Legal opinion

To: Norwegian Association of Importers of Spare Parts, Accessories and Garage Equipment

From: Advokatfirmaet Steenstrup Stordrange DA

Case Attorney: Aksel Joachim Hageler

Oslo, January 2017

DISCLAIMER: The English version is a translation of the original in Norwegian and is for information purposes only. In case of a discrepancy, the Norwegian original will prevail.

Table of contents

Section 8, third paragraph of the PKK Regulations – particularly concerning the interpretation of the formulation "in accordance with the manufacturer's specifications"

1 Main conclusion

Section 8, third paragraph, first sentence of Regulation No. 591 of 13 May 2009 on periodic roadworthiness tests of vehicles (hereinafter referred to as the "PKK Regulations") states that *"Technical equipment, including measuring instruments, shall be used, calibrated and maintained according to the manufacturer's specifications."* The third sentence in the same paragraph states, *"The testing centre must have documentation showing that the maintenance and calibration have been performed in accordance with the manufacturer's specifications and that the calibration has been performed by a calibration laboratory certified according to ISO Standard 17025." [our underscoring]*

The Norwegian Association of Importers of Spare Parts, Accessories and Garage Equipment (hereinafter "ABL") has asked us to undertake a legal interpretation of Section 8, third paragraph of the PKK Regulations and particularly its requirements for calibration in accordance with the "manufacturer's specifications", compared with the obligation to use a calibration laboratory accredited according to ISO Standard 17025. We have furthermore been asked to answer several specific questions relating to the content and scope of the provision compared with other rules and said ISO Standard. We have also been asked to give our opinion about violations of Section 8, third paragraph of the PKK Regulations that may entail legal consequences. Our conclusions can be summarised as follows.

1. In our view, a clear source of law suggests that the requirement pursuant to Section 8, third paragraph of the PKK Regulations that calibration is to be performed *"in accordance with the manufacturer's specifications*", is to be understood as the only calibration methodology permitted by Section 8 of the PKK Regulations. Neither Section 8, third paragraph of the regulations nor any other relevant regulations allow for the calibration of technical equipment to be done in a manner other than "in accordance with the manufacturer's specifications".

   The reference to ISO Standard 17025 specifies a requirement to the calibration laboratories that are to perform the calibration work (they must be accredited in accordance with ISO Standard 17025). The reference does not specify ISO Standard 17025 as an alternative calibration methodology (how the calibration is to be performed). Calibration according to ISO Standard 17025 or other methodology will therefore be in violation of Section 8, third paragraph of the PKK Regulations, cf. details in Section 3.

2. In our opinion, Section 8, third paragraph of the PKK Regulations, overrides and excludes the calibration methodology prescribed in ISO Standard 17025 or other standards and regulations. ISO Standard 17025 can thus not be used as an alternative calibration methodology when the regulation does not permit it (which it does not). As of today, prior to the implementation of Directive 2014/45/EU, EEA law does not lay down guidelines for the calibration methodology to be used, further substantiating that the provisions of the PKK Regulations take precedence. Our detailed assessments of this are included in Section 4 below.

3. Norwegian Accreditation and their technical assessors can and must adopt the "manufacturer's specifications" as the sole acceptable calibration methodology in connection with their supervisory activities vis-á-vis accredited calibration laboratories. Under Section 8, third paragraph of the PKK Regulations, Norwegian Accreditation or their technical assessors are not empowered to make

exceptions from this requirement or approve a different calibration methodology for calibration pursuant to Section 8, third paragraph, third sentence. Our assessments of this question are included in Section 5.

4. In our opinion, breach of the injunction contained in Section 8, third paragraph of the PKK Regulations that *"manufacturer's specifications"* are the only approved calibration methodology could have legal consequences in several ways, including potentially also liability for damages for the Norwegian Public Roads Administration, Norwegian Accreditation and calibration laboratories. Whether or not liability for damages actually exists in the individual case must be specifically assessed based on each case's individual characteristics and the facts, cf. further details in Section 6.

5. In our opinion, Section 8, third paragraph, of the PKK Regulations is sufficiently clear and unambiguous and should accordingly not be amended. Nor does Directive 2014/45/EU, which is to be implemented in Norwegian law in 2018, require any amendment of the provision, but allows keeping the *"manufacturer's specifications"* as the only approved calibration methodology. The uncertainty that might exist about the scope of the provision is probably due to factors other than the regulation itself, and may best be terminated by a statement of interpretation from the Norwegian Public Roads Administration.

In Section 2, we lay out the background and context of the issue and our assignment, including a brief review of the relevant sources of law and the relevant actors impacted by Section 8 of the PKK Regulations.

2 Background and context

2.1 Background of the issue

We have learned that certain quarters have raised questions about how the requirement pursuant to Section 8, third paragraph, last sentence of the PKK Regulations, that the calibration shall be *"performed in accordance with the manufacturer's specifications"*, is to be understood. In particular, it shall have been questioned in this connection whether the aforementioned regulatory provisions allow for the calibration to be performed in full or in part by alternative or supplementary methodologies, typically according to the specifications given in ISO Standard 17025.

As an extension of the above-mentioned issues, the distribution of the roles and authority between the Norwegian Public Roads Administration and Norwegian Accreditation has also been problematised, cf. that the latter is the body in Norway that will be able to accredit calibration laboratories according to ISO Standard 17025, cf. Section 8, third paragraph, last sentence *in fine* of the PKK Regulations. In connection with the latter, the relationship and hierarchy between, respectively, the PKK Regulations and the ISO Standard and the Norwegian Public Roads Administration and Norwegian Accreditation have also been debated among business actors and public authorities.

These issues are the reason why ABL has asked us to evaluate the above-mentioned and related questions, cf. also Section 2 above, where the contents of the assignment and the structure of this memorandum are explained. The actual requirement pursuant to Section 8, third paragraph, last sentence that the calibration laboratory must be accredited in accordance with ISO Standard 17025 will not create much doubt concerning its interpretation, and will therefore not be dealt with in particular by this memorandum. As such, it will only be dealt with briefly in connection with the review below of the wording of Section 8, third paragraph, last sentence.

2.2 Summary of relevant sources of law

The legal basis of the PKK Regulations is Sections 19 and 43 of the Road Traffic Act. However, we consider that neither the preparatory works of the applicable statutory provisions of the Road Traffic Act nor the preparatory works of the originally enacted PKK Regulations (enacted in 2009) cast particular light over the specific interpretation questions that this memorandum deals with.

The basis for the interpretation assessment will be the wording and systematics of the regulation. There are also relevant preparatory works, including the Directorate of Public Road's consultation memorandum of 21 March 2012 and the Directorate's consultation summary dated 5 November 2012. The former suggested and justified the proposals submitted for consultation, while the latter expresses the Directorate's assessments in connection with the establishment of the regulation; assessments made in light of input from the consultation bodies.

It can be derived from the aforementioned consultation memorandum that promoting road safety is the key underlying purpose behind the regulation. Such a signal from the legislator regarding the purpose of regulation is a relevant and compelling real consideration.

It is also legally relevant to look at subsequent statements from the Directorate concerning the understanding and enforcement of the regulation. From a jurisprudence-based perspective, it can be viewed as an expression of administrative practice, which is a relevant source of law.

We will also take into account statements in the Directorate's recent consultation memorandum of 21 December 2016. Methodologically speaking, statements to that effect can be regarded as so-called supplementary works, which means statements put forward from the legislator (in this case, the Directorate of Public Roads) regarding the understanding of the current regulations after their enactment. Such subsequent statements are also legally relevant for the interpretation of current rules.[1]

Our assessment will also take into account the relevant content of Directive 2014/45/EU, which is intended to be implemented through the regulatory changes that have just been submitted for consultation. Nevertheless, it should be emphasised that the "new" Directive does not require its national implementation provisions to not be implemented before 20 May 2018.[2]

2.3 Actor scenario – roles and authority

The current PKK Regulations have been adopted by the Directorate of Public Roads based on authority delegated by the Ministry of Transport and Communications. The Directorate of Public Roads heads the Norwegian Public Roads Administration and its five regional units. The regional units are both the approval and supervisory authorities of the testing centres, cf. Sections 7 and 23 of the PKK Regulations.

---

1 See for example the article in Norwegian Law Journal 1994 p. 323 by Professor Emeritus Dr. juris Erik Boe, with further references to case law. Note that, under the circumstances, it may be a matter of taste if something is termed administrative practice or supplementary work, as there may be grey areas between the two – which will be particularly the case when, as here, the "legislator" in question is also enforcing the regulations on a daily basis, and for that reason relatively often speaks to how the body deems the regulations are to be understood.

2 It is nevertheless required that the implementation rules shall be adopted, announced and notified to the EFTA Surveillance Authority ("ESA") one year earlier, on 20 May 2017, cf. Article 23 (1) of the Directive. Directive 2014/45/EU is incorporated into EEA Agreement Annex XIII, paragraph 16b, no. 61.

In the light of this memorandum's issues, it means that it is within the regional unit's supervisory authority to verify that the testing centre has *"documentation that shows that [...] the calibration has been performed in accordance with the manufacturer's specifications",* and further that *"the calibration has been performed by a calibration laboratory certified according to ISO Standard 17025".*

In order to exercise its supervisory authority, the regional units have been given relatively broad supervisory powers, including access rights to the testing centres' premises and technical equipment, cf. Section 23, second and third paragraphs of the PKK Regulations. Under Section 24 of the PKK Regulations, the regional units may issue warnings and rectification orders to the testing centres or issue a temporary or permanent revocation of their approval, depending on the severity of the circumstances and case history. The Directorate of Public Roads is the appeals body for such decisions.

Concerning the present issue, the wording of Section 8, third paragraph, last sentence of the PKK Regulations, practical circumstances and signals from the Norwegian Public Roads Administration indicate that the supervision will actually be limited to "formal control" of whether documentation exists of correctly performed calibrations, and "formal control" of whether the calibration laboratory used has proper accreditation.[3] Note, however, with reference to the latter that it is the testing centre that is the subject of the Norwegian Public Roads Administration's supervision, not the calibration laboratory.

Under Section 29, first and second paragraphs of the PKK Regulations, respectively, the Directorate of Public Roads and regional units may derogate from the regulations. For the part of the regional unit, the second paragraph specifies that it is a matter of individual decision-making competence and that this includes Section 8 of the regulations. For the Directorate of Public Road's part, the authority generally applies to the entire regulation.[4] The Directorate's competence to grant exemption applies to individual decisions is also not specified, but it nevertheless seems to be practical.[5]
We have no knowledge of whether the regional units or the Directorate have used their exemption competence pursuant to Section 29 in relation to Section 8, third paragraph.

Norwegian Accreditation is not mentioned directly in Section 8, third paragraph, last sentence of the PKK Regulations. There is only a requirement that the calibration laboratory shall be accredited according to ISO Standard 17025. However, under the latter regulatory requirements, Norwegian Accreditation still plays an actual role in that Norwegian Accreditation, an administrative agency, is the only entity in Norway to carry out technical accreditation, including according to ISO Standard 17025, cf. Section 3, first paragraph of the Norwegian EEA Goods Act, and Article 7 of EEA Regulation 765/2008.

---

[3] See the Directorate of Public Roads' statements in Item 1 of the minutes from the meeting of 29 January 2016 between the Directorate, Norwegian Accreditation and ABL. The Directorate forwarded the minutes to ABL on 25 August 2016.

[4] Section 29 of the PKK Regulations complies with the requirement that Section 40 of the Public Administration Act stipulates for such dispensation provisions.

[5] If an exemption decision by the Directorate of Public Roads concerns "rights or duties of an indefinite number or an indeterminate group of persons", it will be a regulation in the sense of the Public Administration Act, cf. Section 2 a) and c) of the Public Administration Act. It will then be a change that would in any case be within the assigned regulatory competence under which the Directorate of Public Roads has adopted the PKK Regulations in pursuance thereof, and, as such, be a de facto amendment regulation. Regulatory decisions must comply with the procedural rules pursuant to Chapter VII of the Public Administration Act, including the consultation obligation pursuant to Section 37, second paragraph.

Undertakings that are to operate as calibration laboratories pursuant to Section 8, third paragraph, last sentence of the PKK Regulations must therefore have accreditation according to ISO Standard 17025 granted by Norwegian Accreditation or foreign accreditation body.

As indicated above, the PKK Regulations do not prevent Norwegian testing centres from using foreign calibration laboratories that are ISO-certified in accordance with Section 8, third paragraph, last sentence of the PKK Regulations. To some extent this already takes place in practice, typically by using Swedish-based calibration laboratories accredited by Swedac. Swedac is Norwegian Accreditation's Swedish sister entity, appointed by the Swedish state in the same way that Norwegian Accreditation is appointed by the Norwegian state.

Although there are no formal obstacles to Norwegian-established testing centres using Swedish-based Swedac-accredited calibration laboratories, it can still cause challenges in practice, as Sweden does not operate with a corresponding calibration requirement according to the *"manufacturer's specifications"*.[6]

According to our information, the requirements in Sweden are less strict concerning how the calibration of the technical equipment is to be carried out, which may have the potential consequence that Swedish-accredited actors performing calibration services in Norway carry out the calibration according to Swedish requirements for calibration methodology, and thereby do not meet the Norwegian PKK Regulations requirements for calibration *"in accordance with the manufacturer's specifications"*.

3 Understanding of Section 8, third paragraph of the PKK Regulations – "the manufacturer's specifications"

3.1 The wording of the provision

Section 8, first and second paragraphs of the PKK Regulations impose obligations relating to premises and technical equipment on testing centres. The first paragraph states that *"[p]remises and technical equipment shall be suitable for the purpose and have the necessary permits"* while the second paragraph lists specific equipment requirements that depend on the types of vehicles that are inspected.

The connection between the second paragraph and the third paragraph is that parts of the equipment included in the second paragraph are subject to the calibration that the third paragraph regulates. The third paragraph reads as follows:

"Technical equipment, including the measuring instruments, shall be used, calibrated and maintained according to the manufacturer's specifications. If the specifications specify calibration with special equipment, the testing centre must have such equipment or it must have a calibration agreement for the devices with a competent calibration laboratory. The testing centre must have documentation showing that the maintenance and calibration are carried out in accordance with the manufacturer's specifications and that the calibration is performed by a calibration laboratory certified according to ISO Standard 17025." [our underscoring].

[6] Regardless of whether the accreditation body is Norwegian Accreditation, Swedac or otherwise, the requirement of Section 8, third paragraph, last sentence *in fine* of the current PKK Regulations is of course that the calibration laboratory has accreditation according to ISO Standard 17025.

Exactly as in the first and second paragraphs, it is the testing centres that are formally the obligated party also pursuant to the third paragraph. It is up to the testing centre to ensure that equipment is used, calibrated and maintained according to the manufacturer's specifications (first sentence); it is the testing centre which shall have the necessary equipment if the manufacturer's specifications call for calibration with special equipment, or alternatively access to such calibration equipment by agreement with a competent calibration laboratory (second sentence); and it is the testing centre that must have documentation that maintenance and calibration are performed according to the manufacturer's specifications and that the calibration is performed by the ISO-accredited calibration laboratory (third sentence).

According to the wording in the third paragraph, first and third sentences, the testing centre is therefore required to prove that the calibration has been performed according to/pursuant to the *"manufacturer's specifications"*. Apart from this, the testing centre shall also be able to prove that the calibration has been performed *"by a calibration laboratory [accredited] in accordance with ISO Standard 17025".*[7]

Therefore, we see that the third paragraph makes requirements as to *who* is to perform the calibration the (*"calibration laboratory"* accredited according to ISO Standard 17025), *how* it is to take place (*"in accordance with the manufacturer's specifications"*) and that the testing centre must be able to prove that the requirements for *who* and *how* are fulfilled. The source of the uncertainty that reportedly may exist about the understanding of the provision may well lie in a conflation of the requirements relating to who and the requirements relating to how.

As for who is going to perform the calibration, it is clear that it must be a calibration laboratory accredited according ISO Standard 17025. This requires that the testing centre must be able to document that a calibration laboratory accredited according to ISO Standard 17025 has been used and that the calibration laboratory's accreditation was valid and in effect at the time the calibration was performed. There seems to be no doubt about the practising of this condition.

Regarding how the calibration is to take place, the testing centre is required to prove that the calibration has been performed *"in accordance with the manufacturer's specifications".* The wording of the regulation thus permits only a single method of calibration; the one that the relevant manufacturer specifies. The wording of the regulation indicates no alternative calibration methodologies.

As we understand it, the meaning of *"manufacturer's specifications"* basically seems to be undisputed, among other things because the formulation also appears elsewhere in relevant national and EEA-based legislation.[8] *"Manufacturer's specifications"* is normally taken to mean the descriptions and specifications given in the documentation issued by the manufacturer in, for example, instruction manual-like documents.

[7] See Item 2 ii in the Directorate of Public Roads' minutes from the meeting held on 29 January 2016 between the Directorate, Norwegian Accreditation and ABL. The Directorate forwarded the minutes to ABL on 25 August 2016. See also proposals for wording changes in paragraph 11.1 of the Directorate of Public Road's consultation memorandum of 21 December 2016.

[8] Cf. for example Section 8, third paragraph, first sentence of the current PKK Regulations, the proposed changes to Section 8 of the PKK Regulations in Item 11.1 of the Directorate of Public Road's consultation memorandum of 21 December 2016, and Directive 2014/4/EU, specifically paragraph 29 in the preamble and Article 11.

For the sake of clarity it is emphasised that if the *"manufacturer's specifications"* should refer directly to ISO Standard 17025 or other outside standards or regulations, and prescribe that the calibration is done according to such an "external standard", calibration according to such specifications will also comply with the *"manufacturer's specifications"*.

In regard to the regulatory wording, it can therefore be summarily concluded that this source-of-law factor determines that calibration shall be performed according to the *"manufacturer's specifications"* and that the wording does not allow for alternative calibration methodology. The reference to ISO Standard 17025 only applies to the accreditation of the calibration laboratory (*who* will perform the calibration) and not the calibration methodology (*how* the calibration shall be performed).

3.2 The preparatory works of Section 8, third paragraph, last sentence of the PKK Regulations etc.

It was the Directorate of Public Road's consultation memorandum of 21 March 2012 that proposed Section 8, third paragraph, last sentence of the current PKK Regulations. At that time "*[t]he sole requirement [...] that technical equipment [...] be calibrated in accordance with the manufacturer's specifications*".[9]

Although the wording of the requirement for *how* the calibration should take place was thus the same as today prior to the regulatory change, the regulations previously did not stipulate who should perform the calibration, what kind of competence they should have or what equipment should be used for the calibration. The regulations at that time thus permitted the testing centres to perform the calibration themselves, even without having special accreditation.

With that as the backdrop, the consultation memorandum stated the following about the background for its two alternative legislative amendments:

"Surveys show that calibration is not always performed in accordance with what the manufacturer has prescribed. Against this background, we believe that the current scheme is not working satisfactorily. It is important that calibration is done correctly according to the manufacturer's specifications and that those who perform the calibration do this according to clear procedures and with sound competence in the field. Inadequate calibration may result in directly erroneous inspection results".[10]

In our view, two main issues can be deduced from the Directorate of Public Road's statement:

Firstly, the amendment is justified by a desire to promote road safety. This can be deduced from the ascertainment that *"[i]nadequate calibration may result in directly erroneous inspection results."* Incorrect calibration would mean that the testing centres' control equipment did not provide the correct inspection results, which in turn could lead to a failure to detect defects in a vehicle. Failure to detect defects in vehicles could result in vehicles that should not have been approved, and consequently entail a road safety hazard, nevertheless obtain approval on an incorrect basis.

[9] Directorate of Public Road's consultation memorandum of 21 March 2012 Item 6.2 page 8.

[10] Directorate of Public Road's consultation memorandum 21 March 2012 Item 6.2 page 8.

The fact that the main reason for the regulatory change was traffic safety concerns is a relevant and important interpretation factor.

Secondly, by its proposed amendment the legislator wanted to confirm and enforce compliance with the already existing requirement for how calibration should be performed – ergo according to the *"manufacturer's specifications"* – by stipulating competence requirements for the person who will perform the calibration. The legislator no longer had faith that the testing centres themselves could be responsible for correct calibration according to *"the manufacturer's specifications".*

In other words, the legislator's amendment entailed a confirmation and tighter compliance with the rule that calibration must only be performed *"in accordance with the manufacturer's specifications"*, cf. for example, the underlining that *"[i]t is important that the calibration is done correctly according to the manufacturer's specifications."* The Directorate of Public Road's statement in the consultation memorandum leaves no doubt that the *"manufacturer's specifications"* is the relevant calibration methodology.

The consultation memorandum also does not permit any alternative calibration methodology. On the contrary, the fact that Item 6.2 of the consultation memorandum only refers to the "manufacturer's specifications" can precisely be read as a deliberate consideration by the legislator that only calibration according to the *"manufacturer's specifications"* is acceptable. No references to ISO or other standards as an alternative or supplementary methodology are found in the review of Section 8, third paragraph, last sentence of the PKK Regulations in Item 6.2 of the consultation memorandum. As mentioned, reference is made solely there to the *"manufacturer's specifications"* as the accepted calibration methodology.

The fact that the legislator, upon enactment, deemed calibration *"in accordance with the manufacturer's specifications"* as the sole regulatory calibration methodology is further supported by the Directorate of Public Road's consultation summary document dated 5 November 2012. In Item 3.5 on page 6, the Directorate of Public Roads lays out its assessments of the two alternative regulatory regulations presented in the consultation memorandum of 21 March 2012, on which the Directorate accordingly had received the views of the consultation bodies.

The Directorate of Public Roads considers the regulatory option that requires calibration to be performed by an ISO-accredited calibration laboratory as the *"most reassuring"* in view of the *"quality of control and thus also road safety".* Furthermore, the Directorate of Public Roads states in the same paragraph that the requirement that the calibration shall be performed by an ISO-accredited calibration laboratory *"will also make the inspection work easier and will help strengthen equal competition in the industry."*

These statements confirm and clarify the justification for and considerations behind the regulatory amendment and the choice of the "strictest" regulatory option. As already mentioned above, these conditions will constitute relevant and important interpretation factors as they clarify the purpose of the regulatory provision and its underlying main considerations.

In Item 3.5 of the consultation summary document, the Directorate of Public Roads also addresses a concrete proposal from ABL for a supplementary reference in the text of the regulation that the text should not only refer to *"manufacturer's specifications"* but also *"current NS-ISO standards"*.

The Directorate of Public Roads did not agree with ABL's proposal to be open to alternative calibration methodologies, a position taken by the Directorate, with reference to the European Commission's then proposal for a road worthiness testing regulation containing set calibration requirements *"in accordance with the manufacturer's specifications"*.[11]

In addressing ABL's draft text, the preparatory works explicitly address the question of whether Section 8, third paragraph, last sentence of the PKK Regulations may be interpreted as permission to use alternative or supplementary calibration methodology. In its response to ABL's draft regulation text, the legislator clarifies and confirms that the regulation can be taken on its word; that only calibration *"in accordance with the manufacturer's specifications"* is according to regulations.

Both the regulation and its wording are thus aligned. Both source-of-law factors are clear that it is only calibration in accordance with the *"manufacturer's specifications"* that is accepted in accordance with Section 8, third paragraph, last sentence of the PKK Regulations. As also pointed out above, it is emphasised that if the *"manufacturer's specifications"* themselves prescribe that certain calibrations are to be performed according to an ISO or other standard, it will be a regulation calibration, precisely because it will be in accordance with the *"manufacturer's specifications"*.

3.3 Norwegian Public Roads Administration's administrative practice etc.

We are not aware of the existence of relevant individual decisions from the regional unit or the Directorate of Public Roads, typically individual decisions taken by the regional unit in connection with the issuance of calibration-relevant orders to the testing centre after inspection, with any subsequent appeals to the Directorate.

Although there has been contact between ABL and the Directorate concerning the understanding of Section 8, third paragraph, last sentence of the PKK Regulations, the Directorate has, as far as we know, not addressed its understanding of the regulation in writing in addition to the memorandum forwarded to ABL on 25 August 2015. In this memorandum, the Directorate refers to the meeting with ABL and Norwegian Accreditation held on 29 January 2016.

There is also a report prepared by ABL from this meeting held on 29 January 2016. ABL's report was sent to the Directorate of Public Roads on 27 May 2016. The Directorate has not countered the contents of this report.

In our view, the report and the minutes of the meeting are relevant indications of administrative practice, and thus relevant sources of law. If there are individual decisions from the Directorate or others, there is reason to believe that the statements given to ABL are in line with such. At the same time it goes without saying that sources of law like this generally will have limited weight.

According to ABL's report of the 29 January 2016 meeting, sent to the Directorate on 27 May 2016, the Directorate stated that the *"manufacturer's specifications"* apply to calibration. The meeting report further states that the Directorate *"confirmed that the regulations exceed the [ISO] Standard".* In reality, the Directorate's own minutes from the meeting, forwarded to ABL on 25 August 2016, state

[11] The European Commission's original proposal for a regulation on periodic vehicle inspection was later transformed into a directive through the tripartite legislative processes vis-à-vis the Council and the European Parliament. In addition, the adopted Directive has included *"specifications provided by the Member State"* as an equal alternative to *"manufacturer's specifications"*, cf. Article 11(3) of Directive 2014/45/EU.

the same: In Item 2i of the minutes, the Directorate of Public Roads stated that the Norwegian Public Roads Administration *"is considering changing the requirements so that it is not an absolute requirement that the manufacturer's method is used. In that case it will be circulated for public consultation and presumably at the same time as consultation in connection with the implementation of Directive 2014/45/EU."*

It is difficult to read the Directorate of Public Roads' statement differently than that the Directorate believes that under the applicable law *"it is an absolute requirement that the manufacturer's method is used"* and that permitting the use of a different methodology requires regulatory change.[12] It can accordingly be concluded that existing statements concerning the Norwegian Public Roads Administration's administrative practice are in agreement with the premise that the only regulation calibration methodology is calibration *"in accordance with the manufacturer's specifications".*

Furthermore, there is nothing in the Directorate of Public Roads' consultation memorandum of 21 December 2016 to indicate that the Directorate (in its capacity as legislator) understands Section 8, third paragraph of the current PKK Regulations in a manner other than that which is signalled in the above-mentioned review of administrative practice, preparatory works and regulatory wording. Rather, Item 11.16 of the latter consultation memorandum confirms that calibration *"in accordance with the manufacturer's specifications"* is *"in accordance with how the regulations currently regulate this"*, cf. our above discussion of the legal relevance of such subsequent statements by the legislator regarding applicable law (*supplementary works*).

3.4 Norwegian Accreditation's administrative practice

In view of the fact that Norwegian Accreditation's role under the PKK Regulations is indirect in the sense that it is limited to accreditation of calibration laboratories in accordance with ISO Standard 17025 and further to ensure that the testing centres continuously meet the conditions for continued accreditation, the source of law-related importance that shall, if applicable, be attached to Norwegian Accreditation's practice and their perception of the relationship between the regulations and the ISO Standard can be discussed.

The question, however, has only academic interest, since in the present case, Norwegian Accreditation's opinion is in any case consistent with that contended by the Norwegian Public Roads Administration, and which can also be derived from other source-of-law factors, namely that the PKK Regulations only permit the *"manufacturer's specifications"* as calibration methodology and that the PKK Regulations take precedence over and override ISO standards.

In the Directorate of Public Roads' minutes of the 29 January 2016 meeting, forwarded to ABL on 25 August 2016, the Directorate expresses Norwegian Accreditation's understanding, and states that Norwegian Accreditation perceives the PKK Regulations to mean that the manufacturer's standard/method *"is to be followed"*.[13] That this is Norwegian Accreditation's perception of current law is clearly stated by Norwegian Accreditation's e-mail to ABL dated 25 July 2016, where Norwegian Accreditation gave ABL feedback in the light of ABL's report from the 29 January 2016 meeting. In said e-mail Norwegian Accreditation wrote:

[12] In addition, it is precisely the consultation on the implementation of Directive 2014/45/EU in Norwegian law, which the Directorate of Public Roads has sent out in its consultation memorandum of 21 December 2016, cf. that the meeting minutes of 25 August 2016 refer to an upcoming hearing in connection with the implementation of said Directive.

[13] See the Directorate of Public Roads' memorandum of 25 August 2016 from the meeting between the Directorate, Norwegian Accreditation and ABL held on 29 January 2016, cf. Item 2i.

"In short, the standard is open to calibration laboratories choosing proprietary methods as long as they are appropriate, agreed with the customer and validated. The current statutory regulation restricts this by requiring the use of the manufacturer's specifications. *The regulation overrides [paragraph] 4.1.2 in ISO 17025:2005.* It is not part of NA's role to decide whether or not this restriction is to be maintained. *NA assesses in accordance with applicable requirements in the standard and relevant regulations." [our underscoring]*

Here, Norwegian Accreditation confirms the interpretation that other source-of-law factors also lean towards and also describes the relationship between the PKK Regulations and the Norwegian Public Roads Administration on the one hand, and ISO Standard 17025 and Norwegian Accreditation on the other hand. The consequences of the latter will be discussed in more detail below. Here it is sufficient to note that it is also Norwegian Accreditation's perception and practice, at least as expressed here, that the PKK Regulations' calibration methodology requirements can only be met by following the *"manufacturer's specifications"*.

3.5 Summary and conclusion

The review above of the individual source-of-law factors has shown that there is no real interpretation doubt that Section 8, third paragraph, last sentence of the current PKK Regulations must be understood to mean that the only permitted calibration methodology is calibration *"in accordance with the manufacturer's specifications."* This requirement applies to all Norwegian-established testing centres and applies irrespective of who performs the calibration, including whether it is a Norwegian or Swedish-established calibration laboratory. This requirement also applies regardless of who has accredited the calibration laboratory.

4 Relationship between the PKK Regulations, other national regulations, ISO standards and EU directives

Section 8, third paragraph, last sentence of the PKK Regulations complies with our current and adopted EEA legal obligations. The current PKK Regulations implement Norway's EEA legal obligations under Directive 2009/40/EC, as amended by 2010/48/EU.[14] However, these two directives, which until 20 May 2018 will still be applicable EEA law, contain no specific regulation of the instruments and equipment used for calibration of technical equipment, nor the requirements made of the person who performs the calibration. In other words, EEA law does not provide any direct guidance for what is regulated in Section 8, third paragraph, last sentence of the current PKK Regulations. So, even though the EEA Agreement can provide binding guidelines for the preparation, interpretation and application of Norwegian law, EEA law does not affect the content of Section 8, third paragraph, last sentence of the current PKK Regulations.

Similarly, Section 8, third paragraph, last sentence of the current PKK Regulations, including a requirement that calibration shall only be performed according to the *"manufacturer's specifications"*, is within and in accordance with the substantive regulatory competence that follows from the Road Traffic Act's statutory provisions.

---

[14] Directive 2009/40/EC and 2010/48/EU are incorporated into Annex XIII, paragraph 16a, nos. 59 and 60 of the EEA Agreement.

The PKK Regulations do not allow for calibration to be done according to ISO Standard 17025's own provisions on calibration methodology. The regulations thus override the ISO standard. ISO Standard 17025 – or other external international technical standards – are only relevant to what is regulated by the PKK Regulations insofar as the regulations themselves attach importance to these standards.

The PKK Regulations do so regarding the requirement of who can perform calibration – only calibration laboratories accredited according to ISO Standard 17025 – but not with respect to calibration methodology. Here, only the "manufacturer's specifications" are accepted. The regulations thus override the ISO standard with respect to calibration methodology.

In our view, both the Directorate of Public Roads and Norwegian Accreditation have therefore correctly expressed current law when they stated that it is the PKK Regulation's stipulation for *"manufacturer's specifications"* that is the only accepted calibration methodology and that the regulations as such *"override"* ISO Standard 17025's own alternative calibration methodology, laid out in paragraphs 4.1.2 and 5.4.15 of the Standard.[15]

5 Role and authority for technical assessors acting on behalf of Norwegian Accreditation

The role of Norwegian Accreditation is initially limited to accrediting and further verifying that accredited calibration laboratories meet the conditions for continued accreditation, cf. Section 5 of Norwegian Accreditation's "Conditions for Accreditation", which states that "*[a]ccredited organisations shall comply with the current terms of accreditation at all times".*

The role and authority of the Norwegian Public Roads Administration is initially limited to overseeing whether the testing centre *"has documentation that shows"* that the correct calibration methodology has been used and that the calibration laboratory was accredited for the calibration services that were performed. The supervisory powers of the Norwegian Public Roads Administration is limited to the testing centre, cf. Section 23 of the PKK Regulations. Under the PKK Regulations' system, the Norwegian Public Roads Administration therefore has no direct role or authority vis-à-vis the calibration laboratories.

In line with the interpretation of Section 8, third paragraph, last sentence of the PKK Regulations used above, calibration must be performed "*in accordance with the manufacturer's specifications".* The calibration laboratories are indirectly obliged by this, in that the testing centres will have to require the calibration laboratories to perform the calibration accordingly, in order for the testing centres to comply with the requirements of the regulations, cf. the requirement pursuant to the first and last sentence of the third paragraph that the testing centre must be able to prove that the calibration was performed according to the "*manufacturer's specifications".*

Consequently, it is not doubtful that the substantive calibration norm that applies is *"manufacturer's specifications"* and that Norwegian Accreditation must adopt this standard for its supervisory activities. In addition, such an approach is in accordance with Norwegian Accreditation and ISO Standard 17025's own norms:

In the general requirements document "Conditions for Accreditation", Section 6 states that:

[15] See the Directorate of Public Roads' minutes from the 29 January 2016 meeting, sent to ABL on 25 August 2016, and Norwegian Accreditation's e-mail of 25 July 2016 to ABL.

"[A]ll accredited organisations are obligated to follow national laws and regulations. Where there is conflict between national laws and regulations with requirements for accreditation, national laws and regulations are applicable. The accreditation body can report violations of laws and regulations to the appropriate authorities."

While ISO Standard 17025 paragraph 4.1.2 reads that it is the responsibility of the calibration laboratory to carry out its testing and calibration activities *"in such a way that the [calibration laboratory] meets the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities or [Norwegian Accreditation]".* [Our underscoring] In reality, ISO Standard 17025 itself therefore requires that calibration shall be carried out in accordance with the requirements of the PKK Regulations, cf. also paragraph 5.4.2 of the ISO Standard.

That calibration shall only be carried out according to the *"manufacturer's specifications"* means that it is the calibration methodology that must be used to satisfy the needs of the customer (the testing centre), as well as the needs of regulatory authorities and at Norwegian Accreditation, cf. that Norwegian Accreditation's "Conditions for Accreditation" demand that national legislation be given priority.

In summary, it therefore follows from the PKK Regulations, ISO Standard 17025 and Norwegian Accreditation's "Conditions for Accreditation" that Norwegian Accreditation and its technical assessors can and must use the *"manufacturer's specifications"* as the only acceptable calibration norm/methodology in connection with its supervisory activities vis-à-vis accredited calibration laboratories.

Norwegian Accreditation and its technical assessors will be obliged to respond to failure to comply with this requirement in the same way that Norwegian Accreditation may otherwise be required to respond to other comparable nonconformities concerning compliance with the ISO standard and/or national legislation, cf. for example, the rules in "Conditions for Accreditation" on how nonconformities shall be followed up and the consequences nonconformities may cause in the short or long term, depending on severity.

Norwegian Accreditation must accept that in this instance the PKK Regulations lay down binding guidelines for Norwegian Accreditation's supervision of the testing centre's fulfilment of the accreditation criteria according to ISO Standard 17025. One consequence of these circumstances is that Norwegian Accreditation has in no way the opportunity or authority to accept failure to meet the calibration methodology requirement. First of all, this would mean that the testing centre would not satisfy the calibration methodology requirement. Secondly, it would probably mean that the calibration laboratory also did not act in accordance with the requirements of ISO Standard 17025 paragraphs 4.1.2 and 5.4.2, and will therefore also not meet the requirements to be accredited.

6 Legal consequences in case of violation of Section 8 of the PKK Regulations

6.1 Introduction

Section 8, third paragraph, of the PKK Regulations establishes *"manufacturer's specifications"* as the only approved calibration methodology. If technical equipment is calibrated based on other norms or methods, including ISO standards, it will violate the requirements of the regulations. Such a violation

may cause a number of legal consequences, depending on the specific situation and the actors involved. The most obvious is a calibration laboratory's loss of accreditation and liability for damages. In the following we will only review possible liability for damages.

Three criteria must be met in order to be able to establish liability for damages for an actor. Firstly, there must be a basis of liability, which usually means that an error has been committed for which someone can be blamed. Secondly, the error must have resulted in a financial loss by the claimant, and this financial loss must be caused by the error in a sufficiently clear and predictable manner. Whether there is liability for damages in the individual case will depend on an individual and concrete assessment.

6.2 Possible liability for damages for Norwegian Accreditation

Norwegian Accreditation's decisions on accreditation are considered to be individual decisions within the meaning of Section 2 a) and b) of the Public Administration Act. This will have to apply to all accreditation-related decisions that are determinative for one or more specific actors, typically awarding of accreditation, renewal of accreditation, suspension of accreditation and withdrawal of accreditation, cf. Public Administration Act Section 2 a) and b).[16] Norwegian Accreditation also assumes that the rules of the Public Administration Act apply, including both the general rules on administrative procedure and the rules of procedure in cases of individual decisions.[17]

Norwegian Accreditation and its technical assessors therefore engage in the exercise of *"public authority"* when supervising calibration laboratories accredited according to ISO Standard 17025, and for instance assess whether the calibration laboratory has used the correct calibration methodology for calibration of testing centres' equipment, cf. Section 2 a) of the Public Administration Act. This must apply irrespective of whether the supervision is performed by Norwegian Accreditation's own employees or by "contracted" technical assessors from Swedac or another place.

We concluded above that Section 6 of the "Conditions for Accreditation" and ISO Standard 17025 paragraphs 4.1.2 and 5.4.2 also require that the calibration laboratory must perform the calibrations *"in accordance with the manufacturer's specifications."* If Norwegian Accreditation and its technical assessors fail to base their supervision on this, thus failing to respond adequately to the accredited calibration laboratories' possible application of alternative calibration methodologies – cf. the enforcement powers Norwegian Accreditation possesses under Section 21 of "Conditions for

[16] See Section 3, second paragraph of the Norwegian EEA Goods Act, Prop. 17 L (2012-2013) Chapter 11 (review of Section 3), referring, inter alia, to the statement of 3 April 2009 from the Legislation Department of the Ministry of Justice and Public Security. See also Section 22 of "Conditions for Accreditation".

[17] See Sections 8 (first paragraph) and 22.1 in "Conditions for Accreditation". It also follows directly from Sections 1, 2 a) and b) and 3 of the Public Administration Act.

[18] See also the prerequisite according to Article 5(4) of EEA Regulation 765/2008 whereby the national accreditation body, in our case Norwegian Accreditation, shall have the authority to take measures and, if necessary, withdraw accreditation from accredited bodies that fail to meet their obligations.

Accreditation"[18] – Norwegian Accreditation will therefore act as an authority in violation of the current substantive regulations, cf. "Conditions for Accreditation", Section 6, and ISO Standard 17025, paragraphs 4.1.2 and 5.4.2.

If Norwegian Accreditation exercises public authority in violation of its material competence basis, which would be the case with failure to respond to calibration in violation of the rules Norwegian Accreditation itself is subject to, Norwegian Accreditation may incur financial liability (liability for damages) if the unlawful exercise of authority causes someone financial loss. We do not take a position on whether Norwegian Accreditation has actually acted unlawfully. The circle of actors who might be in a position to claim compensation includes both testing centres and calibration laboratories.

According to Section 2-1 of the Compensation Act, public bodies such as Norwegian Accreditation are liable for damages for financial loss caused by intentional or negligent action. In a judgment contained in Rt. 2010, p. 291, the Supreme Court ruled on the terms and conditions for when the government becomes liable for damages for unauthorised or unlawful exercise of authority. The government's liability in the event of incorrect understanding of the legal rules is strict. If the public body is to be released from liability, the ignorance of the law must be excusable.[19] However, the Supreme Court deems ignorance of the law excusable if the interpretative position taken can be deemed professionally sound.[20]

In light of our interpretation assessments above, it is difficult to see that it could be considered professionally sound of Norwegian Accreditation to base its supervision on calibration methodologies other than the *"manufacturer's specifications"*. It will therefore also be difficult to deem a failure by Norwegian Accreditation to take adequate enforcement action against calibration laboratories that may use alternative calibration methodologies as professionally sound. In this connection, we refer to our assessments above that a collective source of law suggests that the "manufacturer's specifications" are the only accepted calibration methodology, cf. also "Conditions for Accreditation", Section 6 and ISO Standard 17025, paragraphs 4.1.2 and 5.4.2.

However, a closer assessment of any liability must be specifically determined in each individual case and, as mentioned, does not necessarily only require that there is a liability basis – subjective or objective – but also that the error has caused an expected financial loss. Consequently, we will not go into further detail on this question. However, we note that it is uncertain whether the limitation of liability/disclaimer in Section 23 of "Conditions for Accreditation" will stand if liability also exists.

6.3 Possible liability for damages for calibration laboratories

In this section we will discuss whether calibration laboratories that perform calibrations in violation of Section 8, third paragraph, last sentence of the PKK Regulations, which consequently would also be in violation of Section 6 of the "Conditions for Accreditation" and ISO Standard paragraphs 4.1.2 and 5.4.2, may incur liability for damages. We emphasise that we express our opinions on a general basis and that we have not considered whether specific calibration laboratories have actually acted in a manner giving rise to liability in damages.

[19] Paragraph 42 of Rt. 2010 p. 291 and related references to previous Supreme Court practice.

[20] Paragraph 49 and 50 of Rt. 2010 p. 291.

Section 2-1 of the Compensation Act also applies to the calibration laboratories. In addition, the testing centres will typically engage the calibration laboratories through agreements to perform calibration of technical equipment in accordance with the "manufacturer's specifications" because it is the testing centre that must document that it was done. Potential liability for damages for a calibration laboratory that has not calibrated technical equipment in accordance with the "manufacturer's specifications" will then typically also be based on breach of contract as regards the requirements of the testing centres.

It can thus appear as likely that a calibration laboratory which has performed calibration by agreement with a testing centre based on Section 8, third paragraph of the PKK Regulations without doing so in line with the "manufacturer's specifications" may be responsible for any financial loss. It is also possible that a competing calibration laboratory that, for example, has lost orders and earnings as a consequence of irregular calibration may demand compensation. However, a closer assessment must be made in each specific case.

6.4 Possible liability for damages for Norwegian Public Roads Administration

In this section, it is discussed whether the Norwegian Public Roads Administration can be held liable for damages if it is discovered that incorrect advice or incorrect specifications have been given to industry actors about the content of Section 8, third paragraph of the PKK Regulations and the requirement to follow the "manufacturer's specifications". We emphasise that we do not take a position on whether the Norwegian Public Roads Administration has actually given incorrect advice or specifications to industry actors about the understanding of Section 8, third paragraph.

As regards any liability for damages for the Norwegian Public Roads Administration, the same legal norms apply as for Norwegian Accreditation's potential liability for damages, cf. the above account. Nevertheless, as regards the Directorate of Public Roads and the PKK Regulations, important arguments in support of possible liability also exist on objective grounds. It is pointed out in this connection that it is the Directorate of Public Roads itself that has prepared and adopted Section 8, third paragraph, last sentence of the current PKK Regulations. In addition, as a result of the enactment of the relevant regulations, the industry has contacted the Directorate of Public Roads in particular for interpretation clarification and guidance. As a legal basis for demonstrating that objective liability may be applicable, reference is made to the Supreme Court judgment contained in Rt. 2010 p. 291, paragraphs 34 and 35.

In summary, we find that, as long as there otherwise are financial losses and adequate causality, the State represented by the Norwegian Public Roads Administration may in any case become liable for damages on liability for negligence grounds if the criteria for it are met, possibly also on objective grounds, cf. Section 2-1 of the Compensation Act and the Supreme Court judgment contained in Rt. 2010 p. 291, paragraphs 42 and 49 and paragraphs 34 and 35, respectively.

As regards liability on grounds of negligence, we find it difficult to see that any misinterpretations in connection with decisions or industry guidance could be justified as *"sound"*[21] in light of the fact that the collective source of law suggests that the *"manufacturer's specifications"* are the only regulatory calibration methodology. In addition, we find that a good argument could be made on the part of the Directorate of Public Roads that any liability for damages must also exist on objective grounds.

[21] Paragraph 49 in Rt. 2010 p. 291.

Provided that the requirements for financial loss and adequate causal relationship are met, we cannot see that it is decisive per se whether the Norwegian Public Roads Administration acts in a manner giving rise to liability in damages through an individual decision – for example related to an appeal about the compliance of a testing centre with Section 8, third paragraph – or through more general guidance of the industry in the form of circulars, interpretation guides or verbal information to the industry. The circle of potential injured parties typically includes those who suffered a loss as a result of receiving incorrect guidance and those who suffered a loss as a result of others receiving incorrect guidance. However, each situation must be assessed in concrete terms.

7 Concluding remarks

In conclusion, we are asked to comment on the need to clarify or amend the regulation that the "manufacturer's specifications" are the only approved calibration methodology, cf. Section 8, third paragraph of the PKK Regulations. First of all, such a need could be due to the fact that a new EEA regulatory framework makes it necessary, cf. that Directive 2014/45/EU will be implemented in 2018. A change or clarification of the regulation might possibly be necessary if the regulation was unclear or contradictory to other regulations.

Regarding the relationship to future EEA regulations, it follows from Article 11(3) of Directive 2014/45/EU that *"[e]quipment used for measurements shall be periodically calibrated in accordance with Annex III and verified in accordance with the specifications provided by the Member State concerned or by the manufacturer of the equipment".* Paragraph 29 of the preamble of the Directive is similarly worded. Annex III, as referred to in Article 11(3), does not regulate calibration itself beyond that its subsection II prescribes minimum calibration frequency requirements.

Thus, when Article 11(3) of the Directive gives Member States the choice between alternative forms of regulation and methodologies, it cannot be doubtful that each State is also fully entitled to pursue a regime that accepts only one of the alternative methodologies, namely calibration and verification according to *"specifications provided by the manufacturer of the equipment".* And, to the extent that the Directive could be interpreted to mean that the Member State must also offer that it can take place *"in accordance with specifications provided by the Member State concerned"*, Norway would in any case only be able to specify the *"manufacturer's specifications"* as current *"specifications"*.

Concerning the choice of calibration methodology, Directive 2014/45/EU thus fully entitles Norway to continue the current regime with the *"manufacturer's specifications"* as the only permitted calibration methodology. Directive 2014/45/EU therefore provides no grounds to amend Section 8, third paragraph of the PKK Regulations.

Regarding the regulation in Section 8, third paragraph, we believe that the source of law clearly indicates that calibration *"in accordance with the manufacturer's specifications"* is the only accepted calibration methodology. Looking at the source of law, including the wording of the regulation, there should therefore be no need to amend the regulation.

The uncertainty that may exist was therefore more likely based on the fact that Section 8, third paragraph, last sentence of the PKK Regulations represented something new through its accreditation requirement for calibration laboratories and that the requirement for accreditation according to ISO Standard 17025 (the question about *who* performs the calibration) was conflated by some with the calibration methodology (the question about *how* calibration should be performed).

In our view, no clarifying amendment of the wording of Section 8, third paragraph, last sentence of the PKK Regulations should be necessary. A more practical and simultaneously less resource-intensive measure on the part of the relevant administrative authorities would be to provide the industry with a more comprehensive and practically-oriented interpretation guide than the industry actors have previously received. Relevant Swedish administrative authorities and industry actors should also be the recipients of any such interpretation guide. Our recommendation is that any interpretative doubt that still exists be cleared up in this manner.

Advokatfirmaet Steenstrup Stordrange DA

Aksel Joachim Hageler
Partner | Attorney

Lennart Garnes
Senior Attorney