

Best Practices for Acquiring Machines and Equipment

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Use of this Guideline

If you can answer yes to points 1 and/or 2 below, this guide must be followed.

The new machinery and equipment that is considered:

- 1. Brings a new risk.
- 2. Entails demands on buildings and/or installations:
 - a) Need for e.g., ventilation, drainage, utilities (water, electricity, heating, cooling etc.), checking if the floor can support etc.
 - b) Affects overall space utilization at TEK.
 - c) Affects the surrounding environment (e.g., noise, vibrations, emissions).

Please note: The instructions must also be followed if it is a donation, loan of equipment, and in connection with equipment we build ourselves; in this case, however, the Purchasing Department must not be involved.

Purpose

As part of the prevention of accidents and health damage at SDU, there must be a focus on safety and health in the procurement process, including a focus on machine safety, the requirement for CE marking and the requirements of the Machinery Directive in general, as well as other relevant legislation. The purpose of this guide is to:

- ...ensure that all relevant parties in the organisation know their responsibilities and roles.
- ...ensure that installation requirements as well as safety and health measures are identified and dealt with *before* purchase, so that commissioning of new equipment is not delayed unnecessarily.
- ...ensure that the procurement process becomes even more systematic and efficient, including the involvement of relevant parties, e.g., Technical Services, early in the decision-making process.
- ...reduce accidents and health damage risk in connection with new equipment.

Target Group

The target group is all relevant parties in the purchasing process, including:

Users/requesters of the equipment

Relevant managers

The purchasing organisation

The working environment organisation



Technical Services

Summary

In general: When purchasing, contact your purchaser as soon as possible so that you can receive guidance as early as possible in the process.

Before acquiring new (electrical) machines and equipment which entail new risks, a working environment assessment/risk assessment must be made. This is carried out by the person responsible for the process/equipment and must be reviewed and approved by the institute's own working environment group. Be aware of the requirement for a manual or safety sheet that must be in Danish and a language that the users understand. This also applies to donations or loans of equipment/machines.

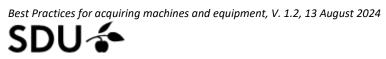
In the case of machines/equipment that entail requirements for building installations, and/or have consequences in terms of space utilization, noise, vibrations, anchoring in the floor, need for a cage/shield, extraction, etc., the assessment is sent to the TEK Building Committee. The TEK Building Committee must then ensure the involvement of Technical Services.

The process is the same in cases where the institute itself constructs equipment/machines/experimental setups.

Technical Services, in collaboration with the faculty, will assess the desired acquisition in relation to legislation, the suitability of the buildings and supplies. Based on this dialogue, the work can either be initiated, or an order form must be filled in if the task is of a certain size.

Equipment - especially special equipment - must be purchased with installation as far as possible. However, Technical Services must always be involved in relation to special requirements for installation (contact: 8888@sdu.dk).

Please be aware that there are special requirements when purchasing outside SDU's purchasing agreements, and especially challenges when purchasing outside the EU and Switzerland.



1. Risk Assessment

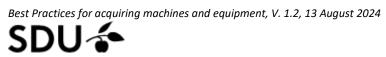
Before ordering			
Action	Responsible	Sources/Tools	
An initial risk assessment must be made, including:	User/department prepares risk	<u>Templates for risk assessments</u> (see Appendix 1).	
Substitution considerations: Choose	assessment. Must be approved by	Guideline from "BFA Industri" (Danish only):	
machine/equipment/materials with the least risk that	the working environment group and	Purchasing Machines and Machinery / Køb af	
fulfills the purpose.	immediate supervisor.	maskiner og anlæg: https://www.bfa-	
		i.dk/generelt/koeb-salg-og-service/koeb-af-	
		maskiner-og-anlaeg	
Investigate whether machine/equipment can be	User/department.	Contact your purchaser, who can help on the way	
purchased within SDU's procurement agreements. If		in relation to clarification, possibly with the	
this is not possible, purchases should preferably be		involvement of SDU's purchasing network, which	
made within the EU or Switzerland.		may have experience from similar	
Are there others at SDU who have bought similar		purchases/dealers.	
equipment who can share their experiences?			
Define required security measures, incl. any need for	User/department.	Safety information from supplier.	
protective equipment, permits, etc.; see checklist in		Risk assessment.	
Appendix 2, which must be completed.		Legislation, e.g., the Machinery Directive and	
		relevant product directives.	
If the risk assessment/supplier information shows that	User/department.	Following chapter in this guideline:	
there are requirements for buildings/installations, you		2. Requirements to buildings and /or installations	
must also follow the instructions in section 2.			
Ensure that equipment meets applicable legal	User/department.	Danish Standards: https://www.ds.dk/en/about-	
requirements, including the Machinery Directive's		standards/ce-marking/what-is-to-be-ce-marked	
requirements/requirements for CE marking and various			
product directives.		About requirement for a manual in Danish and the	
Secure detailed offer and specifications from supplier.		original language:	
Special attention points:		See Order Regarding the Use of Equipment	
Ensure that the equipment/machine is CE-marked and		(Bekendtgørelse om anvendelse af tekniske	
complies with relevant product regulations.		hjælpemidler), § 16,	
If possible, order equipment with installation.		https://www.retsinformation.dk/eli/lta/2022/428.	
Is a service agreement required after delivery?		See also:	



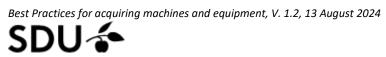
REMEMBER that a user manual, which is at least in	Appendix 1 to the Machinery Directive, section
Danish and a language that the users understand, must	1.7.4, as well as the Low Voltage Directive
be included as part of the delivery.	2014/35/EU, that's been implemented in Denmark
When is payment due? For example, the last part after	via the Act 2516 of 14/12/2021: "Bekendtgørelse
testing the equipment?	om sikkerhed for elektrisk materiel", §§ 19, 29 og
Contact your purchaser at TEK for guidance.	33:
	https://www.retsinformation.dk/eli/lta/2021/2516
	Act about the arrangement of technical aids, BEK
	nr 429 af 05/04/2022:
	https://www.retsinformation.dk/eli/lta/2022/429
	<u>§ 34.</u>
	TEK Purchaser.

2. Requirements to Buildings and/or Installations

Before ordering			
Action	Responsible	Sources/Tools	
Requirements for installation; including required safety and health	User/department.	Installation instructions from supplier.	
measures: Complete the checklist in Appendix 2.		Risk assessment (see section 1).	
Ensure that equipment meets applicable legal requirements,	User/department.	Danish Standards:	
including the Machinery Directive's requirements/requirements for		https://www.ds.dk/en/about-	
CE marking and various product directives.		standards/ce-marking/which-product-	
		groups-are-to-be-ce-marked	
Send the following information/material to TEK Building Committee	User/department.	Safety information from supplier.	
(https://sdunet.dk/en/enheder/fakulteter/teknik/praktisk-info-og-	Purchase and installation/use of		
<u>faciliteter/ombygninger-og-installationer</u>):	space must be approved by the	Risk assessment.	
1. Completed TEK request template.	manager before the TEK Building		
2. The completed checklist in Appendix 2.	Committee and Technical Services	Internal approvals.	
3. Installation instructions and manual from supplier.	carry out an assessment.		
4. Sketch of location in premises.			



5. Risk assessment with safety instructions approved by the working environment group (template in Appendix 1).		
Assessment of the request in relation to the suitability of the buildings/location, prioritisation of budget and space at TEK etc. After this, the involvement of Technical Services and securing their approval before procurement is initiated.	TEK Building Committee coordinate with Technical Services and reply to user/department.	
Feedback to the user/department whether the purchase can be initiated. Ensure continued coordination and follow-up with Technical Services.	TEK Building Committee.	
Ordering		
Action	Responsible	Sources
When placing an order, include: When it comes to products involving new risk: Approval of the risk assessment by the Working Environment Group. For larger machines/installations: TEK Building Committee's approval of space/installation. Where there is an offer from/an agreement with a supplier, must also be included.	User/department.	Risk assessment (see section 1).
Is it a matter of cross-border interest (GOI)? Observe the special rules for SDU.	User/department. TEK Purchaser.	Appendix 4.
Always pay attention when purchasing for more than DKK 100,000, as these purchases must go through SDU's Procurement and Tendering via your purchaser at TEK in accordance with contract drafting and legal assistance. Additional processing time must be expected.	User/department. TEK Purchaser.	TEK Purchaser. SDU's <u>Procurement and Tendering</u> .
Connection and installation		
Action	Responsible	Sources
Installation/connection must be done according to the instructions in the manual. Pay attention to whether an authorized installation contractor is required.	User/department.	Manual accompanying the equipment. Technical Services.

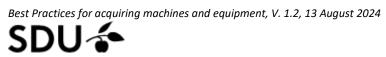


Remember the involvement of Technical Services according. It	
must, among other things, be ensured that equipment and setups	
are supplied via sockets protected with HPFI relay and the correct	
size fuse, and that equipment is placed appropriately in the	
room/building in relation to escape routes, installations, etc.	



3. Test and Commissioning

Test and commissioning		
Action	Responsible	Sources
In the case of electrical appliances/equipment: Remember to check whether the equipment is grounded all the way from the equipment and to the switch. In case of special risks: A plan is made for safe testing and running-in. The plan for testing and commissioning must be approved by the working environment group before testing is started.	User/department.	Manual/Safety Data Sheet/accompanying the equipment/material. Guideline from "BFA Industri" (Danish only): Purchasing Machines and Machinery / Køb af maskiner og anlæg: https://www.bfa-i.dk/generelt/koeb-salg-og-service/koeb-afmaskiner-og-anlaeg Risk assessment (see section 1).
Risk assessment and safety instructions are continuously adapted during the test in relation to the actual conditions. Security procedures are documented as part of this: Does the machine need to be secured with a key, for example, and where is the key kept safely?	User/department.	Test result. Manual. Risk assessment.
Necessary adjustments/calibrations are done, and any extra safety measures based on the experience from testing/commissioning, including e.g. shielding and/or marking of the work area around the equipment. As far as possible, refrain from making changes to the machine/equipment itself, as the warranty may then be void, and the department then takes over responsibility for the equipment and renewed CE marking.	User/department.	Appendix 3 on CE marking.
Any required safety signage must be set up at the entrance to the room and/or at the equipment/machine.	User/department. Head of Department is overall responsible.	
If necessary, access to rooms/areas/equipment must be restricted, and relevant persons must receive safety	User/department. Head of Department is overall responsible.	



instructions (remember information for the cleaning staff/Technical Services, when relevant).		
For special risks: The working environment group must have a thorough introduction to the process and all safety procedures (risk assessment, safety instruction, emergency management). The working environment group must approve the entire setup, procedures and documentation before the new equipment can be put into operation.	User/department. Head of Department is overall responsible.	
Implementation		
Training of users. NB: Is special training/certification required?	User/department.	Manual. Relevant legislation and product directives.
Users must receive risk assessment and safety instruction: They must have access to the written material, which must be supplemented with oral instruction and training.	User/department.	
Follow-up		
Action	Responsible	Sources
Establish routines for equipment/machines to be maintained and serviced in accordance with legal requirements/manual requirements. Pay attention to whether service must be carried out by an expert or an authorized expert.	User/department.	 Manual. Relevant product directives. <u>Information about mandatory</u> <u>inspections ("lovpligtige eftersyn")</u>.
Risk assessment and instructions must be updated in case of changes, and at least every three years.	User/department.	Danish Working Environment Authority: https://at.dk/en/regulations/guidelines/risk-assessment-apv-d-1-1-3/
Instruction of users must be repeated at intervals determined based on the users' level of education in relation to the process, how often they use the equipment, risk level, complexity, etc.	User/department.	



Contacts and Sources

Internal Contacts

TEK Building Committee: https://sdunet.dk/en/enheder/fakulteter/teknik/praktisk-info-og-faciliteter/ombygninger-og-installationer

TEK Purchasing Coordinator: Richard Beck, beck@tek.sdu.dk TEK Purchasing Sønderborg: Lars Bjerrum, lvbj@tek.sdu.dk

Working Environment Organisation; find link here: https://sdunet.dk/en/enheder/fakulteter/teknik/arbejdsmiljoe-og-personaleforhold/safety

TEK Senior Consultant for Working Environment: Susanne Arnsted, suar@tek.sdu.dk

SDU's Procurement and Tendering (Contact information: https://sdunet.dk/da/servicesider/oekonomi/indkoeb-og-udbud/kontakt)

Sources

Machinery Directive: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32006L0042

Danish Working Environment Authority: https://at.dk/en (especially: https://at.dk/en/regulations/executive-orders/use-technical-work-equipment-1109/)

Danish Standards: https://www.ds.dk/en (especially: https://www.ds.dk/en (especially: https://www.ds.dk/en/about-standards/ce-marking/which-product-groups-are-to-be-ce-marked)

Lov om indretning m.v. af visse produkter: https://at.dk/regler/love-eu-forordninger/indretning-produkter-155-sam/ (in Danish only)

Order on the design of technical equipment: https://at.dk/en/regulations/executive-orders/design-technical-equipment-612/

Danish Safety Technology Authority: https://www.sik.dk/en

Bekendtgørelse om maskiner: https://www.retsinformation.dk/eli/lta/2021/1094 (Danish only)



Appendix 1: Template for Risk Assessment (Machines and Equipment)

Risk Assessment

Date: [Fill in date]
Latest update: [Fill in date]

Room: [Fill in room number and name]

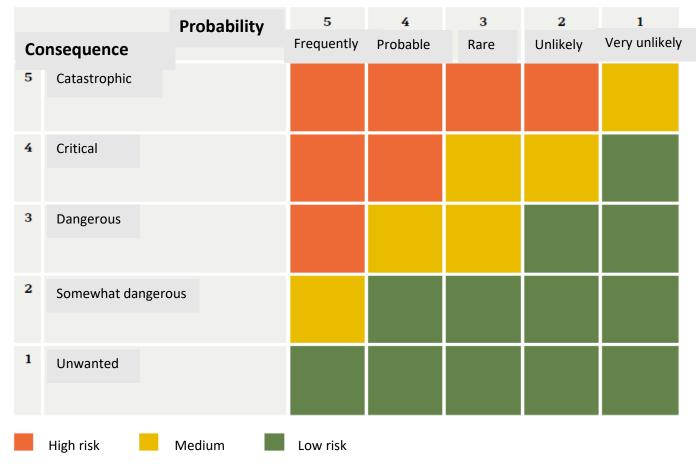
Responsible for room: [Fill in name]

Participants: [Names of participants in risk assessment]

Participa	ints:	[Names of participants in risk assessment]	
What	Risk Management/ description/"extent" (see last page)		Management/precautions
Machine Technical appliance Robot	Normal use	Other use: maintenance, cleaning, transport etc. (high risk of wrong use?)	 User manual available (legal requirement) Instructions, oral / written Precautions: signage, shield / safeguarding, ventilation, protective gear etc. Instructions in case of accidents Red: Only for use after thorough safety instructions and carefully sticking to the guidelines. Students are not allowed to be alone in the room or use the equipment alone; there must minimum be one other person present who has also received the safety instructions (can be a fellow student). Yellow: Only access after safety instructions. Students may use the lab /equipment without supervisor after thorough safety instructions. Green: No risk. Students can use the lab /equipment without any preceding safety instructions.
EXAMPLE: Spectroscopy: Laser class 4	 Risk of eye damage Risk of skin damage etc. 	 HIGH Risk of eye damage Risk of skin damage etc. 	 Safety glasses class 4 wavelength 500-2000 nm are mandatory for all persons in the room when the laser is in use No jewelry etc. that may reflect / divert the light is allowed Ensure that the laser beam is shielded and not directed at any persons Always turn on red warning light before turning on the laser, and remember to turn it off again when laser is turned off In case of injury,[procedures] etc.



Check matrix – risk assessment (probability vs. consequences)



In this matrix, the risk level is assessed based on the combination of probability and consequences of an adverse event.

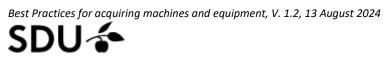
Please note: Even if an event is very unlikely to happen, the risk will never be categorised as "low" if possible consequences are catastrophic.



Source: Risikovurdering, Industriens Branchearbejdsmiljøråd: https://www.bfa-i.dk/media/3070715/risikovurdering net.pdf

Appendix 2: Requirements to Installation and Safety Measures

Define requirements, e.g.:	Yes/No and Definition plus Comments
Installations	•
Electricity:	
- Volt	
- kW consumption	
- Are there the needed sockets	
- HPFI relay and right size of fuse	
- Other	
(NB: Remember grounding of all electrical equipment)	
Lighting – special requirements	
Water supply? Type? (Tap water or demineralised)	
Need for supply of gases etc.	
Drainage or collection of process water/wastewater	
Collection in case of spills/leaks	
Space conditions/location (Please note: Escape routes and	
installations must be kept clear)	
Anchoring in floor/wall/ceiling	
Access: Transport of equipment all the way to the place of use,	
special requirements (width of doors, ramps, lift, etc.)	
Special floor covering (e.g., earthed, acid-resistant, antistatic, etc.)	
Also: Can the floor support the equipment	
Need for ATEX protection	
Need for noise reduction (dB)	
Vibrations	
Emissions, gases, smells, etc.: Need for process ventilation	
Need for fume cupboard etc.	
Need for cooling (take heat generation from equipment into	
consideration)	
Shielding of moving parts	
Encapsulation of work area	
Need for extra access control	
Safety signage	



Other safety measures and environmental requirements etc.		
Personal protective equipment (PPE)		
Requirement for special education/course/certification		
Requirement for registration/permits from authorities		
Requirement for special treatment of process air, wastewater,		
waste etc.		
Need/requirement for safety equipment, e.g., fire extinguishers,		
safety showers, eyewash etc.		
Special requirements for storage, e.g., ventilation, locked		
room/cabinet etc.		
Other special requirements		



Appendix 3: CE Marking

The rules about CE marking of Machinery (from after 1995) can be found in the Machine directive:

https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32006L0042&from=EN

Find some guidelines / how-to and more information here:

Dansk Standard: https://www.ds.dk/en/about-standards/ce-marking

- 1. Machines/systems/electrical products etc. which have been produced from and including 1 January 1995 must be CE-marked.
- 2. Pay particular attention when purchasing from countries outside the EU.
- 3. REMEMBER that CE marking is carried out by or for the manufacturer. The marking is a promise from the manufacturer that various directives have been complied with, including the Machinery Directive, and that dangerous machines have been tested by an impartial body. However, when we have the equipment with us, we are responsible for ensuring that it complies with the regulations. For example, you must check for correct mains and high-voltage plugs.
- 4. Components and safety components may NOT be CE marked; CE marking is only required on finished machines and replaceable equipment.
- 5. As a rule, **temporary** experimental setups do not have to be CE-marked, but they must comply with the requirements of the Machinery Directive, and a (written!) risk assessment must be created.*
- 6. Remember that all equipment must also meet Danish requirements, and the manual must be available at least in Danish, as well as in a language that other users understand.
- 7. If you need to make changes to CE-marked equipment, it is best to leave it to the supplier if possible. If you make changes yourself, you must document the change in the technical file and make a declaration of conformity (CE Marking Conformity Declaration). You must test the equipment and document that it has been tested with the modification, and you then assume responsibility for the CE marking and the product with the modification. Pay particular attention to whether the warranty on the equipment is void in case of modification.

*If a set-up/machine/apparatus (in a laboratory) exists in the same form — with the same properties — for a long period, it is no longer considered an experimental set-up, cf. point 5 above. The Danish Safety Technology Authority (Christoffer Blæsberg, end of October 2019) defines as follows:

As a general rule, an experimental set-up/machine/apparatus should not exist for more than approx. 6 months without being CE marked.

If an extended period is necessary to collect the required data from the experiment, you might, however, justify that an experimental set-up exists for up to a year +/-. The need for continued collection of data must be documented (in writing).

The Danish Safety Technology Authority cannot guarantee that the Working Environment Authority, which is the controlling authority, will not prosecute the lack of CE marking.



When changes are made to the experimental set-up which alter its properties/function, then this is a new experimental set-up. A new or adjusted written risk assessment is therefore made for each trial setup, and then a new period for temporary trial setup begins.

Appendix 4: Cross-Border Interests – Purchases from Abroad

An assessment of the purchase must be made when it exceeds DKK 100,000.

Evaluation of clear cross-border interest will, however, always depend on a specific assessment. This means an assessment of whether a company in another EU member state may have a real interest in submitting an offer for a contract; hypothetical interest is therefore not enough for an assessment to be clear. The assessment only concerns whether a company in another Member State may have an interest in the contract, and not whether the contract may be of interest to a foreign company that is already operating in Denmark.

Before the assessment is made, it is essential that it is thoroughly investigated whether there are existing SDU procurement agreements that can be used. If there is no SDU procurement agreement, relevant market research must be carried out.

The assessment must be journalized in the event that the National Audit Office (Rigsrevisionen) or others wish to document the procurement process.

Is the purchase atypical?

Atypical purchases are purchases of less than DKK 500,000 where the purchase in question is planned or can only be made from foreign suppliers. If the foreign supplier has Danish representation, i.e., has a CVR number, the purchase is not considered atypical.

If the purchase is atypical, this suggests that there is cross-border interest.

Has the purchase been made on market terms?

Purchasing on market terms implies a relevant and fact-based market research in relation to the suppliers who are on the market; including that no supplier gets a disproportionate advantage, e.g., based on conflicts of interest.

Conclusion

Due to the very low contract value, a purchase with a value below DKK 500,000 is only considered to have clear cross-border interest if the purchase in question can only be made from suppliers located in another EU member state, and these have shown concrete interest in bidding for the same or a similar purchase.