National Association of Chemical Distributors

6th Cycle Non-Conformances and CAPAs

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Advancing **Stewardship**, Creating **Connections**™

Agenda

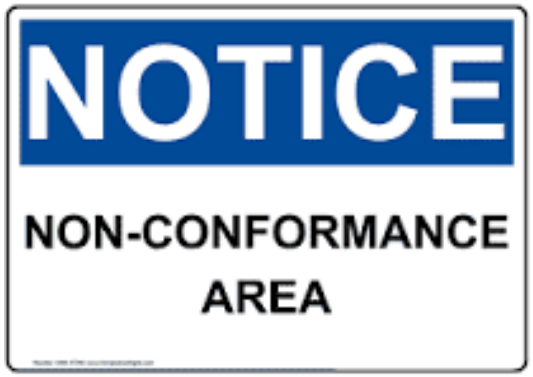
- 6th Cycle Findings
- Verifier Perspective
  - Most common non-conformances
    - Examples: Oldies but Goodies
- Member Perspective
  - Ways to address internal audit or verification findings through Corrective Actions
  - Tips & methods to avoid repeat findings
- Addressing Corrective Actions

6th Cycle Findings (2017-2018)

The Data - 6th Cycle Non-Conformances

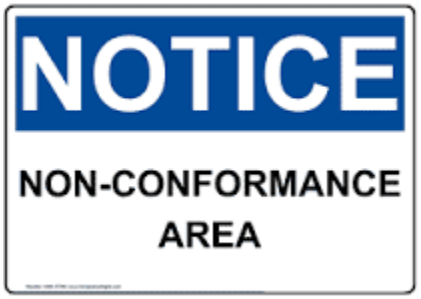
Verifications	Total 6th Cycle (2017-2018)
# Verifications Conducted	244
# of NC Cited	886
Verifications with 0 NCs Cited	47
Verifications with 1-3 NCs Cited	105
Verifications with 4-6 NCs Cited	53
Verifications with 7+ NCs Cited	38
Average # NCs	3.6

The Data - 6th Cycle Non-Conformances



- Code II - 160
- Code VII - 114
- Code X - 101
- Code IV - 101
- Code I - 93

The Data - 6th Cycle Non-Conformances



- **Code X**
  - X.A – Internal Audits (78)
- **Code II**
  - II.B – Regulatory Implementation (69)
  - II.C – Employee Training (51)
- **Code I**
  - I.E – Management of Change (42)
- **Code IV**
  - IV.A –Facility Selection (36)
- **Code III**
  - III.A – Carrier Selection (33)
- **Code VI**
  - VI.A – Waste Management (32)
- **Code XI**
  - XI.A – CAPA Procedures (30)
- **Code VII**
  - VII.E – Media Training (28)
  - VII.F – Emergency Drills (27)

Verifier Perspective

Most Common Non-Conformances: X.A

***10.A. - No documentation to support that annual Responsible Distribution internal audits had been conducted (most recent 3 years).**

- Possible reasons for non-conformance:
  - Member does another audit (ISO, process, Sarbanes-Oxley, etc.) they think will count
  - Member thinks their last site verification will count
  - Dropped ball during Code Coordinator change
  - Just plain didn't get around to it
  - Did internal audit but didn't audit at each location used for chemical distribution

X.A: Which Locations Count?

"Audits shall be conducted on an annual basis at each location used by the member company for the distribution of chemicals … "

- Facilities awaiting verification are listed on the NACD RD dashboard
- In the ***Overview*** for each you have estimated the percentage of your total distribution business done at that site

- Be prepared to provide the verifier with completed internal audits for those locations

X.A: Verifiers Look For…

- ✓All 13 Codes were internally audited
- ✓Audits were conducted each of the last 3 years
- ✓Audits were conducted in enough depth that opportunities were identified
- ✓Audits were conducted at each location used for chemical distribution

Most Common Non-Conformances: II.B

***II.B. - Applicable regulations not implemented.**

- This one covers a lot of ground, e.g. OSHA, DOT, FDA, USCG, DHS, and others.

- Possible reason for non-conformance:
  - Drench stations not inspected weekly
  - Openings in circuit breaker panels
  - Appendix D information not provided
  - Inoperable auxiliary lighting, no documentation of inspections
  - No letter of approval from forklift manufacturers for use of attachments

Not "Regulatory" Inspection But ...

* **II.B. -** Describe how the member company implements applicable ***regulations*** and industry practices that apply to chemical distribution activities.

* **VI.A. -** Describe how the site and/or member company ensures all self-generated waste and empty containers are disposed of in a responsible manner and in accordance with existing ***regulations***.

* **II.C. -** Describe how the site's employees have been trained in the implementation of applicable EHSS ***regulations***, as well as member company's specific requirements.

* **IV.A. -** Describe how the member company's selection of facilities is consistent with ***regulations***.

Most Common Non-Conformances: II.C

***II.C. - Describe how the site's employees have been trained ...**

- Possible reasons for non-conformance:
  - No system for ensuring that applicable training had been conducted at the required interval, e.g., training matrix (initial, annual, periodic)
  - No documentation to support that training completions were on schedule, e.g., sign-in sheets, monthly reports, LMS, etc.

Most Common Non-Conformances: I.E

***I.E. - Describe how changes involving EHSS issues are made and communicated. Include a consideration of management of change ...**

- Possible reasons for non-conformance:
  - No written policy or procedure for managing change
  - No documentation to demonstrate that the appropriate personnel were involved in approving, making, or communicating the EHSS change

Most Common Non-Conformances: IV.A

***IV.A. - Describe how the member company's selection of facilities (and maintenance, inspection, and operating procedures) are consistent with codes, regulations, etc.**

- Possible reasons for non-conformance:
  - Forklift inspections not conducted
  - Lighting in flammable storage room not working
  - Housekeeping not up to standard
  - Fire extinguishers not inspected monthly
  - Scale calibrations past due

Most Common Non-Conformances: III.A

***III.A. - Describe the process for selecting carriers that includes carrier safety and fitness, security, compliance and ongoing performance review.**

- Possible reasons for non-conformance:
  - No written procedure for initial selection and periodic review of carriers
  - Certificates of insurance and/or performance review of carrier selected not available or not current
  - Member company's Carrier Surveys did not address Carrier DOT Security Plans

Most Common Non-Conformances: VI.A

***VI.A. - Describe how the site and/or member company ensures all waste and empty containers are disposed of properly and in accordance with existing regulations.**

- Possible reasons for non-conformance:
  - Universal wastes were not being properly managed. Spent fluorescent tubes were observed without protective packaging, and had not been labeled with accumulation start dates
  - Hazardous waste drums observed in the Hazardous Waste Storage area had not been properly labeled
  - No documentation of waste manifested for last several years

Most Common Non-Conformances: XI.A

***XI.A. - No documentation to support usage, or under-utilization of the CAPA process.**

- Possible reasons for non-conformance:
  - The member company was not using a CAPA form, and could not demonstrate the use of a CAPA log
  - No entries in CAPA log for last 2 years. Are you getting what you want out of the program?
  - No documented CAPA procedure or evidence of a CAPA management system with observations, corrective actions, assignment of responsibility, root cause, due dates, and completion dates

Most Common Non-Conformances: VII.E

***7.E. - Describe how the member company plans for and trains designated staff for media inquiries as appropriate.**

- Possible reasons for non-conformance:
  - The member company had not developed a media inquiry policy, and the designated spokesperson had not received formal media response training
  - How did your designated spokesperson become qualified?

Media Training was the 1 new Spec in the 6th Cycle!

Most Common Non-Conformances

***7.F. - No documentation to support that annual drills (or equivalent assessment of the operability of emergency plans) had been completed**

- Possible reasons for non-conformance:
  - Site personnel admitted that there had not been any recent drills to test the site's readiness
  - The ERP had not been reviewed for several years
  - The Contingency Plan had not been reviewed annually as required by company policy

Dennis' Bully Pulpit

* 7.A., 13.B., 13.F. - No emergency procedures for Armed Intruder/Active Shooter incidents
- One of the 3 "terrorist" type incidents that sites should have response procedures for. The other 2 are Bomb Threat, and Suspicious Mail and Package Handling.
  - Missing all 3 would be a non-conformance
- Too common an occurrence not to be prepared for
- Every time one of these is on the news your employees are probably thinking "What would we do if this happened at my work place?"
  - Is it every man for himself? ... Or do we have a Plan?
- Templates available to modify to your operations

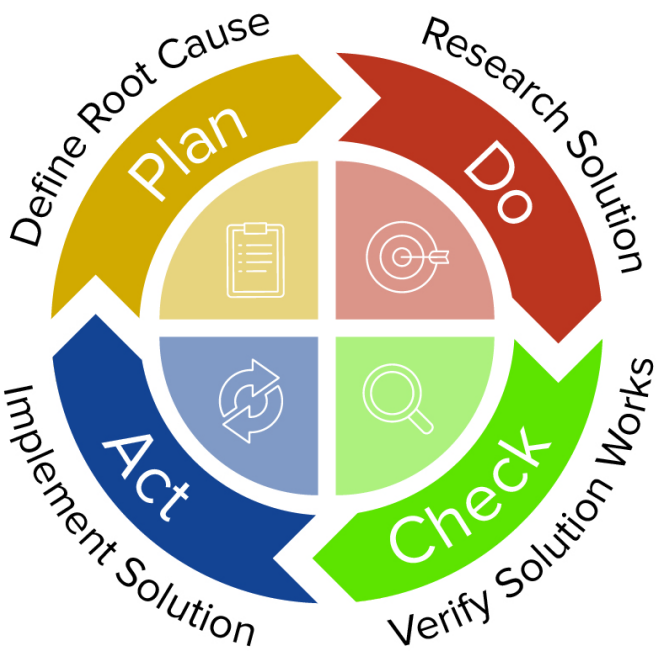
Member Perspective

Addressing Corrective Actions

Use CAPA for All Non-Conformances

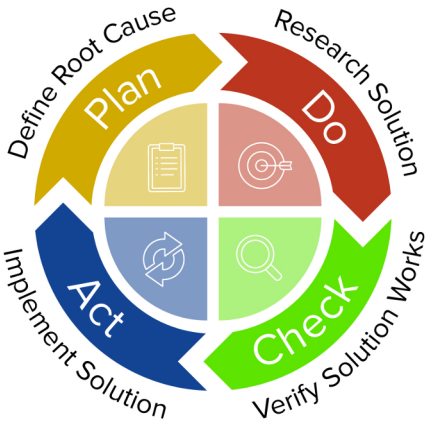
Use CAPA/CPAR for:

- Customer complaints
- Regulatory inspections
- Internal audits
- Accidents, near misses
- Investigations
- Spills or chemical releases
- Security issues
- Quality, safety, product issues, etc.



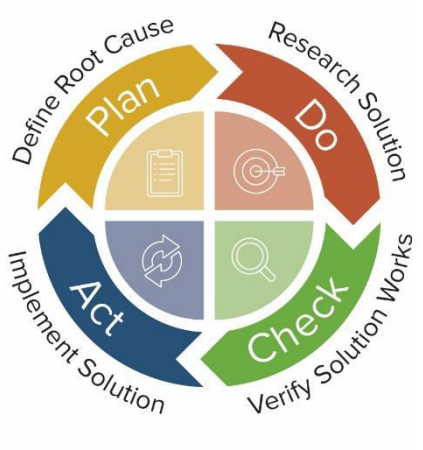
Strength of the CAPA System

- All non-conformances are documented
- All pertinent information captured in one place, the CAPA Log
- CAPA Log facilitates tracking and trend identification
- Allows for timely, efficient responses to customers/stakeholders
- Clarifies responsibilities and due dates
- Standardization ... personnel learn and use one system



Corrective and Preventive Action System

- Use CAPA form to ensure consistency
- CAPA form includes Root Cause Identification
- Corrective actions not developed in vacuum
- Review and approval at appropriate levels
- Follow-up by verification of effectiveness and sharing of key findings
  - Email, meeting minutes, and other correspondence
- Track preventive and corrective actions to closure to prevent recurrence



Questions?

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