**Job Aid 2: Nonconformity Statements 4-71**

*The nonconformity statements will be the most read part of the audit report.*

**ISO 15189 3.12 Nonconformity** - nonfulfillment of a requirement

NOTE Other terms frequently used include: accident, adverse event, error, event, incident, and occurrence.

**3 Elements of a Nonconformity Statement**

1. The nonconformity, or what’s wrong; the problem statement\*\*
2. The requirement, or why is it a nonconformity? What exactly did the laboratory commit itself to doing? What document says so?
3. The evidence or proof to support the finding of a nonconformity
	1. Objective evidence regarding exactly what the laboratory has done that contradicts the commitment stated in the requirement.
	2. The issue must be traceable to its source. To ensure traceability include as many identifiers as possible (e.g. date, time, record title, version, etc.)

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| \*\*Problem Statement Templates* The documented procedure for \_\_\_\_\_ does not match current practice.
* Conformance to requirement \_\_\_\_\_ cannot be demonstrated.
* The process for \_\_\_\_\_ has not been effectively communicated.
* Management should determine if the practice of \_\_\_\_\_ is a potential risk to patient safety.
* The process for \_\_\_\_\_ does not always ensure that ……….
* The process for \_\_\_\_\_ has not been fully implemented.
* The records for \_\_\_\_\_ are inconsistently maintained.
* Risk assessment has not been incorporated into the process for \_\_\_\_\_.

Accessed from IQMH Internal Auditing Course (2016) |

Example:

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| **Problem Statement** | **Requirement** | **Evidence** |
| Conformance to SLIPTA Requirement 5.13b regarding documentation supporting equipment is in proper working order before being put back into service cannot be demonstrated in the microbiology section. | 5.13 b Equipment Repair Monitoring and Documentation Does the laboratory verify and document the equipment is in proper working order before being put back into service?  | Even though the microbiology supervisor stated the temperature was checked and within range for 24 hours before use, there were no records verifying the temperature of the microbiology incubator (ID M13), which was returned from repairs on July 16, 2016.  |