



NRC COMPLIANCE AUDIT

ERIK BOWERS

3/30/20



Corrective Action Classifications



Corrective and Preventive Action (CAPA)

- **Observation**
 - A concern that is not a violation of a direct requirement, but may lead to a violation if left unchecked, an undesirable situation, or an issue to consider as an Opportunity for Improvement.
- **Minor Nonconformity**
 - A single failure or lapse in conformance with a requirement. If a significant number of minor nonconformities are found in a particular area, the auditor may document the cumulative effect as a Major Nonconformity.
- **Significant Minor Nonconformity**
 - A significant condition that warrants immediate management attention and could result in a Major Nonconformity if not corrected.
- **Major Nonconformity**
 - The absence of, or total breakdown of, a Harman/NRC process; or any nonconformity where the effect is judged detrimental to the integrity of the product or service.

Internal Audit Results (Harman Professional NRC Compliance)



REQUIREMENT	OBS	MIN	SIMN	MAJ	Closed
Operations Management Metrics & Processes	1	0	0	0	1
Quality System	0	0	0	0	0
Manufacturing & Test Documentation	0	0	0	0	0
Configuration Management	1	0	0	0	1
Material Utilization	0	0	0	0	0
Test and Measuring Equipment Requirements	0	0	0	0	0
Production	0	0	0	0	0
TOTALS	2	0	0	0	2

Positives



- Annual audits (internal) documented and tracked using ISO templates to insure no breakdowns.
- Key audit items added to warehousing monthly (inventory control) audits to insure stability in process. Audits conducted by team members on-site monthly.
- Use of A3 process for Safety issue in August.
- RSO visits distribution center monthly to check on updated training needs and for assistance to staff.
- Good use of Standardize Work on NRC required processes. Very well documented and followed.

Observation #1

Configuration Management



Problem Description

IS: Payment system in Harman set-up as manual check write from global finance in Budapest, Hungary.

- Checks potential delayed or long lead-time on drafting and fulfillment*
- Tracking completed manually by Compliance Manager, risk of missing dates through manual spreadsheet.*

SHOULD BE: *Use .GOV electronic payment and alert system. Allows for alerts and fail safe process to insure timely payment to NRC through Harman Configuration budget approved by Global Quality Director at Harman Professional Division*

Status: Completed 2/21/20

Observation #2

Operations Management Metrics & Processes



Problem Description

IS: *Incoming and storage process at MT Warehouse*

- *Units checked for damage when receive and scanned into SAP*
- *No FIFO (First in First Out) on products*
- *Units moved from incoming inspection to any open location*

SHOULD BE: *Requirement: Material to use manual FIFO system until SAP updates can be complete Potentially CY21. Additionally all units to be stored I set locations which allow for improved accessibility of NRC compliance product, and quick verification physically during monthly audits.*

Status: *Completed 3/5/20*