Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
1	NC	4.4, 5.3, 5.4.1 The basic IT policy and the structure of the IT system are not documented	Analysis of root cause and extent: The IT policy and the IT system have only been described at user level. Remedial and corrective actions: A Section 4.12 will be added to the QM: 4.12 IT system: DANAK uses an IT system for communication, for creating and filing documents, for managing and registering cases, documents, non-conformities, use of time, and financial affairs. The external part of the IT system is used for information and communication with customers and others and consists of e-mail communication, a website, a searchable database of accredited companies, list of methods and calibration measurement scheme as well as a password protected customer portal and a database for handling of non-compliances. The internal part consists of file servers for case related documents, a database containing information on the accreditation cases, an interface for managing the accreditation cases, a ***report generator for merging standard letters and reports***, a timesheet system and a financial management system.	Closed: Yes/no

[1] NC = Non-conformity; CN = Concern; Cm = Comment

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
			The IT system, its use and security is described in IP (F) 42. Objective evidence of implementation: Revised QM and new IP (F) 42.	
2	NC	4.6.3 DANAK had a sectorial committee for medical laboratories that was closed in 2013. In a letter sent to the committee members, DANAK declared that it would use the existing professional associations when to further developing accreditation of medical laboratories. However, DANAK has not followed up this and established a policy on how to adopt/develop new technical fields.	Analysis of root cause and extent: When the sectoral committee was closed 8th November 2013 the members of that committee was informed in a letter where it was indicated (with the support from the committee chairman) that DANAK would increase cooperation with medical societies, individual applicants and interested parties (eg. the five national regions) in the medical field in order to ensure proper accreditation procedures. This policy has been followed, but has not been described in DANAK's quality system. Remedial and corrective actions: IP 5 pkt. 1.6, 2.4 og 3.4 and QM 6.13.7 is updated and this information is provided on the DANAK homepage. Objective evidence of implementation: The ToR for sectoral co-operation in the medical field according to the above mentioned procedures is established.	Closed: Yes/no
3		5.4 DANAK uses a powerful electronic	Analysis of root cause and extent: The principles in the IT system are not documented	

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
	NC	database. However, the principles and the instructions for use are not documented or referred to in the QM procedures	in the QM and there are no references to user manuals for the databases. Remedial and corrective actions: A new IP (F) 42 The IT system, with a description of the principles and safety of the IT system, including references to user manuals will be issued. Objective evidence of implementation: IP (F) 42	Closed: Yes/no
4	NC	5.5, 7.8 The surveillance assessment report for an office visit carried out on the 02/06/2015 does not exist. NOTE: DANAK has opened the noncompliance number 63 dated on 04/05/2016, this noncompliance identified that other assessment reports were also missing. Corrective actions are going to be implemented During the internal audit the auditor discovered that a number of cases from 2012-2015 are not closed due to missing assessment reports. DANAK performed a root cause analysis and defined a corrective action, which is not complete and not yet implemented	Analysis of root cause and extent: The missing reports are concentrated to a few lead assessors who have unfortunately been overloaded with too many tasks in a period. Remedial and corrective actions: A new section manager has been employed from 1 March 2016 who will secure a satisfactory distribution of tasks between the employees of the section and regularly follow-up on the performance. A list of missing assessment reports has been elaborated, and decisions made whether the reports should be elaborated or “closed” with reference to an internal non-conformity. The last one was the solution if: a) An assessment has been done afterwards b) There are no special decisions which require an action c) The accreditation has been cancelled Assessments reports in other cases shall be	Closed: Yes/no

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
			elaborated before 15. August 2016 Monthly the section manager will follow-up on data from our database system SAGSYS with each lead assessor regarding status of assessments reports to secure they are delivered within a month. Lead assessors whose record indicates one or more missing reports follow-up will be performed with shorter intervals. <u>Objective evidence of implementation:</u> List of all missing reports and the handling of them.	
5	NC	5.6 DANAK has not defined a policy on preventive actions in an adequate way. However, the principles are implemented on several levels and in different processes	<u>Analysis of root cause and extent</u>: Preventive action are described in the quality manual and in a procedure to be considered in connection with internal audits and management review. <u>Remedial and corrective actions</u>: A policy on preventive actions has now been added to section 2.3. of DANAK's Quality Manual which contains the overall Section 4.7.5 is added to QM: In connection with handling complaints, IP 13 (F), new products IP 22(F), acceptance of application for accreditations IP 7 (P) and IP 25 (C), and decision on accreditation IP 32 (F) potential non-conformities and the necessary ***preventive actions…determining and implementing*** are identified as part of the regular case work.	Closed: Yes/no

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
			Objective evidence of implementation: Revised QM	
6	NC	5.9 of 17011 + Art 61 of the A&V Regulation The EU ETS complaints from the competent authority are not managed according to art 61 of the A&V Regulation: 1. There is no evidence of the response to the complainant for the complaint number 114, received on the 25th of November 2014 coming from the Danish EU ETS Competent Authority. 2. There is no evidence of the actions taken by DANAK about the complaint number 114 (affecting a second CAB). NOTE: DANAK informed the Danish Competent Authority in November 2014 about the acceptance of this complaint	Analysis of root cause and extent: The information from the CA was received and then distributed internally as well as discussed by telephone with the CA. Information was requested and received from the concerned CAB. The issue concerning another CAB relates to verification activities which were performed by the CAB in 2012. At that time the verifier was not accredited by DANAK. This was also informed to and discussed with the CA by telephone. However the responsibility for follow up on the complaint was not clearly defined. Remedial and corrective actions: Answer to the CA on the complaint to be sent and filed in DANAK file registration SAGSYS. DANAK procedure IP(C) 23, clause 3.7.4, will be amended to define clearly that the appointed LA responsible for receiving information from the CA is responsible for follow up and responding to the CA: "The appointed LA is responsible for follow up on information and complaints received from the competent authority and to respond to the competent authority within the defined deadline." Objective evidence of implementation:	Closed: Yes/no

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
			Answer to the CA on complaint no. 30-08-01-0114, file no. 4 attached. Revised DANAK procedure IP(c) 23	
7	NC	6.1.1 DANAK has accredited 2 CABs for FSMS using ISO/TS 22003: 2007. According to the IAF Resolution, three years transition period for the new version of ISO/TS 22003 will end in December 2016. However, one CAB has already applied for the assessment according to the new version; DANAK at the moment does not have a trained LA in ISO/TS 22003: 2013 due to the unexpected departure of a competent LA. 6.2.4 The LA assigned for the witnessed assessment for FSMS has not appropriate qualification for FSMS (no experience in food sector, no knowledge of HACCP, no training for ISO/TS 22003 ….). The LA has not been approved either by the head of section nor by the accreditation committee in line with IP(C) 24. 7.9.1 In one case in 2014, the Accreditation Committee decided on extension of FSMS being composed by the Quality Manager and one LA (without appropriate qualification in FSMS).	<u>Analysis of root cause and extent:</u> According to DANAK procedure IP(C) 25, the assessment team consist of a lead assessor (LA) and one or more technical expert(s) (TE). DANAK had in the past two LA on ISO 22003. One retired and the other has changed to work in other fields of accreditation. The recent assessments on ISO 22003 were therefore mainly based on the LA who resigned unexpectedly shortly before the EA evaluation. The committee deciding on accreditation has consisted of persons with in depth knowledge of accreditation on management systems (ISO 17021), but without specific competence on ISO 22003 and HACCP. The LA in the team performing the assessment during the EA evaluation was chosen to replace the resigned LA based on his competence on ISO 17021, knowledge on the client's quality system and his participation in the previous assessment of the client in 2015. However there was no formal documented evaluation and approval of the LA for ISO 22003 assessment. The LA was assisted by a TE competent for the scope of accreditation on food. <u>Remedial and corrective actions:</u> A training seminar has been planned to be carried out the 25 August especially on ISO 22003 and HACCP but also including information on schemes	Closed: Yes/no

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
			for food and feed such as IFS and GMP+. Six employees of DANAK and technical experts will participate. Following the seminar DANAK will evaluate trained LA's on ISO 22003 including witnessing on-site according to the internal procedure IP 24. Based on the result of the evaluation DANAK will decide on approval of LA's for assessment against the standard or further training and evaluation. As we only have 2 accreditations on ISO 22003 it is presently planed that 2 LA's after training and on-site witnessing will be approved as LA for assessment against ISO 22003. The on-site witnessing before approval of the 2 LA's will be performed at the first possible ordinary assessment. DANAK will also decide on approval of LA's for being qualified to decide on accreditation to ISO 22003 based on participation in above mentioned training seminar. According to DANAK procedure IP(F) 32 the decision committee consist of 2 persons, where one needs to be qualified for the specific field. Decisions taken by the committee in the present accreditation cycle for the concerned 2 accreditations will be reviewed after the approval of LA's as mentioned above. <u>Objective evidence of implementation:</u> Attached is the training program.	
8	NC	6.2.1 DANAK has not specified competence criteria for an assessment team in the	<u>Analysis of root cause and extent</u>: DANAK's requirements for qualification of lead assessors and experts in the area of certification,	

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
		field of FSMS and has not yet implemented IAF MD 16 (version 2014 and 2015)	inspection and verification are elaborated in internal procedure IP(C) 24. The requirements of IAF MD 16 were not included. Remedial and corrective actions: IP(C) 24 has been updated to cover the requirements in IAF MD 16:2015. It is now explicitly mentioned that competence shall be present for document review, for assessment, and for the accreditation decision on HACCP, food safety management and legal framework. Objective evidence of implementation: Attached is an updated procedure IP(C) 24.	Closed: Yes/no
9	NC	6.3.2 DANAK does not meet its own policy on on-site monitoring (once in 3 years) of LA in some cases.	Analysis of root cause and extent: During the EA-audit the requirement was not fulfilled for 1 LA, as the other LA discussed during the evaluation (DANAK's managing director) had stopped acting as LA in 2014 and was before this monitored in 2012. Remedial and corrective actions: The missing on-site monitoring is planned to August 2016. It is stated clearly if the LA has stopped as LA in the monitoring plan. A new form (Monitoring plan) is elaborated to give an overview of performed and planned on-site monitoring. IP 20 (F) is revised and reference to the form is	Closed: Yes/no

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
			given. Cl. 3.1 is revised to: **"3.1** SLs plans the evaluation of LAs through periodic monitoring of the assessment activities. Once a year SL defines which activities shall be monitored based on the experience with LA and which on-site monitoring of the LA that has been done before. The result is recorded in the spreadsheet Monitoring plan " <u>Objective evidence of implementation:</u> Filled in Monitoring Plan Revised IP 20 (F)	
10	NC	7.5.6 The policy for sampling for product certification (AMC 15) does not ensure that all necessary scopes and activities are covered during the accreditation cycle. The procedure describes the necessary witnessing and files review activities for specific schemes; however, this is not translated into forward planning for each accredited CB (audit Plan). (note that there are some recent examples using the portal system where such information is included – this is a new process being developed). In the inspection area, it is not ensured that the witness activities cover the whole accreditation scope within the 4-year accreditation cycle, since it was observed	<u>Analysis of root cause and extent</u>: The lack of an AMI regarding witness activities for inspection and an in-complete AMC regarding witness activities for certification and verification combined with a new system for using SAGSYS for planning witness audits is the root. Regarding the forensic activities witness assessments are done in the autopsy room at the hospitals normally when an on-site assessment is done. Witness assessment has not yet been done at the place of finding, as the police only allow a few people to be there and inspection of places of findings are done unannounced within a very short time limit. <u>Remedial and corrective actions</u>: As a supplement to the plan for on-site assessment (office) there shall be a plan for all witness	Closed: Yes/no

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
		that in certain cases (forensic activities) witness activities have not been performed at all. At least in one case DANAK has not conducted witnessing of all required categories (FSMS) and has no plan how to fulfil the requirements on witnessing during the accreditation cycle	assessments in SAGSYS for the accreditation period. It shall be stated which parts of the scope/ accreditation shall be covered at each witness assessment. AMC 15 will be revised and cover FSSC 22000 etc. An AMI 1 for Inspection corresponding to AMC 15 for certification and verification shall be issued. Clause 3.9 in IP 25 (C) is revised. A plan for the witness assessments for the accreditation period shall be delivered to the accreditation committee and when accreditation is granted/renewed it shall be put in to SAGSYS. Clause 3.1.2 in IP 26 C is revised. A plan for the witness assessments for the rest of the accreditation period shall be elaborated and put in to SAGSSYS. <u>Objective evidence of implementation:</u> Revised AMC 15, IP 25 (C) , IP 26(c) and a new AMI 1.	
11	NC	7.5.6 DANAK does not establish a specific plan for sampling tests. It uses a competence matrix in which it registers the main technical fields and the activities that are assessed (IP(P)7 point 3.1.3 f). In some	<u>Analysis of root cause and extent</u>: Although the procedure is in place for establishing competence matrices and in a number of cases request for revision of competence matrices have been made at renewal of accreditation (decisions), a number of competence matrices are not	

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
		cases not all accredited technical fields have been checked during an accreditation cycle 7.5.8 Procedure IP (P) 7 does not define a policy for: -Planning sites in case of multi-site laboratories: CAB 1 all the sites where verified during one accreditation cycle but in CAB 2 not In case of multisite testing laboratories, DANAK does not document the scope of accreditation for the different sites. It produces only one list of tests without specification where the single test is accredited.	appropriate in the field of testing. This is not the case in the medical field or in calibration. <u>Remedial and corrective actions</u>: The following remedial actions are made: 1. All testing competence matrices are reviewed systematically and changed accordingly. 2. A process for ensuring that requests made in the visit note (supporting the decision for accreditation is made) are implemented is installed in IP7 cl. 3.1.3 f) to ensure that an alarm is established by the decision makers in the electronic system. 3. For sampling among sites the policy is clarified in IP 7 cl. 3.1.3 d) and f). Those clauses for sampling are collected in a separate clause and a form is created to support a uniform approach in sampling among sites. 4. Laboratories are requested to include location in the list of methods. AB 3 is revised accordingly and this will be followed up at future surveillance and . <u>Objective evidence of implementation:</u> 1. A table with indications of the changes made to competence matrices of all testing labs is included. 2. One example of change to competence matrix is included IP 7 is included, see cl. 3.1.3.	Closed: Yes/no

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
12	NC	7.7.2 DANAK reaccredited a CAB although there is little evidence that chapter 4 of ISO/IEC 17043 has been assessed properly. At the previous surveillance visit there is also little evidence that chapter 4 of ISO/IEC 17043 has been assessed. DANAK did not realise this gap in the report. At the decision-making DANAK waived the requirement.	<u>Analysis of root cause and extent</u>: When DANAK established accreditation of PT providers this activity was a part of ISO 17025 accreditation. When separate accreditation according to ISO 17043 was developed in June 2010 DANAK issued a first edition of IP 8 which allowed combined reporting with laboratory accreditation to ISO 17025. During accreditation committees in the years 2010 - 2014 it was discovered that this approach did not satisfy decision makers and IP 8 was consequently changed in both 2011 and 2012 where the requirements to separate filing on laboratory case and PT case and to separate reporting was required. Due to the low number of PT providers (in total 4) experience is gathered at very low speed. The 4th version of IP 8 from September 2014 is however considered appropriate. For one case in march 2015 the decision makers discovered that reporting as required by IP 8 was not very good and the technical assessor reported all of chapter 4 in a vertical audit which however covered all activities that year (The PTP only organized one PT that year). For that reason the decision makers decided to renew the accreditation despite the poor reporting and required that reporting at the next assessment shall cover all requirements in chapter 4 and that this shall be clear from the reporting. All lead assessors dealing with PT were at the same time made aware that reports need to be better and all other newer reports show adequate reporting. <u>Remedial and corrective actions</u>:	Closed: Yes/no

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
			There is not considered any need for changes to IP 8 and therefore the following two actions are made: - A dummy report is made displaying proper reporting similar to what is found in all other areas (ISO 17025 and ISO 15189) in the laboratory section. - The team for the CAB in question is informed of the need for better reporting and the outcome of the next surveillance will be monitored by the manager of section. <u>Objective evidence of implementation:</u> The dummy report and the report from the surveillance June 2016 are included.	
13	NC	7.8 of 17011 + art 47 of the Regulation A&V During the GHG witnessing the LA assessed as satisfactory an onsite monitoring plan for EU ETS auditors of a 6 years period claiming that there was no requirement for this monitoring. The EA 06/03 includes that the maximum frequency for on-site monitoring shall not be more than 3 years.	<u>Analysis of root cause and extent</u>: The 6-year period monitoring plan was given as an observation to the verifier in 2015. In praxis the monitoring of LAs are done within 3 years. During the on-site assessment LA did not remember the requirement. <u>Remedial and corrective actions</u>: It has been required to the verifier to adjust the monitoring plan to 3-years periods. The implementation of this will be assessed on next office visit. The requirement will be stated in the checklist <u>Objective evidence of implementation:</u>	Closed: Yes/no

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
			Copy of revised checklist DANAK has required the VB to implement a 3 year monitoring plan as stated in the report. Copy of report to the VB, page 4, in which it is stated (translated): "Competences in "Skills" demonstrated. The date of expiry was 6 years, but EA -6/ 03 6.2.1 indicates max 3 years. Given that observation in 2015. DANAK will at the next office visit follow up on monitoring planned with 3-year interval."	
14	NC	7.9.5 The accreditation certificate of inspection bodies in the forensic area does not include the specific requirements against which the inspection body was assessed	<u>Analysis of root cause and extent</u>: DANAK was not aware of the need for the details during the original accreditation, probably because it is a rather regulated area. <u>Remedial and corrective actions</u>: As mentioned during the interview of the LA at the EA-evaluation, the 3 forensic pathology departments accredited by DANAK, had already been requested to define a list of specific requirements for the scope of accreditation. This is documented in the reports for the assessments 2015-09-25, 2015-09-28 and 2016-01-22: "*The scope of accreditation shall be described more specific, to include the standards and / or references which are the basis for the methods and procedures for the performance of the activities.* The time for implementing the specific requirements has been agreed to be before the 16	Closed: Yes/no

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
			September 2016 considering the need for discussion and coordination. Objective evidence of implementation: Copy of the reports from the 3 forensic departments.	
15	NC	7.15 In the AB 3 cl.3.9 DANAK requests from the laboratory to elaborate a plan for participating in PT that shall be worked out in a way that makes it possible to evaluate whether the extent adequately covers the scope of the accreditation. In some cases in testing, no evidence for the assessment of the plan was found. During the visits TA register in the check list if laboratories have participated in PT. In some cases there is no information in the report on the existence of a PT policy nor if PT is not available or just no participation.	Analysis of root cause and extent: All AB's and IP 7 are considered to be sufficient. Further dummy reports exist to support proper reporting in all areas of testing and calibration. The root cause is therefore considered to be lack of awareness among assessors to assess the plan and especially when PT is not available or impossible. Remedial and corrective actions: All LA and TA will be informed in writing about the need for addressing PT plans specifically at every assessment and also awareness of difference between a PT policy and a plan for PT. Further PT activities will be marked to be addressed at every assessment. Objective evidence of implementation: Communication to TA about how to address PT in reports and during assessment.	Closed: Yes/no
1	CN	4.3.2 The process of identifying and analysing of potential conflicts of interests and the involvement of the interested parties is not transparently described	Analysis of root cause and extent: Potential conflicts have been handled by the Board of Directors, however not in a systematic and transparent way.	

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
			Corrective action plan: The agenda for management review as listed in IP 2 (F) will be extended with an item regarding identifying and analysing potential conflicts of interest. The outcome of management review is addressed annually by the Board of Directors, where stakeholders are represented. Revised IP 2 (F) is attached.	Closed: Yes/no
2	CN	5.3 In the quality manual a reference to the procedure IP(P)8 for accreditation according to ISO/IEC 17043 is missing in section 6.5.2 (paragraph 6) Document RL 16 in both versions (Danish and English) refers to an obsolete standard (EN 16001)	Analysis of root cause and extent: IP 8 refers to IP 7 for decision making so it has been understood that the same procedure applied to labs shall be utilized for PTP's. In all cases the same process is applied. Corrective action plan: QM cl. 6.5.2 is updated to include IP 8 specifially in 6th dot, so that this clause takes the form: "prepare the appropriate assessment documentation for the review by the accreditation committee as specified in IP(P) 7, **IP(P) 8,** IP(C) 25 or IP(C) 26;"	Closed: Yes/no
3	CN	5.5 e The DANAK electronic database is a good tool to show open non-compliances and their nature. However, the existing process does not guarantee that open findings are closed within reasonable time	Analysis of root cause and extent: There has not been installed a mechanism in the database to alert the Quality Manager and the receiver of a NC when deadlines have been passed. Corrective action plan:	Closed: Yes/no

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
			Alarms have been created so that receivers of NC's and QM are made aware when a deadline is passed. The alarms are communicated electronically by email to receiver and QM every week.	
4	CN	5.9 IP(F) 13 is not clear on the fact who is taking decisions on the final answer to the complainant. The head of section and a LA are involved. The records do not give clear evidence who has taken a decision	Analysis of root cause and extent: The procedure is not clear. Corrective action plan: IP(F) 13 is corrected to clarify that the head of section (SL) takes the decision unless the complaint concerns the SL. In that case the director takes the decision.	Closed: Yes/no
5	CN	6.2 DANAK has not formally qualified specialists in activity group 12 "aviation" (Regulation A&V) DANAK has delivered trainings in March 2014 and in 2012, for Lead Assessors and Specialists including the requirements for this activity group. DANAK has one accredited body in this field. A witnessing in this field was made on the 2nd and 3rd of March in 2015	Analysis of root cause and extent: The competences in the Qualification form GHG (form 48a) was by mistake not updated after the training and by that formally qualifying the specialist. Corrective action plan: Training and registration of specialist's competences will be updated according to IP(C)24, formally qualifying the specialist.	Closed: Yes/no
6	CN	6.2 There are no evidences in the DANAK´s management system to support the justification about the competence evaluation carried out in the case of the specialist in the field of production of pig	Analysis of root cause and extent: By mistake documentation of justification for competence related to activity group 3 of the AVR was not ensured to have a specific reference.	

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
		iron or steel (activity group 3 of the Regulation A&V): In form 48a the competence evaluation for the activity group 3 of the RA&V is based on a previous job carried out for DANAK in a company. No information to support this justification has been found in the DANAK record systems. The form 48a for this person was signed on the 19/03/2013.	Corrective action plan: Justification for the concerned person will be acquired and documented in form 48a and the evaluated and approved by the SL. IP(C) 24 to be amended to ensure that justification is recorded.	Closed: Yes/no
7	CN	6.2.1 The Annex to IP(P)19 contains the "competence profile" of a LA. However, this are the criteria for hiring new staff. (same for technical assessors in IP(P) 18). The competence criteria for assessors are not properly defined.	Analysis of root cause and extent: The competence profiles in IP 18 and 19 were understood to clarify profiles for applicants to be employed as LA and TA which means that the competence for LA and TA shall be supplemented with the competences acquired through training. Corrective action plan: IP 18 and 19 are updated to clarify the competence requirements for LA and TA and to align with ILAC G3.	Closed: Yes/no
8	CN	6.2.1 For product certification Lead Assessors, the competence requirements as stated in IP24 do not include any required knowledge for the general scope area concerned. 6.2.3 In the certification section DANAK has not defined technical areas (areas of scope) for the different accreditation activities in a consistent way	Analysis of root cause and extent: For the scope area of product certification it is required for each lead assessor to search knowledge by studying the scheme documents and product requirements. DANAK has also made a competence matrix where it appears who are competent for specific areas and who are the key persons for these areas responsible to obtain any information and share this. Corrective action plan: Above description is added in IP(C) 24.	Closed: Yes/no

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
9	CN	6.4.1 Records on assessors' qualifications and competence are not kept in a systematic way. The competence matrix is used for assessors (although not regularly updated) but not for technical experts. TEs are sometimes trained in specific scheme requirements as "on the job" training, but this is not recorded in competence records Training certificates of assessors do not distinguish between participation of the assessor as a trainer or as a trainee	Analysis of root cause and extent: Lead assessors approved competence to a specific standard (e.g. ISO 17065) is registered in the case management system and in the competence matrix mentioned in CN 8. The competence matrix refers to the documents for approval for a specific standard. The competence matrix is a new tool that still had a few errors at the evaluation. Some training activities have been performed as workshops where some of the participant presented some of the sessions Corrective action plan: The competence matrix has been reviewed and updated. It is referred in the QMS and will be maintained. Records of training for TE's will be maintained to also include DANAK training. For future workshops there will not be issued certificates but a document showing the items presented and discussed.	Closed: Yes/no
10	CN	6.4.2 Personnel files of internal LAs for medical laboratories: Training activities for ISO 15189:2012 and ISO 22870:2006 are not documented	Analysis of root cause and extent: Training has been performed in group of LA and also with meetings of the TA and in newsletter 2014. TA hired after 2013 (check year) have not received this training. Corrective action plan: The following steps are taken: - All LA and TA in the medical field shall be	Closed: Yes/no

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
			trained to ISO 22870 in combination with ISO 15189. - ISO 22870:2006 is included in the training courses for TA starting 2017 as the training 2016 has been made. - All TA not receiving this training shall receive that through circulation of the information in the newsletter 2014. Qualification of all LA to ISO 22870:2006 is documented on personnel files based on received training….. included in CV….	
11	CN	Document AMC 03, 2015/09/02 refers to IAF MD16 and specifies the rules for witnessing in the field of FSMS according to this. IAF MD 16 was developed taking into account ISO/TS 22003:2013. Since DANAK still uses ISO/TS 22003:2007 for the accreditation in field of FSMS, the rules for witnessing are misleading from the point of view of the specific marking of the food chains categories which is different in the old and the new version of ISO/TS 22003.	Analysis of root cause and extent: DANAK has by mistake not considered the differences in the two versions of the standards. Corrective action plan: A new AMC has been published to address the requirements in ISO 22003:2007.	Closed: Yes/no
12	CN	7.1.1 DANAK policy on traceability does not include ILAC P10 option 3a and 3b. By doing so there is a risk that not all measurement quantities are metrologically traceable. (DANAK document AB 3 cl. 4)	Analysis of root cause and extent: The AB 3 in Danish is understood to not exclude option 3a and 3b of ILAC P10 and such is the tradition. Since all NMI's in Denmark are accredited for all services they offer in the KCDB DANAK is not aware of any lack of service that can only be achieved through 3a and 3b Corrective action plan: Option 3a and 3b are now included in DANAK AB3 chapter 4 as a separate clause.	Closed: Yes/no

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
13	CN	7.5.5 It has been observed that when the assessment team comprises more than one member, the tasks of each member are not always clearly defined in the assessment plan	Analysis of root cause and extent: For certification bodies with several areas of accreditations the areas are often assessed simultaneously. The team can therefore consist of more lead assessors, each responsible for an area of accreditation. The tasks for each team member have not always been clearly defined but based on dialog between them. Corrective action plan: An IP 43 (C) on assessment of certification bodies with several accreditations will be issued. A team leader will be appointed for certification bodies with several accreditations. This person will be responsible for communication with the management, drafting assessment plan, determination of each team members tasks, assessment of the customers ***main*** QMS. IP 43 (C) is attached.	Closed: Yes/no
14	CN	7.9.4 **Accreditation scopes medical laboratories:** Locations on the front page and in the method list are not always explicitly given, examples: • CAB 1 – Abbreviations used in the method list are not identifiable on the front page. • CAB 2 -– two locations are listed in	Analysis of root cause and extent: It has never occurred to us at DANAK that the location codes in lists of methods are not self-explaining. CAB 2 is closed at the end of 2015. Corrective action plan: In all cases where a code is provided for location DANAK will make this code clear from the overview	Closed: Yes/no

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
		the method list and nine locations are given on the front page. Names of the locations in the method list are not identifiable on the front page.	on the list of sites. See LINK XXXXX.	
15	CN	7.11.4 DANAK collected information according to IAF MD 12, but there are no written rules or guidance for LA describing how to use the collected data for assessment planning	Analysis of root cause and extent: The collected information has been used by the LA's for planning in an informal way. Corrective action plan: The collected data shall be used in the plan for witness and on-site assessments. IP 25 (c) and IP 26 (c) are revised, and now includes a description that the plan shall be evaluated each year when the information about foreign activities is received. A note shall be in SAGSYS of the result of the evaluation of the information and if the plan needs to be revised.	Closed: Yes/no
16	CN	8.2.1 A CAB has notified DANAK that they were closing the lab by end of December 2015. However, DANAK suspended the lab and did still not update the website to state that the lab is closed down.	Analysis of root cause and extent: It was a mistake by the lead assessor to tick the suspension box in the electronic system. This is seen as a single incident. Corrective action plan: The laboratory has been informed about the closure of the file and all electronic information is adjusted to reveal that this accreditation was closed by the end of 2015. Letter for termination is included.	Closed: Yes/no
17	CN	8.3.3 Incorrect use of DANAK's logo on a list of orders was not noticed by the LA and was	Analysis of root cause and extent: The issuing organisation is part of the legal identity holding the accreditation.	

Number and Classification[1]		Requirement and Finding	Response from AB	Team Comments/Conclusions
		not discussed with the IB representatives during a witnessed assessment. (the issuing organisation is not accredited)	Corrective action plan: The use of DANAK's symbol by departments of an accredited legal identity will be discussed at DANAK for clarification to secure that it cannot give reason for any misunderstanding as to what the accreditation is covering.	Closed: Yes/no
1	Cm	5.3 In section 6.9.1 of the quality manual about the technical assessors procedure IP(P)8 is mentioned. However, a team of a lead assessor and technical experts performs assessments. This is also not clarified in IP(P)8.	The QM 6.10 as well as IP8 are reviewed to clarify the team composition in PT (and RM which is also covered by IP 8). QM 6.10 was revised for consistency with IP 8 cl. 3.2 and with the change to 6.10 the need for change in IP 8 is unnecessary.	
2	Cm	6.4.2 The summary records for a technical expert for product certification identify for which overall area they are considered competent but not the specific scheme or scope, although this information can be found by further searching it is not easily accessible.	Technical experts on certification, inspection and verification are registered in the case management system but there is not a search engine for their technical area of expertise. DANAK will define a list of competences for certification, inspection and verification and allocate the experts to the relevant categories as done for the experts used for laboratory accreditation.	
3	Cm	7.5.5 The Program refers to document AMC 09 dealing with scheme FSSC that is not included in the scope of accreditation. Reference to IAF MD 1 and MD 5 are also misleading (applicable rules for multisite certification and audit time for FSMS are in ISO/TS 22003).	The problems is seen as a single incident and arise from our merging of information from the SAGSYS and the standard program. Due to an human error the FSSC has been marked as a part of the accreditation scope. The references to IAF MD 1 and MD5 are relevant for the accreditation with the same number, but not for FSMS. Normally on-site assessments are done together during several days for several scopes as quality, food etc.; but due to the EA-evaluation	

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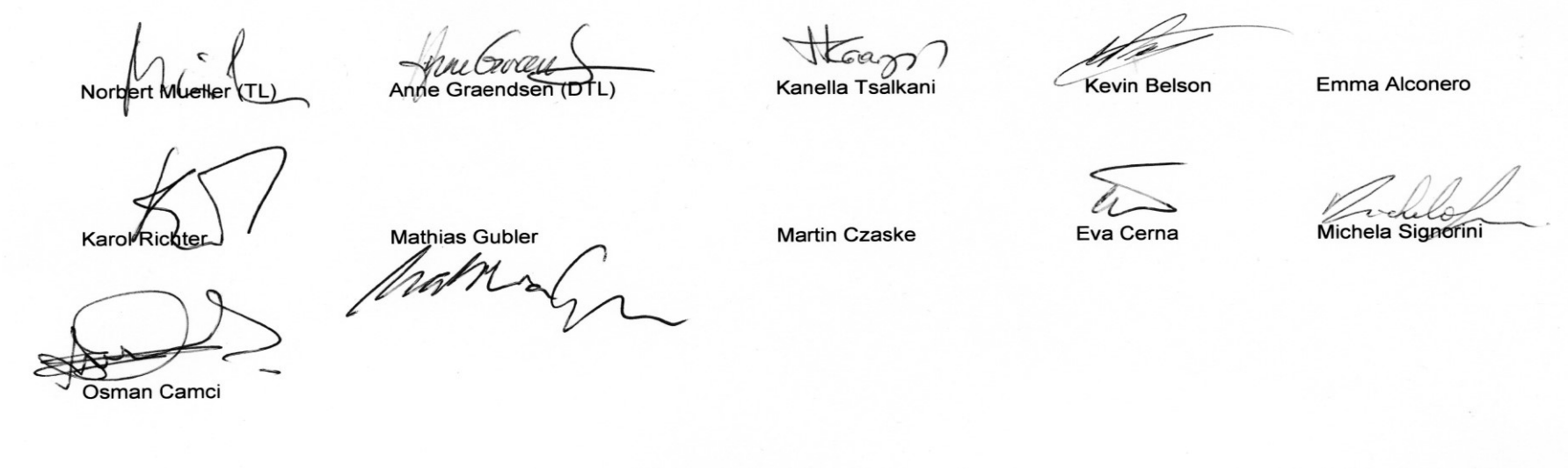
			FSMS was done separate, and the lead assessor did not evaluate the merge program properly enough. The “check mark” of FSSC is removed from the database. The process of merging documents and quality control will be discussed at intern meetings.	
4	Cm	7.7.3 Information on the number of inspectors in each IB is not consistently obtained in order to allow for a representative number of staff of the IB to be witnessed	This information is often listed in DANAK’s assessment reports to be used for the next assessment. It has now been stressed at the section meeting in May 2016 to include the number of inspectors in reports. For further actions DANAK awaits any requirements from EA or ILAC.	



Emma Alconero and Martin Czaske finished their visit before the final meeting.