

SPECTARIS

German Industry Association for

Optics, Photonics, Analytical and Medical Technologies

- hereinafter referred to as SPECTARIS German Industry Association or simply SPECTARIS –

SPECTARIS 'Networked laboratory units' communication standard

- Code of Cooperation -

Guidelines relating to this working group covering collaboration in the development, distribution, establishment, revision and further development of solutions spanning its branch of industry and relating to standardised interfaces for the communication between laboratory equipment from various manufacturers as an overarching industry-wide alternative to proprietary models manufactured by large suppliers.

Status: May 13, 2020

A.

General section

I. Part: Preamble

1. Not least in view of (current) Covid-19 experiences, the pharmaceutical industry as well as private and public research bodies are increasingly faced with growing pressure to accelerate their processes and speed up their production and quality control processes. Within the framework of possible optimisation, existing laboratory infrastructure, digital connectivity of various pieces of equipment from a variety of manufacturers (in particular for the purpose of automating laboratory infrastructure) is the order of the day and frequently has a key role to play.

In the interests of connectivity, standardised interfaces to promote communication between equipment across manufacturers are required, with the aid of which equipment can be integrated into the respective laboratory environment for the purpose of interaction and collaboration. Only this approach enables the central control and efficient cross-equipment interaction between all these components from a wide variety of manufacturers and permits their deployment in flexible laboratory lines.

2. In order to develop a common communication standard for digital connectivity, the **SPECTARIS 'Networked laboratory units' working group** (hereinafter Working Group) was inaugurated in October 2016 as a **working committee** (§ 14 of SPECTARIS statutes). The resultant SPECTARIS communication standard for networked laboratory equipment (in the context of this guideline hereinafter referred to as SPECTARIS Standard or simply Standard) is purely pre-competitive; as an industry association, SPECTARIS aims to publish this standard via the corresponding national and international committees and make the standard available to its members for their individual use.
3. The development and production of hardware utilising this communication standard are the individual and exclusive responsibility of laboratory equipment developers and manufacturers.
4. The degree of success of any such standard depends largely on (i) broad and comprehensive deployment of the standard by the highest possible number of market players, (ii) the ongoing revision of standards, and (iii) its continued development. Therefore, this communication standard should be made available on the broadest front and as far as possible without restrictions and, where possible, without costs on the part

of users. Similarly, many users representing a representative cross-section of those involved are not only engaged in development, distribution and establishment but also in the ongoing review and further development process of the standard whilst observing and complying with existing regulations without any compensation.

**II. Part:
Involved parties**

1. According to the internal organisation of the **SPECTARIS 'Networked laboratory units' working group**, the following groups of entities are party to the process:
 - a) Core Members,
 - b) Contributing Members,
 - c) Observing Members, and
 - d) Users with an interest in standardisation in affected branches.
2. Furthermore, the following committees of interested parties are involved:
 - a) User Review Committees,
 - b) Core Workshops, and
 - c) Working Groups.
3. Far-reaching competencies derived from the SPECTARIS Board and the SPECTARIS Chair on controlling this working group is the responsibility of the Chair of the 'Analyses, Bio- and Laboratory Technology' association which, inter alia, decides on the nomination of parties and relevant committees. This and the SPECTARIS Board and the SPECTARIS Chair are supported in discharging their relevant duties by members of the SPECTARIS Board.
4. All involved pledge to observe and comply with valid regulations. Involved parties in contravention of these regulations or those who bring the reputation of the working group into disrepute can be expelled by the Chair of the 'Analyses, Bio- and Laboratory Technology' association; further expulsions can be imposed on the involved parties as follows:
 - a) to enforce a judgement with respect to parties' assess in the event that enforcement measures are not complied with within a period of one month
 - b) if the person involved warrants expulsion on account of compelling reasons pursuant to §§ 133, 140 of the German Commercial Code which makes remaining within the working group unreasonable.

The expulsion becomes active on receipt of a decision by the expelled party.

In the case of parties subject to insolvency proceedings or where the commencement of such proceedings has been refused on account of a lack of assets, parties are automatically expelled w.e.f. the date on which proceedings are opened or the date on which proceedings are refused, without the need for a decision on the part of the committee or any contact with the party concerned.

**III. Part:
Decisions**

1. Insofar as matters relating to groups and committees of parties are not covered by the SPECTARIS Chair, they are the responsibility of the SPECTARIS Board, SPECTARIS Management, the chair of the 'Analyses, Bio- and Laboratory Technology' association or other SPECTARIS body, regulated by decisions made by persons belonging to the respective group or committee. Each person has one casting

vote. Votes can be transferred to another person, the respective group or the committee. In order to avoid the unfavourable concentration of votes, any single person can only be transferred one vote.

2. Voting on decisions are not reliant on a particular form; a meeting in person of those eligible to cast votes is not required. A majority of votes cast decides. Important modifications, including such changes which have immediate impact on the ability of the working group to execute its duties or continue to exist or on the continued existence of the SPECTARIS standard, require a three-quarter majority of votes cast.
3. The outcome of each vote must be documented. This, in general, must include the wording of the resolution and the number of votes FOR and AGAINST the proposition as well as any ABSTENTIONS.

**IV. Part:
Resolution of conflicts**

1. In the event of disputes between individual parties, a solution is to be sought promptly in a manner agreeable to both parties with a view to preventing similar conflicts in future.
2. If such a resolution cannot be found promptly, the Chair of the 'Analyses, Bio- and Laboratory Technology' association is to present a proposed solution to which the parties in disagreement should, where possible, agree.
3. If this does not result in the resolution of differences in opinion, it is the duty of the SPECTARIS Chair to finally and bindingly resolve the dispute.
4. Promptly in the context of this guideline describes a period of time which should not exceed two weeks.
5. Legal recourse remains open to all parties. In the event of disputes involving a path of legal recourse, the final decision of the SPECTARIS Chair is only binding with respect to the parties in dispute if legal action is not instigated with a proper court within one month of receipt of the Chair's decision.

**V. Part:
Validity, Modifications, Annulment**

1. The relevant version of the guideline takes effect on the day after passage and approval by the SPECTARIS Board.
2. Modifications to this guideline must be submitted to the SPECTARIS Board as recommended propositions (which must not necessarily be implemented) for their decision. All parties are entitled to submit such proposals which are collected and submitted to the SPECTARIS Board by the Chair of the 'Analyses, Bio- and Laboratory Technology' association at regular intervals in preparation for their decisions.

A recommended decision is worded by the respective group of parties or by the relevant committee in which the proposal originates.

3. In the event of the complete dissolution of the working group, these guidelines relinquish their validity.

**B.
Special section
Collaboration between various parties and their responsibilities**

**I. Part:
Core Members**

1. Core Members are recruited from within the body of SPECTARIS members; core members form the central committee in establishing and developing the SPECTARIS standards beyond the interests of

individual companies; they must identify clearly, wholly and unconditionally with the SPECTARIS objectives and the goals of the SPECTARIS 'Networked laboratory units' working group and support these without reservation. These also network with users and other initiatives and collaborate with these.

2. Core Members are under obligation to regularly attend and participate in core workshops which may take the form of in-person meetings or telephone or video conferences amounting to a time commitment of at least 1 to 2 days per month and person.
3. The number of core members seconded by a SPECTARIS member company should not exceed two natural persons.
4. Core Members are responsible for the following:
 - a) the formulation of requirements relating to the SPECTARIS standard,
 - b) outlining the architecture of the SPECTARIS standard,
 - c) the development of use cases,
 - d) the approval of (software) artefacts,
 - e) the approval of the SPECTARIS standard and its continued development.
5. Core Members contribute to core workshops and take on the chairmanship of working groups.
6. Any extension to the body of Core Members is subject to the following conditions:
 - a) Interested parties present themselves at a meeting of Core Members in an attempt to convince core members of their motivation and the relevance of their potential contribution,
 - b) Interested parties consent to induction by Core Members with a view to preparation for their future tasks.
 - c) Existing and relevant competencies of Core Members must be objectively extended by the expertise of the interested party.

II. Part Contributing members

1. Contributing Members must provide the necessary development capacities extending beyond the interests of their own companies and advise Core Members in particular based on their detailed knowledge of their own customer base and with regard to technological aspects.
2. Contributing Members support the objectives of SPECTARIS and actively and regularly work together in the form of in-person meetings or telephone or video conferences in working groups aimed at formulating the specifications of the standard and the development of reference implementations.
3. Contributing Members are under obligation to regularly attend and participate in working groups which may take the form of in-person meetings or telephone or video conferences amounting to a time commitment of approx. 4 to 20 days per month and person.
4. The number of Contributing Members seconded by a participating SPECTARIS member company should not exceed two natural persons, excluding their deputies.
5. Any extension to the body of Contributing Members is subject to the following conditions:
 - a) Interested parties present themselves at a meeting of the working group in an attempt to convince current Contributing Members of their motivation and the relevance of their potential contribution,

- b) Interested parties consent to induction by Contributing Members with a view to preparation for their future tasks.
- c) The interested party must have the objective ability to collaborate to the required extent within the necessary framework,
- d) The group of Core Members has the right of consent to any extension of the group of Contributing Members.

**III. Part:
Observing members**

- 1. Observing Members must have an objective interest in collaboration and observe the development of the SPECTARIS standard; they provide feedback on trends in the various markets.
- 2. Observing Members are requested to provide their opinions to the working group and comment on requirements relating to the SPECTARIS standard, use cases and related specifications and ongoing reference implementations at regular intervals.
- 3. Observing Members who are simultaneously SPECTARIS members or affiliated with such are furthermore obliged to take part regularly in meetings of the 'Networked Laboratory Units' working group.

**IV. Part:
Users**

Users are invited to comment on all aspects of the SPECTARIS standards in a competent and substantiated manner.

**V. Part:
User Review Committees**

- 1. The User Review Committees ensure a close exchange between manufacturers and users relating to the SPECTARIS standard; proposals are made in a manner relating to their context by Core Members and on the basis of situation-related criteria and procedures which must be documented.

Participation in User Review Committees is at the invitation of a Core Member; invitations can be extended to persons with the objective ability to collaborate and regularly attend events convened by the 'Networked Laboratory Units' working group.

- 2. User Review Committees are responsible for proving actual, financial and factual support to enable the implementation of proof of concept.
- 3. User Review Committees also comment on the architecture of the SPECTARIS standard along with associated specifications and provide the working group with their opinions on requirements relating to the SPECTARIS standard, its use cases and reference implementations on a regular basis.

**VI. Part:
Core Workshops**

Core Workshops are meetings of Core Members to deal with specific tasks.

**VII. Part:
Working Groups**

Working Groups are meetings of Contributing Members to deal with specific tasks. Chairmanship of working groups is assumed by a Core Member.

VIII. Part:

Procedure through to approval and publication of a SPECTARIS standards

1. Description of a use case and associated requirements:
 - a) Approvals and publication are the responsibility of Core Members.
 - b) Contributing Members, Observing Members and the User Review Committees submit change requests as and when necessary.
 - c) Users can also submit their comments.
2. Description of the architecture of a solution in individual use cases:
 - a) Approvals and publication are the responsibility of Core Members.
 - b) Contributing Members submit change requests as and when necessary.
 - c) Observing Members, User Review Committees and users can also contribute their comments.
3. Solution specifications:
 - a) Approvals and publication are the responsibility of Core Members.
 - b) Contributing Members are responsible for creating a solution.
 - c) Observing Members, User Review Committees and users can also contribute their comments.
4. Reference implementation:
 - a) Approvals and publication are the responsibility of Core Members.
 - b) Contributing Members are responsible for creating a solution.
 - c) Contributing Members and User Review Committees submit change requests as and when necessary.
 - d) Users can also submit their comments.
5. Final approval and publication on the use of the SPECTARIS standard (release) is the responsibility of Core Members.

C. Co-valent regulations

1. Furthermore, legal relationships with respect to the SPECTARIS standards are regulated by the following bodies of legislation:
 - a) Obligation to secrecy under the threat of punishment involving all parties imposed on all parties in the development, distribution, establishment, revision and further development of the SPECTARIS standards.
 - b) Declaration of recognition and compliance with the Code of Cooperation.
 - c) Any transfer of rights to SPECTARIS (development contract) for the issue of further licences, possibly expanded by an agreement on the administration of rights.
 - d) Protection of brand and marks

- e) User licences, e.g. as freely accessible software as a Lesser General Public Licence – LGPL with restricted 'copyleft' or alternatively as Free Licence such as BSD licence without 'copyleft'; in all cases it must be a standardised licence model under the auspices of SPECTARIS relating exclusively to and limited to the communication interface and which strictly excludes the software of manufactures and involved parties.

2. Rights are reserved to issue further regulations and modifications to the aforementioned rules.

D.

Approval of SPECTARIS Board

This confirms that the Board passed the currently valid guidelines on July 1, 2020 with 13 AYE votes, no NAY votes and no abstentions.

Berlin, July 2, 2020
SPECTARIS German Industry Association

Josef May, Board Chairman

Jörg Mayer, Managing Director