REASON FOR UPDATE: Annex A – Updated audit type T3 who can lead audit to Internal Audit Team

ASSOCIATED DOCUMENTS: F050, F271, F604, F651

1. PURPOSE

1.1 To provide a procedure for the internal auditing of the Quality Management System and its processes for conformance and effectiveness.

2. SCOPE

2.1 This document applies to all those involved with internal auditing.

3. RESPONSIBILITY

3.1 The Quality Manager is responsible for updating and communicating the details within this procedure.

4. PROCEDURE

4.1 Internal auditor qualifications and requirements

4.1.1 Internal auditors should have completed an ISO9001 Internal audit course as a minimum prior to undertaking a T2 or T3 audit independently.

4.1.2 Internal auditors are not permitted to conduct an audit of their own process or area of responsibility to ensure objectivity and impartiality.

4.1.3 A list of qualified internal auditors is maintained within QPD06.

4.2 Internal audit planning

4.2.1 The internal audit schedule is based on a 3 year audit cycle and audits are conducted against James Walker's own requirements for its Quality Management System and the applicable requirements of EN9100 (latest version).

4.2.2 Within the internal audit schedule, a compliance matrix has been developed to ensure 100% clause coverage of EN9100 (latest version) is achieved within the audit cycle duration.

4.2.3 Audit frequency must be a minimum of one audit per process (as defined by the audit schedule) over the 3 year cycle. Additional audits may be built in to increase frequency in response to elevated importance of the activity or evidence of poor capability of the process.

4.2.4 Internal auditors are assigned to audits within the schedule and it is their responsibility to arrange a suitable time and date with the auditee(s) within the timeframe determined.

4.2.5 A tiered approach to internal audits has been taken based on the table in Annex A below.

4.3 Completion of audit

4.3.1 Each audit is allocated a unique reference number with the formatting of *MM-YYY- Initials – Process audited*

4.3.2 The results of the audit including objective evidence are recorded in the relevant audit reports as defined in Annex A.

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4.3.3 The audit report (with the exception of T1 audits) may identify nonconformities (NC's) and opportunities for improvement (OFI's)

4.4 Audit conclusion

4.4.1 Audit Report issued to the relevant management representative of the process/area audited along with a copy of NCR reports (if applicable)

4.4.2 Signed copies are retained in the relevant internal audit folder on LionShare.

4.5 Non-conformity management (T2 and T3 audits)

4.5.1 Non Conformity management is in line with guidance from BS EN 9101:

I. Where immediate containment action is required: containment is required within 48h from issuing of NC, and correction must be in place no later than 7 calendar days after issuing NC.
II. All other NC's: corrective action plan(s) must be clearly identified and formulated within a maximum of 30 calendar days after issuing NC.
III. The timescale for completion of corrective actions is to be agreed with the manager of the audited process. Completion is to be targeted to be no later than 14 calendar days after issuing NC (for Major NC's) and max 60 calendar days (for Minor NC's).
IV. Verification of effectiveness of corrective actions will happen as soon as those are regarded as completed by the auditor(s), and verification details and closure of internal audit.

4.5.2 Non-conformances are recorded by completion of "Nonconformity Report" F271.

4.5.3 Based on the root cause analysis, cause codes as defined in Annex B are to be captured on the F271 for the purpose of further analysis.

4.5.4 Non-conformances are to be logged onto the internal audit schedule for tracking and for the purpose of further analysis.

4.5.5 A non-conformance is only closed out after verification of effectiveness of the corrective action has been determined by the auditor.

4.6 Escalation

4.6.1 If responses to non-conformities are not provided within the timescales agreed, the NC should be escalated to the next level manager.

4.6.2 Failure to resolve the NC should be escalated to the Quality Manager after a further 10 days.

4.7 Reporting

4.7.1 Reporting of the results of internal audits are through the Quality Manager as an input to Management Review.

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Annex A – Tiered approach

Audit type	Description of audit	Report Form used	Who can lead audit	Key processes audited	Frequency
T3	Tailored audits on systems and processes in line with EN9100 (latest version) clauses	F050 – Internal Audit Report	Internal Audit Team	PEAR 1 – Product Engineering PEAR 2 – Purchasing Other support processes and specifically targeted audits	Minimum of once per 3 year audit cycle
T2	Checklist based process and product audits	F651 – T2 Key Process Audit Checklist	Internal Audit Team	PEAR 3 – Product Realisation	Minimum of once per 3 year audit cycle
T1	Regular compliance checks within a given production based process	F604 – T1 Audit Checklist	Internal Audit Team and Quality Coordinators	PEAR 3 Product realisation – Manufacturing Units only	A minimum of one per month per process

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Annex B – Cause Codes

Resources			Management			Methods			Human Factors		
Code	Title	Definition	Code	Title	Definition	Code	Title	Definition	Code	Title	Definition
RE1	Inadequate people capability.	Appropriate education, training or experience was not adequately determined, or competent people were not available.	MG1	Lack of training provision.	Identified training and competency requirements were not adequately deployed and/or sustained to meet the ongoing needs of the organization.	ME1	Lack of operational planning and control.	The organization did not adequately deploy planning and control activities to ensure that operational tasks were conducted in accordance with requirements.	HF1	Lack of attention or concentration.	A state of being unfocused or uninterested in the task.
RE2	Inadequate operating infrastructure.	Operating infrastructure such as utilities, information technology, buildings, transportation was not adequate to support operational requirements.	MG2	Unclear roles and responsibilities.	Authorities, responsibilities or duties lacked clarity or were not fully understood. As a result operational tasks and related authorities/approvals were improperly assigned.	ME2	Inadequate documented information.	Documented information did not clearly describe the applicable requirements for the process, product or service.	HF2	Pressure and stress.	A state of being overloaded or pressurised by urgent and changing or conflicting demands. A lack of time or resource to perform the task.
RE3	Inadequate operating environment.	Operating environment elements such as temperature, humidity, lighting, noise and cleanliness were not adequate to support operational requirements.	MG3	Inadequate organizational governance.	The organization did not determine or implement sufficient arrangements to ensure continued application effectiveness of the QMS and its processes.	ME3	Inadequate control of documented information.	Documented information was not adequately maintained, retained or made available to demonstrate effective control.	HF3	Distraction.	A state caused by being disturbed or side-tracked by other people or by any other disruption in the workplace.
RE4	Inadequate provision of equipment.	Equipment was not capable of meeting and sustaining operational requirements, or was not adequately controlled or available.	MG4	Inadequate communication.	Key information was not adequately communicated within the organization within a timeframe that makes the information relevant and allows for feedback as required.	ME4	Inadequate verification or validation of process, product or service.	Verification/validation activities were not conducted in accordance with the stated requirements.	HF4	Fatigue.	A state caused by being physically and / or mentally tired as a result of workplace ergonomics, workload, working hours, personal situations etc.

(*taken from www.iagg.org - 9101 Form 4 – Annex A (16 Oct 2018)*)

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