PROCEDURE

FOR

INTERNAL QUALITY

AUDIT

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DOCUMENT NO: SP-07

REVISION O

AUGUST 2006

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Status	Author	**Agreed**	**Approved**
For Implementation			

1 PURPOSE

1.1 ISO 9001 requires that documentation procedures be established and maintained "for planning and implementing internal quality to verify whether quality activities and related results comply with planned arrangements and to determined the effectiveness of the quality system".

1.2 The purpose of this Procedure is to describe the method to be adopted for the carrying out of Internal Quality Audits.

2 RESPONSIBILITIES FOR IMPLEMENTATION

All staff taking part in internal Quality Audits is responsible for the procedures implementation.

3 REFERENCES

ISO 9001:2000	Clause 8.2.2 & 8.2.3
ISO 10011	Guidelines for Auditing Quality System, Parts 1, 2 and 3
Document No.QS-01	Quality Manual
Document No.SP-08	Control of Nonconformities, Corrective and Preventative Action
Document No.SP-09	Management Review of Quality System
Document No PP-16	Maintenance of records and archiving

4 IMPLEMENTATION

4.1 Audit schedule

4.1.1 The Quality System Manager shall prepare and keep up-to-date a schedule for the carrying out of internal Quality Audits. The schedule shall provide for the comprehensive auditing of implementation by all staff of all aspect of all aspects of the company's Quality System at least once per year.

4.1.2 Each Audit shall have a unique number that shall be identified on the schedule. The schedules shall be reviewed as part of the Management Review of the Company's Quality System (See Document No.SP-09), and shall be revised as may be agreed in such reviews.

4.1.3 Unscheduled Quality Audits may be conducted, in addition to those scheduled, as considered necessary by the Quality System Manager.

4.2 Auditor independence

4.2.1 Auditors shall be appointed by the Quality System Manager shall be free from bias, independent of the operation to be audited and free of influences that could affect objectivity.

4.3 Auditee Notification

4.3.1 The Auditee shall be given prior notice by the Auditor of the intention to carry out an audit. A date or dates of the Audits shall be agreed with the Auditee, as shall be the scope of the Audit. The Auditor shall confirm details of this agreement in writing.

4.4 Audit Preparation

4.4.1 The Auditor, having agreed the date and scope of the auditee, shall ensure that he possesses all documentation relevant to the audit and that this is reviewed prior to the audit taking place. Relevant documentation shall include Procedures, job descriptions, previous audit reports, etc.

4.4.2 The Auditor shall prepare, in advance of each audit, checklists utilising the Quality System procedural requirements as a basic requirement. The checklist shall be prepared on copies of Form SP 0701 (see example of attachment SP-07/A).

4.5 Performance of Audit

4.5.1 Audits shall commence with an entry meeting between the Auditor and the Auditee for the propose of:

- Briefly confirming the scope and purpose of the Audit
- Agreeing upon a timetable and agenda of the audit
- Agreeing upon a tentative time for a closing meeting
- Arranging for the auditor to be accompanied during the audit (where appropriate) by an Auditee representative

4.5.2 The timetable for the Audit shall recognise that the Auditee has other business to attend to and shall make a minimum demand on his time that

is compatible with an effective audit being completed.

4.5.3 The Auditor shall record the names of those attending the entry meeting.

4.5.4 Audits shall be conducted, using the prepared checklist as a guide, without necessarily being restricted to it, with a view to determining the degree of conformity with the specified requirements and the effectiveness of the Quality System. Objective evidence of conformity or nonconformity, as appropriate, shall be sought and the details recorded on the checklist.

4.5.5 In the “finding” column on the checklist, the Auditor shall enter “Yes”, “No”, “Not Applicable” or “See Comments”. The “Action” column shall be used to record what action (if any) was taken in the light of the finding, e.g. Corrective Active Request Issued, (see paragraph 4.5.6 below), observation made in Audit Report, etc. The “comment” column shall be used for identifying objective evidence, expanding on the finding, etc.

4.5.6 Upon conclusion of the audit, the Auditor shall analyse any apparent nonconformities to ensure their validity as Audit findings. Where objective evidence has been recorded of departure from approved procedures or other documented requirements, this shall constitute valid justification of nonconformity. All such nonconformities shall be recorded on copies of Form SP 0702 (see example at Attachment SP-07/B) and shall be categorised 1, 2 or 3 in accordance from the following:

- Category 1 – *Major breakdown* in implementation of a Quality System Procedure

- Category 2 – *More than one minor deficiency* in implementation of a Quality System Procedure

- Category 3 – *A minor disruption* in implementation of a Quality System Procedure.

4.5.7 Having reviewed the findings, the Auditor shall complete the Forms SP 0702 as far as and including the section headed “Nonconformity”. The Auditor shall then convene an exit meeting with the Auditee for the purpose of:

- Presenting an overview of the Audit results and its findings
- Ensuring that the finding are understood by the Auditee

4.5.8 The Auditor shall obtain the signature of the Auditee in the “Nonconformity” box to confirm that the Auditee accepts the nonconformity and understands its nature.

4.5.9 The Auditor shall advise the intended issue date of his formal audit report (see paragraph 4.6 below).

4.6 Audit Report

4.6.1 The Auditor shall issue to the Auditee, as quickly as possible after the conclusion of each audit report to a standard format.

4.6.2 A summary of the audit and audit findings shall appear at the beginning of the Audit Report. Reference shall be made in the summary to any correctible action requests that have been issued.

4.6.3 The body of the Audit report shall include the following sections (where as a section is not applicable, the words' not applicable' shall appear beneath the heading):

- **Entry meeting** - This shall comprise a brief summary of the meeting with details of the attendance. Any specific requests made by and /or agreements reached with the Auditee at the meeting shall be listed.

- **Audit** - A detailed account of the audit shall be provided, listing:

    1. Areas /activities found to be satisfactory and in conformity with requirements
    2. Areas /activities found not to be conforming and the subject of corrective Action Requests

- **Exit meeting** - This shall comprise of a brief summary of the meeting with details of attendance. It shall include of any Corrective Action Requests withdrawn as a result of discussion at the at the exit meeting, as well as a record (where appropriate) of a refusal by the Auditee to sign any Corrective Action Requests.

- **Follow-up** - The Auditor shall set out here his attention to carry out a follow-up visit, where appropriate, for the purpose of verifying compliance of each Corrective Action Request. The date of the follow-up visit shall follow the final date to be stated by the Auditee for completion of corrective actives.

- **General observations** - This shall include any observations by the Auditor that he may consider applicable and constructive, or of any areas where, as a results of the audit, the auditor considers that procedures can be improved.

4.6.4 Upon completion, the Auditor shall sign the cover sheet, as shall the Quality System Manager (if not himself the Auditor) to indicate that the

report has been reviewed and approved. The report shall be issued to the Auditee under cover of a memorandum stating the dates by which response shall be made to the corrective action requests, i.e. completion of the “Action to be Taken” section of the corrective action requests and their return to the Auditor. Such dates shall reflect the severity of the nonconformities as evidenced by their categorisations.

4.6.5 When an audit has generated a need for one or more corrective actions, the white (top) copy of each Corrective Action Request (Form 0703) together with the yellow (second) copy shall accompany the Audit report. The Auditor shall retain the green (third) copy in an appropriate file.

4.6.6 The Auditor shall also file a copy of the audit report together with the completed checklists.

4.7 Action on Audit Report

4.7.1 Upon receipt of the Audit Report, the Auditee shall consider each nonconformity identified in the Audit and shall proceed in accordance with the requirements of Document No.SP-08, “Procedure for Control of Nonconformities Corrective Active and Preventive Action”.

4.7.2 Having identified the remedial and/or corrective actions necessary and appropriate in relation to each corrective Action Request, the Auditee shall enter details of these in the appropriate spaces on the Form SP 0702 together with the date by which he estimates that the actions can be complete. Having done so, he shall sign and date the form in the spaces provided.

4.7.3 The yellow (second) copy of Form SP 0702, thus annotated, shall be returned by the Auditee to the Auditor not later than the date specified by the Auditor. The Auditee shall retain the white (top) copy in an appropriate file.

4.8 Follow Up

4.8.1 On receipt of the yellow (second) copy of Form SP 0702, the Auditor shall substitute this copy of the previously retained green (third) copy (which shall be destroyed), thus indicating that this stage of the audit procedure is complete. Following the estimated dates for completion of the corrective actions (as shown by the Auditee on Form SP 0702), the Auditor shall carry out a follow-up visit to verify the completion of actions to correct the nonconformities and to prevent reappearance.

4.8.2 If the follow-up indicates that actions taken have not corrected the

nonconformity or that they will not prevent reappearance, the Auditor shall not sign the last section of the form until a follow-up visit establishes that the requirements of paragraph 4.8.1 above have been satisfied.

4.8.3 In the event of continuing failure to take appropriate action on Corrective Action Requests, the Quality System Manager shall inform the Quality System Director who shall take whatever action he deems appropriate to remedy the situation.

4.9 Report Status and Corrective Action Request Logs

4.9.1 The Quality System Manager shall maintain an up-to-date Audit Report Status Log (Form SP-0703, see example of Attachment SP-07/D).

4.10 Quality Records

4.10.1 Audit reports, and Corrective Action Request shall form part of the Company's Quality Records and shall be subject to the requirements of Documents No.PP-16.

5 ATTACHMENTS

Attachments SP-07/A is an example of an Audit Check List (Form SP 0701)

Attachment SP -07/B is an example of a Corrective Action Request (Form SP 0702)

Attachment SP -07/ C is an example of an Audit Report Status Log (Form SP 0703)

Attachment SP -07/D is an example of a Corrective Active Request Status Log (Form SP 0704).

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ATTACHMENT SP-07/A – EXAMPLE OF AUDIT CHECK LIST (FORM SP 0701)

	CHECK LIST FOR AUDIT NO:			Page of
Item No.	Requirement	Finding	Action	Comments

ATTACHMENT SP -07 /B -EXAMPLE OF CORRECTIVE ACTION REQUEST (FORM SP 0702)

<table>
<tr><td colspan="3"></td><td colspan="4">CORRECTIVE ACTION REQUEST NO:</td></tr>
<tr><td colspan="3">Auditee</td><td colspan="4">Audit No.
Date of Audit</td></tr>
<tr><td colspan="7">Basis of Audit -QS Requirements for</td></tr>
<tr><td colspan="3">Auditor</td><td colspan="4">Auditee Representative</td></tr>
<tr><td colspan="3">NON -CONFORMITY</td><td>Category
(/ as applicable)</td><td>1</td><td>2</td><td>3</td></tr>
<tr><td colspan="7"></td></tr>
<tr><td colspan="3">Signature: (Auditee Representative)</td><td colspan="4">Signature:
(Auditor)</td></tr>
<tr><td colspan="7">ACTION TAKEN TO CORRECT NON-CONFORMITY

Date for completion of Remedial Action:</td></tr>
<tr><td colspan="3">Signature:
(Auditee presentation)</td><td colspan="4">Date:</td></tr>
<tr><td colspan="7">ACTION TAKEN TO PREVENT RECURRENCE OF NON-CONFORMITY

Date of correction Action</td></tr>
</table>

	CORRECTIVE ACTION REQUEST NO:
Signature: (Auditee Representative)	Date:
FOLLOW -UP AND CLOSE OUT Proposed Follow -up -date: Follow -up Details: CAR Close Out Date Signature: (Auditor)	

SP 0702

ATTACHMENT SP -07/C -EXAMPLE OF AUDIT REPORT STATUS LOG (FORM SP 0703)

	AUDIT REPORT STATUS LOG						Page
Audit Report No.	Auditor	Audit Date	Auditee	Re QS Requirements for	Date Audit Report issued	CAR's Issued	Remarks

SP 0703

ATTACHMENT SP – 07/D -EXAMPLE OF CORRECTIVE ACTION REQUEST STATUS LOG (FORM SP 0704)

				CORRECTIVE ACTION REQUEST STATUS LOG				Page	
C.A.R. Serial No.	Issue To	Audit Date	Auditor	Response Due Date	Date Reminder Sent	Action to Correct Non-conformity Completion Date	Action to Prevent Recurrence completion Date	Proposed Follow-up Date	Date C.A.R. Closed

EXPLANATORY NOTE SP-O7 - INTERNAL QUALITY AUDITS

1. Apart from details, design of forms, etc. there is not a lot of room for manoeuvre here because the procedure is based on ISO 10011, Guidelines for Auditing Quality Systems.

2. Like SP 02, the procedure envisages use of 3-part NCR stationary (for the corrective Action request forms). It is suggested that this is not printed until several audits have been carried out and the design of the form and its use have been validated. Until then, the original can be photocopied onto coloured paper.

3. Because the Quality System Manager cannot audit his own work, at least two members of the staff-Quality System Manager and one other-will need to undergo training quality audit. This is normal a 2-day course. The South African Bureau of standards runs such a course itself at frequent intervals. If 2nd party audits on any suppliers (e.g. sub-contractors, sub-consultants) are envisaged as part of purchasing procedures, then the GSM at least should take a 4/5-day external audit course.

4. The procedure may be best considered after this audit training has taken place.