

Q & A about QA/QM

November 2010

Maintenance of Infrastructure

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Question:

Some ISO registrar auditor is insisting that Clause 6.3 of ISO 9001 (Infrastructure) covers all maintenance and that they will audit the maintenance of the truck that moves products and materials between buildings as well as the maintenance of the heating and air-conditioning. Is this a reasonable interpretation? (From a Member of ASQ)

See next page for our response.

Answer:

“Infrastructure” for company operation specifically includes equipment, facilities and utilities. The company should control all of its properties, i.e., equipment and facilities (including building and transportation vehicles), processes, work environment, utilities and support services.

Maintenance and protection of all these items must be included in management system. It is important to ensure safety and health of employees, of course. There are many companies and people who take that we have to control and maintain support services just because it is required in ISO 9001, and that they do not have to control and maintain them

if it is not required in ISO 9001. We have to be careful not to be misguided by the wrong concept of such people.

The control and management of all these properties are necessary for the company, irrespective of ISO 9001. Daily check and periodic maintenance should be carried out as appropriate. The scope and method of control should be defined in corporate procedures and adhered to by all participating employees.

Air-conditioning needs to be strictly controlled in clean rooms and laboratories where temperature control is required. Other facilities and equipment, including power supply, water supply and drainage systems also need to be controlled.

Performance, temperature and pressure in such systems should be monitored as necessary. Good management practice including control of these items is the best way for cost reduction as well as for prevention of failure and losses.

The interpretation by the ISO registrar auditor in question is not considered to be reasonable because the truck and air-conditioning do not necessarily affect the operation processes. The auditor's job is checking in accordance with the applicable standard, internal procedures and instructions given to him. If the maintenance of the truck and the heating and air-conditioning facilities is described in corporate procedures, then the auditor should audit them accordingly.

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