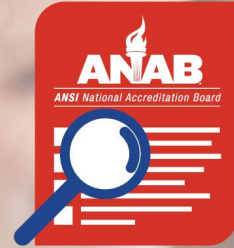




2024



CONFORMITY
ASSESSMENT
**CASE
STUDY**

INSTRUCTIONS

The 2024 Conformity Assessment Case Study is fictional but based on real events and pertinent information. Read through the text on the following page; you will be asked to use the information in the case study to identify or describe the following:

- » OBJECT(S) OF CONFORMITY
- » SPECIFIED REQUIREMENT(S)
- » BODY(IES)
- » SCHEME(S)
- » SELECTION FUNCTION ACTIVITY(IES)
- » DETERMINATION FUNCTION ACTIVITY(IES)
- » REVIEW-DECISION-ATTESTATION FUNCTION ACTIVITY(IES)
- » 1ST PARTY ACTIVITY(IES)
- » 2ND PARTY ACTIVITY(IES)
- » 3RD PARTY ACTIVITY(IES)

CASE STUDY

Ann Lersik had put her recently attained Doctor of Nursing Practice (DNP) degree to good use in her work for the Ridge Valley Health System. Like many health care systems, Ridge Valley had a challenge in the area of nurse retention and knew that their objectives for patient outcomes could only be met by improving retention of nurses.

Ann created a process for nurse management which addressed the underlying causes of nurse retention challenges she had identified in her research. The process was implemented within the Ridge Valley Health System and delivered positive outcomes that far exceeded expectations. In addition, it was not only compatible with, but advanced Ridge Valley's accreditations in the health care field.

This success was noticed by the Business Development Department at Ridge Valley who approached Ann with the idea of licensing the process for nurse management to other healthcare systems. Soon the "Lersik Management Process" was documented and being licensed to health care systems around the region, and based on its success, interest was expanding across the entire nation.

But, as is often the case, success resulted in an unforeseen problem. Some health care systems initially adopted the "Lersik Management Process" and advertised its use when recruiting Registered Nurses (RNs). However, after some time these health care systems lapsed in their implementation but continued to refer to the "Lersik Management Process" in their recruiting initiatives. In a few cases, health care systems portrayed themselves as users of the "Lersik Management Process" without actu-

ally licensing it nor completing the implementation activities. The reputation of the "Lersik Management Process" was starting to suffer, and worse, in some cases, nurse retention and the related health care outcomes were not improving. In fact, heightened but unfulfilled RN expectations from less than full implementation of the "Lersik Management Process" had the potential to make matters worse.

The Ridge Valley Business Development Department addressed these concerns by introducing a new optional program in the "Lersik Management Process". At each annual anniversary of a health care system's licensing agreement, the licensee could identify which parts of its nursing operations it wanted to have audited for implementation of the "Lersik Management Process". The Business Development Department, with input from Ann, created an audit plan and checklist to clearly show whether the commitment to and implementation of the "Lersik Management Process" was being maintained in the identified parts of nursing operations. The results of the audit would be reviewed by Ann and her team, and if they determined the audit results demonstrated fulfillment of predetermined criteria, the Business Development Department would send a "Lersik-Certified" letter to the licensee identifying those nursing operations which had been successfully audited. The letter would indicate it would be valid for one year. To receive a new letter a licensee would need to repeat the entire process. The letters were intended to support information used by healthcare systems for their recruitment of RNs. Copies of letters would also be posted on "Lersik Management Process" website

already maintained by the Business Development Department to deal with potential counterfeit letters. RNs seeking employment could consult the website to confirm the authenticity of a letter or identify those parts of health care systems with current, demonstrated commitment to, and implementation of, the “Lersik Management Process”.

Auditing would be performed by peer nurse managers from other healthcare systems which licensed the process. Individual nurse managers could become peer auditors by completing online training with a final test and submitting proof of their test scores. Initially and each year, nurse

managers would also submit information about their responsibilities related to their systems’ implementation of the “Lersik Management Process” and annually submit a brief paper in response to selected questions about the process. Ann Lersik and her team would review the initial and annual submissions and if they found the information met requirements the Ridge Valley Business Development Department would add or retain the name of the individual on a listing of available peer auditors on the “Lersik Management Process” website. In addition, the “Lersik-Certified” letter on the web site would be annotated if the licensee also contributed one or more peer auditors.



QUESTIONS

Answer the following for conformity assessment described in detail in the Case Study (italicized terms are defined or described in ISO/IEC 17000:2020):

1. What are the two types of *objects of conformity assessment*?

- a. Ridge Valley Health Care System and the “Lersik Management Process”
- b. Ann Lersik as a DNP and Registered Nurses
- c. Retention of nurses and improvement of health care outcomes
- d. Implementations of the “Lersik Management Process” and nurse managers

2. Who is the *conformity assessment scheme owner*?

- a. Ridge Valley Business Development Department
- b. Ann Lersik
- c. Ridge Valley Health Care System
- d. Organizations granting DNP degrees and RN registrations

3. Which best describes the *conformity assessment bodies*?

- a. Ridge Valley Business Development Department and Ann Lersik
- b. Ridge Valley Health System, Ann Lersik with her team, and peer auditors
- c. Licensees, peer auditors, Ann Lersik with her team, and Ridge Valley Business Development Department
- d. Peer auditors and RNs

4. What *statements of conformity* are issued?

- a. DNP degrees and RN registrations
- b. Licenses for the “Lersik Management Process”
- c. “Lersik-Certified” letters, annotations to “Lersik-Certified” letters, website listings of peer auditors
- d. Recruiting documents for RNs and claims of using the “Lersik Management Process”

5. Which best characterizes *surveillance activities in the conformity assessment scheme*?

- a. Neither of the methodologies include surveillance activities
- b. Both of the methodologies include surveillance activities
- c. One of the methodologies includes surveillance activities
- d. Surveillance activities are not relevant given the specifics of the methodologies

6. Which shows the ranking of *conformity assessment activities*, from most to least?
- a. *First-party activities, second-party activities, third-party activities*
 - b. *Third-party activities, second-party activities, first-party activities*
 - c. *Second-party activities, first-party activities, third-party activities*
 - d. *Third-party activities, first-party activities, second-party activities*
7. Which two Standards, with some alterations, would provide the best requirements for competence, impartiality and consistent operation for the *conformity assessment bodies*?
- a. ISO/IEC 17021-1 and ISO/IEC 17065
 - b. ISO/IEC 17065 and ISO 19011
 - c. ISO/IEC 17029 and ISO/IEC 17021-1
 - d. ISO/IEC 17065 and ISO/IEC 17024
8. The *conformity assessment scheme owner*:
- a. Primarily performs *Selection function* activities
 - b. Primarily performs *Determination function* activities
 - c. Primarily performs *Review-Decision-Attestation function* activities
 - d. Does not perform *conformity assessment activities*
9. Which of the following is described in the least amount of detail:
- a. *Specified requirements*
 - b. *Conformity assessment scheme*
 - c. *Determination function* activities
 - d. *Decision*
10. Which of the following best describes licensing related to *statements of conformity* in the case study:
- a. Through licensing, the use of the term “Lersik Management Process” as a *statement of conformity* is granted
 - b. Through licensing, the use of a “Lersik-Certified” letter as a *statement of conformity* is granted
 - c. Licensing does not pertain to a *statement of conformity* and is not a Functional Approach activity
 - d. Professional designations in this field (e.g., DNP, RN) are granted under licensing

READY TO PARTICIPATE?

Check out the [ANAB Case Study page](#) to participate and get your answers scored.