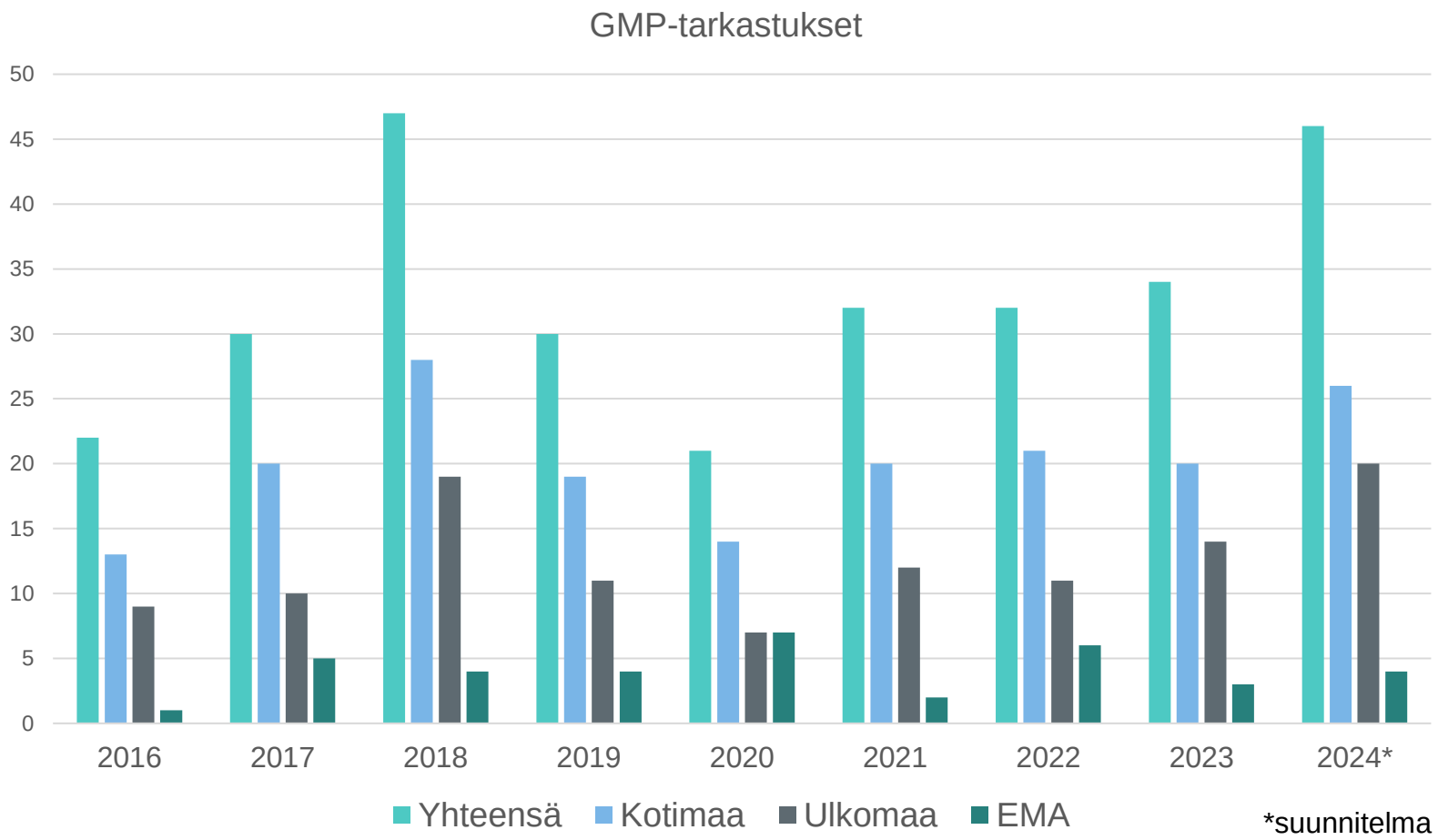
GMP-tarkastushavainnot

9.2.2024

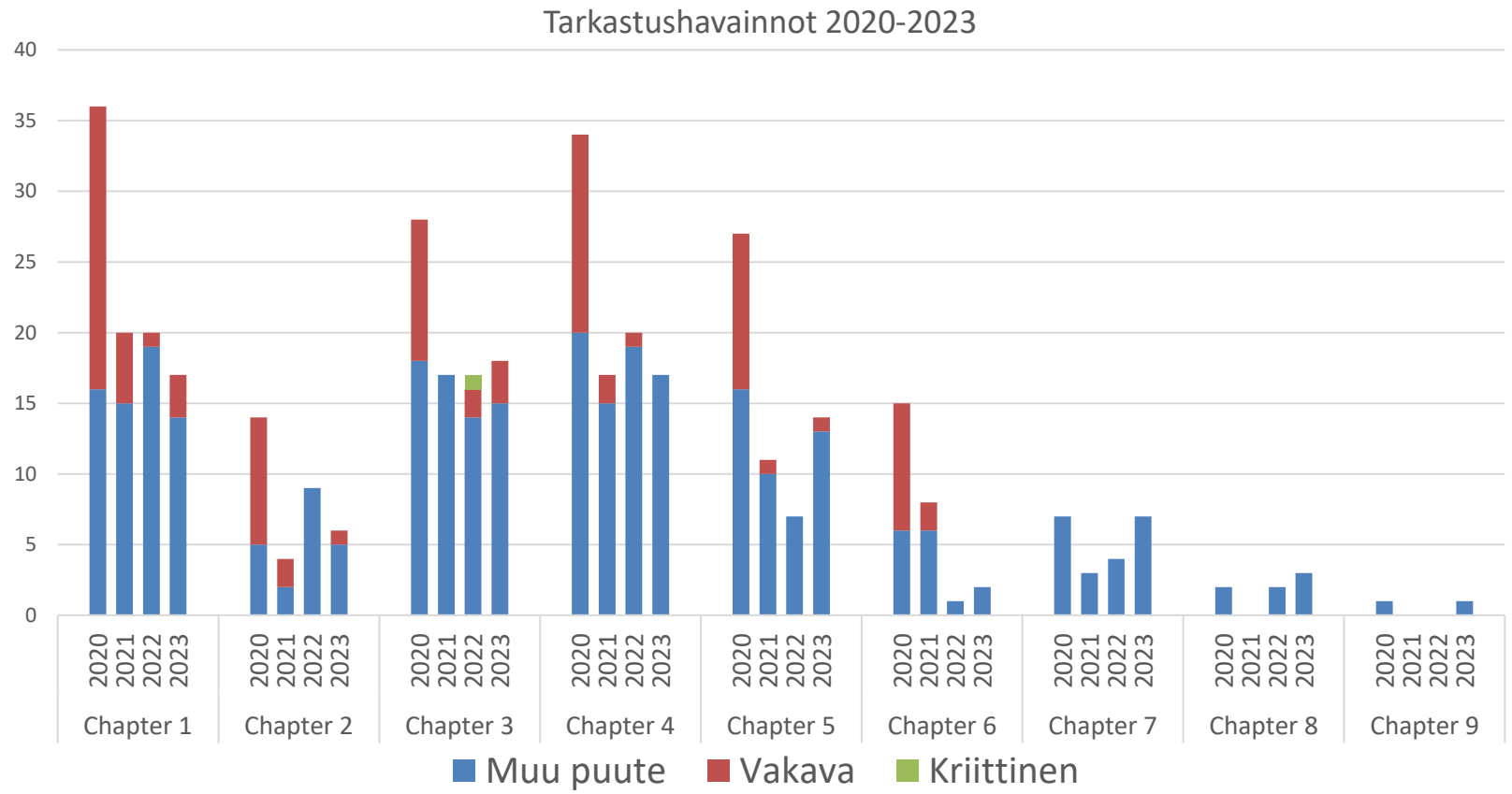
Katja Belt

Ylitarkastaja

Tehdyt GMP-tarkastukset

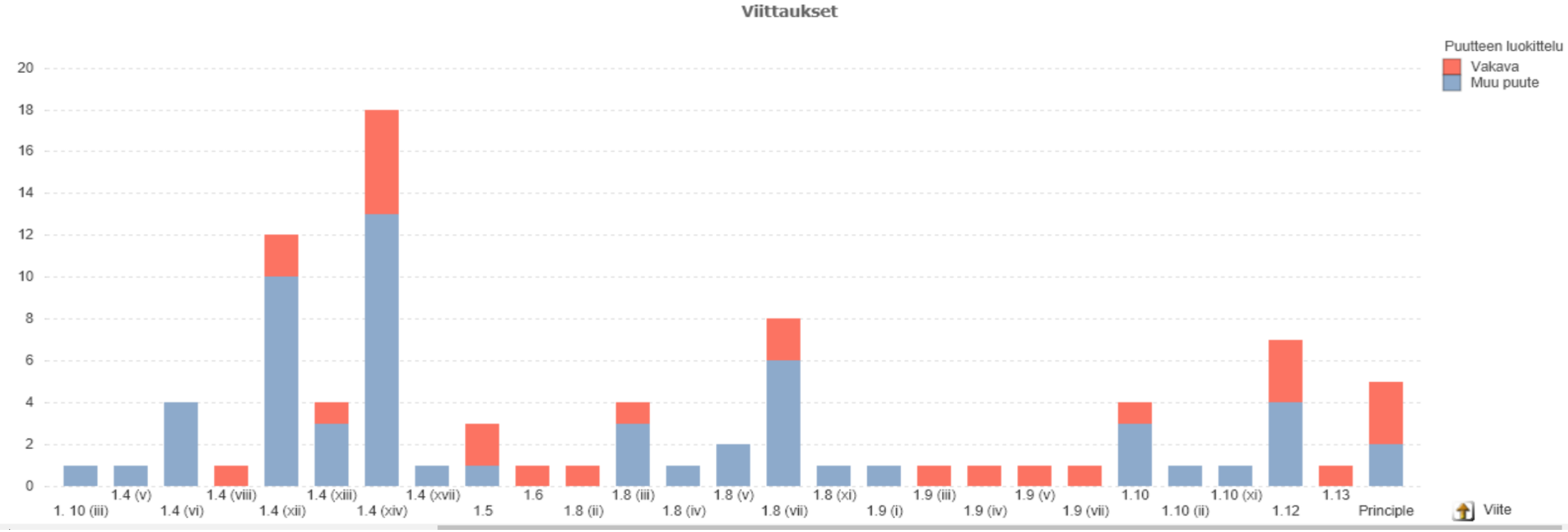


Tarkastushavainnot* 2020-2023 (Part 1)



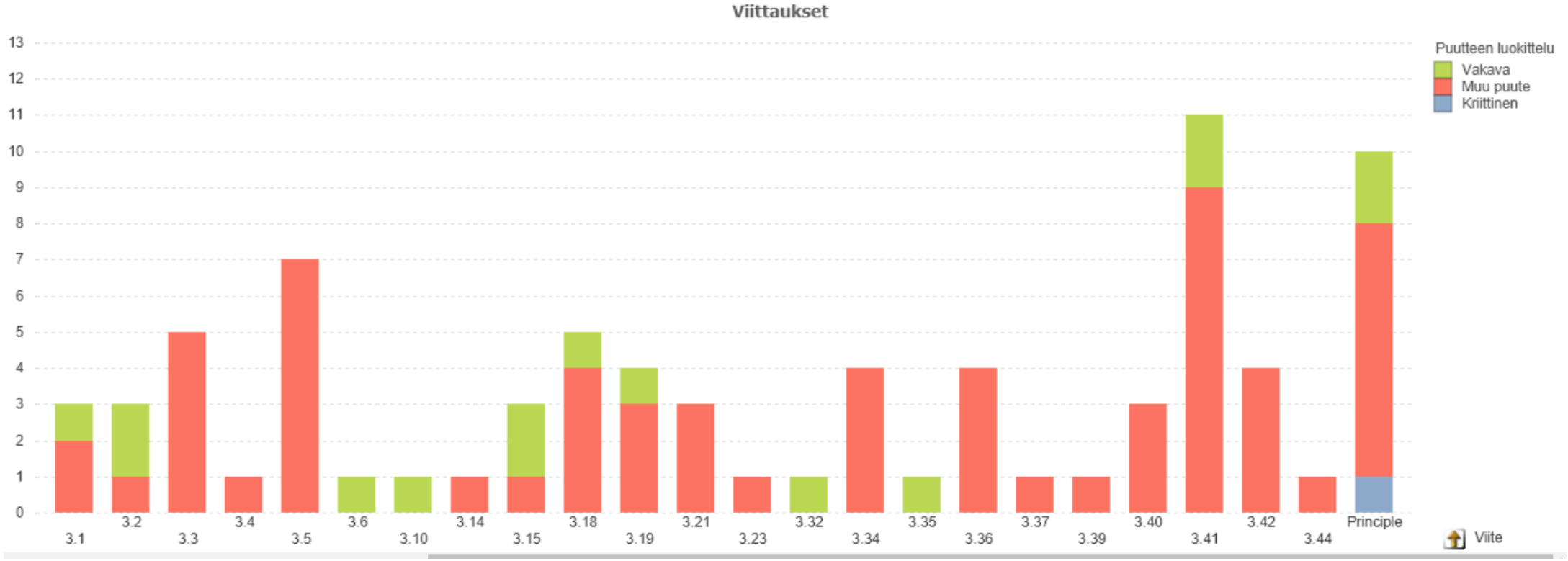
* Kotimaan tarkastukset

Laatujärjestelmä (Chapter 1)



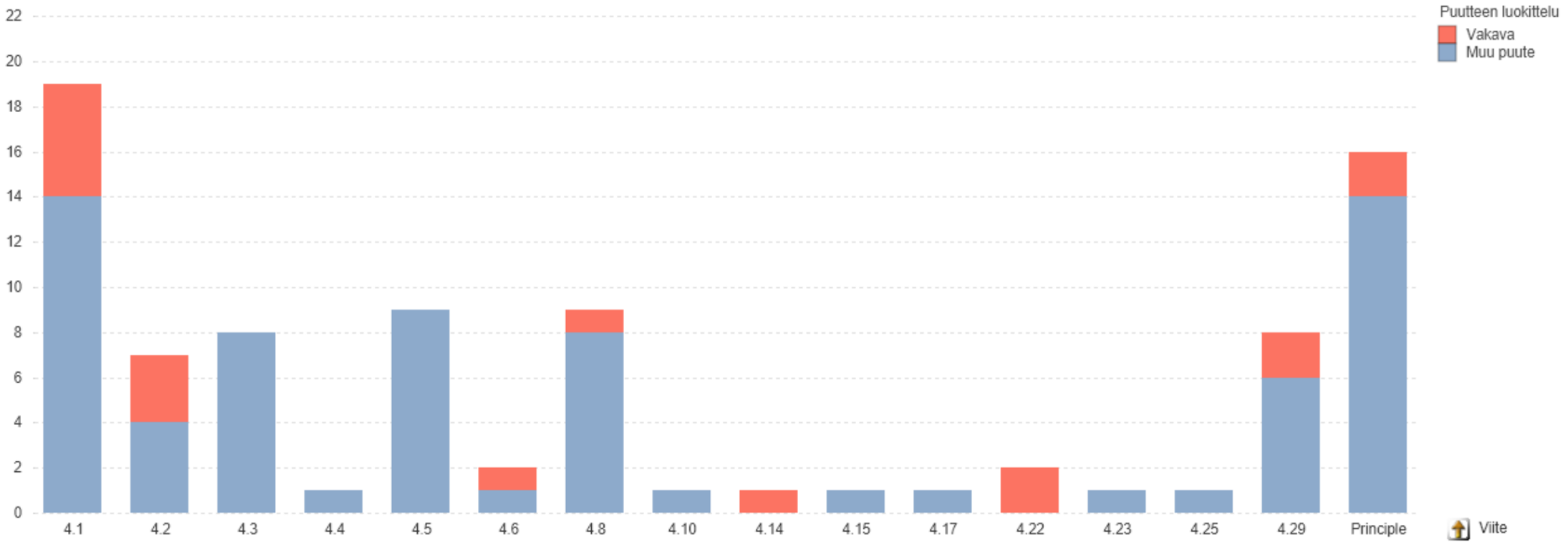
- 1.4 (xiv) appropriate level of root cause analysis should be applied during the investigation of deviations, suspected product defects and other problem
- 1.4 (xii) Arrangements are in place for the prospective evaluation of planned changes and their approval prior to implementation

Tilat ja Laitteet (Chapter 3)



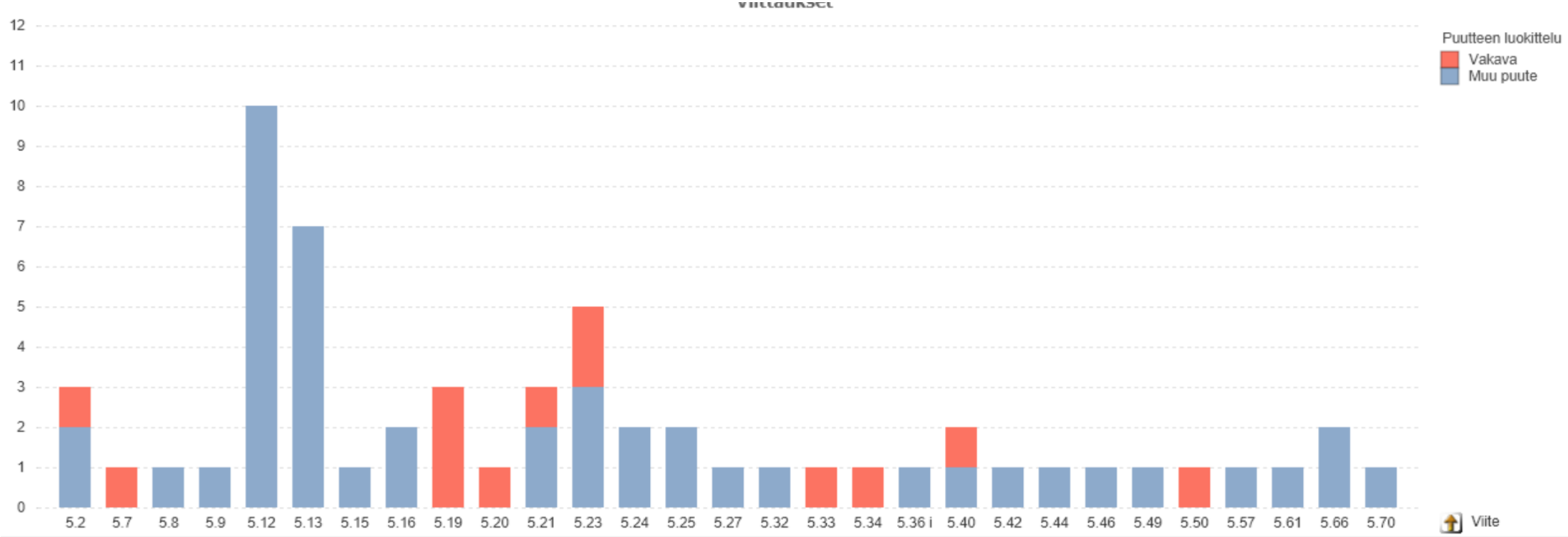
- 3.41 Measuring, weighing, recording and control equipment should be calibrated and checked at defined intervals by appropriate methods
- PRINCIPLE Premises and equipment must be located, designed, constructed, adapted and maintained to suit the operations to be carried out. Their layout and design must aim to minimise the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt and, in general, any adverse effect on the quality of products.

Dokumentaatio(Chapter 4)



- 4.1 All types of document should be defined and adhered to.

Tuotanto (Chapter 5)

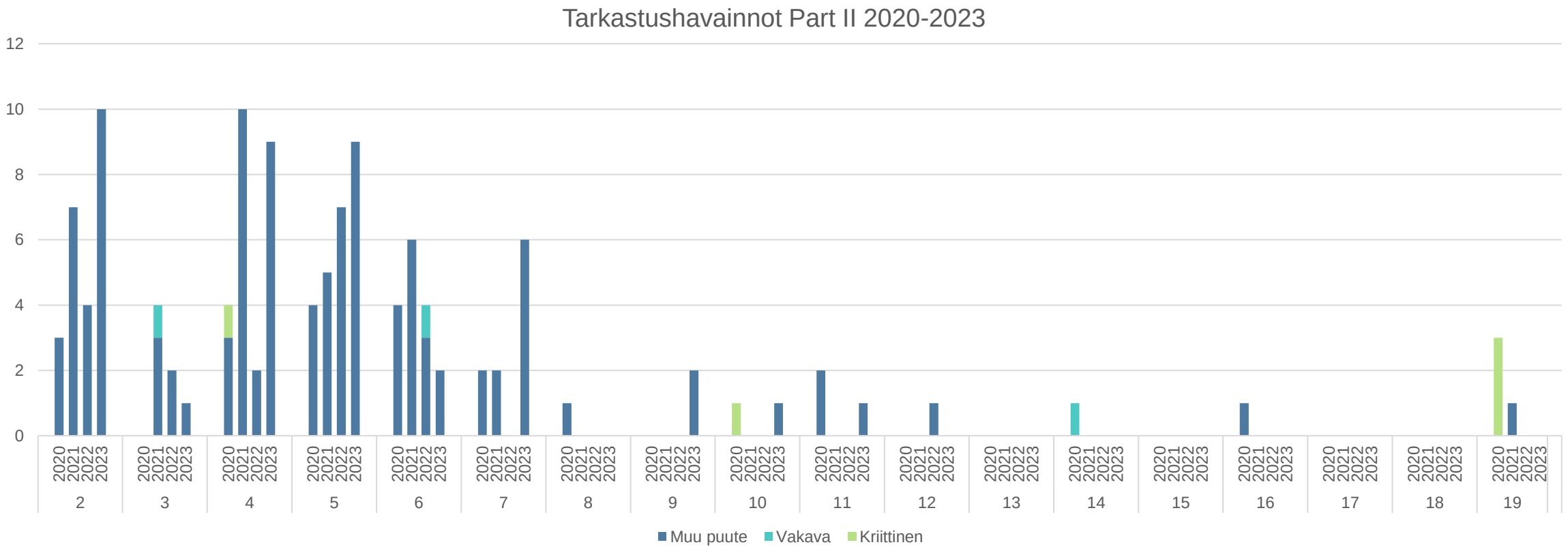


- 5.12 At all times during processing, all materials, bulk containers, major items of equipment and where appropriate rooms used should be labelled
- 5.13 Labels applied to containers, equipment or premises should be clear, unambiguous and in the company’s agreed format.

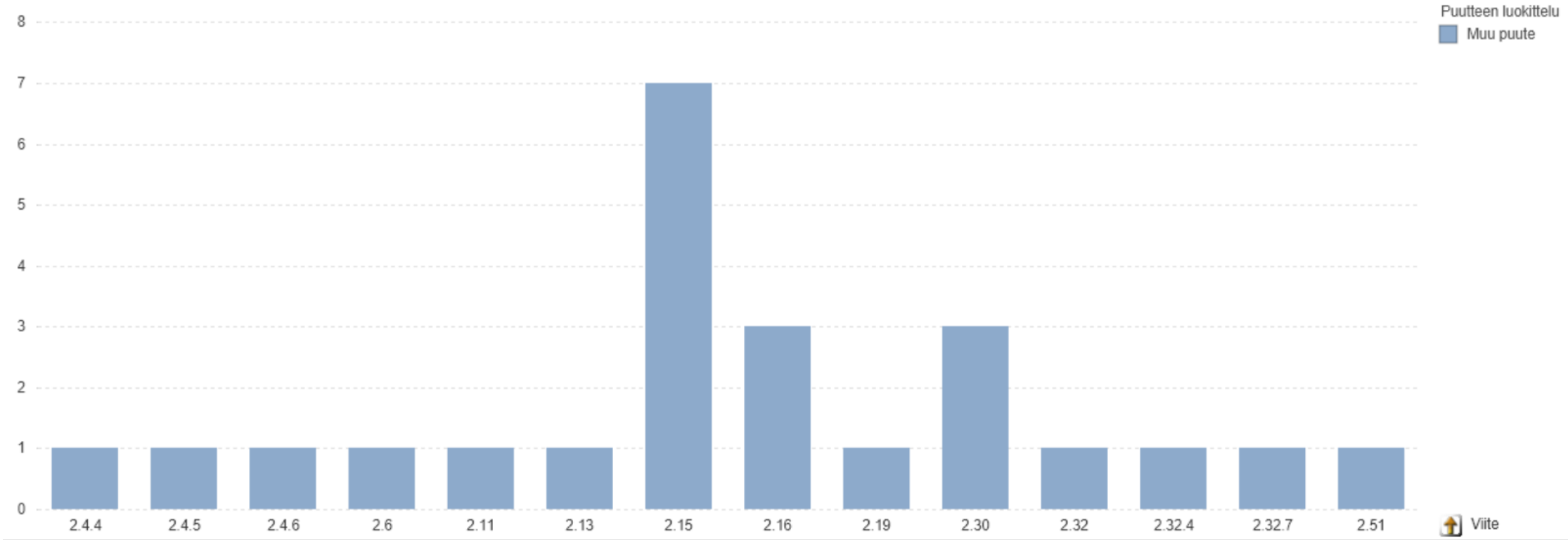
Ulkoistetut toiminnot (Chapter 7)

- 7.11 The Contract Acceptor should not subcontract to a third party any of the work entrusted to him under the Contract without the Contract Giver’s prior evaluation and approval of the arrangements.

Tarkastushavainnot 2020-2023 (Part II)

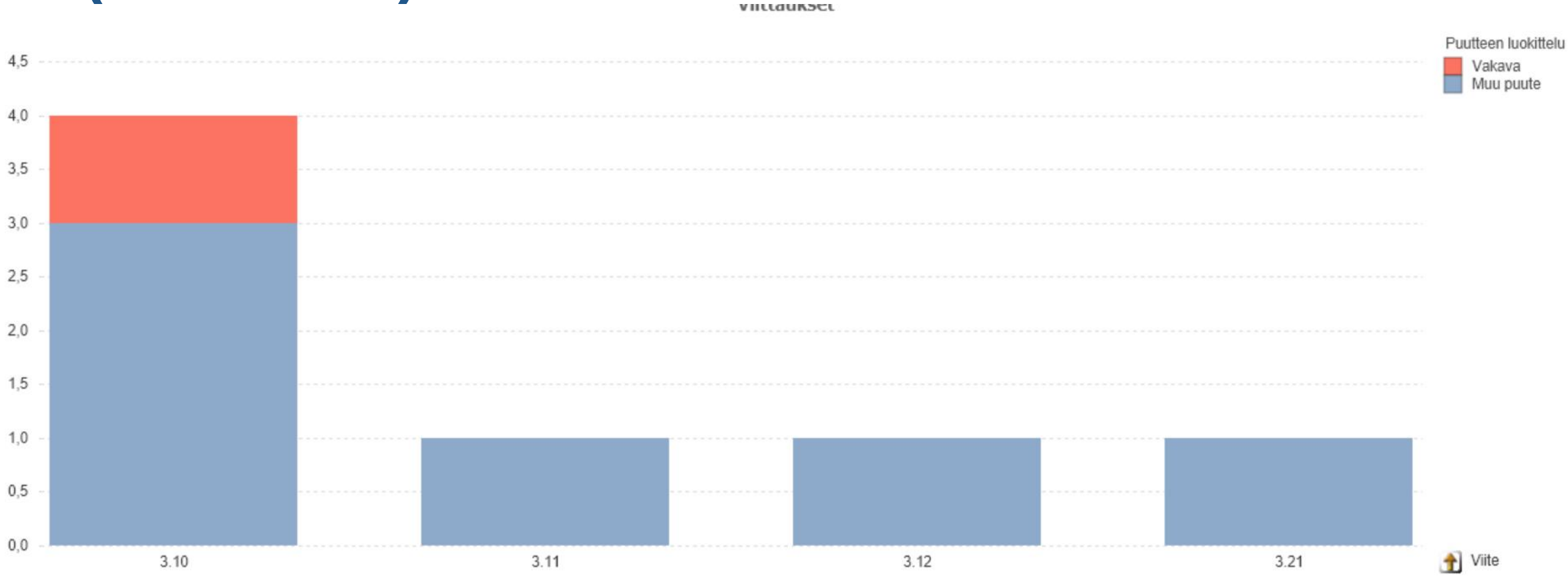


2 (Quality Management)



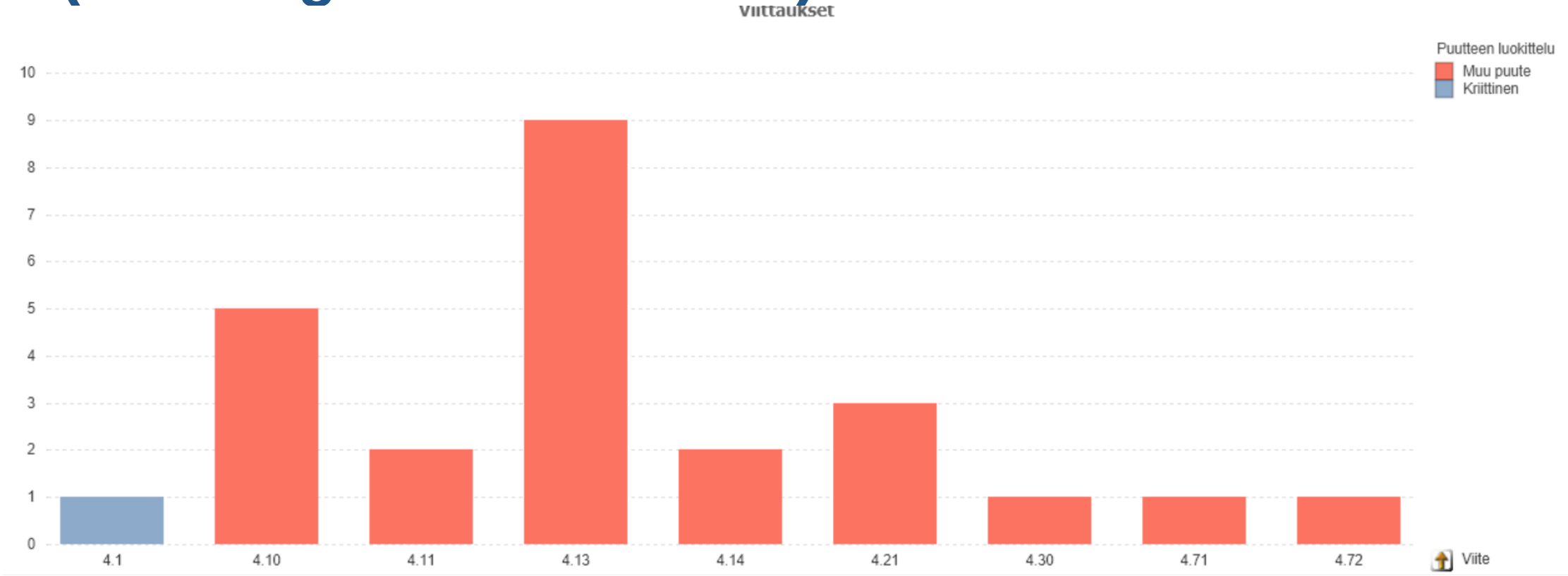
- 2.15 All quality related activities should be recorded at the time they are performed

3 (Personnel)



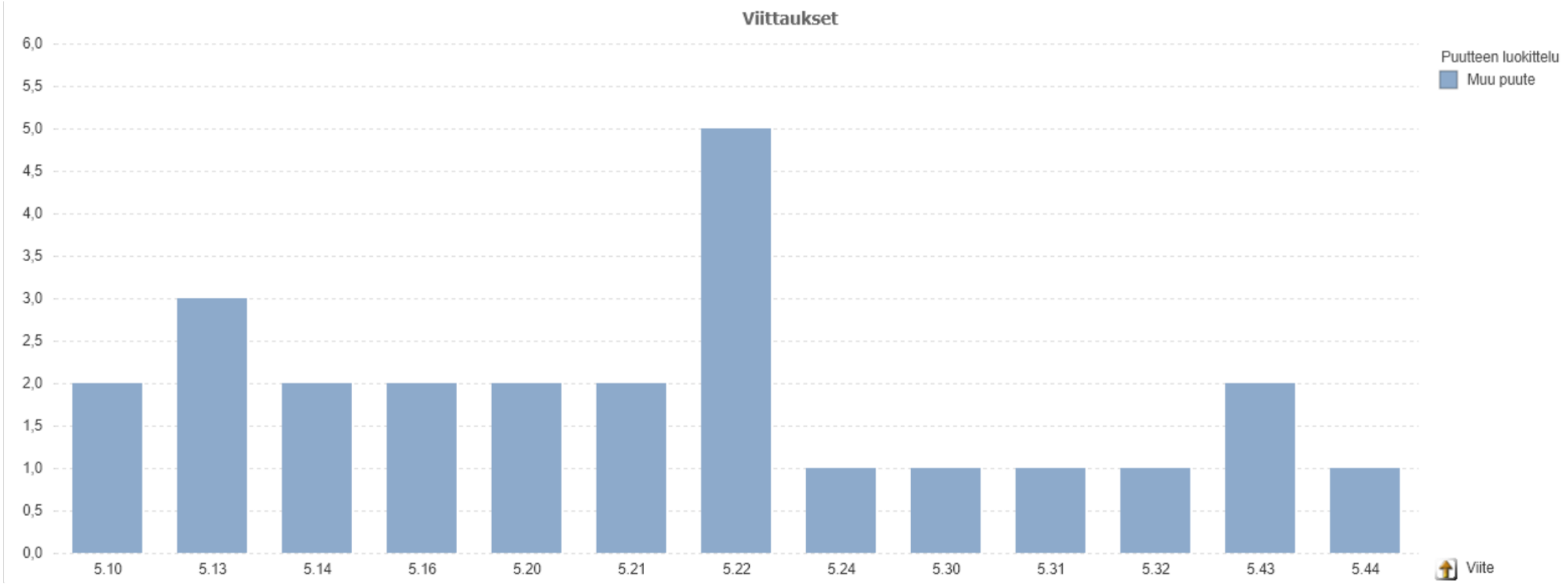
- 3.10 There should be an adequate number of personnel qualified by appropriate education, training and/or experience to perform and supervise the manufacture of intermediates and APIs

4 (Buildings and Facilities)



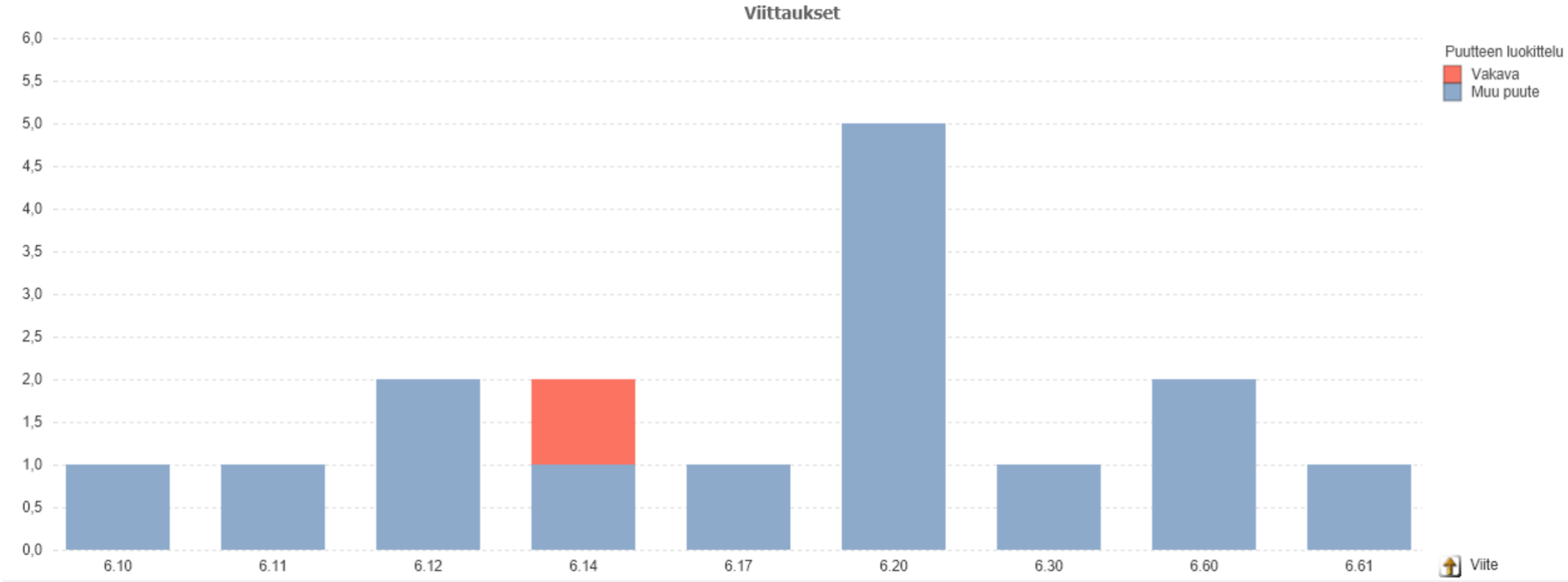
- 4.13 The flow of materials and personnel through the building or facilities should be designed to prevent mix-ups or contamination

5 (Process Equipment)



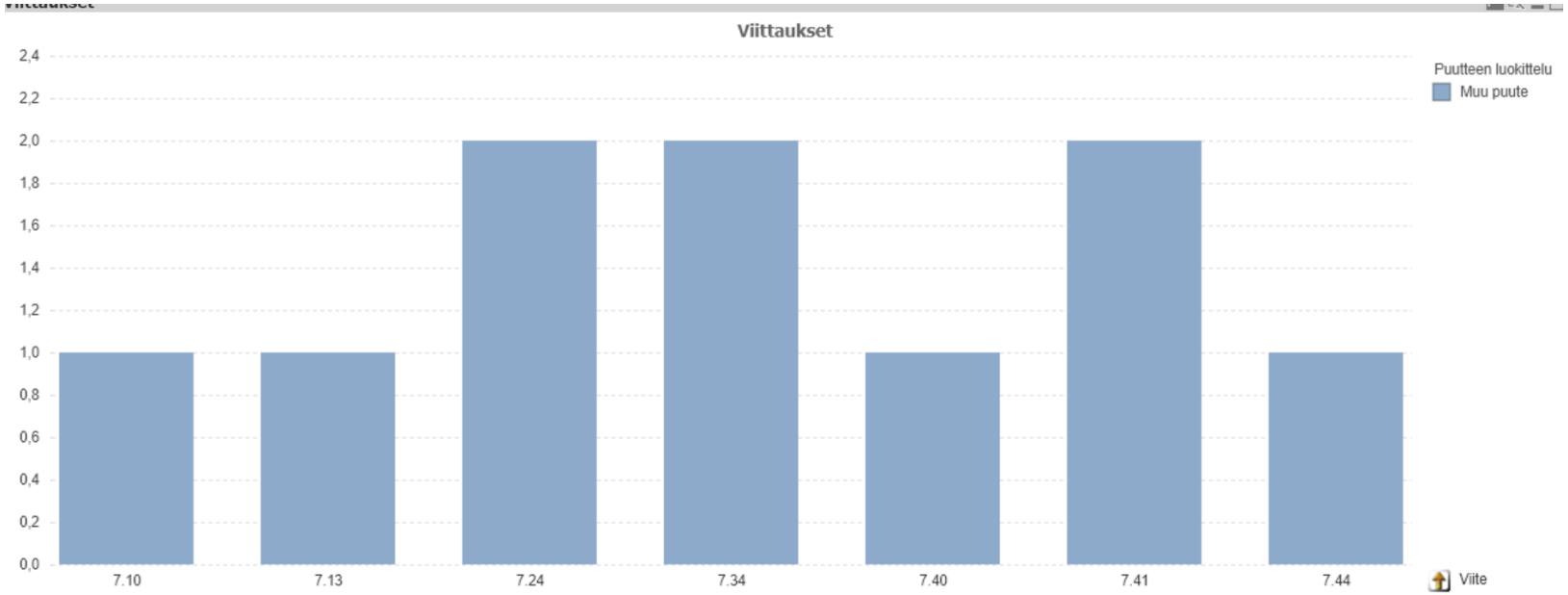
5.22 Equipment and utensils should be cleaned, stored, and, where appropriate, sanitized or sterilized to prevent contamination or carry-over of a material that would alter the quality of the intermediate or API beyond the official or other established specifications.

6 (Documentation and Records)



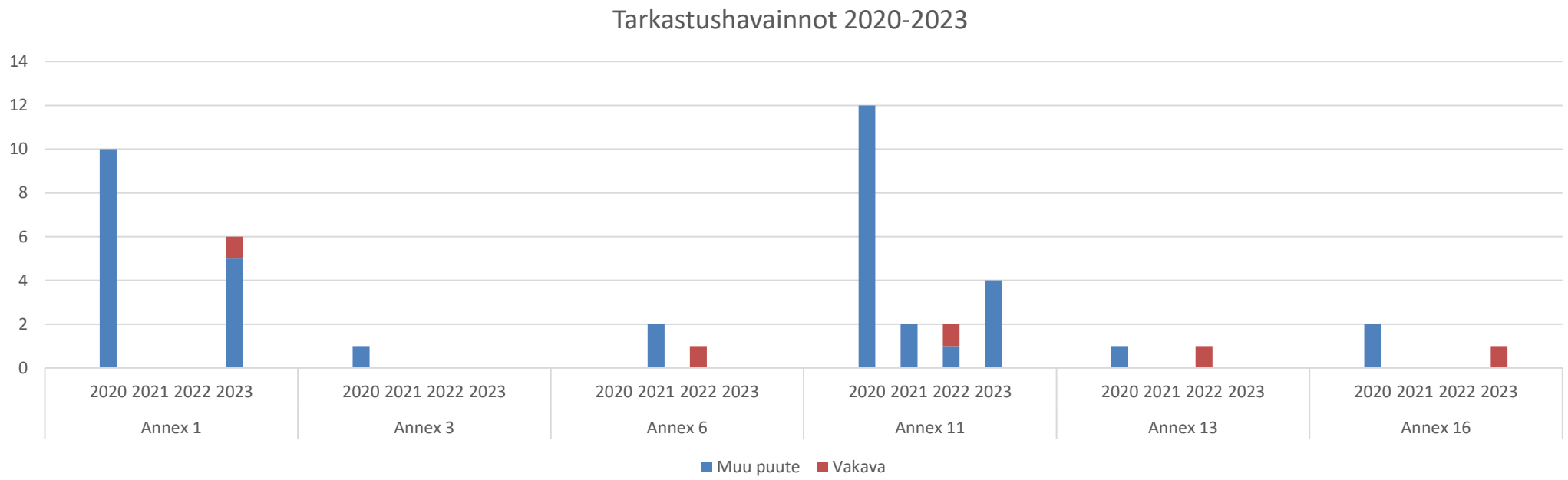
- 6.14 When entries are made in records, these should be made indelibly in spaces provided for such entries, directly after performing the activities, and should identify the person making the entry
- 6.20 Records of major equipment use, cleaning, sanitization and/or sterilization and maintenance should show the date, time (if appropriate), product, and batch number of each batch processed in the equipment, and the person who performed the cleaning and maintenance

7 (Material Management)



- 7.24 Each container or grouping of containers (batches) of materials should be assigned and identified with a distinctive code, batch, or receipt number..
- 7.34 Sampling should be conducted at defined locations and by procedures designed to prevent contamination of the material sampled and contamination of other materials.
- 7.41 Materials stored in fiber drums, bags, or boxes should be stored off the floor.

Tarkastushavainnot, Annexit



- Annex 11:11 Computerised systems should be periodically evaluated to confirm that they remain in a valid state and are compliant with GMP. Such evaluations should include, where appropriate, the current range of functionality, deviation records, incidents, problems, upgrade history, performance, reliability, security and validation status reports. .

Kiitos!