[redacted] - Business Management System Manual to ISO 9001 – 2008 Systems Assessment Report

[redacted]

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Summary

Where there is insufficient description of commitment toward Quality Management System Standard ISO 9001 compliance, the reference to these clauses is prefixed with GAP.
Suggested text amendments and inclusions are prefixed with IO, Improvement Opportunity.
As well as Improvements identified in the comments section of the report, some suggested edits and additions of written text has been included in File: [redacted] BMS Edits

It is suggested to include the relevant references/ links to the mandatory ISO 9001 procedures and other documents at the end of each section. This simplifies the navigation for readers to understand the Business Management System.

Throughout the Manual, the use and the interpretation of 'product' sometimes appears unclear. i.e. 3.7 "products are concentrates of copper, silver…" 7.1 Product realisation pertains to products developed to mine and produce concentrate". It is suggested this be clarified [redacted] product is ultimately ore concentrate, produced to customer requirements. It is understood the satisfactory completion of the numerous processes and their sub processes, i.e. optimal process design, project management services provided by subcontractors, design/purchasing of plant and equipment is a fundamental requirement toward providing the end product, ore concentrate.

Also included Improvement Opportunities (IO) to enhance on the emphasis of the business management system. It is to your discretion if you choose to include these.
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Ref No.	Title	Guidelines	Comments
1	Scope		IO Add more descriptive overview of [redacted] exploration and planned operational capability
2.1	Approval Issue Access		IO Manual overview to include: a) Manual based on the requirements of Quality Management Systems requirements ISO 9001 b) Contact details of the Business Systems Manual controller c) Specific file location path of manual in [redacted] d) A statement that hard copies are uncontrolled
2.2	Revisions		IO Edit content. Remove Last 2 sentences
2.3	Revision History:		IO A number of techniques can be used to maintain revision control: a) Rather than include a separate revision number, it may be sufficient to use the date of issue. b) If separate references are to be used they should be consistent., i.e. Revision Numbers 0,1,2,3 in 2.3 or A,B,C at document footer
3.	Terms and Acronyms		IO Suggest to include these in alphabetical order. Not required to have each of these listed as numbered sub clauses, unless specifically requested. IO 3.1 Remove. Suggest to include the description of [redacted] in the Manual Overview, Sect 1 IO 3.4 suggest to separate Process Maps and Procedures. Process Maps, diagrammatical representations organisational of process flows, defining activities, responsibilities and process interrelationships, where Procedures are predominately text based IO 3.5 No need to differentiate between Business Management System and Quality management. The Business Management Systems will incorporate all aspects of the ISO 9001 Quality Management Systems- Requirements. GAP Add definition of correction and corrective actions from ISO 9000: a) Correction is “Action to eliminate a detected nonconformity.” It is also called commonly called “containment” b) Corrective action is “Action to eliminate the cause of a detected nonconformity or other undesirable situation
4.	Quality Management System		The process approach could be further explained as a series of interrelated process each with inputs, from previous processes and outputs to the next processes. Appendix A
4.1	Quality Management Systems Overview	ISOI 9001 – 2008	The Business Systems Manual is a [redacted] document which describes the business systems policies incorporating the requirements of ISO 9001. IO Include specific policies and methods on how, through metrics, audit, management review, [redacted] management monitors the effectiveness of the Management System GAP Add here a statement on how all outsourced processes, products or services, affecting product conformity with requirements, should be controlled and the linkage to 7.4 Purchasing. ISO 9001 – 2008 shown i.e. subcontracted products and service requirements clearly specified during purchasing.

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4.2 **4.2.1**	Documentation Business Systems Manual and Policies		IO Refer the manual as the Business Systems Manual, with the requirements of [redacted] ISO 9001 based Quality Systems Requirements included. Rather than separate reference to Quality Manual and Business Systems Manual (include actual quality objectives within the business systems manual)
4.2.2	Operating Procedures/Business Process Maps		IO add Process Maps as well as Operating Procedures, which will further demonstrate compliance to interaction of key processes.
4.2.3	Control Of Documents	ISO 9001 – 2008	IO All Business Systems documents, not only Quality Management compliance documents should be placed under control GAP Add Documents of external origin are identified and their distribution is controlled e.g. statutory and regulatory documents, standards, laboratory testing methods
4.2.4	Control of Records		IO Refer [redacted] BMS edits.
5.1	Management Commitment		IO Improve clarity with bullet points. [redacted] BMS edits IO Add Examples of the Critical to Quality Metrics to be Monitored i.e. Customer Complaints, Reduction of internal nonconformity
5.2	Customer Focus		IO Refer [redacted] BMS edits
5.3	Quality Policy		Quality Policy commitment evidence will need to be demonstrated, if not already done so, IO Best to write the policy in the first person. e.g. 'We will strive and commit to the achievement of excellence.."
5.4 .1	Planning Quality Objectives		GAP Add key Quality Objectives here. Measurable and consistent with the Quality Policy
5.4.2.	Quality Management Systems Planning		OK.
5.5 **5.5.1**	Responsibility, Authority and Communication		GAP Add provision for competencies for each position description summary.
5.5.2	Management Representative		OK
5.5.3	Internal Communication		OK subject to verification of objective evidence
5.5.4	Management Review		IO Minor changes. Refer [redacted] BMS edits Evidence will be required for each of the reviewed items listed.
5.7	Change Management		IO Change Management is generally seen as a continuous improvement activity. May be more appropriate to include in 8.4, Improvement.
6.0,6.1	Provision of Resources		OK, Subject to verification of objective evidence
6.2	Human Resources		Reference to form to be deleted. Or alternatively include the specific form name and number

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6.3	Infrastructure and Work Environment	ISO 9001 2008	GAP Add information systems to scope of Infrastructure. Examples of human and physical factors affecting the work environment. Human Factors, Safety rules, Ergonomics, Physical Factors: Temperature, Humidity, Noise.
7.1	Product Realisation Planning of product Realisation	ISO 9001 – 2008	IO Include a comment product realisation is covered by the [redacted] Core Business Processes, Generate, Explore, Develop, Operation and Close. IO More emphasis on the commitment of project plan preparation for defining the Planning of the Product Realisation Process. e.g. Project plans are created early in the process. Project Plans define: a) Tasks need to be completed b) Resources assigned to the project c) Time targeted to complete the project GAP 3rd bullet point – required verification, validation, monitoring, measurements, inspection and test activities and corresponding product acceptance criteria Note : measurement added IO If [redacted] have documented Disaster Recovery, Emergency and Business Continuity Plans, these should be referenced in this section. (e.g. cyclones, fire, chemical spills)
7.2 **7.2.1**	Customer Related Processes Determination of requirements related to the product.	ISO 9001 2008	IO Separate current 7.2.1 into 2 clauses: 7.1 Determination of Product requirements and 7.2 Review of Product Requirements GAP Requirements expounded to include statements covering the following: [redacted] [redacted] , through Sales and Marketing, has developed processes to determine and understand customer requirements including: a) The requirements specified by the customer, including requirements for delivery and post-delivery activities Note: Post-delivery activities may include any warranty provision set out in contractual documents b) Requirements not stated by the customer but necessary for specified use or known and intended use c) Statutory and regulatory requirements related to the product d) Any additional requirements determined by [redacted] The sales and marketing quotation/tender Submission process would generally cover this.
7.2.2	Review of requirements related to the product		GAP Include an additional clause on how the Quality Management Plan ensures customer requirements defined in contracts/orders are reviewed, e.g.: a) Requirements related to the product are reviewed prior to the commitment to supply product b) The review should ensure: a) Product requirements are defined

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			b) Contract or order requirements differing from those previously expressed are resolved c) [redacted]'s capability to meet defined requirements c) Records of the results of the review and actions arising from the review are maintained. d) As applicable, how it will be demonstrated [redacted] confirms customer requirements when no documented statement is provided by the customer e) Available evidence shows relevant documents are amended and relevant personnel made aware of changes Note: This is likely to be a sales marketing activity which should be systemised to ensure standardisation and consistency. It is often beneficial have a separate Contract Review Procedure or process map to define the system and responsibilities of ensuring customer/stakeholder requirements are clearly understood.
7.2.3	Customer communication		From 7.2.2. Expand on text test to ensure commitment to ensuring that all issues of product information, ordering, order changes, handling, any customer/stakeholder feedback are carried out in a timely and effective manner Examples of effective methods include: contact management systems, customer contact forms, and applicable, order entry systems that allow for comments and notes. IO Product information on company publications, WEB Site and fact sheets.
7.3	Design and Development Planning		GAP Include a statement committing that the interfaces between different groups involved in the design and development are managed to ensure clear assignment responsibility.
7.3.2	Design and Development Inputs		OK
7.3.3	Development Output		OK
7.3.4	Design Review Validation and Verification		OK
7.4 **7.4.1**	Purchasing Purchasing Process		GAP Add detail on control of "outsourced processes". (Clause 4.1). The type and extent of control to be applied to outsourced processes shall be defined "Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as: a) Potential impact of the outsourced process on the organization's capability to provide product conforming to requirements b) Degree to which the control for the process is shared c) Capability of achieving the necessary control through the application of 7.4."

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7.4.2	Purchasing Information		OK
7.4.2	Verification of Purchased Product/ Service		GAP A statement should be included provision of any purchasing verification activities (either by [redacted] or their customers), which are performed at the suppliers premises, prior to receipt.
7.5 **7.5.1**	Product and Service Provision Control of Product and Service Provision		GAP Focus this clause on production and service operations which will be carried out under controlled conditions, including, as applicable,: a) Availability of information describing the characteristics of the product b) Availability of Operational Work Instructions c) Use of suitable equipment d) Availability and use of monitoring and measurement equipment e) Implementation of monitoring and measurement f) Implementation of release, delivery of product and post-delivery activities
7.5.2	Validation of Process for Production and Service Realisation		IO The interpretation of this clause is designed to cover namely outputs of processes which cannot be verified by subsequent monitoring or measurement, without destruction of the product. As [redacted] does not have such operations, this clause can be exempt from the compliance scope.
7.5.3	Identification and Traceability		Note The intent of this clause is to track batches and serial number for warranty and liability purposes. GAP Identification and traceability when a requirement, should be maintained throughout the product realisation process.
7.5.4	Customer Property		GAP Add 'personal data' Refer [redacted] BMS edits. GAP Add lost, damaged or unsuitable customer property is reported to the customer and records maintained.
7.5.5	Preservation of Product		GAP Include a statement on how it will be demonstrated product conformity is preserved during internal processing and delivery to the intended destination Product preservation methods need to be established for handling, packing, storage and protection
7.6	Control of Monitoring and measuring Equipment	ISO 9001 -2008	Note: "the word Devices in the title is now changed to Equipment. IO It is unclear from the text on how inspection, measuring and testing equipment is controlled during "servicing of product"
8.1 **8.1.1**	Monitoring and measurement Customer Satisfaction		GAP Refer [redacted] BMS edits
8.1.2	Internal Audit		GAP A requirement for management responsible for the area audited to ensure that 'necessary corrections and corrective actions' has been added. Add reference to necessary correction and corrective actions instead of "actions". Add definition of correction and corrective actions from ISO 9000.

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			a) Correction is “Action to eliminate a detected nonconformity.” It is also called commonly called “containment.” b) Corrective action is “Action to eliminate the cause of a detected nonconformity or other undesirable situation.” Add the organisation shall define requirements for reviewing the effectiveness of the corrective action taken.
8.1.3	Monitoring and Measurement of Processes		GAP Add Correction Action Refer [redacted] BMS edits
8.1.4	Monitoring and Measurement of Product and Services.		GAP Expand this clause further to include: a) Measurement and monitoring of the product is carried out at various stages of the product realisation process in accordance with planned arrangements b) Evidence of conformity within the acceptance criteria is maintained and records indicate the person authorising release of conforming product c) Controls are in place to ensure that product release and service delivery to the customer does not proceed until all planned arrangements, 7.1 are satisfactorily completed. If not, release approval evidence, from a relevant approval authority or customer, is provided
8.2	Control of Non-conforming Product		GAP Further expand to include provision for: a) Defining controls and related responsibilities and authorities for dealing with non-conforming product in the documented procedure/process map b) Available evidence that non-conforming product is dealt with by one or more of the following ways: - Action taken to eliminate the detected nonconformity - By authorising its use, release or acceptance under concession by a relevant authority, as applicable, by the customer - By taking action to preclude its original intended use or application, i.e. segregation - Maintained records of nonconformities, subsequent actions, including concessions - Corrected nonconforming product is subject to re verification to demonstrate conformity to requirements - After delivery or use, the actions taken are appropriate to the effect or potential effects of detected non-conforming product
8.3	Analysis of Data		OK
8.4 **8.4.1**	Improvement Continuous Improvement		Note Definitions of corrective and preventive action are primarily Statistical Process Control based. Although, these are valid, there are many more initiators for Corrective and Preventive Actions. GAP Include statement Continuous Improvement is based upon review of quality policy,

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			quality objectives, audit results, analysis of data, corrective and preventive actions and management review.
8.4.2	Corrective Action		IO Refer [redacted] BMS edits IO Definition, to include in Section 3, Correction Action or Containment Action is the immediate short term action which contains the problem. Corrective Action Long term fix to evaluate root causes which lead to permanent actions, preventing the recurrence of problems. Corrective action is re-active i.e. dealing with the problem after the event
8.4.3	Preventive Action		IO Refer [redacted] BMS edits IO Definition, to include in Section 3, Preventive Action is the procedure to eliminate causes of potential non conformities. These are pro-active actions, dealing with the problem before it happens. The preventive action procedure may include: data analysis (8.4) setting objectives (5.4.1), clarifying customer requirements (7.2 and 7.3), applying proven corrective actions (8.5.2) to other areas of the business and awareness changes (5.6)

APPENDIX A