clearer path to better reliability engineering outcomes

Executive Summary

OVERALL	**30.0 %**
Management	33.3 %
Engineering	27.5 %
Manufacturing	29.6 %

The maturity of Components Ltd's reliability program is AVERAGE. While substantial organizational knowledge regarding potential reliability best practices exists, **basic reliability concepts and goals are not shared or clearly defined across the organization**. Engineers and designers don't know where device reliability is, nor where it needs to be. **Because reliability (or unreliability) has never been critically valued or costed, related business and design decisions are generally uninformed**.

Components Ltd's engineering corporate knowledge is tribal – solely existing within the experience and skill sets of senior engineers. Recent workforce reductions targeting senior staff pose a substantial risk that is mitigated only if the next generation of engineers is as skilled as the previous one. Emerging technology (such as smart functionality and connectivity) will exacerbate this issue.

However, with the level of device knowledge, there is scope for immediate improvement.

THREE KEY RECOMMENDATIONS ARE INCLUDED IN THIS REPORT:

1. **Establish Reliability Metrics and Goals.** Without understanding how reliable the device is or how reliable it needs to be, there is limited scope to focus on reliability design and manufacturing effort.

2. **Value Reliability (or the Cost of Unreliability).** The decision to invest money in making a device more reliable is a business one. Without knowing how much it costs if you do (or don't), you are simply guessing what should be done.

3. **Create a 'VITAL FEW' or 'TOP 10 LIST.'** Components Ltd has a good understanding of the likely dominant failure modes in its next model. Reliability engineering efforts aren't targeting these failure modes. Many potential root causes of reliability issues would likely be mitigated while other organizational reliability process improvements are implemented.

This report outlines these recommendations in greater detail, summarizes the organizational reliability survey, and describes Components Ltd's maturity in a matrix. Components Ltd is well-positioned to become a dominant market leader in its industry. Focusing exclusively on the 'VITAL FEW' issues will likely improve market share, revenue, and overall profit.

Survey Report

Overview

Dr Chris Jackson surveyed and interviewed key staff of Components Ltd's Specialty Devices team at the Components Ltd Production Facilities. This report is based primarily on these interviews and supporting ad hoc observations.

Objectives

The objectives of this activity were as follows:

- assess the strengths and weaknesses of Components Ltd's reliability program(s); and
- provide recommendations on how to improve Components Ltd's reliability program(s) and organizational value associated with reliability.

Overall Results

Reliability, risk, and safety are clearly in the minds of Components Ltd's engineering and design workforce. Components Ltd's typically one-off devices are already viewed as highly reliable (2-year reliability exceeds 99 %), but operate in a market where this is the expected minimum performance level. **Components Ltd's (typically) uninformed but substantial reliability efforts provide a feeling of accomplishment, but no validated reliability outcomes**.

Components Ltd has no practical reliability goals. Minimal top-down guidance leaves the organization with a wide array of opinions. Reliability is approached in an ad hoc manner, relying on low-level initiative and experience. Components Ltd's device design knowledge is largely tribal and not formalized. Recent workforce reductions focusing on senior staff are a personnel management practice that quickly erodes the corporate knowledge of tribal organizations.

There is already substantial informal knowledge of the device's likely failure modes and mechanisms. However, this is not being used in a formal or ad hoc manner to prioritize reliability efforts. **In a way, each potential failure mode and mechanism is being treated with equal priority, making them all equally important (or equally unimportant)**.

These issues can be largely mitigated if Components Ltd acts now. New approaches could consolidate Components Ltd as a genuine market leader in the device industry. A reliability plan that streamlines current risk and reliability efforts with a focus on the user will likely produce increasingly reliable, efficient, and desirable products – all while making even more compelling and coherent arguments to the user experience.

Report Structure

Recommendations are outlined in the following section. A more detailed summary of the survey is included in **Appendix 1**. A reliability maturity matrix describing Components Ltd's current organizational structures, norms, procedures, and culture is included in **Appendix 2**.

Recommendations

The following recommendations, if followed, would likely improve reliability, realize design efficiencies, and enhance overall value.

1. **Establish Reliability Metrics and Goals**
2. **Value Reliability (or the cost of unreliability)**
3. **Create 'VITAL FEW' or 'TOP 10 LIST.'**

These recommendations, their respective backgrounds, and enabling steps are discussed in greater detail below.

Components Ltd's engineers and designers may equate these recommendations to imposing something that is already done or adding additional tasks to the design and manufacturing process. This is not the case. Much of the current Design for Reliability (DfR) effort is likely focusing on the 'TRIVIAL THOUSANDS' and not the 'VITAL FEW' failure modes. These recommendations are based on current levels of effort, with outcomes more clearly defined and measurable.

Additional recommendations are also included, noting that organizational change needs to be deliberate and given time to succeed.

Recommendation 1: Establish Reliability Metrics and Goals

Reliability is difficult to measure for high-reliability systems. Failure is expected to be rare. Rare is the baseline – not a statement of goodness. Components Ltd uses some reliability-related metrics (such as complaint rates), but they are not widely or uniformly used.

Components Ltd doesn't have reliability goals. Some incorrectly believe operational lifetimes are reliability goals. Operational lifetimes are indicative timeframes within which the prevalence of failures matters. Quantitative probabilistic statements (such as a failure probability of 1 in 10 000 for a given operational life) are missing, meaning there is no indication of when a device is reliable enough.

Other personnel are confused about the process, with some believing that failure mode and effect analysis (FMEA) allows a reliability assessment that then serves as a goal. This is back to front. A preliminary reliability assessment is not a goal (otherwise, the device will always meet its reliability goal regardless of how good or bad it is).

The reliability of Components Ltd's devices is currently entirely subjective. Components Ltd aims for a level of quality and reliability where actual failure rates (as experienced by users) are so low that there is insufficient field data to accurately assess field reliability until it is too late. These challenges can be overcome.

Specific steps in this recommendation are listed below.

1. **Develop quantitative reliability goals (design focus)**

   Using the failure categories and descriptions from the previous recommendation, Components Ltd should develop quantitative reliability goals. This could see (for example) a safety failure probability goal of 1 in 20,000, and a connectivity failure probability goal of 1 in 5,000 for defined operational lifetimes. These figures are examples only and are dependent on the actual failure categories.

   These reliability goals then drive design efforts with analytical and theoretical assessment made at every key step.

2. **Allocate reliability (and quality) goals to subsystems, components, and processes.**

   Producing a device requires multiple teams working independently, as well as third parties (manufacturers and suppliers). This requires system-level reliability goals to be apportioned appropriately so teams can independently work toward a common reliability performance level.

3. **Develop quantitative reliability 'health indicators' (user focus)**

   A 'health indicator' for a device or system is often a proxy for a metric that is difficult to identify or the precursor to more significant issues. In the case of Components Ltd's devices, potential health indicators include:

   - complaint rates,
   - returns, and
   - improved average online user reviews.

   Field failure rates will ideally be so low that field failure probabilities become difficult to measure. This is where health indicators are useful, as you expect many more health indicators for each failure. Health indicators will typically be based on user experience feedback.

A key benefit of a user-based health indicator is that it provides a closed feedback loop between the engineering workforce's aims and the market's needs. Complaint rates (for example) could be broken down into categories aligned with the reliability goals developed above. It should always be assumed that complaint rates underestimate the actual level of dissatisfaction (with only a certain percentage of users ever complaining about issues).

Health indicators aren't true reliability metrics. But this often does not matter if you are trying to motivate engineers and designers to produce increasingly reliable devices.

4. **Awareness**

Reliability metrics identified in previous steps need to be communicated across Components Ltd so that future technical and platform leads know the terms in which they need to articulate goals in future products. This should always come from the highest level of leadership or management to demonstrate buy-in and commitment.

5. **Formalize reliability goals and health indicators**

Components Ltd should ensure that all goals are expressed in terms of relevant reliability metrics and health indicators in its specifications. This means that an overarching document mandates that reliability (and reliability health) goals be indicated, along with the rationale behind them. The rationale could include incremental improvement from previous models.

6. **Review progress toward reliability goals at all stages of the design process**

Components Ltd should routinely incorporate test data, field data from previous systems, simulation outputs, failure mechanism analysis, and expert judgment to estimate device component and subsystem reliabilities, and then, in turn, estimate system-level reliability performance characteristics.

Likely Value of 'Establishing Reliability Metrics and Goals'

There are several things Components Ltd can expect by understanding device reliability performance in terms of agreed reliability metrics.

- **More reliable devices.** And the monetary benefits that come with this.
- **Informed decision making.** Not knowing which goals exist and how they are measured prevents designers and engineers from fully understanding quality and reliability. Without

goals, everything is important. Which means nothing is important. And not knowing how reliability is measured increases the risk that substandard components will be selected.

- **Informed Vendors.** Components Ltd is highly dependent on suppliers and third-party manufacturers. Without knowing the reliability goals for each component and subsystem, suppliers and third-party suppliers cannot be held accountable. And they cannot exercise judgment to reduce costs if they never know what is good enough.

- **Continual improvement.** It is not possible to know if you are improving without knowing where you were once and where you are going. Incrementally improving reliability goals makes continual improvement natural.

Recommendation 2: Value Reliability (or the cost of unreliability)

Components Ltd's devices have unusually high failure costs when compared to (for example) consumer electronics. Devices cost $ 100 or less. Their failures can cost users $ 5,000 or more. However, the current focus of Components Ltd's device design teams tends to be device-centric budgets and goals – not the total cost associated with a lost sale of a device or the costs users incur.

Valuing reliability consistently makes it easier to make business decisions throughout the device design process. The potential lost sales costs are currently not informing device design decisions.

Specific steps in this recommendation are listed below.

1. **Identify sources of reliability value and costs.**

   Understanding why we focus on reliability is important. And it often comes down to money. Components Ltd should develop a reliability value map that identifies all sources of value and costs associated with devices that work (or fail). These sources include hard cost drivers such as:

   - the costs of all steps Components Ltd takes when a customer complains,
   - the costs of all steps Components Ltd takes when a customer reports a failed device (cataloguing complaints, root cause analysis (RCA), etc.),
   - the costs of mitigating a failure (warranty, replacement, etc.), and
   - damages (if required).

   Soft cost drivers are often ignored because they are more difficult to characterize. But they often form most of the lost revenue in the event of failure. Soft cost drivers include:

- lost revenue associated with the user requesting their doctor to switch to a competing device they are happier with,
- lost sales associated with doctors forming opinions about the efficacy of devices based on feedback from their users, and
- reputation costs associated with high-profile court cases or recalls.

More sophisticated reliability value maps can include costs associated with activities or systems that impart reliability into devices, such as highly accelerated life test (HALT) chambers or other failure mechanism-specific tests.

2. Estimate the cost per failure type

Using the reliability value map, identify the cost of each failure type. For soft cost drivers, estimation can involve establishing a flowchart of user reactions. For example:

breakdown of users by those likely to complain to Components Ltd about failure or not

↳ of these users, those likely to request doctors to prescribe an alternate device

↳ of these users, the costs associated with not purchasing Components Ltd devices

↳ number of lost users from sales representatives recommending alternate devices to other users

↳ lost sales

↳ and so on.

This flow chart breaks down users and their actions based on educated estimates. These estimates are often very useful for nothing but identifying which of these elements drives value and costs the most. These critical estimates then become the focus of future refinement. The aim is not have a 'perfect' estimate of reputational cost, but an indicative figure that helps guide decision-making.

3. Circulation and Awareness.

The cost of failure (which may need to be broken down by platform) must be circulated and well understood across the organization. Management must be aware of this cost when allocating resources to specific design and manufacturing activities. Platform and technical leads need to be aware of costs so they can understand how much unreliability in their product costs.

Likely Value of 'Valuing Reliability (or the cost of unreliability)'

There are several things Components Ltd can expect by having a better understanding of the cost of unreliability.

- **Better business decisions.** Incorporating reliability into the design and manufacturing processes can be expensive. Knowing the likely benefit of these efforts is crucial for determining when something should be done and when it will have limited benefit.
- **Unity of effort.** It does not matter what causes a device to fail. The cost of failure will not depend on whether a design team oversight or a manufacturing defect caused it. Being able to have different design and manufacturing teams work together in an informed, well-resourced framework towards common goals can now be easily valued.

Recommendation 3: Create a 'VITAL FEW' or 'TOP 10 LIST'

Components Ltd conducts FMEAs that would ordinarily identify the most dominant potential failure modes and mechanisms. For whatever reason, these outputs don't align with what appears to be a more accurate tribal understanding of the likely device-dominant failure modes and mechanisms.

Specific steps in this recommendation are listed below.

1. **Create an informal 'VITAL FEW' or 'TOP 10 LIST' workshop**

   Gather representatives from across the organization, and in a structured brainstorm, identify and prioritize likely device failure modes and mechanisms. It is recommended that a certain number of issues or problems be identified (no more than 10).

2. **Circulate and advertise 'VITAL FEW' or 'TOP 10 LIST.'**

   This list should be treated as a 'continually updated' list, with resolved issues removed and replaced by the 'next most pressing' issue. This list needs to be continually reviewed for progress, and reliability resources should be allocated to these issues as a priority over other potential reliability concerns (if everything is important, then nothing is important).

3. **Appoint a 'champion' of this list**

   Appoint someone of appropriate authority and seniority to own and monitor this list, ensuring it reflects the 'as-is' state and that people buy into its ongoing relevance.

Likely Value of creating a 'VITAL FEW' or 'TOP 10 LIST.'

There are several things Components Ltd can expect by having a better understanding of the cost of unreliability.

- **Quick reliability improvement.** Being able to divert resources from potential reliability problems and issues
- **Unity of effort.** It does not matter what causes a device to fail. The cost of failure will not depend on whether a design team oversight or a manufacturing defect caused it. Being able to have different design and manufacturing teams work together in an informed, well-resourced framework towards common goals can now be easily valued.

Additional Recommendations

Organizational change is difficult. Change should be deliberate and well-resourced, and implementing too many recommendations may be ill-advised in the short term. Should Components Ltd successfully complete the recommendations above in a timely fashion, the following recommendations can be considered.

1. **Revolutionize FMEAs.** It is recommended that Components Ltd. engage a trusted FMEA training service provider to teach how to conduct FMEAs and to establish internal procedures to ensure they identify timely, prioritized, and effective corrective actions (rather than being used solely to develop reliability specifications).
2. **Review extant design lifecycle documents** to ensure they provide more relevant and practical guidance, moving away from high-level compliance checking and toward an aide memoire. This should include design rules and derating guidelines.
3. **Characterize operational environmental conditions** through analysis, surveys, and review to better characterize the way in which devices are used and stored (including extreme stress) to more completely inform reliability testing.
4. **Conduct a gap assessment** to identify the delta between where Components Ltd's device production teams are now and where they need to be to optimize reliability performance.
5. **Develop a reliability plan** to coordinate change and incorporate a mature reliability culture with management buy-in, commitment, and involvement.

Appendix 1 - Survey Summary

The Organizational Reliability Survey involved one-on-one interviews with key staff across the engineering, manufacturing, and management teams to assess Components Ltd's reliability program(s). This formed the basis for the subsequent recommendations outlined above.

Customer Background

Components Ltd's Device Delivery team creates typically (but not always) single-use devices to (*do some amazing thing*). These devices often need to be stored in challenging environments for years. They are also inherently highly reliable, but future market share will be based (in part) on differences in reliability between the devices of Components Ltd's competitors. Much of the manufacturing is undertaken by third parties, with final assembly conducted by Components Ltd.

The relatively new technical lead positions oversee each device design. Technical leads maintain corporate knowledge through mentorship and guidance. Technical leads are also responsible for the risk management of their device. The device performance is summarized in the specifications document. Once the device is designed, a manufacturing requirements document is generated, and a manufacturing process engineer assists the technical lead. Finally, a product steward is appointed to oversee the largely third-party manufacturing.

Components Ltd has seven stakeholders who review device design to whom the technical leads need to report.

There are also platform leads who oversee multiple devices and are collectively responsible for commercial development and clinical trial support.

Survey Scoring

The survey is broken down into key categories of reliability activities or frameworks, with scores assigned based on interview feedback.

4 ... 100%, top priority, always done
3 ... >75%, use normally, expected
2 ... 25% - 75%, variable use
1 ... <25%, only occasional use
0 ... not done or discontinued
- .... not visible, no comment

The scoring allows a discussion (if needed) on specific organizational characteristics – not personnel qualifications. For example, if an organization has highly competent and qualified engineers but lacks a personnel management framework to retain them and train the next generation, it receives a relatively low score.

Not all reliability tools are appropriate for use in all situations. If an organization uses inappropriate reliability tools, it will also receive a relatively low score.

Summary Reliability Scoring

The actual numbers and scores below are not meant for comparison with other organizations. They simply characterize the extent to which Components Ltd is implementing best practices related to reliability. These figures serve as the baseline or datum for future surveys to assess the extent of improvements.

Overall	1.20 (30.0 %)
Management	1.33 - (33.3 %)
Manufacturing	1.10 - (27.5.0 %)
Engineering	1.18 - (29.6 %)

Management

Goal setting	(1 out of 4)

There is substantial ambiguity across the Components Ltd. Some personnel view the design life as a reliability requirement, which it is not. There is always a finite chance of failure, and reliability is a probabilistic measure. Others believe the FMEA drives goals and requirements. This is again incorrect, as goals precede all design effort (including FMEAs). Users will treat these devices like consumer electronics, meaning goals need to be updated as often as customers expect a technological refresh, even if the user impact remains the same.

There is some evidence that reliability goals have been established within specific teams, such as the 90/90 goal (90 per cent reliability demonstrated to 90 per cent confidence). This implies a 1-in-10 failure rate, which is unacceptably high for devices. These goals are likely selected based on the test sample size to achieve the confidence level, not to support a business plan.

Priority of Quality & Reliability **(2 out of 4)**

Substantial effort is expended in some areas (though with minimal quantification), whereas it is clearly absent in others. The effort expended is largely confined to the mechanical design of the device and is based on tribal knowledge. There is a distinct (and unnecessary) separation between failures caused by poor design and failures caused by manufacturing issues, with the latter receiving considerably less attention.

Management attention & follow-up **(1 out of 4)**

There was consensus that management struggles to prioritize effort or even acknowledge that what is being asked of the design and engineering teams is beyond their capacity. This typically means that management decisions are practically delegated to technical leads (who have no choice but to determine how to best use their time and resources) while management assumes there are no problems.

Quality initiatives appear to be driven from the bottom up but not enabled from the top down. There is a reliance on local heroes, which is an unsustainable approach. A recent initiative to hire a reliability engineer is a promising development.

There is also evidence of an exhortation leadership style across Components Ltd in terms of quality and reliability. Initiatives that once garnered management attention are now described as buzzwords (such as Design for Manufacturability). This typically means the idea never received resources or management commitment, and the idea inevitably lost momentum.

Manufacturing

Design for Manufacturability **(2 out of 4)**

This was an initiative (as per the previous point) which is now referred to as a buzzword. There are substantial efforts at lower levels to design manufacturable devices, but this is very tribal. Components Ltd is very exposed in terms of device design and corporate knowledge as a result.

Priority of Quality and Reliability goals **(2 out of 4)**

There were minimal manufacturing-specific quality or reliability goals identified, perhaps most evident in the manufacture of electronic subsystems. Manufacturer selection and oversight is outsourced to a design partner (electrical design overseer Flextronics Design), with neither the design partner nor the manufacturers they select easily auditable.

There appears to be substantial margins incorporated in the design process (overengineering). This is an understandable approach. Conservative approaches to design are generally prevalent, with a focus on doing things well rather than working toward quality goals. A highly reliable product is inherently difficult to measure in terms of reliability, making it hard to set goals. But this does not mean they can't and shouldn't be established.

Ownership of Quality and Reliability goals (2 out of 4)

A lack of overall vision (what the devices need to feel like, where device design is heading, what failure means, and so on) has resulted in quality and reliability goals driven from the bottom up. Any goals specified by the technical or platform leads are subject to review, meaning reliability performance relies on initiative from below in an environment characterized by passivity from above.

Reliability performance communicated in this way is rarely effective. Those in executive positions don't have a clear vision of quality and reliability. They are then unlikely to rigorously interrogate reliability performance, meaning everything passes or is approved. In short, people value perceived effort over actual performance.

An example of a lack of ownership of quality and reliability is a manual gluing procedure for which the design partner provided only a completed photo for manufacturing guidance. Only a single person has ever been able to master this gluing process, regardless of training and re-evaluation. This person is now being prepared to fly to various manufacturing locations to enable production. This is an archaic and risky manufacturing practice that has no place in a contemporary manufacturing organization. Rather than anyone identifying a better glue or more appropriate gluing technique, the single person who seems to inherently master the gluing process becomes the single point of failure for an entire product line.

A promising initiative is the adoption of a more robust systems engineering framework to better control requirements and outputs. Care must be taken to ensure that the focus is not the framework (which may result in a compliance or checklist approach to goodness). The reliability and quality of the product are paramount.

Quality training programs (0 out of 4)

None observed.

Statistical Process and Quality Control (1 out of 4)

There was a concerning anecdote about a button breaking off a device during final functional tests. While the button met the tolerances of the design dimensions, there was a manufacturing error that resulted in it being porous (with multiple air bubble voids). The button consequently reduced in size over time. It was suggested that the manufacturers may have known about the porosity but did nothing about it, as it met the prescribed tolerances. This is indicative of a compliance-centric approach to quality control that will likely yield significant problems in the future.

Internal process audits (1 out of 4)

Several Components Ltd staff expressed concerns that there was a drift towards a statistical and sampling approach to reliability rather than a first-principles approach. That means processes are not being interrogated and questioned based on underlying physics.

A process improvement team recently reviewed Components Ltd's processes, but the engineers have not received the outputs well. Processes were perhaps unnecessarily broken down into regulatory and business areas, doing little to reduce or streamline workloads. Components Ltd personnel generally don't like the outcomes of this review and have seen little in terms of reduced workload. In some cases, the workload has increased.

Supplier process audits (2 out of 4)

Suppliers are sourced through a request for proposal (RFP) framework. Once a supplier is selected, it is difficult to change them due to scheduling and contractual constraints.

There is an approved supplier list, but this is based on historical performance. While historical performance provides some assurance of future performance, it will not guarantee robust procedures. In some cases (see above regarding manufacturers selected by design partners), Components Ltd has almost no visibility of how suppliers produce parts and components. In other cases, quality staff visit third-party manufacturers and production lines, but this is primarily limited to the mechanical aspects of the devices.

There have been examples of electronic components not being manufactured with the correct number of inputs and outputs. This issue was not picked up until it was received by Components Ltd, forcing a substantial redesign.

Material and mechanical component suppliers typically have better relationships with Components Ltd, as there are no intermediary parties. These relationships tend to be partnerships more than strictly transactional arrangements. These relationships should be encouraged and become the norm for all suppliers (not just material manufacturers).

Incoming inspection **(0 out of 4)**

No incoming inspection regime was observed, and it is unclear whether this is a logistics or manufacturing issue. Manufacturers undertake substantial inspections, but issues (such as the porosity described above) are sometimes omitted from consideration. There is widespread opinion that manufacturing has a compliance-based framework for quality and reliability.

Product burn-in (... only if failure mechanisms are known) **(- out of 4)**

Does not appear to be applicable to Components Ltd.

Defect-Tracking **(0 out of 4)**

There is a perception that defect tracking primarily revolves around customer complaints and feedback. There also appears to be no visibility of defect tracking within third-party manufacturers. Components Ltd does not necessarily need to have its own defect-tracking mechanisms for all components, but it does need an understanding of supplier defect-tracking systems.

The defect tracking that exists tends to focus only on materials. Not electronic components or software.

Corrective Action **(1 out of 4)**

A corrective action procedure exists, but many personnel indicate it is rarely used. Actual corrective action approaches are described as 'crisis-centric.' The intensity of the situation sees people ignore procedures, meaning the corrective action may either not address the root cause (with the issue persisting) or be an inefficient solution.

Engineering

Documented design cycle **(11 out of 4)**

Reference documents do exist, but these are largely qualification in nature, focusing on the mechanical aspect of devices only. There is minimal documentation of the design cycle as it relates to device electronics and connectivity. Components Ltd's focus on design-cycle information is largely tribal, with an ongoing mentorship program. While this can be an appropriate approach, it is highly risky in an organization such as Components Ltd, which has shown a propensity to reduce workforce size by retiring senior staff. Many of the more senior personnel interviewed suggest that Components Ltd is now reinventing processes that were lost during previous workforce downsizing events.

As a rule, a documented design process is the bedrock of a reliable product. It appears as if Components Ltd's approach to workforce management makes a documented design cycle particularly critical.

Components Ltd's reference documents are considered unreasonably complex and overly high-level. This typically means the reference document is trying to pre-emptively mitigate every known way the device (or design process) can fail. Making everything important often makes nothing important. That is, if designers can only practically incorporate a fraction of mandated activities, then nothing is mandated. Authoritative guidance is replaced with low-level judgment, and these documents lose relevance.

Complex design documents also created the illusion that the design process is formalized in practice. Given its practical impossibility to adhere to, management felt assured that everything was due to the existence of an exhaustive resource document. But because no one adheres to it, management is oblivious to the reality.

The documents provide minimal practical guidance, and there have been instances of devices manufactured in violation of industry standards or norms.

It is also worth mentioning that no cybersecurity plan was identified during the survey. This will become a very significant focus in the future, but requires consideration now.

Reliability goal budgeting (0 out of 4)

None apparent.

Priority of reliability improvement (2 out of 4)

None apparent in practice, as there is no understanding of what current reliability is, what reliability needs to be, and the level of effort involved to get there. Multiple personnel interviewed indicated that historical reliability improvement priorities have been low. There is now an increased desire to improve reliability, but this has yet to translate into a higher practical priority.

DFR training programs (0 out of 4)

None observed. There is a focus on mentorship and procedures, but this means that DfR best practices are unlikely to be developed and sustained. All engineers have an individual training plan (ITP), but this is typically focused on workplace rules and regulatory compliance – not professional development.

Preferred technology program (3 out of 4)

Device technologies are relatively static in terms of best design practice. Preferred technologies are perhaps manifested in the standardization of device containers. As devices are simple (but sophisticated), there is limited choice in terms of available technologies. That said, there will come a time when standard approaches to connectivity (such as communication protocols that comply with global market regulatory requirements) need to be developed and articulated.

Components Ltd also has an extensive materials database that it uses to assist with device design.

Component qualification testing (1 out of 4)

Components Ltd has a sampling standard operating procedure (SOP). Several personnel were concerned that there is a drift toward a statistical and sampling approach that subsumes a first principles approach to reliability.

Rapid AA testing was conducted, but its use and interpretation of results were based primarily on experience. It was difficult to identify which failure mechanisms were actively being tested (beyond creep). The Arrhenius model (1st-order chemical reaction) is often used, though creep acceleration factors can be difficult to model.

OEM selection & qualification testing (1 out of 4)

OEM selection is primarily based on a preferred supplier list. This is reactive - not proactive. Issues involving batteries showed that testing was substantially limited and did not reflect an as-assembled state. Entire product lines had to be retired as a result.

Physical failure analysis (1 out of 4)

Durability, ageing, and challenge testing are undertaken. However, perhaps the most useful capability Components Ltd has in this regard is its Computational Modelling Failure Team. Not all personnel were aware of this team, and its incorporation in the design process is not widespread.

Root cause analysis (RCA) (1 out of 4)

Components Ltd's quality team is involved in RCA, but a member of the design team often conducts it. The process is not always followed, and many people identified instances in which RCA outcomes were so late that the resulting fixes could not be incorporated into the design.

Engineering experiments (2 out of 4)

Experiments tend to focus on qualification. That is, devices are tested to pass, not tested to learn. Existing tests include things like drop tests. A concerning sentiment was that ongoing testing may identify issues that will initiate a recall, which is to be avoided. So, ongoing testing is avoided. This means that failure mechanisms are not actively being sought out, and, by extension, reliability cannot improve.

Some personnel stated that six-sigma principles are used in manufacturing, but this was not consistently reported by all interviewees. One interviewee said that six-sigma principles have recently removed from Components Ltd's manufacturing principles. There is clear ambiguity about what processes are being followed.

Design & stress derating rules (1 out of 4)

The only evidence of design and stress derating rules was a suggestion that the electronics design partner uses them internally. This is speculative and has not been verified. The mechanical design technical leads seem to believe that design and stress derating rules are incumbent on individual designers and engineers, who become proficient in these areas through experience and mentorship. This approach (as outlined above) is organizationally risky.

Appendix 2 – Reliability Maturity Matrix

The reliability maturity matrix that shows Components Ltd's assessed maturity is illustrated on the following page (via red shaded boxes).

		Stage 1: Uncertainty	Stage 2: Awakening	Stage 3: Enlightenment	Stage 4: Wisdom	Stage 5: Certainty
Requirements	Requirements & Planning	Informal or non-existent	Basic customer req. met: plans have required activities	Requirements include environment & use profiles: plans more detailed	Plans customized: distributions used for environmental & use conditions	Contingency planning occurs: decisions based on business & market
	Training & Development	Informally available	Some training in concepts & data analysis	Reliability training for managers: manager training on reliability & lifecycle impact	Reliability statistics courses for engineers: senior managers trained on the impact for business	New technologies & reliability tools tracked: reliability training supported by management
Engineering	Reliability Analysis	Non-existent or based on manufacturing issues	Use of point estimates a& hand-book parts count: basic ID of failure modes & impact	Formal use of FMEA: field data from similar products analyzed; design changes cause re-evaluation	Predictions expressed as distributions of environmental & use conditions used for simulation & testing	Lifecycle cost considered in design; stress & damage models used; extensive risk analysis for new technologies
	Reliability Testing	Primarily functional	Generic test plans; testing only to meet customer or std. specs	Detailed reliability test plans; results used for design changes & vendor evaluation	Accelerated tests & models used; testing done to failure or destruct limits	Test results used to update component models; new technologies characterized
	Supply Chain Management	Selection based on function & price	Approved Vendor List (AVL) maintained; audits on issues or key parts; vendor datasheets used	AVL updated by assessments & audit results; field data & failure analysis related to vendors	Vendor reliability data used for vendor selection; suppliers conduct external assessments & audit	Changes trigger vendor reliability assessment; component parameters & reliability monitored
Feedback Process	Failure Data Tracking & Analysis	Only looks at function failures	Field returns analysis & internal testing; Failure Analysis (FA) reliant on vendor	AVL & prediction models updated by root cause analysis, and results shared	Focus on failure mechanisms; failure distribution models updated via failure data	Customer satisfaction vs product failures understood, prognostic methods used
	Validation & Verification	Informal, without process	Basic verification of plans followed; Field data regularly reported	Supplier reliability agreements & failure modes are regularly monitored	Internal reviews of reliability processes & tools, failure mechanisms monitored	Reliability predictions match observed field reliability
	Reliability Improvement	Nonexistent or informal	Design & process change processes followed, correction action taken	Effectiveness of corrective actions tracked; failure modes addressed in other products; improvements identified.	Failure mechanisms addressed in all products, modelling techniques, & lessons learned process adopted	New technologies evaluated & adopted; designs updated per field failure analysis
Management	Understand. & Attitude	Has no grasp	Recognizes but takes no action	Becoming supportive & helpful	Actively participating	Considers essential to the company
	Status	No status	Conduct of specific and routine product Testing & failure analysis tasks	Reliability manager reports to senior management & has involvement in managing the division	Reliability manager is an officer, reporting on actions & involved with consumer affairs	Reliability manager is a board member; prevention is a key concern
	Cost of unreliability	Not done	Direct warranty expenses only	Warranty, corrective action materials, & engineering costs monitored	Customer & lifecycle unreliability costs identified & tracked	Lifecycle cost reduction done via product reliability improvements