

Disclaimer:

The IKB Kip certification scheme has been translated with the greatest care and accuracy. In the event of any disagreement concerning the correct translation, the content, interpretation and operation of the IKB Kip certification scheme, the Dutch text of the IKB Kip certification scheme takes precedence in all cases.



ANNEX 1.3: IKB KIP REGULATIONS FOR MAIN SITE OF A MULTI-SITE

On 27 March 2014, the management of the PLUIMNED foundation established the IKB Kip regulations below for the main site of multi-sites, setting out the regulations which participants to the IKB Kip certification scheme must comply with, in view of Article 14 of the General Terms and Conditions of IKB Kip. These regulations use the same terminology as the General Terms and Conditions for IKB Kip.

Tab	Version	Determined	Effective date
Main site of a multi-site	4	29-04-20	01-06-20

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Version: 4 / Approved: 29-04-2020 / Effective date: 01-06-2020

Norm	Regulation	Interpretation of regulation	Measuring method	Interpretation of the measuring method	Weighing of 1st observation	Weighing of 2nd observation	N/A	Exceeds statutory regulations	Start date
A	GENERAL MULTI-SITE								
A01	An up-to-date register of companies associated to the multi-site must be available.	The register must contain the names and addresses of the associated companies, including the KIP number or the IKB Kip number for foreign companies.	administrative	Check whether an up-to-date register is present of associated companies, containing the correct details. Check whether it matches the companies known to be associated by the CI and CO.	heavy	suspension	N/A is not possible	Yes	Amended on: 1-4-2012
A02	The main site must have entered into agreements with all the companies that are covered by the multi-site.	Accreditation audit: Check that an agreement has been concluded with associated companies. Re-inspection: Check whether an agreement has been concluded with newly associated companies.	administrative	If no new companies have been associated to the multi-site, verify this by randomly checking the administrative records (if possible at least five).	heavy	suspension	N/A is not possible	Yes	Amended on: 01-04-2012 01-06-2020
A04	The agreement specified in A02 contains the following information: - company name, legal status, company address, type of company (link in chain), KIP registration number (or IKB Kip number for a foreign company) and name of contact person. - the contractor undertakes to comply with the IKB Kip regulation; - the contractor undertakes to undergo internal inspections performed by the main site and to take remedial measures; - the contractor undertakes to undergo inspections in the context of the main site's certification ; - the contractor agrees for its company to be registered in the IKB Kip database and listed on the public register.		administrative	Verify whether the information required under the regulation is present in the agreement by taking a random sample. Record from which companies the agreements have been checked so that other agreements are checked at each re-inspection.	heavy	suspension	N/A is not possible	Yes	Amended on: 01-04-2012 01-06-2020
A05	The tasks, responsibilities and authorities of the company's own staff at the main site, which relate to activities concerning IKB Kip, are demonstrable in writing.	This includes inspectors and contact names	administrative		heavy	suspension	N/A is not possible	Yes	Amended on: 01-04-2012 01-06-2020
A06	The internal inspectors comply at least with the requirements for inspectors as set out in 'Accreditation criteria for IKB Kip certifying authorities' (Annex 5b of annex 5 to the IKB Kip regulation). The main site must be able to demonstrate this in writing.	The criteria and requirements are registered for each internal inspector. Points from accreditation conditions include training courses followed and demonstrable knowledge. Professional knowledge and audit skills related to methods and techniques for monitoring of the IKB Kip certification scheme. Induction period of at least 20 inspections attended. Continuing professional development through additional work experience, training, study, gatherings, seminars or other activities. If there is more than one inspector, mandatory attendance of internal (harmonisation) meetings at least once per year.	administrative		heavy	suspension	N/A is not possible	Yes	Amended on: 01-04-2012 01-06-2020
A07	The main site has a (digital) quality manual containing all relevant and applicable documents of the IKB Kip certification scheme .	The quality manual includes at least all applicable documents of the IKB Kip Certification Scheme (General Terms and Conditions and its annexes), and describes at least how the main site communicates amendments to the IKB Kip certification scheme to associated companies.	administrative	Check the date/version number of the quality manual and effective date of IKB Kip documents.	heavy	suspension	N/A is not possible	Yes	Amended on: 1-4-2012 01-05-2014 01-06-2020

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Norm	Regulation	Interpretation of regulation	Measuring method	Interpretation of the measuring method	Weighing of 1st observation	Weighing of 2nd observation	N/A	Exceeds statutory regulations	Start date
A20	The participant has procedures and work instructions in place concerning - the frequency and when internal inspections are carried out at the associated companies; - how inspections are assessed; - how remedial measures are checked; - how internal inspections and follow-up inspections are documented; - how procedures are maintained and distributed in good time to those responsible.	Procedures may also be included in the quality manual.	administrative	Check that points mentioned in the regulations are present at the main site of a multi-site.	heavy	suspension	N/A is not possible	Yes	1-6-2020
A09	At least once a calendar year, an internal IKB Kip inspection must be performed at the main site. The report of this inspection must cover at least the following: - the content of the IKB Kip quality manual; - qualification and staff training in relation to IKB Kip activities; - assessment of service providers such as laboratories, PSB companies, CAs etc.; - schedule of internal inspections on associated companies for the coming year.	A report must be made of the internal inspection, specifying what has been checked, the areas of improvement and how they have been resolved.	administrative	Check that the subjects described in the regulation have been inspected and that a report has been made containing the correct elements as stated in the regulation. Record the date of the internal inspection.	heavy	suspension	N/A in case of accreditation inspection	Yes	Amended on: 01-04-2012 01-06-2020
SUPERVISION OF SUBLOCATIONS									
A10	The main site inspects all associated companies at least once a calendar year (internal inspection).	In compliance with IKB Kip certification criteria, the interval between the inspections must not be more than 18 months.	administrative	Record deviations..	heavy	suspension	N/A is not possible	Yes	Amended on: 01-04-2012 01-06-2020
A11	The internal inspections of associated companies must be documented at the main site, including (follow-up) inspection reports, (follow-up) assessment reports.	The documentation must be filed per associated company.	administrative	Check for five randomly selected associated companies whether the internal inspections at the associated companies are documented per company, including (follow-up) inspection reports, and (follow-up) assessment reports. Check five different associated companies during each re-inspection.	heavy	suspension	N/A is not possible	Yes	Amended on: 01-04-2012 01-06-2020
A12	The internal checks are carried out based on prevailing IKB Kip regulations for the link concerned.	The main site must be able to demonstrate that inspections are performed on based on the current, prevailing version of the IKB Kip regulations.	administrative	Check through the (follow-up) inspection reports whether the internal checks are carried out based on the prevailing IKB Kip regulations for the links concerned; check this with five associated companies. Check five different associated companies during each re-inspection.	heavy	suspension	N/A is not possible	Yes	Amended on: 01-04-2012 01-06-2020
A14	If remedial measures (arising from an internal inspection) were necessary, these remedial measures implemented by associated companies are demonstrable	The main location can make this demonstrable through follow-up inspection reports and follow-up inspection assessment reports.	administrative	Check this for up to five different associated companies that were given remedial measures to implement.	heavy	suspension	N/A: no remedial measures were imposed during internal inspections	Yes	Amended on: 01-04-2012 01-06-2020
EXTRERNAL AUDITS									
A17	How many and which associated companies were physically re-inspected and assessed by the inspector carrying out this multi-site assessment ?	Record KIP numbers or IKB Kip numbers of the companies inspected.	administrative	Not an inspection point, only an administrative point .	NONE	NONE	N/A is not possible	Yes	Amended on: 01-04-2012 01-06-2020
QUALITY MARK REGULATION									
A18	Only the main site has the right to use the IKB Kip quality mark; the main site ensures that the IKB Kip quality mark is not used by the companies associated to the multi-site.		physical	Check during the re-inspection of the associated sites whether the IKB Kip quality mark is being used.	heavy	suspension	N/A is not possible	Yes	1-4-2012
COMPLAINT REGISTRATION AND HANDLING									
A15	The main location must have a complaint handling procedure. The associated companies must be aware of this procedure and comply with it.		administrative	Check whether the main location has a complaint handling procedure.	heavy	suspension	N/A is not possible	Yes	1-1-2011
A19	The participant registers complaints.	This registration records the complaints received including proof of how complaints were handled (e.g. copy of correspondence or phone call notes).	administrative	Check the date of the last registered complaint.	light	medium	N/A is not possible	yes	1-6-2020