Outline process and form for stakeholder initiated CAPA process ("Hatto Report"), from Levinson Productivity Systems PC. It is intended to be modified by users to conform to their needs and quality management systems.

Scope

A stakeholder initiated corrective and preventive action (CAPA) request, or "hatto report" (hatto = sudden awareness or recognition) can be issued by any relevant interested party (ISO 9001:2015 clause 4.2) who perceives a risk or opportunity (ISO 9001:2015 clause 6.1) that relates to safety, quality, or waste (muda). Stakeholder initiated CAPA takes advantage of the fact that stakeholders, or relevant interested parties, are often in the best position to notice risks and opportunities related to safety, quality, and waste.

- Hiyari hatto = "experience of almost accident situation" or "recognition of a safety risk." (hiyari = incident). "I could have put my hand into the machine because there are exposed moving parts!"
- Poka hatto = recognition of the chance for error (poka), which might be remedied through error-proofing (poka yoke). "I almost assembled the parts backward." This category applies, however, to all quality-related risks, not just those that involve worker error.
- Muda hatto = recognition of waste (muda). "Has anybody else noticed that we spend more time and effort picking up bricks from the ground than we do on putting them into the wall?" This was not, in fact, recognized for thousands of years, until Frank Gilbreth introduced his non-stooping scaffold in the early 20th century.

This process applies to situations upon which actions can be taken by the process owner (the person with the resources and authority necessary to implement a solution) without recourse to a formal CAPA process such as 8D (8 Disciplines) or the Automotive Industry Action Group's Effective Problem Solving guide (CQI-20), and when management of change (MOC) issues are not involved.

References (add or remove as necessary)

- ISO 9001:2015
- ISO 45001:2018 with regard to the workforce participation clauses
- ISO 14001:2015 (recognition of material waste, including that which could become an environmental aspect)
- Organization's formal CAPA process as required by ISO 9001:2015 clauses 6.1 (with regard to preventive action) and 10.2 (nonconformity and corrective action).
- Organization's lessons learned data base, or similar process that supports ISO 9001:2015 clause 7.1.6, organizational knowledge.
- J.F. Halpin, *Zero Defects* (1966) describes an error cause removal (ECR) program.

Process

Step 1. Identify Problem or Opportunity.

WHO: Any stakeholder (relevant interested party). INPUT is from the stakeholder.
WHAT: Identify the problem or opportunity, and its priority. Safety requires immediate attention if a condition exists that could result in an incident.
WHEN: Upon identification, safety issues should be reported immediately.
HOW: (Organization's mechanism for filing the report)
WHY: Identify a problem or opportunity at the shop floor level.

- Submitted by: Name, title, and role (employee, customer, supplier, contractor, visitor)
- Date: date submitted
- Type: Safety, Quality, or Waste/Muda
- Location: where observed
- Description and Recommendation: The person who submits the report can recommend a solution, if appropriate.

Step 2: Can the issue be resolved on the shop floor level?

WHO: Process owner or worker's supervisor (as defined by the organization)
WHAT: Determine whether a solution can be identified or implemented on the shop floor level.
WHEN: Safety issues require immediate attention, and containment if they present a serious threat. The organization defines the urgency of quality and waste issues.
HOW: Use organizational knowledge (RESOURCE) to see if similar issues have been addressed in the past.
      YES: Continue to Step 3.
      NO: Handoff (OUTPUT) to formal CAPA process
WHY: Ensure that management of change (MOC) issues are addressed where appropriate, and that cross-functional knowledge is accessed when necessary.[1]

- Received by (process owner or supervisor): name and title
- Date: date received

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[1] Management of Change (MOC): whenever we change anything, there is a chance of unintended and undesirable consequences. Installation of a shadow board to organize tools, a 5S activity, is unlikely to create MOC issues, but a change in tooling to increase throughput could conceivably make the output a new or changed something or other for a downstream internal or external customer. Consider cause and effect categories:
- Manpower (new operators)
- Machine (new or changed tooling)
- Method (new or changed work instructions)
- Measurement (new or changed gages)
- Material (changes in material, or new suppliers)
- Environment (changes in temperature, humidity, and/or other relevant factors)

- Can the issue be resolved without formal CAPA?   Yes No
- If yes, describe the reason briefly: Describe why formal CAPA is not needed, and MOC does not apply.
- If no, date of handoff to formal CAPA process: date of handoff
- Interim containment actions, if any: Describe interim containment actions to address safety and quality-related risks, and possibly remove waste or muda. (Safety must be addressed immediately regardless of whether formal CAPA is needed for a permanent solution.)

Step 3. Identify and implement a solution, and make sure it works.
WHO: Process owner, possibly with the aid of the worker(s) who recommended the solution.
WHAT: Identify and implement the solution, and ensure that it works.
WHERE: At point of use
HOW: Task-dependent
WHEN: Safety-related issues must be acted on immediately
WHY: Ensure that the selected solution really solves or prevents the problem.

- Action Plan Responsibility (who): name and title
- Action Plan: Describe what is to be done
- Date implemented: Date of implementation
- Results: Describe why it was effective. How did the change reduce or eliminate the risk of a safety incident or quality-related error, or remove waste?

Step 4. Update organizational knowledge.
WHO: Process owner (or coordinator)
WHAT: File the completed project as a quality record to support organizational knowledge ISO 9001:2015 clause 7.1.6). This is an OUTPUT of this process to another process.
WHEN: Upon completion and verification of effectiveness
WHERE/HOW: Keyword searchable lessons learned data base, if possible.
WHY: Enable others with similar applications to find a possible solution or partial solution.

- Keywords for Lessons Learned Data Base: Add keywords that make the completed project easy to find by others who encounter similar situations
- Filed in Lessons Learned Data Base (date): date filed

Stakeholder Initiated CAPA

Submitted by:
Date:
Type: Safety   Quality   Waste/Muda
Location:

Description and Recommendation (if any):

Received by (process owner or supervisor):
Date:
Can the issue be resolved without formal CAPA? Yes No
If yes, describe the reason briefly:

If no, date of handoff to formal CAPA process:

Interim containment actions, if any:

Action Plan Responsibility (who):
Action Plan:

Date implemented:

Results:

Keywords for Lessons Learned Data Base:
Filed in Lessons Learned Data Base (date):